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Preliminary Draft Report of the IBC Working Group on Social Responsibility and Health

This document presents a preliminary draft report on social responsibility and health, as established by the IBC Working Group taking into consideration the discussion on this issue at the Twelfth session of IBC (Tokyo, Japan, 2005) and at the Thirteenth session (Paris, 2006), as well as the written contributions received from members of the working group.

In this preliminary edition the essentials of all contributions are presented in an attempt to integrate a logical structure. This document is preliminary in nature and should not be considered as definite but as a step in the work of the Working Group and IBC in its entirety.

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EXECUTIVE SUMMARY

Global health conditions at the beginning of this new century are marked by growing inequities related mostly to poverty and lack of access to health care services. Health policy has been considered recently to be more than the provision and funding of medical care, by taking into consideration that for the health of the population as a whole the social and economic conditions that make people ill and in need of medical care are clearly of utmost importance. These include, among others, the lifelong importance of health determinants in early childhood, and the effects of poverty, unemployment, malnutrition, working conditions, drugs, social support, adequate food, and position in the social ladder. In contrast, the influence of biological and physical factors on health has been estimated at less than 15% and 10%, respectively.

It is an accepted fact that more than one billion people – one sixth of the total population of the world – live in extreme poverty, lacking the safe water, proper nutrition, basic health care, and social services needed to survive. Poverty is reflected in various aspects of the life of individuals and populations living under deprived conditions in developing countries, but also in some regions of industrialized countries. There is poverty in food, which is scarce in quantity and deficient in quality; there is poverty in housing, which nearly always is inadequate, and there is poverty in knowledge, education and culture. Finally, there is poverty, which approaches real misery that involves the hygiene of persons, housing and the community.

The development of new technologies has improved life expectancy and quality of life of people around the world, especially in developed countries. But as a paradox, while technology grows, more resources are available and progress is becoming more and more evident, ethical problems, inequities, inequalities are also growing, in even greater proportions. The new technical advances, which have been very useful in improving the quality of life of human beings, have been inefficient in solving this problem and instead of helping in some way or another, they have contributed to increasing them. Almost 60 years have passed since the Universal Declaration of Human Rights was approved. Since that time other declarations have also been approved and different programmes have been developed, but in the practical setting, the reality is still hopeless. Important inequalities and inequities persist all around the world and some of them have dramatic consequences in the undeveloped countries.

The guiding principles of most governments have been those of equality of access to health care and solidarity in sharing the financial burden proportionate to income. However, pressures on health care systems are already imposed by the impact of financial and demographic determinants. These factors were recognized almost 30 years ago in the development of international strategies for health promotion, such as the WHO commitment to a global strategy for Health for All and the principles of primary health care through the 1978 Declaration of Alma Ata. Today, after not being able to reach Health for All by the Year 2000, health promotion is still a crucial topic of debate.

Subsequent international health policy guidelines have promoted health as a basic human right, essential for social and economic development. It has been considered that health promotion, through investment and action, has a marked impact on the determinants of health so as to create the greatest health gain for people, to contribute significantly to the reduction of inequities in health, to further human rights, and to build social capital. The ultimate goal is to increase health expectancy, and to narrow the gap in health expectancy between countries and groups. To make this come about investment in social and economic development should be given prime attention.

Social responsibilities for health are a fundamental concern for the ethics of professional public health practices. Central concerns are accountability and commitment and the reliable performance of professional tasks in the pursuit of social goods.

In conclusion, the widening gaps in health conditions described above are best explained in terms of social, economic, and cultural differences and the value that individuals and societies attribute to the idea of a healthy society. Therefore, individual responsibility and social responsibility are usually inextricably intertwined and are related to moral judgments and political strategies that may or may not seek equity as a goal. Health is everyone's responsibility: the public and private sectors, governments of developed and developing countries, NGOs, multilateral agencies and civil societies, and obviously, individuals as well.

I. INTRODUCTION

Shortly after the adoption of the Universal Declaration on Bioethics and Human Rights by the General Conference of UNESCO at its 33rd session (2005), the International Bioethics Committee of UNESCO (IBC) decided at its Twelfth session (Tokyo, Japan, 15-17 December 2005) to focus on the principle of social responsibility and health, as set forth in Article 14 of the Declaration⁽¹⁾.

There is no doubt that article 14 of the Declaration sums up many of the most important issues faced by our societies at this time to address the problem of global inequities in health. All these issues have ethical, economical, cultural, political, technical, and philosophical implications, and any discussion about them requires a multidisciplinary approach. As a society, one of our biggest challenges today is to assume our responsibility in analyzing and solving these problems.

Given this state of affairs, how can the Universal Declaration on Bioethics and Human Rights be applied so that it will not remain a "dead letter" with no impact on the social and health situation of individual countries and the world as a whole?

This document discusses the bioethical perspective of social responsibility in promoting health. It contains an analysis of values, responsibilities, human dignity, equality, equity, justice, benefits and harm, solidarity, cooperation, sharing benefits, protection of future generations and other important ethical principles in the context of the development and uses of biotechnology and its relationship with every human's life. The document will also analyze the negative effects that the development and uses of biotechnology have had on health care, access to nutrition and water, marginalization and the benefits that we could obtain from new technologies which could contribute to solve all these problems.

Social responsibility for health is the commitment that a society as a whole (from government to individuals) must assume in taking active participation in solving those problems which affect human's health. In particular, the problems related to equitable access to health, nutrition, water, and reduction of poverty and illiteracy, as well as protection of the environment. The report will review different bioethics issues that have emerged as a consequence of the development of new techniques, discuss how bioethics can contribute to solving these problems, and identify different ways in which biotechnology can be used to solve these problems.

The report is addressed to States, international, national institutions, professionals, society, and individuals.

1. "1. *The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.*

2. *Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:*

- (a) *access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;*
- (b) *access to adequate nutrition and water;*
- (c) *improvement of living conditions and the environment;*
- (d) *elimination of the marginalization and the exclusion of persons on the basis of any grounds;*
- (e) *reduction of poverty and illiteracy."*

II. INTERNATIONAL FRAMEWORK

II.1. INITIATIVES UNDERTAKEN WITHIN THE UN SYSTEM

The normative context regarding health and social responsibility can be traced back to many existing international instruments declarations, international covenants or statements, as well as initiatives, which explicitly refer to health and welfare of human beings.

Constitution of the World Health Organization (WHO)

The well-known Constitution of WHO defines health as “*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*” and affirms that “*the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition*”.

Universal Declaration of Human Rights

The Universal Declaration of Human Rights (1948) refers to health and welfare of human beings in article 25, which states that: “*Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services...*” and follow:

“(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection”.

International Covenant on Economic, Social and Cultural Rights

Article 15 of the International Covenant on Economic, Social and Cultural Rights (1966), states that “*everyone has the right to enjoy the benefits of scientific progress and its applications*” and Article 12 states:

- “1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*
- 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:*
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;*
 - (b) The improvement of all aspects of environmental and industrial hygiene;*
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;*
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”*

Health-for-All by the Year 2000

In 1977 the Thirtieth World Health Assembly decided that the main social goal of governments and WHO in the coming decades should be the attainment by all people of the world by the year 2000 of a level of health that would permit them to lead a socially and economically productive life. This goal is commonly known as Health-for-All by the Year 2000 (Resolution WHA30.43).

The commitment to global improvements in health, especially for the most disadvantaged populations, was reviewed in 1998 by the World Health Assembly. This led to the development of ‘Health-for-All for the Twenty-First Century’ policy and programme, within which the commitment to primary health care is restated.

In the report of the 51st World Health Assembly on this issue, it is indicated: “*Over the past two decades primary health care as a cornerstone of Health-for-All. Despite gains, however, progress has been hampered for several reasons, including insufficient political commitment to the implementation of Health-for-All, slow socioeconomic development, difficulty in*

achieving intersectorial action for health, insufficient funding for health, rapid demographic and epidemiological changes, and natural and man-made disasters. Further, poverty has increased worldwide. Health has suffered most where countries have been unable to secure adequate income levels for all.” The report also indicated that primary health-care policy approaches should reinforce the following points:

- make health central to development and enhance prospects for intersectorial action;
- combat poverty as a reflection of primary health care’s concern for social justice;
- promote equity in access to health care;
- build partnerships to include families, communities and organizations;
- reorient health systems towards promotion of health and prevention of disease.

The ‘Health-for-All’ WHO commitment and programme were marked by a series of Global Conferences on Health Promotion which began in Ottawa in 1986 and produced the Ottawa Charter on Health Promotion. This benchmark conference was followed by conferences in Adelaide (1988), Sundsvall (1991), Jakarta (1997) Mexico City (2000) and Bangkok (2005).

Alma Ata Declaration

The International Conference on Primary Health Care (PHC), held in Alma-Ata, Kazakhstan, in 1978, realized that improving health called for a comprehensive approach whereby primary health care was seen as “the key to achieving an acceptable level of health throughout the world in the foreseeable future as a part of social development and in the spirit of social justice”. The Conference adopted “The Alma-Ata Declaration” which reaffirmed that *“health... is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector”*. The Conference called for a transformation of conventional health-care systems and for broad intersectorial collaboration and community organizing.

Ljubljana Charter

The Ljubljana Charter, adopted by the Ministers of Health or their representatives from the European Member States of WHO at the WHO Conference on European Health Care Reforms in Ljubljana, Slovenia in June 1996, addresses health-care reforms in the specific context of Europe. The purpose of this Charter is to articulate a set of principles which are an integral part of current health-care systems or which could improve health care in all the Member States of WHO in the European Region. These principles emerge from the experience of countries implementing health-care reforms and from the European health-for-all targets, especially those related to health-care systems.

Jakarta Declaration

The promotion of social responsibility for health was first established as a priority at the WHO Fourth International Conference on Health Promotion: New Players for a New Era – Leading Health Promotion into the 21st Century, held in Jakarta, Indonesia in July 1997.

In the final Declaration, the Conference, the first to be held in a developing country, and the first to involve the private sector in supporting health promotion, recommended that decision makers must be *“firmly committed to social responsibility”* and both public and private sectors *“should promote health by pursuing policies and practices that:*

- *avoid harming the health of individuals,*
- *protect the environment and ensure sustainable use of resources,*
- *restrict production of, and trade in, inherently harmful goods and substances such as tobacco and armaments, as well as discourage unhealthy marketing prices,*

- *safeguard both the citizen in the marketplace and the individual in the workplace,*
- *include equity-focused health impact assessments as an integral part of policy development.”*

Bangkok Charter

More recently, the Bangkok Charter, adopted at the WHO Sixth Conference on Global Health Promotion held in Thailand in August 2005, identifies actions, commitments and pledges required to address the determinants of health in a globalized world through health promotion. Thus, it is recommended that *“governments at all levels must tackle poor health and inequalities as a matter of urgency because health is a major determinant of socioeconomic and political development”*. Its four key commitments are to make promotion of health:

- central to the global development agenda: strong intergovernment agreements that improve health and collective health security and effective mechanisms for global governance for health are needed;
- a core responsibility for government as a whole: the determinants of health need to be addressed by all ministries at all levels of government;
- a key focus of communities and civil society: well-organized and empowered communities are highly effective in determining their own health, and are capable of encouraging governments and the private sector to be accountable for the health consequences of their policies and practices;
- a requirement for good corporate practice: the private sector has a responsibility to ensure health and safety in the workplace and to promote the health and well-being of employees, their families and communities, and to contribute to lessening wider impacts on global health.

UN Millennium Development Goals

Further international efforts to meet the needs of the poorest, including better health, have been included in the eight UN Millennium Development Goals (MDG) (United Nations Millennium Declaration adopted by the General Assembly in September 2000). The UN Millennium Development Goals address health in a global and social perspective. Indeed, among the development goals, reduction of child mortality (Goal 4), improvement of maternal health (Goal 5) and combat HIV/AIDS, malaria and other diseases (Goal 7) can be found. Moreover, one of the seven modalities set out to achieve Goal 8 “Develop a global partnership for development” is to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies.

UNESCO Universal Declaration on Bioethics and Human Rights

Apart from the already well-established principles in the scientific community such as consent, the principle of autonomy and individual responsibility, respect for privacy and confidentiality, the Universal Declaration on Bioethics and Human Rights (2005) opens up perspectives for action that reach further than just medical ethics and reiterates the need to place bioethics and scientific progress within the context of reflection open to the political and social world.

Right from the Preamble, the Universal Declaration expresses the desirability of *“developing new approaches to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity”*.

Article 14 specifically addresses the issue of social responsibility and health. This principle is designed to draw the attention of policy makers in the field of medicine and life sciences to the practical concerns of bioethics contributing to re-orienting bioethical decision-making towards issues that are urgent for many countries. Even though the list is not exhaustive, five specific elements are singled out as priority and universal areas of decision to be taken into assessment: access to quality health care and essential medicines, especially health of women and children; access to adequate nutrition and water; improvement of living conditions and the environment; the elimination of the marginalization and exclusion of persons on the basis of whatever grounds, and the reduction of poverty and illiteracy.

Article 14 should also be read in the light of Article 13 on solidarity and co-operation (*"Solidarity among human beings and international cooperation towards that end are to be encouraged."*), which reflects the commitment that the Declaration is based not only on the individualist concept of *rights* but that it also recognizes the importance of *solidarity* between individuals and across communities. The idea of collective social protection and fair opportunity should be a governing principle in policy decisions and it is an essential element of a population-based ethics.

Cooperation between and among individuals, families, groups and communities, with special regard for those rendered vulnerable (also expressed in Article 8), should be of special concern in the relevant decision-making and the establishment of appropriate practices within the scope of the Declaration. The international dimensions of health care today are more significant than ever before. Rare diseases that are sometimes neglected by health-care systems at the national level may be very dangerous in other parts of the world, and this requires international cooperation. In the case of HIV/AIDS-prevention, for example, the ethical dimensions of health care frequently go beyond national frontiers.

Finally, Article 15⁽²⁾ in dealing with the benefits resulting from scientific research and its applications and the need to share them with society and the international community, echoes Article 14. It identifies as concrete areas of implementation of such sharing, access to quality health care, provision of new diagnostic facilities for new treatment or medical products stemming from the research and support for health services.

II.2. INITIATIVES UNDERTAKEN BY OTHER ORGANIZATIONS

Outside the United Nations systems, a number of alliances between public, private, nongovernmental and international organizations and civil society have been organized with the aim to address the determinants of health in a globalized world through health promotion. Recent initiatives are described below as examples.

Global Forum for Health Research. At recent parallel meetings of the Forum 8 organized by the Global Forum for Health Research and the Ministerial Summit on Health Research, held in Mexico City in November, 2004, over 1,400 policy makers, health ministers, researchers and representatives of governments, development agencies and research institutions examined the issue on how research could improve strategies and help to attain the MDG. One of the conclusions of both the Forum and the Summit was that achieving the

2. "1. *Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:*

- (a) *special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;*
- (b) *access to quality health care;*
- (c) *provision of new diagnostic and therapeutic modalities or products stemming from research;*
- (d) *support for health services;*
- (e) *access to scientific and technological knowledge;*
- (f) *capacity-building facilities for research purposes;*
- (g) *other forms of benefit consistent with the principles set out in this Declaration.*

2. *Benefits should not constitute improper inducements to participate in research."*

Goals will require addressing health and its determinants in a comprehensive way and will necessitate further health research, of high quality, focused on the needs of developing countries and vulnerable populations. It must give systematic attention to cross-cutting issues of poverty and equity, taking account of inequities based on gender, ability, ethnicity and social class, among others; the needs of both the aged and the largest generation ever of young people 0-19 years, and the needs of other specifically disadvantaged groups such as migrants, refugees and those exposed to violent conflict. It was concluded that all the participants must commit themselves to the shared responsibility of advancing the volume and pace of health research that is focused on improving the lifespan and health of people everywhere. Special consideration was given to increase funding for health systems research, as this activity of research is the one that may have the largest impact on improving health.

Grand Challenges in Global Health. This initiative is a partnership dedicated to supporting scientific and technical research to solve critical health problems in the developing world. The initiative's partners are the Bill & Melinda Gates Foundation, the Canadian Institutes of Health Research, the Foundation for the National Institutes of Health, and the Wellcome Trust. A grand challenge is meant to direct investigators to a specific scientific or technical breakthrough that would be expected to overcome one or more bottlenecks in an imagined path towards a solution to one or preferably several significant health problems. Therefore a grand challenge is envisioned as distinct from a simple statement of one of the major problems in global health, such as malnutrition or the lack of access to medical care. The initiative has identified and supported seven long-term goals to improve health in the developing world:

- to improve childhood vaccines,
- to create new vaccines,
- to control insects that transmit agents of disease,
- to improve nutrition to promote health,
- to improve drug treatment of infectious diseases,
- to cure latent and chronic infection,
- to measure health status accurately and economically.

Reaching the Poor Programme (RPP). This is an effort to begin finding better ways of ensuring that the benefits of health, nutrition, and population (HNP) programmes flow to disadvantaged population groups. It has been undertaken by the World Bank, in cooperation with the Gates Foundation, and the Dutch and Swedish Governments. In order to help improve how well HNP programmes reach poor people, the RPP seeks to:

- determine which HNP programmes do or do not reach disadvantaged groups effectively. The resulting information, produced through application of recently-developed quantitative techniques for assessing programmes' distributional performance, is intended to provide guidance to policy makers about which approaches to adopt and to avoid in developing pro-poor initiatives;
- encourage others to undertake similar determinations of HNP programme effectiveness in reaching the poor. More widespread application of the techniques just mentioned, derived from the "benefit incidence" approach used to determine who benefits most from government expenditures, would allow policy makers to assess and then improve their performance in reaching the poor on an ongoing basis.

The programme considers that health policies do not have to be inequitable: "While most health, nutrition, and population services exacerbate poor-rich inequalities by achieving much lower coverage among the disadvantaged than among the better-off, many significant and instructive exceptions exist. This demonstrates the feasibility of reaching the poor much more effectively than at present, and point to promising strategies for doing so".

III. GLOBAL HEALTH CONDITIONS

At the beginning of the new century, global health conditions are marked by growing inequities due mostly to poverty and lack of access to health-care services. Health policy has been considered recently to be more than the provision and funding of medical care, by taking into consideration that for the health of the population as a whole, the social and economic conditions that make people ill and in need of medical care are clearly of utmost importance. These include, among others, the lifelong importance of health determinants in early childhood, and the effects of poverty, unemployment, malnutrition, working conditions, drugs, social support, adequate food and position in the social ladder. In contrast, the influence of biological and physical factors on health has been estimated as less than 15% and 10%, respectively.

It is an accepted fact that more than one billion people – one sixth of the total population of the world – live in extreme poverty, lacking safe water, proper nutrition, basic health care and social services needed to survive. Poverty is reflected in various aspects of the life of individuals and populations living under deprived conditions in developing countries, but also in some regions of industrialized countries. There is poverty in food, which is scarce in quantity and deficient in quality; there is poverty in housing, which nearly always is inadequate; and there is poverty in knowledge, education and culture. Finally, there is poverty, which approaches real misery that involves the hygiene of persons, houses and the community.

Global health conditions at present have been summarized in 2006 by WHO: “In this first decade of the 21st century, immense advances in human well-being coexist with extreme deprivation. In global health we are witnessing the benefits of new medicines and technologies. But there are unprecedented reversals. Life expectancies have collapsed in some of the poorest countries to half the level of the richest – attributable to the ravages of HIV/AIDS in parts of sub-Saharan Africa and to more than a dozen “failed states”. These setbacks have been accompanied by growing fears, in rich and poor countries alike, of new infectious threats such as SARS and avian influenza and “hidden” behavioural conditions such as mental disorders and domestic violence. The world community has sufficient financial resources and technologies to tackle most of these health challenges; yet today many national health systems are weak, unresponsive, inequitable – even unsafe. What is needed now is the political will to implement national plans, together with international cooperation to align resources, harness knowledge and build robust health systems for treating and preventing disease and promoting population health”.

III.1. MAJOR PUBLIC HEALTH PROBLEMS

Despite progress in the medical and health field, major public health problems and inequalities of health care between North and South still remain. Today 800 million individuals suffer from hunger and malnutrition, and more than a billion people do not have access to safe drinking water, basic education and health care. In this information age where future development is supposed to be based on knowledge, two billion are not connected to an electricity supply and more than 4.5 billion or 80% of the world’s population is deprived of basic telecommunication technology.

Maternal mortality

Notwithstanding all the advances of science and technology in medical and health fields witnessed in the 20th century, maternal deaths continue unabated – the annual total now stands at 529,000 often sudden, unpredicted deaths which occur during pregnancy itself (some 68,000 as a consequence of unsafe abortion), during childbirth, or after the baby has been born – leaving behind devastated families, often pushed into poverty because of the cost of health care that came too late or was ineffective. These deaths are even more unevenly spread than newborn or child deaths: only 1% occur in rich countries, every day more than 1,600 women die in developing countries of causes related to child birth. Every 45

seconds a woman dies from pregnancy related causes, and every seven and a half minutes, a woman dies from an unsafe, often self-induced abortion. Over 300 million women suffer from short-term or long-term illness brought about by pregnancy and childbirth.

Child mortality

Globally, mortality rates in children under five years of age fell throughout the latter part of the 20th century: from 146 per 1000 live births in 1970 to 79 in 2003. Towards the turn of the millennium, however, the overall downward trend started to falter in some parts of the world. In 93 countries, totalling 40% of the world population, under-five mortality is decreasing fast. A further 51 countries, with 48% of the world population, are making slower progress: they will only reach the Millennium Development Goals if improvements are accelerated significantly. Even more worrying are the 43 countries that contain the remaining 12% of the world's population, where under-five mortality was high or very high to start with and is now stagnating or reversing.

At the beginning of the 21st century over 10 million children (more than 27,000 per day) die each year, although most of these deaths can be avoided. Each year some 3.3 million babies are stillborn and more than 4 million die within 28 days of coming into the world, and a further 6.6 million young children die before their fifth birthday, most of them from the poor countries. The main causes of death among children under five years of age are avoidable illnesses. Six illnesses account for 70% to 80% of all these deaths: acute respiratory infections, diarrhoea, malaria, measles, HIV/AIDS, premature birth and neonatal problems. Three quarters of neonatal deaths could be avoided if pregnant women received better nutrition and adequate perinatal care.

Infectious diseases

Infectious diseases continue to be a serious burden around the world, in developing as well as industrialized countries. Infections can cause illness, disability and death in individuals while disrupting whole populations, economies and governments. Transmissible diseases constitute the main cause of death in the poorest countries: 59% of deaths reported in the 20 poorest countries are caused by such diseases, compared with 8% in the 20 richest countries. WHO estimates for 2002 that some 11 million people died from infectious and parasitic diseases, 52% of them in Africa, 26% in South-East Asia and 3% in Latin America. The main causes of annual deaths from transmissible diseases were respiratory infections (4 million), HIV/AIDS (2.8 million), tuberculosis (1.5 million), diarrhoea (1.8 million) and malaria (1.3 million).

As people, products, food and capital travel the world in unprecedented numbers and at historic speeds, so, too, do the myriad of disease-causing microorganisms. Because national borders offer trivial impediment to such threats, especially in the highly interconnected and readily traversed "global village" of our time, one nation's problem soon becomes every nation's problem. The worldwide resurgence of dengue fever, the introduction of West Nile virus into New York City in 1999, the rapid spread of human immunodeficiency virus (HIV) infection in Russia, and the global spread of multidrug-resistant tuberculosis (TB) are but a few examples of the profound effects of globalizing forces on the emergence, distribution and spread of infectious diseases. No nation is immune to the growing global threat that can be posed by an isolated outbreak of infectious disease in a seemingly remote part of the world. In addition to the known diseases, there are new epidemics such as SARS, which infected some 8,000 people in 30 countries in 2003, and avian influenza, which led to the slaughter of millions of animals in three continents, and experts fear that the virus could mutate and unleash a human influenza pandemic.

Chronic diseases

Heart disease, stroke, cancer, chronic respiratory diseases and diabetes are by far the leading cause of mortality in the world, representing 60% of all deaths. Out of the 35 million people who died from chronic disease in 2005, half were under 70 and half were women. Visual impairment and blindness, hearing impairment and deafness, oral diseases and genetic disorders are other chronic conditions that account for a substantial portion of the global burden of disease.

Deaths from infectious diseases, maternal and perinatal conditions, and nutritional deficiencies combined are projected to decline by 3% over the next 10 years. In the same period, deaths due to chronic diseases are projected to increase by 17%. This means that of the projected 64 million people who will die in 2015, 41 million will die of a chronic disease – unless urgent action is taken. Contrary to common perception, 80% of chronic disease deaths occur in low and middle-income countries. From a projected total of 58 million deaths from all causes in 2005, it is estimated that chronic diseases will account for 35 million, which is double the number of deaths from all infectious diseases (including HIV/AIDS, tuberculosis and malaria), maternal and perinatal conditions, and nutritional deficiencies combined. The total deaths from chronic diseases are projected to increase by a further 17% over the next 10 years, while deaths from infectious diseases, maternal and perinatal and nutritional deficiencies combined are expected to decline.

The threat is growing – the number of people, families and communities afflicted is increasing. This growing threat is an under-appreciated cause of poverty and hinders the economic development of many countries. Common, modifiable risk factors underlie the major chronic diseases. These risk factors explain the vast majority of chronic disease deaths at all ages, in men and women, and in all parts of the world. They include: unhealthy diet, physical inactivity and tobacco use. The burden of chronic disease has major adverse effects on the quality of life of affected individuals, causes premature death, creates large adverse – and underappreciated – economic effects on families, communities and societies in general: \$558 billion - the estimated amount China will forego in national income over the next 10 years as a result of premature deaths caused by heart disease, stroke and diabetes.

Despite global successes, chronic diseases have generally been neglected in international health and development work. Furthermore, these diseases have not been included within the global Millennium Development Goal targets. Chronic diseases hinder economic growth and reduce the development potential of countries, and this is especially true for countries experiencing rapid economic growth, such as China and India. However, it is important that prevention is addressed within the context of international health and development work even in least developed countries, which are already undergoing an upsurge in chronic disease risks and deaths.

Malnutrition

Malnutrition is still one of the major public-health problems in the world, as shown by the low nutrition indices in many countries of the South, but above all in East and West Africa (0.46 and 0.50 respectively). Furthermore, it is estimated that over 800 million people do not have access to good-quality food in sufficient quantity and that over 2 billion suffer from deficiencies of micronutrients such as vitamin A, iodine and iron. Every year, nearly 11 million children under-five die and almost all of these deaths occur in developing countries, three quarters of them in sub-Saharan Africa and South Asia, two regions that also record the highest incidence of problems relating to hunger and malnutrition. Generally, although these children do not die from famine but from neonatal ailments and a variety of curable infectious diseases, particularly diarrhoea, pneumonia, malaria and measles, most of these children would not die if their bodies and immune systems were not weakened by malnutrition. Finally, hunger and malnutrition are the main causes of destitution and extreme poverty, giving rise to criminal and violent behaviour.

Hungry children start attending school late (if at all), they finish their studies earlier and learn less, which impedes progress towards primary and secondary education for all. Under-nutrition of women is one of the most destructive results of gender inequality: it reduces their education and employment opportunities and impedes progress towards gender equality and women's autonomy. Hunger and malnutrition increase the incidence and lethality rate of the health problems that cause most deaths during pregnancy and parturition. Hunger and poverty destroy the immune systems of population groups, force them to adopt risky survival strategies and substantially increase the risk of infection and death from HIV/AIDS, malaria, tuberculosis and other infectious diseases.

III.2. DETERMINANTS OF HEALTH

General background

Today an unprecedented opportunity exists to improve health in some of the world's poorest and most vulnerable communities by tackling the root causes of disease and health inequalities.

According to WHO, *“the determinants of health include: the social and economic environment, the physical environment, and the person's individual characteristics and behaviours. The context of people's lives determine their health, and so blaming individuals for having poor health or crediting them for good health is inappropriate. Individuals are unlikely to be able to directly control many of the determinants of health. These determinants - or things that make people healthy or not - include the above factors, and many others such as:*

- *income and social status - higher income and social status are linked to better health. The greater the gap between the richest and poorest people, the greater the differences in health;*
- *education – low education levels are linked with poor health, more stress and lower self-confidence;*
- *physical environment – safe water and clean air, healthy workplaces, safe houses, communities and roads all contribute to good health;*
- *employment and working conditions – people in employment are healthier, particularly those who have more control over their working conditions;*
- *social support networks – greater support from families, friends and communities is linked to better health;*
- *culture - customs and traditions, and the beliefs of the family and community all affect health;*
- *Genetics - inheritance plays a part in determining lifespan, healthiness and the likelihood of developing certain illnesses. Personal behavior and coping skills – balanced eating, keeping active, smoking, drinking, and how we deal with life's stresses and challenges all affect health;*
- *health services - access and use of services that prevent and treat disease influences health;*
- *gender - Men and women suffer from different types of diseases at different ages.”*

Tackling major health determinants is of great importance for reducing the burden of disease and promoting the health of the general population. Action to reduce health inequalities aims to improve everyone's level of health closer to that of the most advantaged, to ensure that the health needs of the most disadvantaged are fully addressed, and to help the health of people in countries and regions with lower levels of health to improve faster.

Social determinants

Throughout the world, people who are vulnerable and socially disadvantaged have less access to health resources, get sicker and die earlier than people in more privileged social positions. The greatest share of health problems is attributable to the social conditions in which people live and work, referred to as the social determinants of health. Good medical care is vital to the well being of populations, but improved clinical care is not enough to meet today's major health challenges and overcome health inequities.

Without action on social determinants, those countries in greatest need will neither meet the health-related MDG nor achieve global targets for reducing chronic diseases such as cardiovascular diseases, cancer and diabetes. Problems are especially urgent in developing countries where the burden of chronic illnesses is growing rapidly on top of the burden of unresolved infectious epidemics.

Health status, therefore, should be of concern to policy makers in every sector, not solely those involved in health policy. To reduce inequalities in health across the world there is a need for a major thrust that is complementary to development of health systems and relief of poverty: to take action on the social determinants of health. Such action will include relief of poverty but it will have the broader aim of improving the circumstances in which people live and work. It will, therefore, address not only the major infectious diseases linked with poverty but also non-communicable diseases - both physical and mental - and violent deaths that form the major burden of disease and death in every region of the world outside Africa and add substantially to the burden of communicable disease in sub-Saharan Africa. If the major determinants of health are social, so must be the remedies. Treating existing disease is urgent and will always receive high priority but should not be to the exclusion of taking action on the underlying social determinants of health. Disease control, properly planned and directed, has a good history, but so too does social and economic development in combating major diseases and improving population health. Wider social policy will be crucial to the reduction of inequalities in health.

Poverty. Links between poverty, increasing population, environmental degradation, poor health, human migration and strife are well known. One could be the cause and the effect of the other. A vast amount of data is now available to establish that the health problems of the poor differ significantly from those of the rich, within a country and between countries. The current trade and economic policies (the free flow of trade and money) around the world has brought economic growth for the fortunate in the largest and strongest economies but has also created widening gaps in wealth and health between and within the countries. To realize an environmentally sound, economically productive, socially responsible and behaviourally possible development requires a developmental strategy which ensures economic growth translated into human development: only then can it be sustainable.

Overpopulation. High fertility rates have historically been strongly correlated with poverty, high childhood mortality rates, low status and educational levels of women, deficiencies in reproductive health services and inadequate availability and acceptance of contraceptives. Poverty and population are linked so closely that their solution must go hand in hand. At the moment poor countries are unable to provide for the total resources required for this purpose. With the exception of sub-Saharan Africa much of the developing world is now well into a transition from high fertility and mortality rates to low ones. The world is thus both younger and older than ever before. Today half the population in developing countries is under 23 years old, an estimated 800 million people – 15% of the world's population is thus in their teens. This results in a "demographic momentum" implying that even after the fertility rate falls below replacement levels, the population would continue to increase for several decades hereafter. A doubling of the number of older people in developing countries in the next 25 years will mount to "an unprecedented demographic revolution". Ageing populations add to the national pool of chronic debilitating diseases like cardiac and cerebrovascular disorders, degenerative arthritis, osteoporosis, dementia, Parkinson's disease, cancer etc., which add to the already rising cost of health care.

Malnutrition. Altogether it looks as if the global race between population and food is at best going to be rather too close, for the poorest communities (because the prices are rising) it is already being lost. Everyone agrees that the world's population will exceed 8 billion by 2025, an increase of 30% in 25 years. Future increases in food supplies, required to feed these extra numbers, must come primarily from rising biological yields, rather than from area expansion and large-scale irrigation expansion. The challenge is world wide, and both technological and political in nature. The technological challenge is enormous, requiring the development of new, high productive, more nutritious, environmentally sustainable production systems. New technologies such as genetically modified organisms (GMOs), post-harvest technologies, pest control, food storage etc. already known can help meet some of these challenges. It is not more of the same. Under-nutrition triggers an array of health problems like stunted growth, proneness to infections and worst of all mental retardation and cognitive impairment. Adverse socioeconomic circumstances during foetal life and in early childhood also have a specific influence on mortality from stroke and stomach cancer in adulthood, which is not due to the continuity of social disadvantage throughout life. Deprivation in childhood influences risk of mortality from coronary heart disease in adulthood, although an additive influence of adulthood circumstances is seen in these cases.

Life styles. Evidence suggests that modern inactive life styles, affluence related over consumption of food, stress associated with "get rich quick" or "extremely competitive world", over indulgence in unhealthy food and beverages, smoking and recreational drugs, promiscuous sex, breaking down of conventional joint family systems are responsible for the emerging morbidity and mortality profile already prevalent in many developed countries. Obesity, diabetes, hypertension, cardio and cerebrovascular and mental disorders are already responsible for increasing cost of health care globally. The number of people suffering from diabetes worldwide is projected to more than double from 135 million now to almost 300 million by 2025. Globally, the prevalence of chronic, non-communicable diseases is increasing at an alarming rate. About 18 million people die every year from cardiovascular disease, for which diabetes and hypertension are major predisposing factors. Propelling the upsurge in cases of diabetes and hypertension is the growing prevalence of overweight and obesity - which have, during the past decade, joined underweight, malnutrition, and infectious diseases as major health problems threatening the developing world. The main culprit is an environment which promotes behaviour that causes obesity.

Lack of access to health care. Health care has a limited but not negligible role as a determinant of health. It has been estimated that 5 years of the 30-year increase in life expectancy achieved has been attributed to improved health services. Of these 5 years, it has been estimated that curative services contributed about 3.5 and clinical preventive services about 1.5 years. The greatest share of this gain from health care can be attributed to diagnosis and treatment of coronary heart disease, which contributes 1 to 2 of these additional years of life.

Physical environment. The physical environment affects health and disease in diverse ways. Safe water and clean air, healthy workplaces, safe houses, communities and roads all contribute to good health. Examples also include exposure to toxic substances that produce lung disease or cancers; safety at work, which influences injury rates; poor housing conditions and overcrowding, which can increase the likelihood of violence, transmission of infectious diseases and mental health problems, and urban-rural differences in cancer rates. The presence of natural or man-made hazards is a source of environmental diseases, which might be seen as the visible and clinical indication of inadequate environmental conditions. Key areas of action could be outdoor and indoor air pollutants, noise, indoor environment and housing conditions, water quality contamination, radiation and chemical exposures. The impact of these factors are felt in association with hearing problems, sleeping disorders, stress leading to hypertension and other circulatory diseases, skin and other cancers, asthma, or birth defects.

Genetic endowment. Genetic factors are recognized as having a significant influence on health, and it will be important to gain a better understanding of these influences. Genetic determinants are important constitutive factors for individual health; however, they presently

fall beyond the scope of public health interventions. The field of genetics will become in future years more and more important as nearly every disease has constitutive and/or acquired genetic components. The identification of disease-susceptibility genes as well as the identification of acquired somatic mutations underlying a specific disease, e.g., cancer, can provide a wealth of new information vital to a more thorough understanding of many common illnesses. Such information can be used to determine both how diseases are diagnosed and how new treatments or more specific drug targets can be identified. For the most part, genetic factors are currently understood as contributing to a greater or lesser risk for health outcomes, rather than determining them with certainty. Genetic factors also interact with social and environmental factors to influence health and disease. It will be important to understand these interactions to learn why certain individuals with similar environmental exposure develop diseases whereas others do not.

Travel/Migration. The present world is characterized by increasing mobility of populations and individuals. Modern means of transportation facilitate greatly the speed and diversity of this mobility. International travellers now number nearly one billion persons per year. The vast majority travel for short periods of time for recreational or professional reasons. But there are some international migrants - approximately 150 million in the world – who travel primarily on a one way ticket, usually from poor to rich countries, their conditions of travel and living conditions in their new country may be difficult with restricted access to medical services. And some (refugees) are forced to leave their country for reasons of insecurity and war. Those travellers and migrants will facilitate the transmitting the epidemic of the emergency and re-emergency diseases such as SARS Avian Flu, HIV/AIDS, TB...

Lack of access to safe water leads to 8 million deaths every year, as a result of water-borne diseases (cholera, typhoid, diarrhoea), half of them children. Currently, 1.4 billion people do not have access to safe drinking water and 2.6 billion, that is, 42% of the world's population, are not served by basic sanitation systems (sewage collection and treatment). The United Nations estimates that some 1.6 million lives could be saved each year if access to clean drinking water and to sanitation and hygiene services could be improved. Moreover, natural disasters are increasingly common and 90% of them are water-related. They are the result of improper land use. The case of Lake Chad in Africa is a striking example since it has lost nearly 90% of its surface area since the 1960s, mainly because of overgrazing, deforestation and large unsustainable irrigation projects.

Much of the same prospect - reflecting fast growing consumption in relation to expanding populations and environmentally adverse technology - applies to other strategic resource stocks such as topsoil, forests, grasslands, fisheries, biodiversity, climate and the atmosphere.

Environmental consequences of development. Development under the best of circumstances has some adverse effects on health by affecting the environment on one hand and life style on the other. These are further exacerbated when socio-political compulsions demand rapid economic “development - development at all cost” - unmindful of their socio-cultural, administrative milieu - as happens in many developing countries. The inescapable, though commonly recognized fact is that the introduction of new technologies, necessary for development brings with it irreversible social, ecological and health consequences, which under certain circumstances can be harmful. A proliferation of water bodies for irrigation purposes increases the number of breeding sites for disease vectors such as mosquitoes resulting in resurgent malaria, dengue and Japanese encephalitis. Deforestation and soil erosion expand the habitat of sand flies, which transmit leishmaniasis. Increasing use of pesticides for purposes of agricultural production is estimated to be responsible for more than 2 million cases of human poisoning every year with a resultant of 20,000 deaths.

Some signals of threat to sustainability of our ecosystem are: global warming, enlarging ozone hole, acid rain, increasing loss of forests and biodiversity, diminishing availability of cultivable land, environmental pollution of air, water and land, threatened water resources, perceptible reduction in global food reserves, progressive depletion of non-renewable sources of energy, large scale population migrations - within a country (rural-urban) and across national boundaries - in search of sustenance, growing menace of urban slums,

unacceptable levels of unemployment in most countries of the world, increasing inequities of wealth distribution between “the haves” and “the have nots” nationally and internationally resulting in social strife, criminality and wars.

IV. BIOETHICAL CONSIDERATIONS AND IMPLICATIONS

Health policy was once thought to be about little more than the provision and funding of medical care. This is now changing. While medical care can prolong survival and improve prognosis after some serious diseases, more important for the health of the population as a whole are the social and economic conditions that make people ill and in need of medical care in the first place. This is why life expectancy has improved so dramatically over recent generations; it is also why some countries have improved their health while others have not, and it is why health differences between different social groups have widened or narrowed as social and economic conditions have changed. It is not simply that poor material circumstances are harmful to health; the social meaning of being poor, unemployed, socially excluded, or otherwise stigmatized also matters. From the evidence reviewed above it becomes clear that those responsible for the creation of healthy societies are located at all levels – the social responsibility for health lies equally in governments, public and private institutions, workplaces and the communities.

The guiding principles of most governments have been those of equality of access to health care and solidarity in sharing the financial burden proportionate to income. However, pressures on health-care systems are already imposed by the impact of financial and demographic determinants. These factors were recognized almost 30 years ago in the development of international strategies for health promotion, such as the WHO commitment to a global strategy for Health for All and the principles of primary health care through the 1978 Declaration of Alma Ata. Today, after not being able to reach the goal of health-for-all in the year 2000, health promotion is still a crucial topic of debate.

Subsequent international health-policy guidelines have promoted health as a basic human right, essential for social and economic development. It has been considered that health promotion, through investment and action, has a marked impact on the determinants of health so as to create the greatest health gain for people, to contribute significantly to the reduction of inequities in health, to further human rights, and to build social capital. The ultimate goal is to increase health expectancy, and to narrow the gap in health expectancy between countries and groups.

Social responsibilities for health are a fundamental concern for the ethics of professional public health practices. The recent identification of the great significance of the social determinants of health has rendered imperative to review guidelines concerning the ethics of social responsibility in the promotion of health.

Many of the health problems of the poor, both in developed and developing countries mentioned above represent clear examples of injustice, inequities and inequalities in access to health care, nutrition, sanitation and safe water. Most of these problems persist despite the fact that international instruments have been adopted and programmes have been approved to reduce them. The new technical advances, which have been so useful in improving the quality of life of many people, have been inefficient in solving health inequities and instead of helping in some way or another, they have contributed to increasing them. Gains in average life expectancy have not been distributed equally either among or within countries. Advances in life expectancies and quality of life observed in many countries clearly contrast with no advances or even negatives outcomes in other countries. Important differences can be observed within countries according to social groups or regions. An inherent tension exists between our technical capabilities and our ethical willingness, which has become one of the most important concerns in bioethics.

The challenge of global health has been summarized recently as follows: “Less than a decade ago, the biggest problem in global health seemed to be the lack of resources available to combat the multiple scourges ravaging the world’s poor and sick. Today, thanks to a recent extraordinary and unprecedented rise in public and private giving, more money is being directed toward pressing health challenges than ever before. But because the efforts this money is paying for are largely uncoordinated and directed mostly at specific high-profile diseases – rather than at public health in general – and unless the brain drain from the developing world can be stopped – there is a grave danger that the current age of generosity could not only fall short of expectations but actually make things worse on the ground. This danger exists despite the fact that today, for the first time in history, the world is poised to spend enormous resources to conquer the diseases of the poor. Tackling the developing world’s diseases has become a key feature of many nations’ foreign policies over the last five years, for a variety of reasons. Some see stopping the spread of HIV, tuberculosis (TB), malaria, avian influenza, and other major killers as a moral duty. Some see it as a form of public diplomacy. And some see it as an investment in self-protection, given that microbes know no borders. Governments have been joined by a long list of private donors, whose contributions to today’s war on disease are mind-boggling. Thanks to their efforts, there are now billions of dollars being made available for health spending – and thousands of nongovernmental organizations (NGOs) and humanitarian groups vying to spend it. But much more than money is required. It takes states, health-care systems, and at least passable local infrastructure to improve public health in the developing world. And because decades of neglect there have rendered local hospitals, clinics, laboratories, medical schools, and health talent dangerously deficient, much of the cash now flooding the field is leaking away without result” (Garrett, 2007).

Health care

Access to health care, measured on the basis of the maternal and child health care index and other important indexes, are far from satisfactory in many countries, particularly in East and West Africa and South-East Asia. It is important to note that the problem of access to health care in quantitative and qualitative terms is linked not only to the health system but also to geographical, financial and cultural accessibility. The growing evidence of stagnation and deterioration of health status in many social groups, despite many international efforts have renewed the interest in health inequalities and have unveiled a series of ethical issues which have received insufficient attention. In this regard a new set of questions must be discussed. “Inequalities on health constitute inequality in people’s capacity to function or more in their positive freedom”, in this regard inequalities on health is even worse than inequalities in other dimensions.

Quality health care requires the following steps: 1) prevention and/or treatment of illnesses at the right time; 2) prevention and treatment based on evidence; 3) primary or secondary harm avoided or reduced; 4) patient’s wishes respected; 5) the cost-benefit relationship preserved. To accomplish these goals three more steps are needed: 1) a budget based on the societal health necessities; 2) an efficient management of this budget; 3) a definition of the limits of health-care rights. At present, most countries do not have a health care budget based on societal health necessities, these necessities are not well defined, and the management of the health budget is inefficient. Finally the limits of the right to health care in regard to scarce resources, has never been clearly discussed.

Despite the important biomedical and biotechnological advances, many patients do not receive adequate treatment or they do not even receive any treatment at all. Many well established preventive treatments are not used, having as a consequence future complications and the use of more expensive methods. The current investments in health protection are far overshadowed by expenditures to restore health once it is lost. Some patients are exposed to expensive treatments simply because the technology exists without there being any reasonable expectation of receiving a benefit. Inequalities in treatments and diagnostic methods based on race, gender, economic status or place of residence are evident and

scientifically proven. Many people die due to errors in the actual health-care system. A new paradox has appeared: as development increases morbidity, mortality, inequalities and inequities also increase. Recent studies have revealed that in some developed countries as material wealth has raised so has depression. The depression levels in the United States of America are 10 times higher today than in 1960. Institutions and professionals must assume the responsibility of promoting an approach to solving this situation.

In 2005, it was estimated that 40.3 million people were living with HIV and that there were 4.9 million new infections and 3.1 million deaths, the largest number of cases occurring in Africa. In regard to access to medicines, while the situation is difficult in the countries of the South, it is critical in African countries affected by malaria or HIV/AIDS: whereas 45.6% of under-fives suffering from fever are treated with anti-malarial drugs, this percentage is lower in East Africa (21.8%). There is still very little access to antiretroviral treatment and health-care provision for other HIV-related illnesses. Five to six million people in low- and middle-income countries are in immediate need of antiretroviral treatment. According to the World Health Organization, some 400,000 people had access to such treatment at the end of 2003, which means that 90% of those in urgent need of HIV treatment were not treated. So many patients with pathologies like AIDS suffer from discrimination, stigmatization and inequities in terms of access to the treatments they need. Despite the important programmes developed by the UN, WHO, etc. and despite the recent gains in new treatments, only about one out of five people in low- and middle-income countries who need retroviral drugs receive them.

The development of new diagnostic and therapeutic approaches has improved the health, life expectancy and quality of life of so many people around the world. But at the same time, the costs of medical care have driven up expenses far beyond the limits of any realistic budget, even in the richest countries. The increase in health care costs reduces the opportunities of many patients to receive the treatment they might need. Every day, we have more and more technologies which are used on less people because of the increase in costs.

Even if it is accepted, that full equality for the best possible care will not be achievable, nowadays each member of society, irrespective of his or her economic position, should have equal access to an adequate, although not maximal, level of health care. In order for a health-care system to be just and equitable, it needs, first of all, to be efficient in terms of cost-benefit. This means that there must be an efficient management of the limited budget in order to cover the basic needs as a minimum. This easy-to-read but hard-to-accomplish issue is not limited to management decisions; it needs to answer important ethical questions. Should all the new technologies be used in every patient? Should all patients be treated? Are the new medical technologies being used for saving people with good chances of having an acceptable quality of life or, instead of that, are these new treatments being used on persons with bad prognosis, in terms of life expectancy and quality of life?

Today, it is accepted that some rationing in health care is needed. A decent minimum has to be defined. In such a case, what criteria should be followed? Will it be possible to accept a trade off? In practical terms, is it possible to guarantee the highest attainable standard of health care? What does the highest attainable standard mean? What are the real goals of medicine in the twenty-first century? What must be considered just when all these new technologies are applied? None of these questions has an answer yet and answering them will require, first of all, an intense educational programme which should include all members of society, followed by a wide deliberation process which should be addressed to: re-define the concepts of health and illness, to understand the technology's limits, to set forth strategies for defining the health necessities in health care, as well as the criteria for establishing a decent minimum in health care; discuss acceptable criteria for rationing; clarify the limits of the patients' rights regarding the use of new technologies, etc. But above all, the deliberations process must be addressed to redefine new reasonable goals of medicine.

Access to technology. New technologies used at the beginning or at the end of life have exposed important concerns about their uses. Frozen embryos produced from new fertilization techniques, stem cells, therapeutic cloning, gene therapy, etc. have created new questions regarding the benefit of using these techniques. Possible future clinical so many clinical

problems, but at the same time could harm societal values such as the dignity of human beings, the right to life, discrimination and confidentiality. Furthermore, serious concerns about their effects over new generations have been raised. What would be considered just, to develop all these techniques to save the patients' life? At the end of life, we have resources that allow us to treat health problems that would have been impossible to treat a few years ago. These techniques have made it possible to improve the quality of many patients lives, but sometimes, the same techniques rather than saving lives might just contribute to prolonging the process of dying, increasing suffering and costs. Serious doubts exist regarding how life-sustaining interventions should be applied and when they should be withheld or withdrawn from patients with vegetative states, advanced forms of cancer, advanced AIDS or from any other patient with low possibilities of surviving, or from patients with some chance of surviving, but with a limited quality of life. How should they be treated to be just and equitable? How can the dignity and rights of those patients be respected appropriately?

The role of health research. Improving health is not only an outcome of development but also a prerequisite for development. Consequently, investment in health yields one of the highest rates of return that a country can achieve. Improving health requires the effective application of existing research. It also, crucially, requires research aimed at creating new knowledge and new technologies. This includes the whole spectrum of research: biomedical sciences (creating affordable and accessible new drugs, vaccines, diagnostics and appliances) health systems and policy research, social sciences, political sciences, health economics, behavioural and operational research, research into the relationship between health and the cultural, physical, political and social environments. Research for health can make a major contribution both to health and to more general development. In many countries, however, the benefits of health research are not optimized due to low investments, absence of a culture of evidence-based decision-making or lack of capacity. Countries that have invested consistently in health research and general science and technology research are now advancing rapidly in health and in economic development. International aid needs to ensure that research for health is part of its total package and is fitted in a manner that enhances national health research systems.

Few of the world's resources for health research are directed to solving the health problems of developing countries. In 1990, the Commission on Health Research for Development estimated that less than 10% of the global health research resources (totaling US\$30 billion/year in 1986) were being applied to the health problems of developing countries, which accounted for over 90% of the world's health problems – an imbalance subsequently captured in the term the “10/90 gap”. In 1996, the WHO Ad Hoc Committee on Health Research Relating to Future Intervention Options estimated that US\$55.8 billion was expended globally on health research in 1992 but noted that the “10/90 gap” persisted. The world now spends considerably more on health research: the latest estimate puts the figure at US\$105.9 billion for 2001, of which 44% by the public sector, 48% by the private for-profit sector and 8% by the private not-for-profit sector. Despite these positive increases, there is still a massive under-investment in health research relevant to the needs of low-and middle-income countries – the imbalance of the “10/90 gap”. More research is needed to address the lack of appropriate drugs and technologies to treat the multiple burdens of communicable and chronic diseases that many developing countries now face, and more research is needed to provide knowledge and evidence about what policies, systems and services work in different places and settings, about what is failing, and about what is needed to improve them.

A specific recommendation on research funding was made at the end of Forum 8, in Mexico City stating: *“To provide the resources necessary for essential research within developing countries, we urge governments of these countries to spend at least 2% of their national health budgets on health research, as recommended by the 1990 Commission on Health Research for Development. These funds should be used locally for health research and research capacity strengthening. Also in line with the Commission's recommendation, donors are urged to allocate 5% of their funding for the health sector to health research and research capacity strengthening in developing countries. Monitoring the use of funds for capacity development is a vital complementary activity”.*

The point here is how governments perceive research. If they see research as an expenditure and not as an investment, the amount of funds will be scarce, mainly when the funds in poor countries have to be distributed among greater needs, relegating health research as an expenditure and one activity that is not a priority, falling with this into a vicious cycle that will not make it possible to improve social determinants of health. But also, we come to a basic question: is there a greater need than health, as a key determinant to development?

The role of the pharmaceutical industry. Development agencies have challenged the pharmaceutical industry to improve its efforts to tackle the health crisis affecting developing countries. They consider that a socially responsible company should have policies on access to treatment for developing countries which include the five priorities of pricing, patent, joint public private initiatives, research and development and the appropriate use of drugs. They comment, in addition, that the industry currently defines its policy on access largely in terms of philanthropic ventures and that critical challenges remain, particularly the issue of pricing.

The generalized lack of interest on the part of industry in research geared to the development of new vaccines and drugs to treat tropical diseases and ailments typical of the poor sections of the community is explained by the extremely high cost of research and the small, not to say negative, profit margins to be expected. Furthermore, since the establishment of the World Trade Organization (WTO) and the signing of the Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS), developing countries have been faced with an increase in the cost of basic medicines, whose protective patents enable the pharmaceutical industry to impose their price. Consequently, some basic medicines cannot be made available to poor population groups at affordable prices. The industrial and commercial rationale of the pharmaceutical industry often runs counter, however, to the public health objectives of developing countries that are confronted by epidemics of diseases such as AIDS, malaria and tuberculosis, and no doubt also conflicts with the terms of the Universal Declaration on Bioethics and Human Rights, since the excessively high price of medicines puts them virtually beyond the reach of the world's poorest communities.

One solution to such prohibitive prices, which are indeed a huge stumbling block, would be to reach agreements with the pharmaceutical industry on a voluntary price differentiation between rich and poor countries, allowing the latter to pay only production costs and not research and development costs. WHO and UNAIDS have had some success in this regard. This system presupposes, however, that poor countries agree not to re-export the medicines to rich countries and that they are careful to ensure that the products are properly used to reduce to the minimum any possibility of resistance. The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) has also been revised in favour of the poorest countries. Those that do not have the capacity to produce medicines, may now request an extension of compulsory licenses for generic products that are still protected by patent so that they may be imported from other countries. The number of generic medicines is quite large at present, but it is likely to rise in the years ahead because of the number of medicines whose patents are due to expire. This situation will lead to a sharp fall in the profits of the pharmaceutical industry.

Recently, new projects have a distinctly charitable aspect and will not generate profits. Examples include the new Institute for Tropical Diseases in Singapore for the discovery of drugs for tuberculosis and dengue, and a considerable number of projects aimed at new treatments for malaria, elephantiasis, river blindness, HIV/AIDS, leprosy, dengue and sleeping sickness.

The role of society and individuals. A more horizontal model of human relationships aimed at promoting and respecting equality between all human beings has substituted the classical vertical human relationships which dominated for many centuries. This important change, which could be considered as one of the most relevant advancements in terms of moral evolution, has brought important benefits regarding equality and other rights, but it has also opened new questions and concerns about how to manage the growing tension that is produced when the high cost of using new techniques needs to be conciliated with human

rights, quality care and distributive justice. A tension exists between the existing rights and the intention of pursuing an equal and equitable use of new technologies. Full equality of care for the best possible care will not be achievable. Currently, no society can afford all of the potential treatments for all the patients that could benefit from them. How the necessary resources should be provided is one of the great contemporary debates. It is a fact that the budget for health care is limited even in the most affluent countries, and as a consequence health care must be limited. Not everyone will have full access to health care and the rationing must be ethically planned. The priorities must be set. To pursue a health-care system which overcomes the reasonable and sustainable limits will do more harm than good. The question again is: Where are the limits going to be set?

Genetic Patenting

The proliferation of genetic patenting has raised practical and ethical concerns. According to a recent estimate, patents have been granted or patent applications have been filed for nearly twenty percent of human genes. Patents are generally considered an important incentive for producers or manufacturers. Several articles, however, suggest the opposite: that patents and licenses have a significant negative effect on the ability of clinical laboratories to develop and provide genetic tests, and hinder patients' access to recent diagnostic tests. These problems block further research and development, and increase the costs of new diagnostic tools in clinical practise.

Responsibility of global / international community regarding patent policy. With respect to the whole patent system, a proper balance should be maintained between the effect of a patent right and the contribution thereto, i.e., between private and public interests, since overly board claims might jeopardise the system instead of supporting it. Despite the existence of patents, there should remain space to develop the invention further instead of prohibiting further research and development. This is particularly important with respect to diagnostic, prognostic, therapeutic and preventive developments for multifactorial diseases, which are anticipated to replace rare monogenic diseases in patent applications. Restricting the granting of a gene patent, being enormously broad in scope at present, to a specific purpose might be necessary because many questions relating to genetic functioning and interactions are still unknown. Licensing strategies, in particular compulsory licensing should be negotiated to respond to the needs and resources at various levels. There could be different standards for basic research, therapies and diagnostics. (Compulsory licensing means the situation when an official instance or a court forces the patent-holder to grant a licence to a third party.)

Responsibility of global / international community regarding ethical frames. In its report on the subject, IBC has proposed that the human genome is not patentable on the basis of public interest. IBC recommended several ways of creating an ethically sound approach to the issue of intellectual property and genomics. IBC should further help the states, specialists, and decision-makers through its standard-setting and awareness raising actions how to secure the benefits of the human genome sequence for the service of the humanity as a whole. The global community of policy makers should assess of how exclusivity of genetic patents fits into the proclamations of ethical principles like benefit sharing. Benefits resulting from the use of human genetic data or biological samples collected for research should in some way be returned to society and/or group of people involved in research in development of diagnostic tests (WHO 2003). Inventions which would be contrary to *ordre public* or morality should not be granted a patent.

Responsibility of governments. The regulation of patenting and in particular compulsory licensing lies in the hands of national laws and court practises. Governments might have a more active role in taking care of that, for instance, public hospitals have access to necessary diagnostic tools and that they do not violate patent rights. The development of drugs and tests for rare diseases is not profitable for industry. It has been suggested that for such non-profitable areas basic research should be publicly funded, and/or broader patents allowed to interest companies. Governments ought to provide needed services, but they cannot, mainly due to lack of resources. Large university hospital units could join their forces and acquire campus licenses to the most relevant research tools.

Responsibility of professional and other groups. Academic researchers should enhance their attention to licensing practices: they should not unduly hinder academic research, possibilities to publish in a timely manner the results of the researcher, and education. Clinical geneticists should perform complex genotype-phenotype comparison analyses for clinical validation of genetic tests to realize the promise of molecular genetics in health care. Patient groups ought to inform the patients and their relatives and also advocate their interests to politicians in order to secure access to diagnostic tests affordable at a reasonable price. Academic institutions should ensure that researchers and students understand their responsibilities and obligations pursuant to different areas of law and agreements.

Responsibility at individual level. The informed consent of the research subject is one of the most established fundamental provisions of research regulation and medical law. Some argue that individuals who provide samples for research are currently undervalued and underestimated even though their importance has grown. Openness and adequate information is crucial to maintain public trust in research and get people recruited also in the future. Sufficient information to research subjects is the first step. But also, general empowerment of the individuals may be relevant, as true autonomy does not necessarily materialise through the established consent procedure.

V. RECOMMENDATIONS AND CONCLUSIONS *[to be drafted]*

In conclusion, the widening gaps in health conditions described above are best explained in terms of social, economic, and cultural differences and the value that individuals and societies attribute to the idea of a healthy society. Therefore, individual responsibility and social responsibility are usually inextricably intertwined and are related to moral judgments and political strategies that may or may not seek equity as a goal.

Health is everyone's responsibility: the public and private sectors, governments of developed and developing countries, NGOs, multilateral agencies and civil societies, and obviously, individuals.

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