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# Public Health Policies in European Union: An Innovation Strategy—Horizon 2020

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## 1. INTRODUCTION

The human condition has been the focus of philosophical thought and quest throughout the history of societies. Nowadays, the significance that is attributed not only in maintaining the health of the individual, but primarily in promoting it as well as improving the quality of life of the modern European citizen, can and should be a fundamental feature of the new European social and cultural reality. With this goal in mind, we can sustain within the fabric of the European Union (EU) the eternal individual and social rights of continuous improvement of the quality of life and the state of health of the population while, at the same time, being aware of the risks as they escalate due to the globalization of economies and societies.

Since 1958, there has been a 56-year-old continuous effort to establish economic cooperation within Europe and transform the European Economic Community from an economic to a political union. The current geopolitical formation of the EU is a powerful factor on a global scale:

- 28 countries, 509 million people representing 7% of the planet
- The third largest population and the world's top economic power
- 25% of global GDP (US\$ 16 trillion), 20% of world trade
- 16.5% of world imports (the United States 15.5%, China 12.0%) and 15.5% of world exports (the United States 13.5%, China 10.5%)
- Life expectancy of over 80 years, 24 years more than countries with low human development index (80 vs 56 years)
- Of the first 25 positions of the human development index, 14 belong to the EU in 2010.

However, the big dilemma inherent in individual and collective European thought is the one between economic optimization and real human development where the latter embodies in a single framework and model both in economic growth and social welfare. The battle between fiscal discipline and public social-health interest in recent years is uneven under the pressure of competition and the prevalence of markets.<sup>1</sup>

This dominant view does not take into account the negative fiscal conditions that may be brought about by an epidemic or pandemic shock, such as the reappearance of the Ebola virus. The loss of life and disruption of economic relations can create a larger fiscal gap than the short-term savings in public spending that may result, for example, from denying coverage to the uninsured and illegal immigrants.

By extension, the theoretical field of health policies should therefore be enriched with the economic theory of externalities, so as to clarify how to resolve the major dilemmas we face when trying to secure minimum social rights.

The fears and serious concerns arising from modern public health risks as well as the strong external impact from transmitted diseases that cause endemics and pandemics make the need to secure and protect health on an international level a top priority. These risks relate to:

- transmitted diseases
- the spread of addictive substances
- environmental pollution and ionizing radiation
- the disturbance of ecological balance and the depletion of natural resources
- industrial risks, nuclear waste, and bioterrorism
- food safety and the cultivation of genetically modified produce
- an unhealthy diet
- hygiene and safety at work,
- migration, poverty, and socioeconomic disparities
- lawlessness, modern way of life, and stressful life events.<sup>2</sup>

The type, the extent, and the complexity of diseases involving the entire population require the creation of a system that will meet health needs and promote health in general. This system must be based on scientific criteria and principles, must take into account developments in the sciences of medicine, biogenetics, biotechnology, economic developments and the requirements of the citizens for protection and promotion of their health.

This whole field of knowledge requires systematic research and study in order to produce innovative responses and best practices, to investigate and verify the assumptions of a structural analysis of the health system and at the same time to highlight the attitudes, perceptions, and behaviors that contribute to disease prevention combined with the protection of the environment and the support of sustainable development.

This combined approach is made possible by processing data showing on one hand the current situation, and on the other the projections of health needs that determine public health policies in the EU. These policies are supported by and are documented in the form of data which, after similar processing, allow both the comparative mapping and the differences of health needs, which help formulate distinct health policies among EU Member States.

In the introductory part of this chapter, we attempt a high-level approach to: (1) the fundamental principles of health policies; (2) the methodological assessment of health needs in conjunction with the investigation of trends in nosology and epidemiology; and (3) the classification of priorities when formulating health policies.

In the first part of the chapter, we attempt to investigate the state of health of the population in the EU with: (1) the theoretical approach to quantitative and qualitative indicators of health and well-being; (2) the analysis of the rate of change in life expectancy; (3) the quantification of the reduction in mortality and the differences in the causes of

mortality; and (4) the estimation of possible years of life lost as well as the expected years of life in good health.

In the second part of the chapter, the redesign of health policies in the EU during the current period is defined through: (1) the approach of the nosology spectrum as a multidimensional and multivariate social phenomenon; (2) the assessment of the new trends in health indicators for defining health policies; (3) the formulation of the new strategy regarding health policies; and (4) the general and specific objectives and proposed actions for 2014–2020.

Finally, in the third part of the chapter, we present the specific actions of the health policies in the field of Cord Blood Stem Cells Banking through: (1) the development of an integrated policy for the sufficiency and the represented collection of cord blood units; (2) the management of the serious adverse reactions (SAR) in tissues and cells quality assurance; (3) the development of vigilance and surveillance across border networks for disease prevention and control; and (4) the promotion of public campaign programs for informing and raising awareness among the general population and among specific/target social groups.

## **2. THE CONFIGURATION FRAMEWORK OF GUIDING PRINCIPLES OF HEALTH POLICIES**

### **2.1 The Fundamental Principles of Health Policies**

Health is a fundamental human right, the exercise of which ensures and protects the lives of people and therefore each country through its constitution protects the health of its citizens.<sup>3</sup>

Health:

- 1.** has the highest multifactor, multidimensional usefulness and the maximum contribution to Human Development because the fulfillment of needs, the psychosocial balance, and work are dependent on the state of health of individuals,
- 2.** is affected externally and therefore is subject to the most serious cross-border threats, and
- 3.** establishes and develops Human Capital.<sup>1</sup>

The lack of basic coverage and provision of health services, even for only one citizen, can cause on one hand loss of the right to life and on the other various problems to the rest of the citizens either at a national or international level. It is therefore an obvious necessity to provide health-care services, a necessity that creates the principle of universal coverage of the population in an inclusive society that makes sure it is covered.

Because health is presented in modern economic relationships of markets both as a public and as a private

consumer good, access to it sometimes depends on: (1) the level of income of citizens; (2) the magnitude of the risk and the nature and the severity of the disease, i.e., the size of the resulting expense; (3) the availability of health services in some areas; (4) the nature of human mobility due to age or disability in conjunction with formal or informal social or family structures; and (5) the type of insurance coverage.

It is therefore obvious that many times, if even one of the above factors comes into play or more than one in combination, there is lack of access to health goods and services causing inequalities because it results in inability to earn income from work and hence the inability to meet basic needs and sociocultural goods, losing the right to equal opportunities. Therefore, equitable access to health services and goods is the second basic principle of health policy.

The type and severity of diseases have a serious external impact in a world of continuous mobility due to: (1) national and international trade relations; (2) tourism exchanges; and (3) migration, and as a result they cause epidemics and pandemics and affect the health of citizens through transmitted diseases.

The maximization of the social cost from transmitted diseases as opposed to the private cost, the loss of human capital in the basic economic activity which is work, the disruption of family and social life, but also the loss of national power, make the protection of public health at national and international level the third basic principle of health policy.

### **2.2 Methodological Assessment of Health Needs and Investigation of the Nosology and Epidemiology Spectrum**

Health planning and policy seek to create a group of mutually interacting bodies to produce goods and services to meet the health needs of a population. The investigation of the state of health of citizens often coincides with the field of health planning and policy because it tries to determine the qualitative and quantitative characteristics of the output of these goods and services. This is achieved through the theory of opportunity cost which aims at not wasting resources in order to allocate these resources to meet other socioeconomic needs. The investigation, therefore, of the nosology and epidemiology spectrum and population and demographic data highlights and continuously reflects on the type and quantity of goods and health services that must be produced.

Many times, however, despite the scientific approach of this investigation, the market of health-care, but also the failures of planning and health system development, produce either services, such as medical services, far in excess of what is necessary, or pharmaceutical products or diagnostic centers or private clinics, creating strong induced demand

and imbalance in demand and supply of the health-care market. In any case, if we do not investigate systematically the size and age structure of the population, its regional distribution, and especially the types of diseases and causes of death, the prevalence and incidence of disease, it is not possible to specify the necessary actions of health policies on a preventive and therapeutic level.

Social planning and health policy explore, on the one hand, the type and quantity of health services and goods needed by the population and on the other, the human, material, and financial resources, i.e., the necessary inputs for the system to operate as well as the outputs and outcomes. This is indispensable to the availability of resources and to the use of innovative methods to ensure: (1) the rationalization of health services; and (2) the planning of appropriate and specialized output for the operation of the health system and the equilibrium in the market of health-care.

The establishment of the criteria of the mode of distribution of produced goods and services takes into account: (1) the strong external influence that health causes; (2) income inequality; (3) the form of the system of social security and thus the way of insurance coverage for citizens; (4) regional inequalities; and (5) the market types prevailing in an economy and the restrictions brought about by the development of private initiatives.

In all countries, even those in which the free market insurance model prevails, a minimum of state intervention exists to protect public health through the delivery of health services and goods to categories of the population who are in a state of absolute poverty and deprivation. The more health is considered a public good, the stronger is the criterion of redistributive justice when it comes to health-care distribution and care is provided irrespective of the financial contributions of the citizens either through taxes or through insurance premiums.

### 2.3 The Classification of Priorities When Formulating Health Policies

The common condition of coverage of health needs under the restriction of the scarcity of financial resources brings forth the theoretical interest regarding the classification of priorities and choices, both for the design of a system for the prevention, preservation, and promotion of health and for other fiscal intervention policies in various areas of socioeconomic activity of individuals. It is also known that these policies affect and shape the state of health of the population to a much greater extent than the health-care system itself. The actual numbers regarding health-care needs, the severity of diseases, the degree of external adverse effects, and the financial resources available determine the hierarchy of options in combination with the analysis of the factors as mentioned above.

Recent developments in the state of health of the population and in the health-care systems are characterized by:<sup>4-6</sup>

- continuous improvement in life expectancy
- chronic diseases which absorb 90% of total health-care expenditure
- the reappearance of transmitted diseases
- more than 70% mortality from cancer, heart and brain, and external causes
- increase in the number of elderly people
- increase in demand for health-care services
- falling rate of patient satisfaction with the quality of health services.

The health-care system enhances the health of a population, but to a much lesser extent than other socioeconomic factors—determinants of health status. Avoidable mortality is significantly influenced by lifestyle and the environment which are the key determinants of population health. Even if the entire budget was allocated to health-care, the health-care system could only determine the state of health of the population by a small proportion. Changing the consumption patterns and behaviors regarding health is the main focus of the new policy for the prevention of disease and promotion of health.

The health-care system must be sustainable in order to be able to offer services on the one hand, and on the other hand to be sufficient to meet the health-care needs of the population. The health system must be efficient and its operations must: (1) abide by the fundamental economic principle of scarcity of resources; and (2) take into account the documented finding that the health system affects the state of health of the population much less than expected. Consequently, resources can be allocated to other public policies that indirectly benefit health and quality of life for the population under an unwavering long-term perspective.

This means an increase in public spending to improve other social sectors that have a positive effect to address the underlying causative factors and key determinants of health. The transition from the perception of further spending increases that simply result in an increase in numbers of the health system to a way of thinking aiming at continuous rationalization and restructuring of the system in order to improve the quality of service, should be the modern scientific guarantee for the development of the health-care system.

Therefore, the key priorities when formulating health policies are:

1. *The prevention of disease and the improvement of life in good health:* The health-care system must prevent disease, promote health, and prolong a healthy and active life.
2. *Accessibility:* The health system should be accessible to all citizens, should offer and distribute in an equitable way health-care services and goods to ensure the basic

human rights such as the fundamental right to life, and at the same time prevent the external adverse effects such as the spread of diseases.

3. *The safety and quality of services:* The system must provide safety and quality of service; it must protect the dignity of the patient.
4. *Readiness to manage crises and health risks:* The system must be prepared to manage crises and major risks from cross-border threats through mechanisms of information and data processing and be in-sync on a cross-European and international level to protect people from the spread of transmitted diseases. The serious cross-border threats that can cause epidemics and pandemics have mobilized the international community to prevent the spread of disease and reduce social cost.

Europe and the global community have created the institutional framework for implementing health policies to combat major health risks at both preventive and interventional level. To address the prevalence and incidence of diseases, international organizations coordinate, monitor disease classification developments, and set the priorities according to the assessment of risk.

### 3. THE HEALTH STATUS OF THE POPULATION IN THE EU

#### 3.1 Current Approach Using Qualitative Indices of Health and Well-being

Demographic changes such as population aging and migration affect the health sector both in terms of the need for increased spending, i.e., the financial viability of the system and in terms of the responsiveness of the system to meet health-care needs. The state of health of the population of the EU follows some general, common trends among the countries of the EU-28 (all the countries in the EU); however, some variations can be observed due to the particular socioeconomic and cultural characteristics but also the relative slowing progression of certain health indicators. This is evident when considering the comparative data of the old EU of 15 (“EU-15”) members and the 13 new member countries (“EU-13”).

Positive indicators approach in an integrated fashion the state of health of the population and are particularly related to the demographic indicators and can be regarded as indicators of well-being. Some of the positive indicators are the birth rate, fertility, and life expectancy. The life expectancy index can represent life expectancy without restriction, disease-free life expectancy, or life expectancy in good health (self-perceived).

The most common negative indicators are the indicators of morbidity, mortality, and disability, expressing the frequency of diseases and serving as the means of comparison and evaluation of the state of health between different countries.

The Crude Mortality Rate approximates the percentage of the population of a territory that dies during a specified period or within a year. It is affected by the age distribution of the population and does not allow for reliable comparisons of international data. For this reason, the standardized mortality rate is used.

To investigate the impact of the large number of deaths at older ages compared to the much lower number in younger age-groups, we use the standardized mortality rate, the weighted average rate per age-group. The weighting factor depends on the age distribution of the fixed reference population. A commonly used indicator is age-specific early mortality at various ages before 65 years. The standard European reference population does not include the age-groups under 5 years of age and over 95 years.

The index of potential years of life lost (PYLLs) to early mortality takes into account the age at death, for example, 65 or 75 years, and records the years that the deceased could have lived until the age X. The index is calculated per age-group among 100,000 inhabitants. The importance of the indicator rests in the way by which the health-care system affects the health of the population or in the determinants that could affect mortality to a lesser extent. For example, according to Halley des Fontaines (2007),<sup>7</sup> prevention policy can reduce the consumption of tobacco and alcohol and reduce accidents, suicides, and AIDS at an early age, while early diagnosis within a reliable health-care system can significantly reduce mortality from circulatory diseases and cancer.

The concept of years of life lost could be extended to those years where a person cannot engage in creative activities, is going through periods of severe symptoms of chronic disease and disability and generally perceives his or her health to be less than good or less than very good. PYLLs are the years that a person could have lived up to a certain age if he or she had not died, including the years lived with disability or chronic illness, i.e., the concept of PYLLs enables the mathematical calculation of the probability for a person to live longer and in good health.

PYLLs and disability-adjusted life years (DALYs) reflect the mortality and morbidity that could have been avoided.<sup>8</sup> To this end, we study the total avoidable mortality. Total avoidable mortality is defined as that part of mortality that could have been curable and could have been avoided had science, technology, and innovation been effectively applied, which means making effective use of all the available human, economic, and material resources to prevent the incident. Total avoidable mortality consists of preventable and treatable avoidable mortality.

We use PYLLs to explain early mortality due to the increase at younger ages of mortality from malignant neoplasms and circulatory diseases, while we use the DALYs to explain mortality due to causes such as malignant

neoplasms, circulatory diseases, external causes, and mental or behavioral disorders.

The PYLLs are directly linked to early mortality, while the DALYs are linked with morbidity. For example, years of life lost per 100,000 inhabitants from malignant neoplasms amount to 918, while the years of life adjusted for disability resulting from malignant neoplasms per 100,000 inhabitants amount to 210.<sup>9,10</sup> In any case, these two indicators reflect the years of active life lost either due to death or disability.

The health-care system and health policies (prevention, preservation, and health promotion) should aim at reducing early mortality, reducing the PYLLs, reducing the avoidable preventable and treatable mortality, and reducing life years with disability, with chronic diseases, and without normal creative activity.

Modern quantitative approaches and qualitative goals such as the increase in life without disability, without problems in daily activities, without chronic diseases, with good social and family life examine the need to identify, besides the classical documentation of the frequency of diseases—the prevalence and incidence of disease—and the number of deaths, new indicators such as:

- life expectancy without disability,
- without chronic diseases,
- early mortality before a certain age,
- life expectancy at age over 65 years,
- and so on.

### 3.2 Rate of Development in Life Expectancy

The population of the EU, as calculated in accordance with the projections for 2060, will not show significant quantitative changes in the EU-28 (from 507,162,571 in 2013 to 525,845,522 in 2060) except for the very significant structural evolution by age-group and cultural composition.

The slight increase in physical mobility of the population, in births, and the fertility index shape the overall developments and highlight the phenomenon of aging of the population. It is estimated that according to recent projections, the number of Europeans aged 65 years and over will almost double over the next 50 years, from 86.7 million (17%) in 2010 to 149 million (29%) in 2060. Also in 2010 in the EU-27, people aged over 80 years amounted to 4.3%. In 2020, this figure is predicted to rise to 5.7% and in 2060 to 12.1%.<sup>11</sup>

It is easily understood that the fifth age-group, those over 80 years of age, will be the main concern of the health system in terms of coverage of multiple health needs. The coverage of the health needs of people aged 65 years and older and especially those over 80 years old will lead to subsequent changes in the health system

which should be designed so as to address more specialized health needs. This is the main reason why we expect health spending to increase by 3% by 2060 due to the aging population.<sup>4</sup>

Eurostat data focus on the increase of pensioners by 39.8% in 2060 in the countries of EU-27, from 119,265,000 in 2010 to 166,683,000 in 2060. This is a historic challenge for health economists because the combination of: (1) multiple needs; (2) available free time; and (3) demands for elongation of healthy and fulfilling life for older people will send health expenditures skyrocketing.

Europe shows continuous improvement in life expectancy, which is confirmed by the growth rate of the index in the EU-15 for both sexes in the last four decades (1970–2010) with an average per decade of 2.39 years. Especially in the decade 2000–2010, the growth rate was the highest with 2.62 years in the EU-15 and 2.71 years in the EU-28. However, it should be noted that the rate of increase in life expectancy shows a tendency to slow down if we look at all countries (EU-28) because from 2.71 years in 2000 it has decreased to 2.18 in 2010.

#### APPENDIX 1: EVOLUTION RATE (%) OF LIFE EXPECTANCY FOR BOTH SEXES PER DECADE (1970–2010)

This relative slowdown is explained by the variations presented in the rate of progression in life expectancy between countries in the EU. In the EU-28, life expectancy at birth for men in 2010 is 77.2 years and for women 83.1 years. Men live more in Cyprus with 78.48 years, while the highest life expectancy for women is noted in France and Spain with 85.4 years. Fewer years of life expectancy are recorded in Lithuania with 73.57 years for men, and Bulgaria with 77.42 years for women. The EU-13 shows the fewest years of life expectancy at 79.6 for women and 71.8 for men in 2010. On the contrary, in the EU-15, life expectancy at birth is comparatively high in 2010 with 84.0 years for women and 81.8 years for men.<sup>10,1</sup>

#### APPENDIX 2: LIFE EXPECTANCY AT BIRTH, MALES–FEMALES (1970–2010)

Similar differences between the sexes are also observed in life expectancy at the age of 65 years where in the EU-28 in 2010 for women it was 21.2 years and for men 17.6 years. Also significant differences between the sexes can be observed in the EU-13 and EU-15. In the EU-13, life expectancy at the age of 65 years appears significantly reduced to 18.7 years for women and 14.7 years for men, whereas in the EU-15 it has increased to 21.9 years for women and 18.4 for men.

### **APPENDIX 3: LIFE EXPECTANCY AT THE AGE OF 65 YEARS, MALES–FEMALES (1980–2010)**

#### **3.3 Reduction in Mortality and Difference in the Causes of Mortality**

The socioeconomic and cultural changes that have occurred with the entry of new Member States to the EU since 2004 and the overall economic growth observed over the past decades, significantly affected the reduction of mortality rates and causes of variation in mortality of the European population.

The trend of mortality in Europe from 1970 onward shows continued reduction (Appendix 4) when of course mortality is weighted by age. The crude mortality rate can be increased, but this is due to the accumulation of most of the morbid cases aged over 65 years.

#### **APPENDIX 4: AGE-STANDARDIZED MORTALITY RATE (SDR-ICD-10-DISEASES OF ALL CAUSES, ALL AGES), PER 100,000 INHABITANTS**

The weighted mortality rate in 2010 for both sexes in the EU-28 decreased to 595 deaths from 965 deaths in 1980 per 100,000 people. However, there is a marked difference between countries in the EU-15 and the EU-13 with 530 and 835 deaths per 100,000 persons, respectively. The lowest index is noted in Spain (478 deaths/100,000 people).<sup>10</sup>

In the comparative mortality between the sexes, men have a higher mortality rate from all causes. Also analysis by cause of mortality reflects the same variations. Mortality by age between the age-groups of 0–64 years and 65 and older has clear negative characteristics for people over 65 years even in the case of suicide, self-inflicted injuries, and traffic accidents.

In the EU-28 in 2010, the mortality rate for men was 762 whereas for women it was just 462 per 100,000. Italy has the lowest index in men with 598 deaths, and Cyprus in women with 361 per 100,000. The index value of 1118 deaths per 100,000 men in the countries of the EU-13 is considered very high.<sup>10</sup>

Cause-specific mortality follows the same trend since the middle of the interwar period. The causes have now shifted from diseases which are transmitted, infectious-parasitic such as malaria, typhoid fever, tuberculosis, pneumonia, etc., to diseases of the modern way of life, social isolation, disruption of social relations, and the environment, such as circulatory diseases, cancer, and mental disorders. The nosological profile of Europeans with 8% deaths from transmitted diseases compared to 80% of deaths in less-developed countries portrays the relationship between

the state of health of a population and the socioeconomic and cultural context within which the people live and work.

In the EU-28 in 2010, 74% of Europeans died from circulatory diseases and neoplasms, while in the EU-13 this rises to 86%. If to these percentages we add deaths from external causes (injuries, poisoning) and deaths from mental and neurological disorders then the percentage of the fundamental causes of mortality in the EU-28 in 2010 increases to 85% and to 94% in the EU-13, respectively.<sup>1,10,12–15</sup>

#### **APPENDIX 5: BASIC CAUSES OF MORTALITY IN THE EU-28, EU-15, EU-13 (2010)**

Diseases of the circulatory system are regarded as the leading cause of mortality with 201 cases per 100,000 in the EU-15 and 417 per 100,000 in the EU-13 in 2010. This percentage is equivalent to the one the EU-15 had back in the 1980s. This means that we need to intensify the policy of prevention for cardiovascular diseases in the new countries of the EU.

Malignancies showed a slight decrease since 1980 in the EU-28 (200–160/100,000) while in the EU-13, a small increase was seen (189–193/100,000), with men having a very high rate with 269 deaths in 100,000 people.

Deaths from external causes (injuries, poisoning) have shown a clear decline in the last three decades with the countries of the EU-13 recording almost twice the rate of the corresponding rate for EU-15 (55–30), and men recording four times the rate for women (90–23) in the EU-13 and more than double in the EU-15 (44–18). These large disparities between men and women are due to work conditions and the participation of men in manual and technological activities.

For suicides and self-inflicted injuries, despite the reduction achieved mainly for women, the rate for the EU-13 remains quite high at 15 deaths/100,000, which corresponds to the rate for the EU-15 in the 1980s. It should also be noted that the rate for men in the EU-13 is five times that of women (26–5).

Diabetes registers a slight decrease for the EU-15 (16–12) from 1980 to 2010 and stabilization in the countries of EU-13 (12–12).

#### **APPENDIX 6: CAUSES OF DEATH—STANDARDIZED DEATH RATE PER 100,000 INHABITANTS IN THE EU-28, EU-15, EU-13 (1980–2010)**

The cultural progress, the continuous effort for economic advancement, consumerism, the prevalence of poorly imitated social standards, the architectural remodeling of cities, and the increase in individualistic relations and solitary-living individuals, are reflected in the increase in mental



illness with the EU-15 exhibiting double the rate of that for the EU-13 (35–15) and double the rate since 1980 (18–35).<sup>10,1</sup>

Infant and maternal mortality in 2010 with four infant deaths in 1000 live births and six cases of maternal deaths in 100,000 live births are considered of lesser importance in the modern European nosological spectrum due to advancements in pediatrics, in the respective health services, and due to income growth and education of European citizens. A serious effort is still required, however, to reduce these indicators in countries like Romania with the highest infant mortality rate (9.79/1000 births) or Latvia with the highest maternal mortality (26.02/100,000 live births).<sup>10,1</sup>

The general evaluative assessment of the state of health of the population is considered satisfactory, showing a trend toward a significantly halting pace of diseases such as ischemic heart disease or mortality from external causes such as traffic accidents or accidents at the workplace. Cancers and vascular diseases of the brain remain at high levels with very low rates of decline.

### 3.4 PYLLs and Life Expectancy in Good Health

In the EU-28 over the last 30 years, 2.9 years have been gained for men before the age of 65 and 1.9 years for women hoping to avoid a deadly event, i.e., how many lost years of life a person could gain if he or she had not died (early mortality). Nevertheless, men still have a greater risk with 5.4 as opposed to 3.1 years for women.<sup>10,1</sup>

## APPENDIX 7: LOSS IN LIFE EXPECTANCY YEARS FOR MEN AND WOMEN FROM DEATH BEFORE THE AGE OF 65 YEARS (1980–2010)

PYLLs per 100,000 in the last 50 years (1961–2010) for men and women have fallen significantly, contributing to the increase in life expectancy. PYLLs from all causes for ages 0–69 years per 100,000 people show significant decreasing trends for both women and men during the period 1961–2010. In women, the greatest reductions are noted in Spain at 78% (from 8238 in 1961 to 1787 in 2010) and Greece at 73% (from 7576 in 1961 to 2036 in 2010). For men, the percentages of reduction are 68% in Spain and 57% in Greece. Therefore, both the falling rate of the indicator and the sharp differences between the sexes can be clearly seen.

In the United States, the corresponding rate of decline of PYLLs during the same period was 53% for women and men equally. In Japan, for women it was 79.9% and for men 76.5%. In 1961, the years of life lost for women was at 8004 years for the OECD countries, and in 2010 only 2457 years, respectively. The years of life lost for men was 12,210 in 1961 for the OECD countries, while in 2010 the corresponding figures stood at 4798.<sup>12,13</sup>

## APPENDIX 8: PYLLS FROM ALL CAUSES WITH COMPARATIVE REFERENCE TO LIFE EXPECTANCY (100,000 MEN–WOMEN AGED 0–69), (1961, 2010)

Health-adjusted life expectancy (HALE) is a measurement developed by the World Health Organization that attempts to capture a more complete estimate of health than standard life expectancy rates (note that HALE was previously referred to as disability-adjusted life expectancy or DALE). HALE estimates the number of healthy years an individual is expected to live at birth by subtracting the years of ill health—weighted according to severity—from overall life expectancy. HALE is also calculated at age 65 to provide a measurement of the quality of life of seniors. By moving beyond mortality data, HALE is meant to measure not just how long people live, but the quality of their health through their lives.

The interest regarding changes in life expectancy centers on the number of years in good health the European citizen hopes to live. The average number of years of life for the European citizen is 80 and by the 65th year, a basic period of life and work comes to an end and he or she usually retires. It is argued that the age of 65 years is a milestone and a comparative point of reference, a benchmark so to speak, as to how many years in good health the European citizen could live beyond this age limit or what he or she would not want to experience in terms of morbidity or disability.

In the EU-28 at age 0, men expect to live in good health 61.3 years and women 61.9 years, a difference of only 0.6 years. At age 65, the difference is even smaller (0.1) with life expectancy for men at 8.4 and women at 8.5 years.

The highest at age 0 is observed in Malta (72.4 for women and 71.8 for men) and the lowest in Slovakia and Estonia (53.1 equally for women and men). Similarly, at age 65 life expectancy is the highest in Sweden (15.4 for women and 14 for men) and the lowest in Slovakia (3.1 for women and 3.5 for men).<sup>16</sup>

## APPENDIX 9: HEALTH-ADJUSTED LIFE EXPECTANCY

### 4. REDESIGNING HEALTH POLICIES IN EUROPE

#### 4.1 New Trends in Health Indicators in the Multidimensional Context of Changing Health Needs

The new trends observed in health indicators, namely the decline in the rate of growth of life expectancy and the differences in the causes of mortality, the new population data with the rapid growth of people aged over 65 years, and the

strong migration flows force us to further investigate phenomena such as the reappearance of tuberculosis, syphilis, and hepatitis which also represents a significant cross-border threat because of the heavy external impact.

These new trends in health indicators define the current health policies and lead to the necessity of adapting the health system so as to meet the changing health needs of the population. These trends are identified by the persistent findings observed in the study of four categories of indicators, namely the state of health, the determinants of health, the efficiency–effectiveness of the health system, demographic trends and changes in the composition of the population, and socioeconomic development.

#### 4.1.1 *State of Health of the Population*

The increase in people aged over 65 years and the new way of life contribute to the increase in chronic diseases and consequently to an increase in health-care spending. Thus, the systematic recording of morbidity and mortality of chronic diseases (asthma, arthritis, migraine, chronic bronchitis, musculoskeletal spine problems, diabetes, stomach ulcer, cerebrovascular problems after injury, Alzheimer's disease, etc.) is a priority for health indicators. Also the increase in mental disorders makes the need for the documentation of relevant indicators the highest priority.

#### 4.1.2 *Sociocultural Determinants of Health*

The growth in cancers, cardiovascular and cerebral diseases, and chronic diseases has given rise to a systematic investigative field for the explanation of a population's state of health, placing a greater emphasis on noniatrogenic health determinants such as:

1. the correlation between free time and systematic exercise,
2. the enrichment of the diet with fruit and vegetable consumption, and
3. the degree of autonomy of individuals in their teens or older within the local community, which has proved to be a strong factor in physical and mental health.

We can also investigate determinants such as the correlation between the absence of sleep disorders and good health, the degree to which people feel healthy in general, or the correlation between the degree of introversion and social and professional advancement on the one hand, and physical or mental disorders on the other.

#### 4.1.3 *Effectiveness of Health Services*

It has been found that the way by which we cover health needs, the speed of the offered services, the specialized scientific skills, and organizational-administrative innovation

in the health system receives considerable contribution from health education, from primary care all the way to tertiary therapeutic intervention aiming at preventing the disease or at achieving full therapeutic rehabilitation. It is therefore reasonable to investigate whether the health system could contribute: (1) to a decline in mortality and reduction of years of life lost at a late age (65 or 75 years), i.e., to reduce early mortality; (2) to rehabilitation without complications; and (3) to safety and patient satisfaction. Thus, potentially avoidable mortality has been introduced in the statistics of health indicators, waiting time for specialized surgery, as for example in the case of hip fracture, and the rate of readmissions within 30 days of discharge for a particular diagnostic category.

Mortality before the age, say, of 65 or 75 years could have been avoided if, thanks to primary prevention and care, the disease had never occurred or if through secondary and tertiary treatment the disease had been dealt with effectively (potentially avoidable mortality). The indicator of PYLLs is now considered a key indicator used to assess the degree of influence of the health system on the population's state of health.

#### 4.1.4 *Efficiency of the Health-care System*

So far the study of the classic health indicators such as the aging index, addiction, unemployment rate, per capita income, square meters per person, public health expenditure per capita, ratio of human, or technological resources has enabled assessment of the adequacy of resources to meet the health needs of the population. Now, however, within the context of curtailing expenditure, the need emerges for investigating the impact of a rational use of health services and especially the flexible forms such as one-day surgeries and to this end, corresponding indicators are being developed. The purpose of these indicators is to highlight the degree of utilization of resources and services, examining the admissions in general or for specific cases comparatively and proportionately to the cases meeting the demand for services in other areas.

#### 4.1.5 *Demand and Supply of Health Services*

The new trend in the investigation of how supply meets demand in health services is in two directions. The first has to do with inequalities depending on the place of residence in combination with income inequality in an area of reference where a strong correlation between the two variables has been observed. The second relates to the disparities in the use of services or in the results of a therapeutic process. In other words, an attempt is made to investigate if the health system treats all citizens the same way, whether they have a very low or very high income, and to measure the relative variations.

The first case of inequalities can be attributed to behavioral and quality of life factors that depend on the socioeconomic level (unemployment, housing conditions, level of education, crime, alcohol, tobacco, food or work conditions affected by the social and professional status of the inhabitants). In the second case, the disparities should be attributed to the allocation of health-care resources that affect health service use (high costs, inability to participate in the costs, waiting time for a medical operation, availability of expert medical opinion doctors with specific experience and expertise, new technologies in micro-robotics or biotechnology, specialized staff for home health-care, complete and fast diagnostic procedures with subsequent effective treatment, etc.).

## APPENDIX 10: THE MULTIDIMENSIONAL FIELD OF POPULATION-APPRECIATED HEALTH NEEDS

### 4.2 The Need for Redesigning Health Policies in the Context of Changes in the Multifactor Nosological Spectrum

In order for a proposal that pinpoints the necessity for redesigning the guidelines of EU health policies to be considered sufficient, it must demonstrate a high degree of scientific credibility and be based on thorough and informed analysis. The initial proposal must move within the limits and the general guidelines of the European policy for health and social care and take into account the changes that have occurred in the macroeconomic, legal, and organizational-administrative level of the health systems. Then it must integrate within the framework of analysis all developments in technology and medical science, to investigate and determine the resulting health needs of the population taking into account socioeconomic, cultural, and environmental factors and health determinants.

More specifically, the proposal must provide an investigative methodological framework for defining the individual objectives taking into account the accelerated aging of the population, economic recession, unemployment, population at risk of poverty, the slowdown in the rate of growth in life expectancy for some countries of the EU, health costs and their significant containment, control of pharmaceutical expenditure, the high private costs, satisfaction of consumer health in relation to the offered services, the level of service quality, and the difficulties in implementing the restructuring of health services.

The proposal should also analyze the correlation between environmental and climatic factors in shaping the state of health of the population and consider in a systematic way the causative factor “working conditions” as a basic cause for shaping the state of the population’s health and as a variable affecting direct and indirect costs of workplace

accidents on GDP, on the system of social security, and on the insured themselves.

This approach, although it highlights goal setting in health-care policies, can be further enhanced by systematic analysis of:

- the epidemiological and nosological spectrum of supply of health goods and services,
- health spending relative to the amount and distribution, and
- policies for promoting biomedical hightech or sociocultural determinants of health,

so as to better specify the objectives relating to policy on cancer, cardiocerebral accidents, transmitted diseases, tobacco policy, and alcohol or dietary beliefs.

The analysis at the micro-level may further specify the proposed measures and prescribe actions for:

- the digital modernization of the system and the introduction of e-health,
- the improvement of skills and competencies of human resources,
- the development of modern procurement systems, analytical cost accounting, compensation methods, methods for preparing and monitoring the budget of hospitals, and
- the introduction of internal control systems, quality management systems, one-day surgery, home health-care, distant care.

The analysis can also focus on interventions regarding a particularly critical field, that of the management of hospital waste and nuclear contaminants.

The redesign of the guiding health policies defines in a rational and documented manner and takes into account the wider European social protection policies. Specifically, the EU has pledged to modernize the social protection systems and improve its social model in the light of shared values of social justice and the active participation of citizens in economic and social life. For this purpose and in order to develop integrated policies and coordinated monitoring methods, the open method of coordination (OMC) was adopted.

In 2005 three areas of coordination were defined: (1) social integration; (2) adequate and sustainable pensions; and (3) high-quality sustainable health-care and long-term care, which merged into a single social OMC.<sup>17</sup> In 2008, the EU further enhanced the OMC as a fundamental tool of social development and revised the term to “Social OMC.”

Member States have defined common objectives emanating from the Lisbon Strategy as well as monitoring indicators and analytical tools through the Progress Program to improve the capabilities of comparative analysis, knowledge transfer, mutual learning, better coordination, and strategic planning. The directions of the OMC for social protection and the basic indicators of an ongoing pan-European

research should be expanded and revised regularly as for example, the indicators of material deprivation (digital exclusion), of affluent households, life expectancy, and the transition from work to retirement.<sup>18</sup>

The directions of the OMC as an intergovernmental cooperation method on accessible, quality and sustainable health-care, and long-term care, focus on the following:

- Access for all to adequate health-care and long-term care, ensuring that the need for care does not lead to poverty and financial dependency while at the same time addressing inequalities related to access to care and the results of health services.
- Quality in health-care and long-term health care and adjustment, including preventive care, to the changing needs and preferences of society and individuals, primarily through the development of quality standards that meet international best practices and through the development of a higher sense of responsibility among health professionals and patients and recipients of care.
- Sustainability of adequate and quality health-care and long-term care through the rational use of resources and mainly through appropriate incentives for users and providers, good governance and coordination between care systems and public and private entities. Long-term sustainability and quality also require the promotion of a healthy and active lifestyle as well as the existence of good human resources for the health-care sector.

### 4.3 The Strategic Context of Health Policies for the Period 2014–2020

#### 4.3.1 *From the Innovation of the Health System to the Promotion of Health and Improvement of the Quality of Life in Good Health*

The fundamental principle of health policies lies in the documented argument that the principal objective of health policies is not solely to improve a health system but primarily to improve the state of health of the population.<sup>1</sup> The success of the guidelines of health policies is an essential prerequisite for the control of health-care spending, for the improvement of satisfaction of health services consumers, and for greater work output due to an increase in productivity from the application of innovation and planning at all operating levels of the health system.

The strategic objectives must specify the design of a strategic framework that centers on ensuring the transition from health system innovation to the promotion of health. The focus on applying best practices in innovation as far as the organization and management of the health system is concerned ensures sustainability, access, safety, and quality in the provision of health-care services, essential

components for the prevention, maintenance, and promotion of the population's health.

The best practices in innovation refer to the methods and techniques of human, financial, and material resources of the health system, the use of technology, the organizational and structural models of health-care services as well as their funding. Innovative e-health applications have a high added value because they have a wide range of applications from complete and personalized care to independent living and distant care.

The transition from innovation in the health system to the promotion of health is a prerequisite for ensuring the long-term supply of health services on an equal basis and with equal distribution of all produced results. However, the dilemma of attaining maximalist objectives—the effective development of the health system—at the expense of the minimalist implementation of coverage for the socially disadvantaged, particularly in times of crisis, is of particular interest and guides the analysis of health policies with regards to the allocation of available resources.

Within the context of the fundamental principles of civil and social rights and health policies the key objectives of the EU regarding health for the period 2014–2020 emerge:<sup>4</sup>

1. Prolonging healthy life by two (2) years,
2. Healthy and active aging (preventing early retirement),
3. Reducing absenteeism from work for health reasons,
4. Reduction of the number of people who are at risk of poverty and those who are socially excluded by 4%.

Especially in the context of the changes in the nosological spectrum and the variability in the indices of morbidity and mortality, the focus is not only to further prolong life expectancy but also to improve life expectancy without chronic diseases and without disabilities and to reduce the avoidable mortality, the PYLLs before the age of 65 years (active aging).

### APPENDIX 11: MAIN OBJECTIVES OF HEALTH POLICIES: PROLONGING LIFE IN GOOD HEALTH AND WITH QUALITY YEARS

According to this approach to the redesign of health policies in conjunction with the quantitative and qualitative results of the positive and negative health indicators and the changing health needs of the population, the following are the strategic priorities of health policy in the EU for the period 2014–2020.<sup>19,20</sup>

#### 4.3.2 *Strategic Objective 1. Viability of the Health System*

The lack of resources and the need for innovation in the health system are dealt with through a series of policy measures for comprehensive EU-based long-term health-care,

for active and healthy aging, for information, awareness, prevention, early diagnosis, cost containment through organizational reforms, product innovation, and the use of information and communication technologies (ICT).

#### 4.3.3 Strategic Objective 2. Patient Access and Safety

Access for all patients to medical expertise and quality of care is addressed by a number of policy measures for their safety, support for low-income patients and the socially excluded, citizens' access to health services across Europe, implementation of best practices, fighting antimicrobial resistance, high safety standards in the blood, organs, tissues, and cells for transplantation and generally reducing and eliminating disparities in health.

#### 4.3.4 Strategic Objective 3. Prevention and Health Promotion

Addressing premature mortality and low growth of healthy years of life requires the development of measures for the prevention and health education that relate, for example, to smoking, alcoholism, poor diet and obesity, lack of exercise, sexually transmitted diseases, cancer screening, and generally changing health behavior that is affected by modern lifestyle, socioeconomic, and cultural factors.

#### 4.3.5 Strategic Objective 4. Protection from Cross-border Threats

Improving preparedness for emergencies and cross-border threats such as pandemic influenza (H1N1) virus, bovine spongiform encephalopathy, sexually transmitted diseases, the Severe Acute Respiratory Syndrome (SARS) pandemic, and *Vibrio cholera* can be managed through a series of policy measures and actions concerning effective coordination, the development of crisis management systems, documented health risk assessments, early warning, monitoring and collection of reliable data and information, and finally, the development of general and specific vigilance and surveillance systems.

The focus, therefore, of the European health policies is to ensure:

1. The adequacy and viability of the health system in order to meet health needs despite of potential shortages of resources (human, material, financial) and the absence of innovative organizational, management, and operation methods.
2. The promotion of accessibility to quality and safe health services and the equitable distribution of health resources (regardless of income, social status, place of residence, ethnicity).
3. Address the critical risk factors for prevention and health promotion.

4. The protection of public health from external impact caused by the spread of diseases such as epidemics or pandemics.
5. The adequacy of efforts to inform and update the population, to create a mechanism to protect public health which is in constant readiness through a permanent cross-European body.

Consequently the up-to-date objectives of health policies are briefly:

1. Coverage of health needs, adequacy, and viability of the health system
2. Mitigation of inequalities and access to health services
3. Prevention, promotion, and elongation of a healthy life
4. Information, preparedness, coordination, and protection from cross-border threats

### 4.4 Proposed Actions for the Achievement of the Strategic Objectives of the European Health Policy

The guidelines and policy measures aggregate and enrich the proposed objectives of health policy. Also, the specialized reconfiguration of health policies leads to specific policy measures and actions in the following areas:

- Meet the needs of a rapidly evolving epidemiological spectrum due to the modern lifestyle and environmental changes
- Prevent diseases, maintain and promote health in the new conditions of the nosological spectrum
- Address the strong external impact from cross-border threats
- Develop bio-vigilance and surveillance systems and control blood derivatives
- Ensure the supply of health services for the population of the third, fourth, and fifth age
- Develop combined measures for mental health to address contemporary psychosocial–pathological phenomena as well as the mentally ill with comprehensive, friendly, and efficient mental health services
- Patient safety
- Examine accessibility and equality in health services
- Improve and expand the primary care and the interconnection between primary and secondary care
- Continuous improvement of quality of health services
- Sustainability, accessibility, effectiveness, efficiency, and preparedness of the health system
- Improve working conditions
- Protect the environment

Following the above analysis and documentation of the redesign of the broad health policies and strategic objectives, we present the proposed interventions describing

the specific objectives, the problems to be addressed, and suggested actions to achieve the objectives.

#### 4.4.1 Viability

*Specific objectives:* To address the lack of resources by adopting innovation at the organizational and administrative level.

*Problems to be addressed:* Excessive increase in costs, low level of organization of health-care, low level of EU care, lack of individualized and comprehensive health-care, lack of use of tools to assess health-care technology and health-care with fewer resources, shortage of health professionals (generally, specifically), low cross-European cooperation, insufficient use of ICT, lack of interconnection functionality for the electronic patient records.

*Actions and measures to achieve the objectives:* Implement innovation (in prevention, in early diagnosis, in treatment, in integrated care, active aging, and independent living), and ensure the adequacy and quality of human resources, of frugal and efficient use of medical technologies. Implement integrated management and administration systems for: (1) the economic efficiency of medical technologies; (2) decision-making processes; (3) organizational–economic management; (4) the performance of health-care units based on measurable quantitative and qualitative targets; (5) the utilization of ICT; (6) the restructuring of resources in the smaller scale within health-care units; and (7) the coordinated and interconnected operations of health services and general or specialized medical departments/clinics within each health district. Respond to increased demand due to an aging population (home health-care, distant care for the elderly and implementation of long-term health-care systems at the local and regional level).

#### 4.4.2 Accessibility

*Specific objectives:* Address the inequalities of access to medical expertise and the problem of low quality and safety of health-care.

*Problems to be addressed:* Increase in poverty and the number of people with low incomes, increase in inequalities and in the number of those who are socially excluded, life in deprived areas or in regions with lack of resources, elimination of regional disparities—inadequate interconnection between service networks at the European level. Increase in antimicrobial resistance, lack of actual rights of patients to cross-border health-care, absence of uniform rules and regulations for the safety of blood, organs, tissues, cells, pharmaceuticals.

*Actions and measures to achieve the objectives:* Access to diagnosis using reliable people with sufficient medical expertise, improve the quality and safety of health-care, support for European reference networks (access regardless

of where one resides), support for low-income and socially excluded people, improvement of the specifications for safety and quality in the substances of human origin such as blood and its derivatives.

#### 4.4.3 Prevention and Health Promotion

*Specific objectives:* Combat diseases associated with the modern way of life, the so-called diseases of civilization, by implementing policies of health education and promotion.

*Problems to be addressed:* Insufficient planning and provision of preventive services, maintenance and promotion of health, absence of a mechanism for systematic intervention for prevention and screening of diseases affecting public health and the modern way of life (behavioral health model).

*Actions and measures to achieve the objectives:* Develop specific and targeted health education programs based on methods and techniques of experiential awareness and psychoemotional empowerment to deal with the impact of the main determinants of health (smoking, alcohol, diet, physical exercise). Also develop awareness programs to improve health and safety conditions at work, traffic education, environmental education, and environmental control regarding air pollution, subsoil and sea, recycling, low energy consumption, promoting alternative energy, sex education and the use of condoms to reduce sexually transmitted diseases, the phytosanitary control, and the protection of public health. Additionally, create a permanent observatory for the promotion of health and quality of life, develop models for long-term care and home health-care, enable the creative involvement of people of the third, fourth, and fifth age, active participation in the local community—these interventions have a positive impact for the design of prevention (not creating new health needs) and for treatment (less treatment in closed-type services).

#### 4.4.4 Protection from Cross-border Threats

*Specific objectives:* To address the external impact from cross-border relations, combating epidemics, pandemics, and contamination from chemical incidents.

*Problems to be addressed:* Pandemic influenza, bird flu, SARS, bovine spongiform encephalopathy, transmitted diseases, sexually transmitted diseases.

*Actions and measures to achieve the objectives of health policy:* Readiness—early warning, coordination of services—public health centers of response to emergencies, development of a specialized information system for collecting and analyzing data. Improve capacity for risk assessment and crisis management, services for the control of immigration, development of common methods for combating cross-border threats, and dissemination and awareness regarding condom use for sexually transmitted diseases.

## 5. HEALTH POLICIES ON CORD BLOOD STEM CELLS BANKING

### 5.1 Development of an Integrated Policy for the Sufficiency and the Represented Collection of Cord Blood Units

Transplantation of hematopoietic cells is the standard therapeutic method and often the only treatment for a range of diseases characterized by malfunction of the bone marrow and the cells it produces. Nowadays, blood derived from an infant's umbilical cord is the appropriate source of hematopoietic progenitor stem cells for bone marrow transplantation.

The increase in the offered therapeutic applications using tissues and cells during the last years, the legal differences among the Member States, and the related risks of the imprudent use of these substances have led the EU lawmakers and the Member States to establish Community standards which ensure the quality and safety of human tissues and cells, and also the quality of the procedures related to donation, procurement, processing, and use of them.<sup>21</sup>

The use of tissues and cells for application on the human body involves the risk of transmission of infectious diseases and other possible side effects on the recipients. The EU takes under serious consideration the transmission of genetic diseases mostly originated from reproductive cells and for this reason has made adjustments to the European Directives for tissues and cells which vary from the general principles referred to in Directive 2004/23/EC for the setting of quality and safety standards for donation, procurement, control, processing, preservation, storage, and distribution of human tissues and cells to the Directives 2006/17/EC and 2006/86/EC which contain detailed technical requirements on processes of standardization and traceability, which means the list of procedures performed in order to prevent serious adverse events (SAE) and SAR.<sup>22-24</sup>

We should also refer to the 2011/2307 (INI) European Parliament report (A7-0223/29-6-2012) related to the voluntary and unpaid donation of tissues and cells, where for the first time it is established that Member States should implement policies for the promotion of the sufficiency of cord blood units. It also urges the States to develop programs which will encourage the general population and especially some specific groups (minorities) to donate cord blood, since it is proved that the cells can be used for the treatment of diseases like childhood diseases, in order to deal with the problem of lack of compatible donors.

In order to optimize the sufficiency of cord blood units in each Member State, the competent authorities (CA) should develop public campaigns in order to raise awareness mostly targeted to expectant mothers and their families more than other groups from the general and special groups of population. In this framework, the development

of an integrated policy in the EU Member States is firstly necessary in order to ensure the sufficiency of genetically varied cord blood units concerning HLA histocompatibility antigens, and secondly to optimize the prediction and provision of predisposing factors for the health restoration of hematological patients who need hematopoietic cell transplantation.

This integrated policy is developed in accordance with the following strategies:

1. Enforcement and support of health services and of the organizations involved in promotion of cord blood units, in order to develop public awareness campaigns targeted to the general and special groups of population.
2. Coordinated health services, through the person-oriented (expectant mother) cord blood donation system and through the management of the most important health risk factors of cord blood donors in order to ensure the suitability of the donor and the good health state of the recipient.

In the context of the above strategies, the main goals are formed into two main courses of management actions:

- Networking and involvement of the organizations, health services, and units for the represented cord blood collection concerning the HLA histocompatibility antigens.
- Creation of HLA-oriented registries so as to map the population's genes.

Furthermore, "Member States take all the necessary measures to ensure that every promotion and advertising activity for the support of the human cells and tissues donation is in accordance with the guidelines or the legislative provisions in force. These guidelines or legislative provisions include appropriate constraints or prohibitions of advertising the need or the availability of human tissues and cells which aim to the offering or the seeking of financial gain or anything similar. Member States try to assure that the procurement of tissues and cells is performed on a non-profit basis."

### 5.2 Management of SAE and SAR: Quality Assurance and Safety of Tissues and Cells

Health policies established by the EU do not deal with the legislative framework for the promotion and the implementation of strict quality regulations. The Directorate General for Health and Consumer Affairs (SANCO),<sup>25</sup> whose aim is to promote a healthier and safer place for European citizens, has financed a number of surveys which were initially expected to help Member States to understand and to conform with the existent legislation and later help them with the detection and dealing with potential problems.

With tools like monitoring, consultation, supporting, and implementation, the EU initially funded the 3-year program Eustite in order to promote the standardization of

procedures for tissues and cells among the Member States through common control guidelines. The Eustite program involved a consortium of organizations from 10 Member States in cooperation with the WHO<sup>26</sup> and coordinated by the National Transplant Center in Italy. Other partners of the project were Austria, Bulgaria, Denmark, France, Ireland, Italy, Poland, Spain, Slovakia, and the United Kingdom.

The aims of the Eustite program were:

1. the promotion of good practice standards for the inspection of tissue establishments, and
2. the development of optimized systems for the reporting and management of adverse events and reactions related to quality and safety of tissues and cells implanted on patients within the EU, regardless if the tissues and cells come from inside the EU or from other countries outside the EU.

Later, the knowledge acquired by the Eustite program was transferred to the 3-year program “Soho Vigilance & Surveillance” which continued one step forward involving issues like the possible relation between the adverse events with tissues and cell donation or if the application on humans has caused events which could be evaluated and investigated. One of the most important Work Packages was responsible for a survey carried out by the Spanish Transplant Organization concerning the development of bio-vigilance systems for tissues and cells and also for assisted reproduction in Member States in the year 2010.

In September 2010, “Soho V&S” cooperated with WHO and with the Italian Transplant Organization (Centro Nazionale Trapianti) to take a global initiative which aimed in the enforcement of promoting substances of human origin. This initiative was called “The Notify Project.”<sup>27</sup> Ten international groups of experts worked together through a Google Web site, where more than 100 participants (clinical doctors, health professionals, representatives of civil societies, experts) collaborated to gather documented cases of adverse reactions and events using published articles and vigilance system reports as their sources. More than 1700 published references were introduced to the database.

The cases were used as the basis for developing draft guidance on detection and confirmation of reactions and events, with an emphasis on the key role of the treating physician, and on July 03, 2013, the European Council approved the proposal of the Commission for issuing the decision concerning serious cross-border health threats. The issue of this decision is a big step forward for the safeguard of health safety in EU and the protection of citizens from a wide range of health risks.

A recently funded program has the acronym “ARTHIQS” (ART and Hsc Improvements for Quality and Safety throughout Europe) and aims to develop guidelines for key aspects of service provision and regulation in ART and HSCT.

The specific goals of the program are:

1. Institutional and organizational guidelines for the enhancement of an ART-specific expertise at official level in each Member State, leading to a more appropriate and consistent level of national organizations.
2. Set up of shared specifications regarding the main characteristics for HSC donor (related and nonrelated) follow-up registries to be implemented locally and/or nationally.
3. Minimum requirements for authorizing/reauthorizing cord blood banks (CBB) and the minimum quality and safety standards for CBB of all sorts (public/private, allogeneic/autologous), in accordance with European Union Tissue and Cell Directives (EUTCD) and existing standards.

ARTHIQS should bring solutions to some current issues related to EUTCD implementation: lack of consistent institutional competencies at CA and EU; lack of defined requirements for safety and quality both for HSC donors and CBB. Vademecum and curriculum for CBB and ART inspectors will also be prepared.

For the first time, in this project the policy followed by the CBB is separated. Since 2002, when EU started legislating for tissues and cells had never separated before the health policy of CBB from the policy followed by the Hematopoietic Stem Cell Volunteer Donor Registries. This happens because tissues and cell applications have the same target group, which is the patients suffering from hematological malignancies, despite the fact that the processing of the cord blood unit until it reaches the recipient has nothing to do with the processing performed until the graft of the volunteer donor reaches its destination.

### **5.3 Development of Bio-vigilance Systems: An Across-border Network for Disease Prevention and Control**

More than 500,000 patients in Europe receive annually tissues and cells of human origin. These substances represent, on the one hand “traditional grafts” whose therapeutic interest has been recognized a long time ago (corneas, bones, skin, blood vessels, heart valves) and on the other hand, state-of-the-art biotechnologies (hematopoietic stem cells of cord blood after special processing for their application on humans). Like all activities which involve products of human origin, these techniques include the risk of adverse events or reactions which are related to the transmission of communicable diseases. The risk of infection is bigger than it is in blood transfusions, since tissues and cells can travel across borders.<sup>28,29</sup>

According to article 7 of European Legislation 2006/86/EC “Member States shall submit to the European Commission, through their Competent Authorities, annual reports



on the notification of serious adverse reactions and events concerning the transplantations of tissues and cells including the centers of assisted reproduction.” The above guidelines promote the application of strict quality requirements in order to reassure the safety of tissues and cells. Traceability and bio-vigilance are the basic tools of quality and safety of tissues and cells intended for transplantation.

Traceability refers to all relevant data relating to products and materials coming into contact with tissues and cells. In this framework, tissues and cell establishments have to implement a system which will be able to locate and identify the donor and the donated tissues and cells and to generate one unique number for every donation and for every product related to this donation in order to safeguard the quality control and the recipient’s safety.<sup>30</sup> In this way, there is the possibility to withdraw from the availability and distribution procedure any product that may cause an SAE or SAR.

Bio-vigilance concerns the timely and valid reporting of all SAE and SAR and it works at three levels:<sup>27,31</sup>

1. At the European level, the European Commission supports preventive action through the early warning system for tissues and cells and also the European Center for Disease Prevention and Control has the mission to identify, assess, and communicate current and emerging threats to human health posed by infectious diseases.
2. At the national level, CA ensures that countries adhere to the requirements coming from the European Directives.
3. At the local level, tissues and cell establishments meet all the quality and safety requirements.

The field of bio-vigilance application is extended from the procurement of tissues and cells to the monitoring of patients after transplantation. The general scope of bio-vigilance involves activities like controlling, processing, transportation, preservation, import, export, and distribution of grafts. For example, the French network of bio-vigilance is running at a national level under the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSaPS) which is responsible for classification of information from local professionals. At a local level, the network consists of health centers, tissues and cell establishments, and private health units and services which are related to this field.

## 5.4 Promotion of Awareness Campaign Programs in Target Groups

Taking into consideration the current percentage of cord blood stem cells stored nowadays, it represents only 1% of the total number of births in the EU. Because it is necessary to create an integrated policy to raise public awareness, the EU stresses the importance of donating cord blood to cord banks which meet the strict requirements and also emphasizes the fact that public awareness and public opinion

play a very important role on the increase of hematopoietic cell donation figures. In this framework, it is necessary to develop a specialized action plan concerning cord blood donation and specifically how to inform the public and future parents in cooperation with CA at a local community level (public health organizations, primary health-care units, etc.).<sup>32</sup>

Moreover, the EU estimates that donations of allogeneic character should be promoted apart from the members of the family, regardless of whether the CBB is public or private, in a way that stored units are available to *Bone Marrow Donors Worldwide* and thus to every hematological patient who needs transplantation. For this reason it is expected that Member States will establish at least one public CBB. For the achievement of the main goal, which is the safeguard and the availability of cord blood units, each EU Member State is invited to establish a regional network of maternity hospitals which will have the authorization to receive samples in order to supply all population centers.

Civil Societies Organizations in collaboration with CA can also play a special role. Institutions like associations of volunteer blood donors or/and organ donors, organizations which promote the information, the procurement, and the distribution of cord blood and do not run only as organized and legal structures but also have the ability to intervene in local communities. After conducting a comprehensive strategic social marketing plan, these organizations can be the core through which cord blood units can be collected, and therefore a representative sample of the most frequent or rare HLA haplotypes of the population can be formed. Finally, it is understandable that in this procedure there are evaluation stages of the actions taken and also strategy redefinition when required, in order to form an applicable, gradually developing, flexible, and efficient plan of investigating the Member States’ registries.

### 5.4.1 Epilogue

The successful implementation of a program for the formulation of health policies depends, to a great extent, on the adoption of a system of ongoing evaluation and feedback. This system can ensure the successful implementation and operation of the proposed program by monitoring the effects resulting from these actions, with continuous modification in the light of the experiences gained from the evaluation itself and from continuous system adjustments. Finally, it should be noted that we need to list the proposed measures in a hierarchy and clarify the priorities mainly with regards to the feasibility of their implementation under the financial constraints of each time period.

Therefore, the knowledge that supports designers of health policies in order for them to ensure the collective public interest and competitiveness of Europe is particularly complex and maximizes their scientific responsibility.

We hope that politics and science will take a common course so that political analysis will incorporate the innovative scientific knowledge and added value that is produced, if we really want to link Europe's mission in history with the vision of its citizens and the future of the global community.

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