MEDICAL DEVICES: MANAGING THE Mismatch

An outcome of the Priority Medical Devices project

World Health Organization

Future public health needs: commonalities and differences between high- and low-resource settings

Background Paper 8

August 2010

Contents

Preface

In 2007, at the request of the Government of the Netherlands, the World Health Organization launched the *Priority Medical Devices (PMD)* project to determine whether medical devices currently on the global market are meeting the needs of health-care providers and patients throughout the world and, if not, to propose remedial action based on sound research.

The project gathered the information required by conducting literature reviews and surveys, and by convening meetings of specialist consultants.

The project addressed various complementary issues:

- the global burdens of disease and disability;
- guidelines on clinical procedures for the management of diseases and disabilities;
- projections of future burdens of disease and disability in the context of demographic trends;
- cross-cutting issues, such as the training of medical device users, medical device design, contextual appropriateness of medical devices, and regulatory oversight;
- catalysts of, and barriers to medical device innovation and research.

The original objective of the *PMD* project was to identify gaps in the availability of medical devices. The findings of the project showed that gaps in the availability of medical devices is not the primary issue, but rather a number of shortcomings spanning several facets of the medical device sphere. This result prompted a change of direction in which the project shifted its focus onto the many shortcomings related to medical devices.

These problems, challenges, and failures amount to a mismatch, rather than a gap, that prevents medical devices from achieving their full public health potential.

The *PMD* project also produced a report *Medical Devices: Managing the Mismatch* aimed at achieving two objectives: the first, to inform national health policy-makers, international organizations, manufacturers and other stakeholders of the factors preventing the current medical device community from achieving its full public health potential; the second, to provide a basis on which all players in the medical device scene can together use the findings and recommendations of the *PMD* project to make public health the central focus of their activities.

This paper is part of a series of documents produced as background material for the *PMD* project report. The following papers are available as part of this series:

1. A stepwise approach to identifying gaps in medical devices (Availability Matrix and survey methodology)
2. Building bridges between diseases, disabilities and assistive devices: linking the GBD, ICF and ISO 9999
3. Clinical evidence for medical devices: regulatory processes focussing on Europe and the United States of America
4. Increasing complexity of medical devices and consequences for training and outcome of care
5. Context dependency of medical devices
6. Barriers to innovation in the field of medical devices
7. Trends in medical technology and expected impact on public health
8. Future public health needs: commonalities and differences between high- and low-resource settings

This document was developed under the primary authorship of Warren Kaplan. His work is gratefully acknowledged. Thanks are also due to Benjamin Schanker and Dima Samaha for providing valuable contributions in editing, writing, and research.

This publication was produced under the direction of Josée Hansen.

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Introduction

Various parties have identified a need from a public health perspective to embark on a research and development agenda to identify pharmaceuticals that, if made more accessible or made to operate in a clinically more effective manner, would have a great impact on public health and health care in Europe and the world *(1)*.

This paper is part of a larger project whose purpose is to try and identify such an agenda for medical devices. The project's main objective is to identify the gaps between the current needs and the current realities with respect to the availability of medical devices on the market. These gaps would constitute priorities to be addressed with regard to various factors, such as the associated disease or disability burden or other socioeconomic issues of medical relevance.

Medical devices are essential to virtually every aspect of clinical practice, from robotic brain surgery to heart pumps to blood transfusions to vitamin injections. For the scope of this project, devices are divided into four categories: (1) preventive, (2) diagnostic, (3) therapeutic and (4) assistive (prostheses, etc.), corresponding to the four stages in health care.

The creation and support of coherent global health policies requires a focus, in equal measure, both on present and future health-care needs. In this paper, the reader will find a summary of the major demographic and epidemiologic trends impacting global health; an analysis, based on Global Burden of Disease data, of health-care needs assessed in the context of current trends in the development of medical technology and devices. The paper suggests that for most low- and middle-income countries, there is a mismatch between actual health-care needs and many existing medical devices, as well as those likely to emerge in the future.

Future health care trends

The global burden of disease and mortality

According to the World Health Organization (WHO), one of the major trends affecting global health care is, with a few exceptions, a worldwide increase in life expectancy at birth, with the largest gains in the WHO African and South-East Asia Regions. Except in the WHO European Region, the increase in life expectancy is, and will continue to be, greater for females than for males *(2)*.

Increasingly, global mortality rates will be driven by lung cancer, diabetes, chronic respiratory diseases, road traffic accidents, violence and war. Tobacco-related deaths are expected to rise significantly, primarily because of increased smoking in low- and middle-income countries *(2)*.

Communicable diseases, including HIV/AIDS, lower respiratory infections, perinatal conditions, diarrhoeal diseases, and parasitic diseases, including malaria, will show a general decline in prevalence and mortality between 2004 and 2030. However, diabetes mellitus, road traffic accidents, chronic obstructive pulmonary disease, hearing loss and refractive eye disease are all projected to increase. By 2030, the three leading causes of the disease burden globally are predicted to be unipolar depressive disorders, ischaemic heart disease and road traffic accidents *(2)*.

Figure 1 shows the projected changes in the leading causes of disability-adjusted-life years (DALYs), globally, from 2004 to 2030.

An emerging health issue is the rise of treatment-resistant infections, such as methicillin-resistant *Staphylococcus aureus or Clostridium difficile* caused by the improper use and overuse of antibiotics. After nearly a century of a steadily improving ability to control and treat bacteria-based infection, antibiotic resistance may prove to be a very pervasive and challenging problem.

Pollution and chemical contamination of the air, earth and water also have a significant impact on public health and morbidity and mortality. Disease and disability caused by environmental factors often take years to be recognized, and eliminating them often does not receive the necessary attention because of economic and political factors. Also contributing to this issue is that frequently the precise ways in which pollutants and contaminants affect human health are not fully understood.

The ageing global population

Ageing of the global population is likely to be the most significant demographic factor influencing health-care needs, including medical device needs, in the future.

At the beginning of the 20th century, world population growth was slow: age structure was relatively constant and relatively few people lived past 65 years of age. These

Figure 1. Ten leading causes of burden of disease, world, 2004 and 2030

2004

Rank	Disease or injury	As % of total DALYs
1	Lower respiratory infections	6.2
2	Diarrhoeal diseases	4.8
3	Unipolar depressive disorders	4.3
4	Ischaemic heart disease	4.1
5	HIV/AIDS	3.8
6	Cerebrovascular disease	3.1
7	Prematurity and low birth weight	2.9
8	Birth asphyxia and birth trauma	2.7
9	Road traffic accidents	2.7
10	Neonatal infections and other[a]	2.7
13	COPD	2.0
14	Refractive errors	1.8
15	Hearing loss, adult onset	1.8
19	Diabetes mellitus	1.3

2030

Rank	Disease or injury	As % of total DALYs
1	Unipolar depressive disorders	6.2
2	Ischaemic heart disease	5.5
3	Road traffic accidents	4.9
4	Cerebrovascular disease	4.3
5	COPD	3.8
6	Lower respiratory infections	3.2
7	Hearing loss, adult onset	2.9
8	Refractive errors	2.7
9	HIV/AIDS	2.5
10	Diabetes mellitus	2.3
11	Neonatal infections and other[a]	1.9
12	Prematurity and low birth weight	1.9
15	Birth asphyxia and birth trauma	1.9
18	Diarrhoeal diseases	1.6

[a] This category also includes other non-infectious causes arising in the perinatal period apart from prematurity, low birth weight, birth trauma and asphyxia. These non-infectious causes are responsible for about 20% of DALYs shown in this category.

Source: WHO *(2)*.

trends began to change over the next 50 years due to rising life expectancy and a resulting ageing of the population. The underlying process in population ageing is a demographic transition in which mortality and then fertility decline. During the last half century, global fertility rates have decreased by almost half, causing a slowing of population growth, even though the total number of births continues to rise *(3)*. Because global fertility levels are unlikely to rise again, population ageing will probably persist.

These demographic changes will be marked by an increase in the prevalence of age-related noncommunicable diseases such as cancer, diabetes, mental conditions and cardiovascular disease. Because women generally live longer than men, increases in these chronic diseases may be especially marked in older women.

Current United Nations global population projections (which extend to 2050) suggest the following *(3)*:

In the next half century, global population growth will continue to slow and by 2050 is expected to amount to only 0.25% a year, compared with 1.25% at present. Although global population will continue to expand, in a number of areas it is actually expected to decline over the next 50 years – by more than 30% in some central and eastern European countries, by 22% in Italy, and by 14% in Japan. In most developing countries – particularly in Africa, the Middle East and parts of Asia – population growth will also slow, although less than in developed countries because of higher fertility rates.

And as we have seen, the world's population will continue to age. As life expectancy overall increases, the elderly (those over 65), a growing percentage of whom will be women, will make up an increasing segment of the population – although the pace and timing of ageing will vary widely among countries and regions. In the fifty years between 2000 and 2050, the median age of the world's population is expected to have increased by over 10 years to 37 years. As noted, population ageing is already occurring in Central and Eastern Europe and is expected to accelerate from about 2015. The process will also begin to accelerate in Asia and Latin America, with China experiencing particularly rapid ageing. However, because of moderating but still persistently high fertility rates, the percentage of elderly in Africa and the Middle East, while rising, will remain relatively low.

The elderly dependency ratio – the ratio of people 65 or older to those of working-age (15–64) – is projected to rise dramatically in Japan and Europe, with lesser increases in the United States of America. In developing countries, the working-age population is expected to increase until 2015, and then stabilize, while the percentage of elderly continues to rise.

The ageing of the world's population has significant health implications. For most of the 20th century, the cost of providing care to the elderly has been covered in large part by people of working age. However, as the number of elderly grows and the prevalence of age-related diseases increases, while the pool of workers financing care shrinks, there are disturbing uncertainties about how such costs will be met in the future *(4)*.

Despite the current weakness in the global economy, the World Bank predicts that trade and global economic integration and interconnectivity will increase in the future, with benefits for hundreds of millions of people. Populations will grow more slowly and age, and international migration will increase. These trends help ensure continuing rapid per-capita economic growth in the developing world (among which is China and India) and, therefore, a concomitant overall decline in global poverty levels *(5)*. One caveat to this positive story upon which most seem to agree, is that a concentration of poverty is projected to remain in Sub-Saharan Africa. Most striking, however, is the World Bank's conclusion that by 2030 the global "middle class" will more than double *(5)*. An educated middle class with a higher average income is likely to increasingly demand more health care overall, especially advanced or high-tech treatments that have traditionally been restricted to more highly industrialized countries *(5)*.

Global urbanization

Another key population trend is the rapid urbanization taking place around the globe. Over the next 30 years, a rapidly ageing population will be found in larger cities, particularly in Asia, Latin America and some African countries *(6)*.

In 2008, more than half of the world's population – 3.3 billion people – were living in or near cities. Urban growth rates are highest in the developing world, whose cities absorb an average of 5 million new urban residents every month and account for 95% of the world's annual urban population growth. Many of the new immigrants are poor. Despite the magnitude of these numbers, the rate of urban population growth is, in fact, slowing in most regions of the developing world. Nevertheless, the world's urban population is expected to continue to rise, as areas of Africa and Asia are transformed from largely rural to predominantly urban during the course of the 21st century.

By 2050, more than two-thirds of the world's population will live in cities. In the developing world, the urban population will total 5.3 billion; Asia alone will have 3.3 million (63%) of the world's urban population, while Africa will have an urban population of 1.2 billion. In sharp contrast, the urban population of the developed world (including the states of the former Soviet Union) is expected to remain largely unchanged, rising only slightly from just over 900 million in 2005 to 1.1 billion in 2050. On the other hand, population in many developed-world cities is actually declining due to ageing, declining fertility rates and other factors *(7)*.

An analysis of future global public health concerns

As the previous sections of this paper suggest, ongoing changes in global population demographics, urbanization, the world economy and the ability to control infectious diseases, as well as new scientific and medical advances, are certain to produce significant changes in the prevalence and ranking of major diseases in the coming decades.

Methodology

This analysis explores how, based on WHO's Burden of Disease and Disability-Adjusted Life Years health measurement tools[1], the DALY burden over time is expected to change. It should be noted that data for 2030 are not intended as firm forecasts of what will happen but as projections of trends, based on various rebuttable assumptions *(8)*. Furthermore, considering that projections are driven by factors that cannot be predicted, uncertainties about many of these projections abound.

In preparing the data presented in Figure 1, future trends in the disease burden of 15 high-burden diseases were examined with respect to the overall changes in the per capita DALY burden of these diseases between 2004 and 2030.

1. For each high-burden disease in a given WHO region,[2] the sum of the DALY burden over the entire age distribution for 2004 was computed. Thus for disease X, in the WHO European Region (EURO):

$$\sum_{0\text{–}4\text{ yr.}}^{80+\text{ yr.}} \text{DALY burden 2004}$$

2. For high-burden disease X, the total DALYs summed over all ages were divided by the total population of WHO EURO to derive an integrated DALY burden per 1000 persons for that disease X:

$$\sum_{0\text{–}4\text{ yr.}}^{80+\text{ yr.}} \text{(DALY burden 2004) / Total population 2004}$$

3. Steps 1–2 were repeated for WHO EURO to determine the DALY age distribution for 2030:

$$\sum_{0\text{–}4\text{ yr.}}^{80+\text{ yr.}} \text{(DALY burden 2030) / Total population 2030}$$

4. The following calculation was then performed for disease X:

$$\sum_{0\text{–}4\text{ yr.}}^{80+\text{ yr.}} \text{(DALY burden per capita (2004) – DALY burden per capita (2030))}^3$$

5. This exercise was repeated for all 15 diseases for WHO EURO.
6. Steps 1 through 4 were performed for each of the diseases in all WHO regions.

Thus, net increase or decrease in DALY burden per capita across the population for the given disease between years 2004 and 2030 for various WHO regions have been calculated.

Summary of per capita DALY changes for all WHO regions

Figure 1 shows the per capita changes in the DALY burden between 2004 and 2030, by WHO region, for 15 diseases specified in the WHO Global Burden of Disease Study *(8)*.

The vast majority of diseases show very small changes in the per capita DALY burden over time. This is because the analysis does not take into account the absolute DALY burden. For example, the reason why the integrated change in per capita DALY burden between 2004 and 2030 for malaria in the WHO Region of the Americas is small (-0.05 DALYS per 1000 persons) compared to the WHO African Region is that the overall malaria DALY burden in the Region of the Americas is trivial as compared to the African Region.

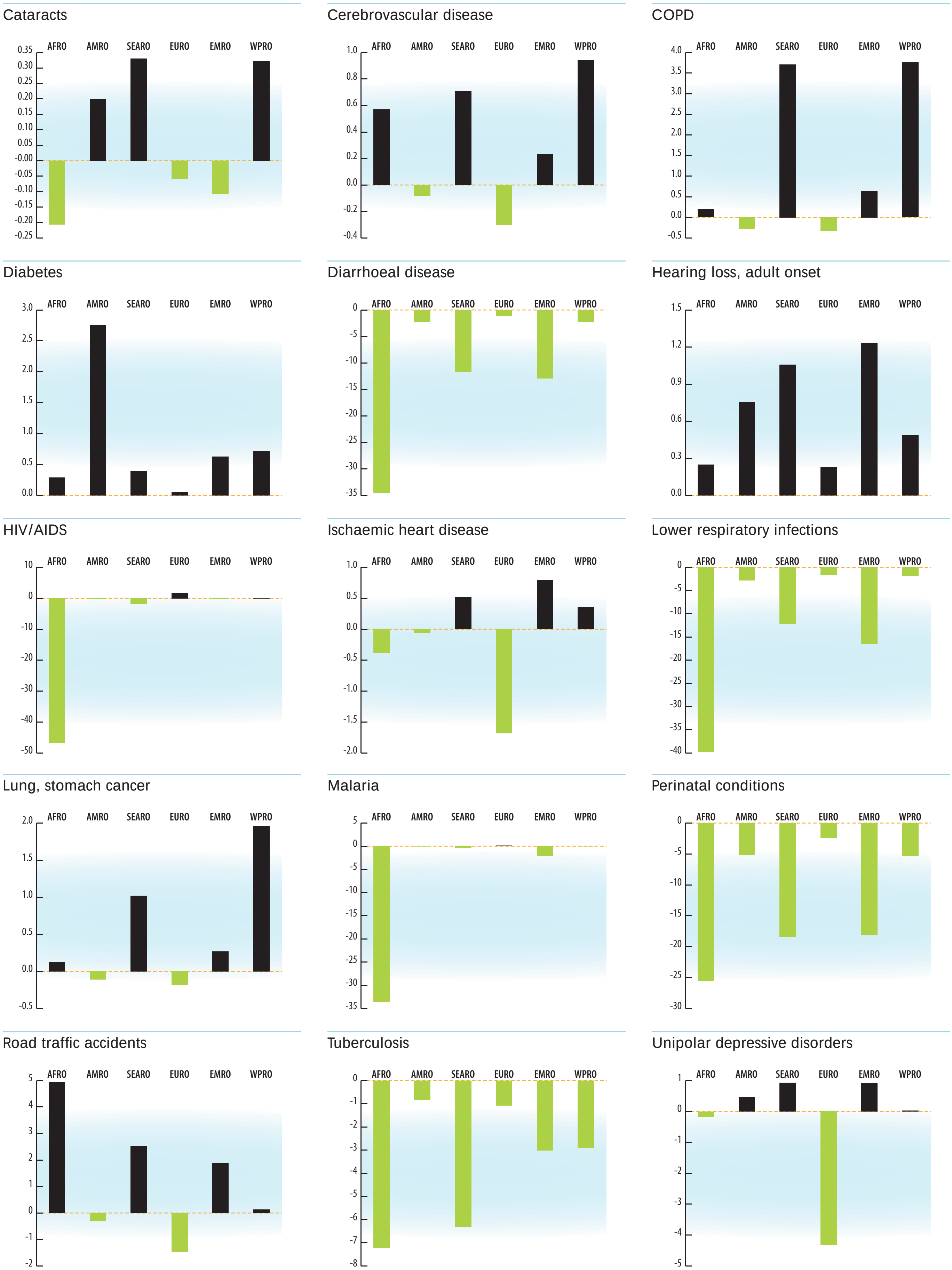
There are some diseases that show very large differences in per capita DALY burden over time. When comparing the WHO European and African Regions (Figure 1), the per capita DALY burden for many diseases will have decreased in both regions between 2004 and 2030. However, there are some diseases that show different trends over time.

As discussed earlier in this paper, populations in most of the regions covered by Figure 1 are projected to increase over time. The positive per capita DALY values recorded in the Figure generally indicate that the disease burden is outpacing population growth.

Figure 1 reflects several noteworthy trends. What are generally regarded as acute conditions (tuberculosis, diarrhoeal diseases, lower respiratory infections, perinatal conditions, etc.) reveal decreasing

1 http://www.who.int/healthinfo/global_burden_disease/ (accessed 5 February 2010).
2 See http://www.who.int for a listing of WHO regions (accessed 5 February 2010).
3 This procedure was discussed with Dr. Colin Mathers (WHO, November 2008).

Figure 1: Change in per capita DALY* burden, 2004–2030 for selected high burden diseases, by WHO region



*DALY,Disability adjusted life year.
AFRO, WHO African Region; AMRO, WHO Region of the Americas; SEARO, WHO South-East Asia Region; EURO, WHO European Region; EMRO, WHO Eastern Mediterranean Region; WPRO, WHO Western Pacific Region.
A positive value (black) reflects an increase in the per capita DALY burden over time. A negative value (green) reflects a decrease in the per capita DALY burden over time. The scale of the Y axis for the different diseases varies as the numbers vary in function of the disease and whether the change in time is large or small. For example, a small difference implies either that the condition did not have a high burden in the area or that there is little change over time.

per capita burdens of disease between 2004 and 2030 in most WHO regions, with the exception of HIV/AIDS in the WHO European and Western Pacific regions. Current projections indicate that across the globe, people will live longer and have less disability, especially disability arising from infectious, maternal, perinatal and nutritional conditions.

Road traffic accidents, ischaemic heart disease and unipolar depressive disorders show increasing per capita DALY burdens in at least three WHO regions, although in varying degrees. Road traffic accidents in particular are expected to rise sharply in the WHO African Region as compared to other regions.

In coming decades, diabetes will be a health issue in all regions – again in varying degrees – with the WHO Region of the Americas having the highest increase of this condition. Because global population is increasing as well, the rising per capita DALY burden for diabetes underscores the ever-growing importance of risk factors for chronic diseases and their sequelae around the world.

Medical technology: future trends

Innovations driving the development of medical technologies for high-resource settings

Breakthroughs in medical technology are likely to be influenced by many scientific and technical areas *(9)*. Nevertheless, several published future scenarios and market projections seem to converge on a specific series of developments in medical devices. For example, in 1998 the U.S. FDA conducted a survey on future trends in medical device technology *(10)*. The major trend categories that emerged from this survey provide background on current and recent developments:

- **Computer-related technology** – Computer-aided diagnosis; "intelligent" devices; biosensors; robotics; integrated patient medical information (i.e. record-keeping) systems; patient smart-cards; clinical laboratory automation and robotics; computer-aided clinical laboratory systems; and robotic surgery.
- **Molecular medicine** – Personalized genetic-based diagnostics and therapy; tissue-engineered devices (i.e. tissue implants).
- **Nanotechnology** – Molecular devices for cellular therapy, oxygen transport, drug transport and targeting, nerve regeneration, basic medical research and numerous other potential applications.
- **Home- and self-care** – Semi-automated home/self monitoring, diagnosis and therapy; telemedicine; home/self urine, blood chemistry and drug concentration tests, designed with particular attention to the needs of elderly patients.
- **Minimally invasive technology** – Refined and extended medical imaging: improved magnetic resonance imaging (MRI), positron emission tomography (PET), endoscopy and image contrast agents; multimodality imaging; microminiaturized diagnostic and therapeutic devices; laser diagnosis, surgery and therapy; robotic surgery and surgical devices; non-implanted sensory aids; and minimally invasive cardiovascular, abdominal and neurological surgeries.
- **Drug Delivery** – Implanted drug delivery systems; and drug impregnated devices (such as cardiac stents) in which drug delivery is an adjunct to the device's function
- **Organ replacement and augmentation** – artificial organs, limbs and other body parts such as heart valves and heart pumps; tissue engineered organs, bone, cartilage, pancreas, blood vessels, kidney, skin, liver, eye, and regenerated nerve cells; electrical nerve stimulation devices.

These projections in 1998 provided a 10-year vision with several discernible characteristics. First, medical hardware was predicted as continuing to become "smarter". Second, the projection expected that these smarter and simpler products will facilitate a growing trend to decentralization of health care from the clinic to the home. Third, product development was expected to increasingly blur the boundaries between biological systems on the one hand, and physical and engineering designs on the other. Integrated and hybrid approaches will play an expanding role.

More recent analyses hardly differ from this 1998 assessment *(11–13)*. Medical technologies such as e-health, genomics and biotechnologies and miniaturisation of devices/nanotechnology are still being touted as developing trends. Improvements in biotechnology and tissue regeneration (regenerative medicine), are intended to enable the development of artificial skin and bones and of replacement organs like an artificial heart, liver or pancreas. Innovations in gene-based diagnostics and molecular imaging diagnostics are likely to help physicians in the early diagnosis of diseases. The types of home diagnostics commonly envisioned were tests involving urine and blood chemistry, as well as drug concentrations – particularly for elderly patients including the possible use of relatively simple forms of telemedicine for home care, especially within the confines of a local or regional medical system.

Other trends that are likely to influence the development of medical devices and healthcare technology in the future include:

- **Nanotechnology** – The engineering of materials and functional systems at a molecular, which is to say submicroscopic, scale. Nanotechnology has many potential medical applications: in surgery, targeted drug and biologic therapy (especially for cancer), for diagnostics, biosensors and biodetection devices, implantable materials and devices, textiles and wound-care products, and drug- or gene-delivery materials and devices *(14)*.
- **Personalized medicine** – Individual treatment plans based on molecular screening and other tests that suggest which regimens will be most effective in specific patients. This approach can be especially useful in selecting chemotherapy drug combinations aimed at specific cancers.
- **Mobile and portable technology** – Increasing numbers of medical devices are being designed for use outside of traditional health-care settings by a range of health-care personnel working in the field.
- **Simulation technology** – Computer simulation and "virtual reality" technology are becoming increasingly be used to teach clinicians new complex surgical techniques before they practice on live patients.

In addition to these trends, information technology (IT) firms will be increasingly involved in developing and/or facilitating the transmission of electronic patient medical records. IT will also be increasingly used to improve repositories of health information.

Development of technologies for low- and medium-resource settings

Despite the fact that globally, public health officials have become accustomed to addressing the disease burden in developing nations, engineers have yet to design and introduce medical devices specifically designed for use in these nations *(15,16)*.

For low- and medium-resource settings, technological forecasts may be of less importance than finding solutions to increase the availability, accessibility, appropriateness, affordability, and cultural acceptability (based on local social norms) of existing medical devices. Many medical devices that are designed for use in high-resource countries are inappropriate, ineffective, and even dangerous when used in low-resource settings *(17)*. Since low- and medium-resource countries are the fastest growing economies, it is likely that a future need for medical technologies will rise in those nations, especially as a growing middleclass with more education and higher incomes demands more healthcare services, including advanced medical procedures and services in these countries. The considerations are, however, complex.

Diffusion of some high-tech, high-cost medical technologies into lower-resource countries might be especially inadvisable when little published evidence is available to demonstrate a meaningful clinical benefit.

Taking disease burden as a starting point, one could argue that future high-burden disease equals a future need, assuming that the higher the burden, the greater the cost to society and thus the greater the healthcare need. On the other hand, from a medical device perspective, not all future high-burden diseases necessarily represent a future need for medical devices, for instance, diseases that are being prevented and treated successfully with current existing devices.

Recognizing the importance of fusing both technical and social realities *(18,19)*, it will be valuable for engineers to design medical devices that are both innovative and adaptable to the realities of health care in developing nations. Ideally, such devices would require little or no electricity, be able to operate on batteries, require little training to operate and maintain, and be locally affordable and sustainable *(20–25)*.

Medical devices, no matter how necessary, rarely stand alone: to be effective, a supportive environment is essential *(26)*. Other support problems include the high cost of maintaining medical equipment and a lack of experienced, well-trained technical and clinical staff to service and use it properly *(20,27)*.

Another common problem in low- and medium-resource countries is the lack of consumables: the disposable, non-reusable supplies that are required for the operation of many medical devices, such as intravenous drip sets, syringes for infusion pumps, filters for dialyzing equipment, disinfectants and reagents. Often, although the equipment itself may be in place, the necessary consumables are simply not available in the country, rendering the devices useless *(26)*. Alternative designs for low-resource settings can focus on minimizing the need for disposables. Such design changes can also aim for low maintenance and modest specialized training for servicing, as well as for low power requirements. In some low-resource countries, re-engineered devices could be manufactured locally, thus both taking advantage of low labour costs and creating jobs *(11)*.

As noted, death and injuries due to traffic accidents are expected to rise very significantly in the coming decades *(2)* and this will undoubtedly result in a further increase in the development and refinement of innovative restorative and implantable devices for trauma victims *(6,8,9)*.

Treating traumatic injuries properly almost always involves surgery, and this is just one of the reasons why increasing both basic and advanced surgical capabilities may be global public health priorities.

Indeed, the need for surgery to treat a wide range of conditions, including injuries and wounds, malignancies, congenital anomalies, heart disease, complications of pregnancy, cataracts and prenatal problems, to name a few, can be thought of as a disease burden in itself. Because of its larger combined population, the developing world has a greater burden of disease requiring surgery than the developed world; yet it receives fewer and has less access to surgical services *(28)*. As the population of some low-income countries increases, and as the global population ages, the need for surgical services can only grow. While building surgical services in developing countries requires costly infrastructure and equipment as well as highly trained human resources, the process will surely help build health-care systems overall and in turn strengthen primary care. The introduction of laparoscopic or minimal invasive surgery, a well established technology in high resource countries could contribute to better health outcome *(29)*.

When weighing whether a particular health technology is appropriate for use in a given environment, the technology can be evaluated in the context of the country's or region's existing health services, infrastructure, health personnel, financial resources and cultural factors. In this process, it is important to understand why, too often, available medical technologyies and devices do not work (either at all or as intended) when employed in local hospitals and clinics *(30–32)*.

The pervasive impact of chronic disease

The models used by WHO include time as a proxy measure for the impact of technological change on health status. This variable captures the effects of accumulating knowledge and technological development, which can lead to more cost-effective health interventions, both preventive and curative, at constant levels of income and human capital *(2)*. Thus, time in this case (i.e. 2004 to 2030) may be regarded as an indirect determinant of health, although it is not necessary for the purposes of the WHO projection to know whether this association is causal. Therefore, the increasing per capita DALY burden over time (time being a proxy for the impact of technological change) regarding some diseases may have important implications for the need for medical devices.

It may mean that whatever medical interventions exist now for various diseases will barely keep pace, in certain regions, with the increase in population and disease burden going forward.

The increasing prevalence of chronic diseases such as obesity and diabetes among the young and the serious health problems that result suggest that at a time when overall health should be showing improvements, there will be large cohorts of people who are less healthy than they could be. The net effect of these trends is unclear. However, in developed countries, advances in bioengineering, genetics, the life sciences, and clinical medicine may succeed in curbing both obesity and diabetes and yield significant gains in many other disease areas as well. How quickly these advances will be diffused to low-income countries is an open question.

Diffusion of medical device technology to low-resource countries: can the gap be closed?

Many barriers impede the diffusion of medical devices and health-care technology in developing nations, with negative consequences for public health. To begin with, there may be a lack of reliable, clean water, electric power and adequate public infrastructure *(21,33,34)*. Other barriers include the gap between standardized health information technology and appropriate implementation *(35)*; low profit margins for device venders; variations in customs and language between countries and even within the same country; political instability; and regulatory constraints and corruption *(36)*. In addition, according to the Engineering World Health (EWH) study, most manufacturers believe that only medical devices that are simple and cheap can be marketed in developing nations. Developing nations, in turn, tend to regard these simple and cheap devices as being of inferior quality *(22)*.

History teaches that medical progress almost always adds to health care costs: this is going to be a problem in a world where the population is ageing and more and more elderly are, in the context of health care, being supported by a diminishing number of workers. It will certainly mean higher health insurance rates and it will probably mean far greater attention to the cost-benefit aspect of advances in medical therapy and technology, especially when these are only incremental. In most of the world's low-resource countries, health insurance, public or private, is essentially non-existent, wholly inadequate or highly fragmented. This is unlikely to change any time soon, and as a result the fruits of medical progress will be unevenly distributed in these countries *(37)*.

In order to meet future health-care needs in low- and middle-income countries, it is important for medical devices and technology, whether based on existing models or new scientific discoveries, to be designed to benefit as many people as possible, at acceptable costs.

Cost is not the only factor that can limit the diffusion of new medical technology into low-resource regions. Such technologies are only useful when clinicians, technicians and other health workers employing them are able to constantly revise their skills and practices based on experience and the best available evidence. Thus, impediments to the use of new medical devices and technologies in developing countries may be less a matter of access per se to these technologies than a function of weaknesses in domestic skills and competencies that impede the exploitation of the technologies.

The complete diffusion of medical and other technologies within a country will require that at least some of these technologies be actually manufactured (and possibly engineered) within that country, or within a nearby countries, thus taking advantage of low labour and distribution costs as well as intimate knowledge of the local and regional health-care environments. While there may be a few medical equipment firms with technologically sophisticated operations in developing countries, most operate in a low-tech environment with unskilled or semi-skilled workers.

To ensure that they are able to take advantage of future opportunities in health care and many other areas, it would be valuable for developing countries to strengthen skills and education levels in their domestic populations. It may be valuable for the education of health workers to become a key priority in improving health, and health-care training in this area within and among countries can be harmonized *(38)*. In low- and middle-income countries with poor and uneven access to quality secondary and tertiary education, efforts to raise the quality and quantity of schooling may have beneficial effects on improving the quality of health-care delivery.

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