

Healthcare: Key Technologies for Europe

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1. Introduction

This synthesis report provides an overview of S&T and R&D in health and healthcare related issues and gives an indication of where the EU stands. It identifies its strength, weaknesses and options, and explores the key trends and a forward look over the next 10-15 years.

The desired future would bring about broad and equal access to high-quality healthcare, within financially sustainable healthcare systems around Europe.¹

However, on the one hand, modern healthcare technologies have the potential to extend the life expectancy of people, to increase their quality of life, to open up new tools for health prevention, monitoring, diagnosis, treatment and aftercare in an ageing and enlarging Europe.

On the other hand, there is a huge difference between a (technologically possible) optimal treatment and the treatment delivered to the patient. There are gaps in the provision of innovative healthcare technologies between the various European countries and between the income groups within a country - depending on its national health delivery system.

For this report a thorough documentary review of relevant information was undertaken, gathered from published sources from the academic and professional literature as well as documentation provided by the EU Commission.

The Introduction displays that health is more than physical and psychological well-being, and that healthcare - though a marketable product - is perceived to be a public good.

Chapter II on socio economic challenges introduces the influence of megatrends such as the ageing society, globalization and enlargement.

Chapter III on the global perspective on healthcare technologies examines healthcare applications that are currently available, gives a picture of the status quo of available technologies and projections for the future.

Chapter IV on EU activities presents the major European activities and legislation relevant to the field of public health and healthcare.

Chapter V introduces preliminary perceptions of the dimension of the future challenges. In a SWOT 2 it represents analysis of the European RTD strengths, weaknesses, gaps but also opportunities.

¹ European Commission (2001), "Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on The future of healthcare and care for the elderly: guaranteeing accessibility, quality and financial viability", COM (2001) 723 final

² Strengths and Weaknesses, Opportunities and Threats

Chapter VI explores healthcare statements in European foresight exercises, in order to portray the larger context for healthcare technologies in the future.

Based on the discussion from these previous chapters, the conclusions display some opportunities for systematic engagement of policy and governance in the implementation of a coherent European healthcare strategy.

Delimitation of the report

It is acknowledged that, in the future, EU healthcare systems will be under the pressure of a series of factors (which are beyond the scope of this report) inducing a general change and restructuring process. Although these are important and guide the adoption of healthcare technologies and applications, this report will address their context, but not specific issues that have been worked on intensively elsewhere, such as:

Issues on sustainability of systems; 3

Issues on telecare and ehealth; 4

Issues on cybersecurity (Identity, Privacy and security); 5

Population ageing aspects, their effect on Healthcare systems and Cost/benefit aspects; 6

Challenges and opportunities from EU Enlargement. 7

The report does not focus entirely on a techno-economic analysis, but rather builds on an inclusive approach, examining the impact of demographic and socio-economic changes which will take place in parallel with technological advances and other influences. The challenge is to identify policy opportunities that arise from this dynamic, and to identify areas with significant potential for policy action.

Definition the “Healthcare system” within this report

The healthcare sector consists of a variety of players - clinicians, hospitals and other healthcare facilities, insurance companies, purchasers of healthcare services, etc. - all operating in various configurations of groups, networks, and interdependent practices. Some are based in the public sector; others operate in the private sector as either profit-making or non-profit entities. In this report, these various players are generally referred

³ Sustainability is defined in this report as the 'development that meets the needs of the present generation without compromising the ability of future generations to meet their own needs. Issues around sustainability have been discussed and analysed in-depthly, for instance, in "Lifestyles, Future Technologies and Sustainable Development" (ISBN 3-929118-05-X) <http://www1.faw.uni-ulm.de/asis/html/f-background.html>.

⁴ <http://www.seniorwatch.de/swa/frame.html>

⁵ These have been discussed and analysed in-depthly, for instance, in some IPTS (socio-economic) impact studies <http://cybersecurity.jrc.es>, and intensively tackled by IPTS Report Special Issue: Volume 57 September 2001

⁶ These have been discussed and analysed in-depthly, for instance, in: European Commission (2001), "Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on The future of healthcare and care for the elderly: guaranteeing accessibility, quality and financial viability", COM (2001) 723 final, European Commission, Brussels. European Commission (2000), "Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Health Strategy of the European Community", COM(2000)285 final, European Commission, Brussels.

⁷ These have been discussed and analysed in-depthly, for instance, in <http://enlargement.jrc.es>, and <http://europa.eu.int/comm/enlargement>.

to collectively as the “healthcare system” (although this term suggests an integration that does not exist).

2. The socio-economic environment

In the past, national healthcare strategies have focused on, first, evaluating the appropriateness of interventions, such as diagnostic and therapeutic procedures, assistive technologies, and organizational standards, and then developing strong policies based on the results. Unfortunately, such policies have generally been ineffective in minimizing inappropriate use. It has, therefore, become crucial that the European Union concentrates its efforts on helping to guide innovators in the development of technologies that are most likely to meet the needs of the people.

In recent years, national health care systems have had to cope with an increasing demand for new health interventions, which have become increasingly more technologically advanced and expensive. Managing technological innovation and diffusion is one of the main issues plaguing health services delivery systems worldwide. Given limited available resources, how do we provide an environment that fosters technological innovation and, at the same time, balances the needs of individual patients with those of entire populations?

The beginning of the twenty-first century provided an early preview of the health challenges the EU will confront in the coming decades. The systems and entities that protect and promote the public's health, already challenged by problems like obesity, toxic environments and health disparities, must also face emerging threats, such as antimicrobial resistance, SARS and bioterrorism, while the scientific and technological advances, such as genomics and informatics evolve faster than the assessment of potential implications (social, cultural, global, ethical).⁸

The socio-economic challenges in the coming years relate primarily to the changing demographics and economics of the enlarging European Union: Greater longevity and falling birthrates together with greater mobility and shifting family structures place increased demand on health systems.

Economic development and consequent rises in standards of living lead to greater expectations of the quality of health systems, while across Europe, national health services struggle in the face of financial resource constraints and shortages of skilled labour.

While economically disadvantaged groups may face significantly higher health risks and mortality, rises in standards of living and lifestyle changes can also be linked to illness levels. At the convergence of these, in the context of an ageing society, the effective delivery of healthcare represents a key challenge to which the responses are likely to be supported by a combination of technological solutions.

For the future, health care systems in EU countries will be under the pressure of a series of factors that will induce a general change and restructuring process.

The current dominant technologies, which are the major drivers of global change at present and will continue to be so for the next two or three decades, are information and communication technologies, materials technologies, genetics and biotechnologies and energy technologies, with with a focus on „prevention and care for the ageing population“.

The advances arising from innovation in gen- and biotechnologies, information-, communication- and medical technologies have been identified as a crucial component

⁸ <http://www.nap.edu/openbook/0309086221/html/1.html>

of the effective delivery of health care in the future. Over the last twenty years, new drugs and surgical therapies have greatly improved the quality of life for patients. Innovation in health care technologies enhance the quality of and prolong life (organ transplants and artificial organs) and to make diagnosis easier.

The ultimate goal of healthcare policy planning is to optimise the health system while **simultaneously reducing costs**.

Achieving a balance between the three objectives of **broad and equal access, high quality healthcare and sustainable reimbursement systems** poses a major challenge for the overall management of healthcare systems.

The demographic development

The demographic development in Europe with an increasing number of non-working retired people will lead to a situation where a decreasing share of the younger population will have to support an increasing part of the older population.

The two forces - declining birth rates and rising life expectancies - are interacting to produce a dramatic change in the size and age structure of Europe's population: There will be more older people in absolute as well as relative terms, there will be considerably more older "old" people and there will be a smaller productive workforce to contribute to the financing of health and social services.

As a report by a High Level Group chaired by Wim Kok concluded in November last year, these trends have several implications:

The total population size is projected to fall by 2020. By 2050, the working-age population (15–64 years) is projected to be 18 % smaller than the current one, and the numbers of those aged over 65 years will have increased by 60 %.

As a result, the average ratio of persons in retirement compared with those of the present working age in Europe will double from 24 % today to almost 50 % in 2050. This dependency ratio will vary in 2050 from 36 % in Denmark to 61 % in Italy.⁹ This development is already at work and in 2015 the EU average dependency ratio will increase to 30%. The impact is then compounded by the low employment rate of older workers.

The USA and Japan are facing the same trends, some are "ageing" at the same speed (USA) or even faster (Japan).¹⁰ These trends also present significant market opportunities. Already now older and disabled citizens represent a significant market

⁹ Facing The Challenge: The Lisbon strategy for growth and employment, Report from the High Level Group chaired by Wim Kok, November 2004, Luxembourg: Office for Official Publications of the European Communities, 2004, ISBN 92-894-7054-2, © European Communities, 2004, http://europa.eu.int/growthandjobs/pdf/kok_report_en.pdf.

¹⁰ Mc Morrow K, Roeger W, The Economic Consequences of Ageing Population. A Comparison of the EU, US and Japan. European Commission, Directorate-General for Economic and Financial Affairs, 1999.

segment. Terms such as the "silver market" or the "golden market segment" which have been adopted primarily in consumer industries so far reflect the strategic importance of these consumers.

The European Ministers have reached an agreement on principles and on an action plan for renewing healthcare in Europe¹¹, to work towards improving access to quality care, to strengthen health education, and to ensure Europeans get appropriate care, from the appropriate providers, in the appropriate setting. Likewise, they have agreed to expand efforts in home care and community care; in evaluating the effectiveness of prescription drugs; and in reporting to Europeans about the overall effectiveness of the healthcare system.

The enlargement of the European Union

The enlargement of the European Union is unprecedented in terms of scope and diversity and will lead to increased information transfer (through mass media and other cultural products such as cinema and Internet) and travel opportunities (including possibility to acquire products and services abroad). There are however, some concerns on social cohesion, which could increase inequalities between young and old, between the rich and the poor, and there is a danger of a so-called social divide.¹²

With regard to the health sector it will bring together a diverse group of countries with considerable variations in health status and health systems. Most applicant countries lag behind the existing member states on key health indicators as well as in terms of spending on health. The overall level of resources invested in healthcare in new member states is still much lower than for the Union prior to enlargement – around 5.8% on average of Gross Domestic Product in the new Member States, compared to 8.6% for the fifteen “old” Member States. Poor health status compounded by under-investment in health and health systems will be a major brake on development, if this is not addressed.¹³

The transformation requires a functional legislation, balanced financing and economy, and optimisation of the structure and function of health care providers. Transformation of the health care system is a social process and, above all, a political problem that has to be first solved politically and then finished with consistent and objective utilisation of all relevant information, including the applied research and development, especially from the research of management and economics. These directions are closely related to

¹¹ European Commission (2001), “Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on The future of healthcare and care for the elderly: guaranteeing accessibility, quality and financial viability”, COM (2001) 723 final, European Commission, Brussels.

European Commission (2000), “Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Health Strategy of the European Community”, COM(2000)285 final, European Commission, Brussels.

¹² European Commission (1996) Living and working in the information society (1996): People first., Green Paper. European Commission; Building the European information society for us all (1997). Final policy report of the high-level expert group. European Commission. Employment and social affairs.

¹³ Speech of Commissioner Markos Kyprianou, Member of the European Commission, responsible for Health and Consumer Protection, The European Voice conference "Healthcare: Is Europe getting better?" Brussels, 20 January 2005.

information, communication and other technologies. It concerns specific medical technologies as well as procedures, educational programs and management regulations. Another aim in the transformation of the health care system is better application of research and development. Similarly to other fields, research and development provides the basic stimulatory impulses and resources for health care. Research and development is one of the most important warranties of continuous health care quality and attractiveness for the young generation. 14

Innovation in healthcare technologies

Even though some of the new innovative therapies will be hugely expensive¹⁵, innovation in healthcare technologies (particularly preventive and screening technologies) have the potential to reduce expenses, to deliver healthcare services remotely and to increase the efficiency of this delivery by, for instance, avoiding unnecessary duplicate examinations.

Effective integration of healthcare applications and -support services could improve the quality of life of citizens by enabling safer independent living and increased social inclusion. Healthcare technologies have, for instance, a considerable potential in helping older and disabled people remain in their own homes for longer by providing increased safety and reassurance to them and their carers, reducing social isolation, and supporting treatment, rehabilitation and intermediate care - even though European seniors (will) form a very heterogeneous group in skills and attitudes as well as in their lifestyles. In the healthcare sector, those who are consumers of products and services are not those who have to pay for them. Taken together, these influences contribute to the same problem: the exodus of the present healthcare systems. However, broad and equal access to healthcare cannot imply unlimited free access to any form of medical treatment or product that one can imagine. More and more it is being acknowledged that there are limits to what can be financed collectively.

Self-care and self-responsibility (empowerment) must be promoted. Patients have a right, and an increasing expectation, to have access to good quality objective information about the medicines they take and to be actively involved in decisions about their treatment. Patients cannot express informed preferences unless they are given sufficient and appropriate information about all relevant treatment and management options and information about the potential benefits and harms of each. This will require a co-ordinated effort involving a wide range of stakeholders.

EU public health legislation

The implementation of the EU public health legislation, such as the free movement of health professionals, free movement of health-related goods and services, including

¹⁴ MUDr. Mgr. Petr Struk: Current Situation and Future Prospects of Small and Medium-Sized Health Care Companies. http://www.tc.cz/dokums_raw/CZ_medicine.pdf.

¹⁵ An example is the now well-established Genzyme therapy - Cerezyme - for Gauchet's syndrome. The cost is \$160,000 per patient per year. Jim Ryan personal information June 2005.

patient mobility, environment, food safety and others, is a huge challenge¹⁶. All applicant countries have made considerable efforts in adapting their structures to meet Community health requirements. However, most of them need to make further efforts to improve the health status of their population and the capacity of their health systems. It is important to bridge the health gap between existing and future EU member states, to reduce inequalities in health, to address specific health problems and to find ways of improving the overall performance of health systems.

The European Commission has taken a number of initiatives in order to support the applicant countries to meet the accession-related health requirements. These include the programme of Community action in the field of public health (2003-2008), whose work plan contains specific actions with regard to health and enlargement.¹⁷

There is a determination to maintain general and comprehensive access to health care (even in the face of increasing costs) and there is a need to develop health care services and preventive strategies relating specifically to age-related illnesses, and these should be aimed at enabling older people to live active, healthy and independent lives, remaining in their own homes, further into old age.

The EU Commission has, for the most part, supported the technologies which underpin many areas of health technology and activity including drug discovery, diagnostics, vaccines, clinical trials etc. In the case of individual diseases such as AIDS or cardiac and circulatory illnesses, investigation into preventive measures has been supported, and the development of numerous technical diagnostic tools such as implanted or extracorporeal sensors to monitor blood pressure, glucose levels and ocular pressure.

Better skilled healthcare workforce in Europe

In this respect, a very important, but very complex question is that of the development of healthcare workforce in Europe. Regardless of the degree of technological innovation in the European health sectors, labor availability has an uncertain future. Significant technological innovation will impact our workforce in at least two important ways: First and foremost, it will improve the working conditions by providing assistance for difficult and repetitive tasks and secondly, it will require a more highly skilled and technologically trained, albeit smaller, workforce. A skilled workforce will receive higher wages and be employed on an annual rather than a seasonal basis, thereby improving the standard of living.

Health information

The collation of high quality, timely, comparable health information, particularly on population-level, is a central objective of the EU's new public health programme.¹⁸

¹⁶ Even though the primary responsibility for healthcare lies with the Member States, in recent years, the European Court of Justice has clarified the rights that citizens have to seek healthcare in other Member States and be reimbursed. In practice, however, it is frequently difficult for citizens to exercise these rights, and when they do, this has an impact on the health service of the country where they are insured, and in the country where care is provided.

¹⁷ European Commission, Community action in the field of public health (2003-2008), Official Journal L 271, 9.10.2002 and Official Journal C 62, 15.3.2003.

¹⁸ See Decision 1786/2002/EC, 23 September 2002, Adopting a programme of Community action in the field of public health (2003-2008), http://europa.eu.int/comm/health/index_en.htm

This will be done drawing on work already undertaken under the former Health Monitoring programme, and coordinated with international work in this field, including that undertaken by the WHO¹⁹, OECD and EUROSTAT and support for the development of new applications in health under the Sixth Framework Programme. ²⁰ The principal sources of such data at national level are health information surveys, registry data and hospital data. ²¹

Economic efficiency and competitiveness on a world market

The Lisbon Summit, in March 2000, European leaders set an ambitious goal for Europe in the next ten years to become the world's most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion, and have put the issues of electronic commerce and the Information Society at the top of their agenda.²²

At the same time, medical technologies have evolved and now capture market share. Yet, just as healthcare technologies are an economic factor, it competes at all scales of operation, with a tendency towards lowering healthcare costs with highest quality possible.

Demand for healthcare, and hence the health funds' budgets, continue to grow faster than Gross National Product in most countries. ²³

¹⁹ E.g. <http://cisid.who.dk/>, <http://hfadb.who.dk/hfa/>

²⁰ Among those: Intelligent Environment for the Health of Citizens (<http://www.cordis.lu/ist/ka1/health/projectbooklet/citizens.htm#cluster>), Intelligent Systems for Patients (<http://www.cordis.lu/ist/ka1/health/projectbooklet/patients.htm>), Intelligent Systems for Health Professionals (<http://www.cordis.lu/ist/ka1/health/projectbooklet/healthprofessionals.htm>). Other projects in the Ten-Telecom/eTen Programme EUREKA, COST, eContent, EUMEDIS (<http://www.cordis.lu/ist/ka1/health/projectbooklet/others>). eHealth projects from the IST 5FP Programme: <http://www.cordis.lu/ist/ka1/health/projectbooklet/others.htm#projects>.

²¹

http://europa.eu.int/comm/health/ph_overview/Documents/hlch_health_telematics_final_report_en.pdf

²² For full details on the development of the Lisbon Strategy see:

http://europa.eu.int/comm/lisbon_strategy/index_en.html#keydocuments.

²³ Links below have the most recent charts and graphs for healthcare statistics and rankings for many nations.

Health: Statistics Portal. OECD. Organisation for Economic Co-operation and Development.

http://www.oecd.org/topicstatsportal/0,2647,en_2825_495642_1_1_1_1_1,00.html

OECD Health Data 2005:

http://www.oecd.org/document/30/0,2340,en_2825_495642_12968734_1_1_1_1,00.html

OECD Health Data 2005 - Frequently Requested Data:

http://www.oecd.org/document/16/0,2340,en_2825_495642_2085200_1_1_1_1,00.html

Total expenditure on health, %GDP. Excel chart:

<http://www.oecd.org/dataoecd/13/13/31963469.xls>

Public expenditure on health, % total expenditure on health:

<http://www.oecd.org/dataoecd/13/12/31963479.xls>

WHO. World Health Reports. Statistics. Select topic and then click. Pulls up ranked stats for all countries.

<http://www.who.int/whr/en> Homepage.

This is because people are living longer, survive illnesses that previously would have been fatal, expect a higher quality of care, and are able to benefit from new and better technology and medicines. At the same time governments are under pressure to contain or reduce public expenditure. ²⁴

Enlargement has made inequality and the problems of EU cohesion more pronounced. The EU population has increased by 20 % while the addition to European GDP is only 5 %, resulting in a drop of output per head of 12.5 % in the EU-25.

Moreover, the new Member States are characterised by strong regional disparities with wealth concentrated in a small number of regions. The population living in regions with output per head of less than 75 % of the EU has increased from 73 million to 123 million. Equally, as noted earlier, the EU-25 will find some of the Lisbon targets even more challenging than the EU-15. For example, the EU-25 average employment rate has dropped as a consequence of enlargement by almost 1.5 percentage points. The long-term unemployment rate for the EU-25 is 4 % compared with 3.3 % for the EU-15.

These developments will have profound implications for the European economy and its capability to finance European welfare systems. Ageing will raise the demand for pensions and healthcare assistance at the same time as it reduces the number of people of working age, to produce the necessary wealth.

European Commission projections²⁵ estimate that the pure impact of ageing populations will be to reduce the potential growth rate of the EU from the present rate of 2–2.25 % to around 1.25 % by 2040. The cumulative impact of such a decline would be a GDP per head some 20 % lower than could otherwise be expected.

Already from 2015, potential economic growth will fall to around 1.5 % if the present use of the labour potential remains unchanged. This same ageing will result in an increase in pension and healthcare spending by 2050, varying between 4 and 8 % of GDP²⁶.

Already from 2020, projected spending on pension and healthcare will increase by some 2 % of GDP in many Member States and in 2030 the increase will amount to 4–5 % of GDP. On top of this, the lower economic growth rate will impact negatively on public finances, and this negative impact will commence from 2010. ²⁷

Quality and cost measurement

The introduction of new types of healthcare technologies and services is closely related to the rating of their quality to achieve better cost effectiveness. But it remains open how the quality of health care, technologies or cost effectiveness can be unequivocally

<http://www.who.int/whr/2004/annex/en/> 2004 statistical annex.

²⁴ Facing The Challenge: The Lisbon strategy for growth and employment, Report from the High Level Group chaired by Wim Kok, November 2004, Luxembourg: Office for Official Publications of the European Communities, 2004, ISBN 92-894-7054-2, © European Communities, 2004, http://europa.eu.int/growthandjobs/pdf/kok_report_en.pdf.

²⁵ The EU economy: 2002 review, European Economy No 6/2002, p. 192.

²⁶ The impact of ageing populations on public finances', EPC/ECFIN/407/04 2003

²⁷ Facing The Challenge: The Lisbon strategy for growth and employment, Report from the High Level Group chaired by Wim Kok, November 2004, Luxembourg: Office for Official Publications of the European Communities, 2004, ISBN 92-894-7054-2, © European Communities, 2004, http://europa.eu.int/growthandjobs/pdf/kok_report_en.pdf.

defined and understood, and how they can be measured and evaluated. A definition of “efficiency” or “productivity” of healthcare technologies or services would require a clearer understanding of the inputs and outputs of the delivery system and the product of a health care service.

Ethical, moral legal issues

There are a number of **legal and ethical issues** that need to be dealt with for the broad application of healthcare technologies, including:

- The possibility of malpractice;
- Issues regarding the security and confidentiality of patient's data.
- The procedure for licensing and accreditation of healthcare professionals
- The need for ‘informed consent’, i.e. patient involvement in decisions over their own treatment and the danger of removing choice and control from the patient

Particularly the advances in genetics, are raising deep ethical, moral or religious concerns among the citizens. Issues around public perceptions and intellectual property arise particularly in biotechnologies and related fields.

The application of modern healthcare technologies on a broad scale requires also a clear legal and regulatory framework of practice. The lack of such a framework may discourage health professionals from introducing technology-based procedures in their standard medical practice. More specifically, standards need to be developed for the delivery of uniform medical practice across Europe, including procedures to be followed in case of malpractice and the liability of such an event. Also standards need to be established for the provision of common medical information in electronic patient records.

3. The S&T base

Healthcare Technologies will globally gain in importance, even though their application will remain quite different from country to country, since the organisation and funding of health care remain matters of national competence. The technical progress within the health care sector will make possible many new or improved, but costly, medical treatments.

The current dominant application clusters with technology development as an enabling or driving issue are found in information and communication technologies, nanotechnologies, materials technologies, genetics and biotechnologies and energy technologies. An increasing convergence of nano-technology biotechnology, information technology and cognition science is expected, with, again, huge application opportunities in the health sector, for instance, in neuroscience or cardiovascular and metabolism illnesses. 28

Technological advances with particular application opportunities in the healthcare sector (particularly for diagnosis and treatment) have been identified in the following areas:

Pharmacogenomics

Pharmacogenomics is the study of the relationship between human genetics and pharmaceutical action. In simple terms, drugs don't have the same effects in all patients. The major factor in the variation of drug action is the genetics of the patient. Our increasing knowledge of the human genomes will provide information about individual differences in ability to metabolize drug products.

Gene therapy

Gene therapy is a potential method of treating genetic disorders by delivering a 'working' gene for the missing protein at the specific locus of appropriate expression in the body. This external gene expresses a protein which takes the place of the protein which is missing due to the genetic disorder. The advantages of this are the local delivery of the protein to a specific tissue, and the on-going nature of the delivery. Gene therapy has been defined as "the correction or prevention of disease through the addition and expression of genetic material that reconstitutes or corrects missing or aberrant genetic functions or interferes with disease-causing processes. Genetic diagnosis and Gene Therapy are accorded great importance for the future. Several of the studies examined agree that in the next five to 20 years monogene diseases will be diagnosed and be treatable with the aid of Gene Therapy and that genetic diagnostics will be widely used to measure the predisposition to particular illnesses. The ethical implications associated with these approaches are specifically mentioned. It is supposed that the use of genetic diagnosis and Gene Therapy methods will contribute furthermore to making new therapeutic approaches possible by the

²⁸ Swedish Technology Foresight.
NBIC

genetic modification of known receptors, ion channels, enzymes or other proteins of intra-cellular signal transmission.²⁹

Genetic diagnostics

Genetic diagnostics is the generic term for a number of diagnostic techniques that are related to the detection and prediction of, and possible remedies for, congenital and hereditary diseases. Such pathologies are either the result of chromosomal abnormalities, which can be visualised by conventional microscopy, or of mutations in DNA (the chemical basis of hereditary characteristics). The development of DNA diagnostics can approach multi-factorial diseases, which are the result of the complex interaction between a genetic susceptibility and certain (mostly unknown) environmental factors. The future impact and significance of genetic diagnostics will increasingly be shaped around the politics and findings of the Human Genome Project (HGP).

Stem cells

Stem cells are the „primordial cells“ of human beings and they have the ability to differentiate into all the other types of cells. Today, it is assumed that stem cells obtained from the human embryo have the greatest potential. However, there is increasing evidence that adult stem cells e.g. from cord blood and fully developed tissue might, if properly treated, exhibit a potential similar to the potential of embryonic stem cells. Both nationally as well as internationally, attention is focused on embryonic stem cells. The major concern is whether the possibility of developing new medical treatments can justify the ethical doubts related to the isolation of stem cells from the embryo.

Telecare, telemedicine and ehealth

Telecare and telemedicine consists of a set of enabling technologies, largely based around ICT. It supports better working between all the stakeholders in health and social care delivery by allowing the collection, management and transfer of information in a timely fashion. Telecare (health and social care provided at a distance using ICT, generally to people in their own homes or the wider environment) and telemedicine (the use of ICT to assist in the practice of medicine at a distance by helping health care workers communicate amongst themselves more effectively) are each a component of “eHealth”, a much broader definition of ICT-driven activities which are transforming the delivery of healthcare.

Ehealth describes here the combined use of electronic communication and information technology in the health sector. It is a broad collection of ICT-driven activities which are transforming the delivery of healthcare (telecare³⁰ and telemedicine³¹ are each a component of ehealth). Ehealth makes use of digital data, transmitted, stored and

²⁹ Delphi '98; Cuhls, K.; Blind, K.; Grupp, H. (Hrsg.) (1998): Delphi '98 – Studie zur globalen Entwicklung von Wissenschaft und Technik, Karlsruhe. URL: <http://www.isi.fhg.de/ti/Projektbeschreibungen/Cu-delphi.html>

³⁰ Telecare: the provision of healthcare at a distance (using ICT facilities).

³¹ TeleMedicine: the "use of information technology to deliver medical services and information from one location to another".

retrieved electronically, for clinical, educational and administrative purposes, both at the local site and at a distance.³²

Bioinformatics

Considerable advances are expected in bioinformatics (in combination with functional genomics) over the next five to ten years in understanding gene and protein functions. It is thought that further developed software programmes will open up new protein functions from considerable DNA and protein sequence databases. Methods to decode information from DNA modification patterns will be available for the complete genome. It is also expected that quick and cheap sequencing methods will be utilised for the analysis of the complete genome including single nucleotide polymorphisms (SNPs), developing individualised therapy concepts. In essence it is presumed that bioinformatics will be crucially important in the processing and utilisation of the large quantities of data emerging from proteomics and functional genomics. Increasingly in this context, further high-throughput-screening approaches will be used. It is equally supposed that bioinformatics will play an important role in future with the simulation of molecular interaction dependencies using structural data derived with the aid of NMR or X-ray crystal analysis.³³

Minimally invasive surgery

Minimally invasive surgery (MIS) is a field that has gained a great deal of attention since the mid-80s. The reason for this is that it is a rapidly growing area of medical treatment that causes substantially reduced trauma to the person undergoing it. In part, it is made up of changing techniques, but it also depends in most cases on new and advanced technologies, especially endoscopes, vascular catheters, and medical imaging devices. It is expected that the demand for MIS procedures increases with the ageing of the population.

Emerging trends in the development of regenerative medicine are signalling a shift from the emphasis on the replacement of tissues towards a more biologically based method for the repair and regeneration of tissues. This trend also signals a move towards less invasive surgical interventions. Trends are also emerging in the development of regenerative neurotechnological devices like mind-controlled prosthetics for amputees and devices for easing an individual's suffering from paralysis. These developments are starting to blur the boundaries between "human" and "machine".

Specialized endoscopes open up new possibilities: Smaller cuts and scars, less post-operative pain, shorter hospital stay: minimally invasive surgery puts less strain on the patient than conventional surgery. The practical use of sensors on the body surface for non-invasive measurement of blood sugar is expected relatively in the short term.

³² For more definitions of ehealth ...see also Eysenbach G. What is ehealth? [editorial]. Journal of Medical Internet Research 2001; 3(2):e20.

³³ Japanese Delphi Study; NISTEP (2001). The Seventh Technology Foresight - Future Technology in Japan toward the Year 2030. NISTEP Report 71. Science and Technology Foresight Centre, National Institute of Science and Technology Policy (NISTEP), Ministry of Education, Culture, Sports, Science and Technology. <http://www.nistep.go.jp/achiev/ftx/eng/rep071e/idx071e.html>

Therapy measures that extend beyond a symptomatic medical treatment of diabetes are only expected in the much longer term. It is thought, for example, that the development of a Gene Therapy for diabetes will come in 2017. 34

Medical imaging techniques: such as magnetic resonance imaging or computer tomography are used routinely in medicine today. They visualize the inner body from the outside and yield three-dimensional pictures of the organs. In the future, their use in diagnostics will be expanded even farther - the aim of the research cooperation. An important trend is the design of increasingly smaller scanners with much lower capital and operating costs. Smaller and less costly magnets will be available for dedicated uses in orthopedics, neurology, and mammography. Magnetic resonance neurography (MRN) can identify the site of damage to a peripheral nerve by detecting increased signals at sites of nerve entrapment and trauma. It can also show the process of peripheral nerve degeneration and regeneration, the first imaging modality to do so. The introduction of multislice imaging, 3-mm resolution, and 3-D resolution has revolutionized the field and made whole-body imaging one of the most exciting developments in imaging for the diagnosis of metastatic and recurrent cancer. For recurrent cancer of the head and neck, a notoriously difficult area to image using current technology, Positron Emission Tomography (PET) has shown an accuracy of greater than 95 percent in detecting recurrent disease. Whole-body PET scanning will be faster, less expensive, more widely available, and the most accurate and rapid means of detecting cancer that has spread beyond the primary site or has recurred. The movement toward minimally invasive surgery has promoted the proliferation of ambulatory surgicenters. The consequent major reduction in the volume of surgical procedures performed in hospital facilities has achieved a remarkable reduction in the length of stay, hence, lowered cost of care. Beauty culture and beauty surgery will boom, the new opportunities of gentechonology will become accessible.

Training systems for minimally invasive surgery help surgeons learn how to perform minimally invasive surgery quickly and safely. In these surgery techniques, the surgeon uses miniature instruments such as endoscopes, therefore avoiding large surgical openings in the patient's body. For the patient, this means less postoperative pain and quicker healing, for the surgeon it means additional difficulties. Endoscopic surgery requires especially precise motions. In this aspect, robots are superior to humans and have therefore found entrance into many hospitals. Robots can assist the physician in many ways during minimally invasive surgery.

Medicinal nanotechnology applications

Nanobiotechnological applications in the medical area belong to the most advanced and promising fields. Products in the area of drug delivery have already reached the market eg. liposomes, nanocrystals or PEGylated proteins. The use of nanoparticles could increase drug solubility, and could facilitate drug targeting to specific tissues and the destruction of damaged and diseased tissue. Nanostructured surfaces and coatings could improve the biocompatibility of implants. Other potential applications include nano-sized diagnostic devices that could be implanted as sensors for earlier diagnosis and

³⁴ Japanese Delphi Study, the UK Foresight Study, the German Delphi '98

detection of diseases. At present available biochip technology is still at the micrometer scale but nanoarrays and lab-on-chips are to be expected in the future.³⁵

Regenerative medicine

Regenerative medicine is judged to have a great future potential in the treatment of neurological diseases. Thus the practical application of cell therapies, including stem cells for Parkinson's disease, Multiple Sclerosis, Alzheimer, spinal cord injuries or also recovery after a stroke is expected in roughly ten to twenty years. In the case of Parkinson's, first clinical trials using cell therapy approaches are expected in about ten years.³⁶

Several foresight studies outline a clear trend towards regenerative medicine in the therapy of heart diseases. In this respect, four of the five foresight studies examined agree that very differing cell therapy methods (Allotransplantations, use of autogenic adult stem cells) will be deployed to treat diseased myocardial tissue, after a heart attack, for example. However, there is a relatively wide band of opinion on regard to the date of achievement: assessments range from 2010 to 2018.³⁷

A similar time perspective is given for neuro implants and artificial limbs. Here, expectations extend to the achievement of interfacing technical systems with brain function, for example an artificial inner ear, artificial retina or also thought controlled movement of individual muscle groups following a stroke or with paraplegia. In principle it is expected that the causes and mechanisms of important neurological diseases such as Alzheimer or Parkinson's can be understood so that appropriate therapies can be achieved. Nonetheless, the time span in which it is thought that this trend may be accomplished is subject to vastly differing estimates, varying from five to 20 years. It is thought possible that therapy for prion-induced diseases is possible in roughly ten years. The precise targeting of drugs at site of action is expected in a similar time period. The vision of developing new therapies against stroke where individual therapy concepts can be developed relative to gene type, lifestyle and environmental factors remains much more distant.

Artificial and bioartificial organs

A significant trend regarding this topic field is the movement towards artificial genesis of biological systems at all complexity levels: going from fully artificial organs for complete implant via bio-compatible artificial tissue right up to the growth of artificial cells. The development of artificial cochlea implants, artificial retina or intelligent artificial legs is expected in the majority of studies as early as in the next ten years. Other plans, such as the development of artificial breathing organs, or an artificial

³⁵ Communication from the Commission: Towards a European Strategy for nanotechnology. COM (2004) 338 final.

³⁶ Janese Delphi Study; NISTEP (2001). The Seventh Technology Foresight - Future Technology in Japan toward the Year 2030. NISTEP Report 71. Science and Technology Foresight Centre, National Institute of Science and Technology Policy (NISTEP), Ministry of Education, Culture, Sports, Science and Technology. <http://www.nistep.go.jp/achiev/ftx/eng/rep071e/idx071e.html>

³⁷ Reiß T.; Cuhls, K.; Hafner, S.; Zimmer, R. (2004), Metaanalyse aktueller Zukunftsstudien zu international beobachtbaren Trends und Themen im Bereich Gesundheit, Bericht an die Helmholtz-Gemeinschaft Deutscher Forschungszentren, Karlsruhe.

placenta, or indeed the growth of artificial muscle tissue, synthetic blood and the production of artificial cells will only be achieved in 15-20 years' time.³⁸

There will be increasing use of artificial organs that are integrated with human cells and tissue. Multifunction materials will make it possible for cells to draw nourishment from the body internally and protect the cells at the same time from immune system attacks. The achievement of such bioartificial organs will probably take another 15 years.³⁹

A further trend is the increasing link between IT and biological tissue. Thus, according to the predictions, in ten years' time, the connection of artificial organs to the nervous system and the brain will have been achieved. In 15 years, it is thought that biosensors will co-ordinate the activity of implanted artificial organs as well as making the computer-based control, independent of the nervous system, possible as well. However, the development of artificial intelligence from circuits and living cells remains in the distant future.⁴⁰

Tissue engineering

The cultivation of differentiated cells in the framework of tissue engineering is perceived to make huge advances. It is thought that in ten to 15 years' time it will be possible to use living dividing cells of a patient on artificially produced biomaterials to grow tissue specific spare parts. Here, the matrix systems are biologically "smart" and accordingly make a better biocompatibility and a targeted cell regulation possible. However tissue engineering will become a true alternative to present day transplantations or artificial organs in 20 years time at the earliest.⁴¹

Rational Drug Design

Rational drug design is the development of new chemical or molecular entities by looking at the physical structure and chemical composition of a target—a molecular receptor or enzyme—and designing drugs that bind to those molecules, turning them on or off. Drug designers use physical chemistry to identify qualities of the specific agent that initiates a pathology; once a known chain of events is identified, designers attempt to intervene at a particular point with a specific method.

Xenotransplantation

Xenotransplantation—the transplantation of cells, tissues, and whole organs from one species to another—resulted in immune rejection after brief periods of normal function in the new host. In contrast, allotransplantation—transplantation within species—of bone marrow and solid organs from related and unrelated human donors has become highly successful because of satisfactory, although less-than-ideal, means of avoiding immune rejection, principally by using immunosuppressive drugs and avoiding major histoincompatibilities to the extent possible.

The enormous medical and technical advances in organ transplants that assure the survival of many patients have led to an acute shortage of donor organs world-wide. On

³⁸ Swedish Technology Foresight; Teknisk Framsyn (2004) and NBIC 2002.

³⁹ British Foresight Programme.

⁴⁰ Japanese Delphi Study; NISTEP (2001).
<http://www.nistep.go.jp/achiev/ftx/eng/rep071e/idx071e.html>

⁴¹ Reiß T.; Cuhls, K.; Hafner, S.; Zimmer, R. (2004), Metaanalyse aktueller Zukunftsstudien zu international beobachtbaren Trends und Themen im Bereich Gesundheit, Bericht an die Helmholtz-Gemeinschaft Deutscher Forschungszentren, Karlsruhe.

the basis of this knowledge, therapeutic approaches to biologically substitute damaged tissue or even whole organs is possible. This kind of treatment strategy is conceivable for any disease due to the loss of organ function, for example diabetes, cardiac insufficiency, liver or kidney failure. The generation of entire organs such as hearts, livers or kidneys for replacement by biological engineering is feasible, thus allowing treatment strategies to be found for those diseases based on the failure of a small number of cell types.

Parallel Market Development

With about 8 per cent of European GDP the healthcare sector is one of the biggest macro-economic branches. The health economy is one of the „hidden Champions“ of the last 20 years, and further growth can be expected⁴² The ongoing health boom is accompanied by two powerful parallel developments which share the market and only appear to compete with each other:

- 1. The lifestyle medicine is driven by services.**

Pharmacies become wellness shops, clinics focus on patient-customizing. Food products and drinks show ever more health attributes. Tourism develops a complete new sub-branch on psycho-social health. In future, wellness in the workplace will play a key role regarding the competence of firms and their competitive strength.

- 2. Healthcare will become more personalised and tailored to the individual.**

Diagnostics will become more predictive; Therapeutic interventions will become more preventive; and we are trending away from a drug development model based on a “one-size-fits-all blockbuster drug” paradigm towards “individualised biologics”, which involves developing drugs for niche sectors (such as tailored treatments for particular genotypes associated with a specific disease).⁴³

⁴² Josef Hilbert, Institut Arbeit und Technik, Gelsenkirchen, Germany. <http://iat-info.iatge.de>

⁴³ Futurewatch - Biotechnologies to 2025, Report to the New Zealand Government Agencies by the Ministry of Research, Science and Technology, January 2005. Part 2: Health and wellbeing. <http://www.morst.govt.nz/uploadedfiles/biotechnology/futurewatchbookfull.pdf>.

4. EU activities: current policy and legal base

Focus of EC efforts regarding public health and healthcare
<ul style="list-style-type: none"> • minimise the wide health inequalities within and between countries and reduce the disease burden. Issues that need to be addressed include tobacco (smoking is behind 90% of lung cancers), rising obesity, alcohol-related harm and HIV/AIDS.
<ul style="list-style-type: none"> • provide better protection, at lower cost, against major threats to public health, for example from influenza or other pandemics and bio terrorism, through the creation and maintenance of a network of rapid response capabilities, and a new legal provision for use of EU Solidarity Fund resources in emergencies.
<ul style="list-style-type: none"> • develop joint strategies to give a high profile to the potential health impact of other Community policies by strengthening links and developing joint approaches in areas such as the internal market, social policy or the environment.
<ul style="list-style-type: none"> • better Member State cooperation to improve the effectiveness and the efficiency of European healthcare systems by enabling proper assessment and use of emerging health technologies, the sharing of expertise, clinical excellence and specialised equipment, to provide a solid evidence base for healthcare management across Europe and promote effective investment in health infrastructure.
<ul style="list-style-type: none"> • EU-wide collation and analysis of health data to provide objective, comparable, and timely information on which to base more effective health policies, strategies and actions at Member State and EU levels and to provide citizens and health professionals with the information they seek.

Public Health

Public health is central to EU competitiveness. The EU spends 8% of GDP on health, yet loses over €100 billion through lung diseases, €135 billion to cardiovascular disease, 3% of GDP and 500 million lost work days in work related health problems and accidents.

Each health euro better spent could make a net saving both for individual well-being and for EU economic competitiveness. Public health activities have had a strong focus on networking and developing models of best practices, with legislation focussing on specific areas of Community competence, and complemented by joint strategies and initiatives with other policy areas.

Preventing the transmission of emerging pathogens and the resurgence of others, as well as enhancing the rapid and co-ordinated response capability to these threats, is a responsibility shared among national health authorities and the European Commission.

The emergence of HIV and AIDS, the re-emergence of tuberculosis, the appearance of variant Creutzfeldt Jacob Disease serve to illustrate the diversity of the threats to health, and the range of factors influencing their spread, that are posed by micro-organisms,

such as bacteria and viruses. Epidemiological surveillance of these and other communicable diseases can bring about interventions that contribute to the reduction of morbidity and/or mortality. The introduction of strict quality and safety criteria for the handling of substances of human origin is another important public health measure.

Moreover, countering health threats from physical, chemical or biological sources, including those relating to terrorist acts, as well as from environmental agents, such as ionising and non-ionising radiation and noise, can benefit from the development and use of Community approaches and mechanisms, including vaccination and immunisation strategies.⁴⁴

The Current Policy

The current EU health policy is based on the Commission Communication 45 on a European Health strategy and on the Public Health programme. This Communication called for concentrating resources where the Community can provide real added value, without duplicating work which can be better done by the Member States or international organisations.

General health policy lines were set out in the concept of a Europe of Health in 2002. Work was undertaken on addressing health threats, including the creation of a European Centre for Disease Prevention and Control (ECDC), developing cross-border co-operation between health systems and tackling health determinants. The Community's health information system provides a key mechanism underpinning the development of health policy.

The EU Health Forum, which brings together organisations active in health to advise the European Commission on health policy, is also a key element of the EU Health policy. The Forum enables the health community to participate in health policy making from the start. EU health policy increasingly involves co-operation with and between the Member States, in particular on cross-border issues such as patient mobility. The programme, which shall complement national policies, shall aim to protect human health and improve public health.

On 23 September 2002, the European Parliament and the Council adopted a new Community action programme for public health. This programme runs for a 6 year period (from 1 January 2003 to 31 December 2008).⁴⁶

The programme is based on three general objectives:

- health information,
- rapid reaction to health threats, and
- health promotion through addressing health determinants.

Activities such as networks, co-ordinated responses, sharing of experience, training and dissemination of information and knowledge will be inter-linked and mutually reinforcing. The aim is to embody an integrated approach towards protecting and improving health.

⁴⁴ http://europa.eu.int/comm/health/ph_threats/threats_en.htm

⁴⁵ COM 2000 285 final of 16 May 2000

⁴⁶ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008)

As part of this integrated approach, particular attention is paid to the creation of links with other Community programmes and actions. Health impact assessment of proposals under other Community policies and activities, such as research, internal market, agriculture or environment will be used as a tool to ensure the consistency of the Community health strategy.

Achieving the overall aim and the general objectives of the Programme requires effective co-operation of the Member States and dialogue with all key partners such as non-governmental organisations. Institutions, associations, organisations and bodies in the health field are encouraged to submit projects for implementing specific priorities, defined on an annual basis by the Commission. In this task, the Commission is assisted by a Committee composed of national representatives of each Member State. The programme also builds on experience acquired in the international context, in particular co-operation with international organisations such as WHO and the Council of Europe. The programme is open for the participation of the Candidate Countries.

The Community's public health programme related to 'Threats to health' endeavours to address these issues. It specifically aims to further the development of a variety of communicable disease surveillance networks and early warning and rapid response systems (Decision 2119/98/EC), address the problems of antimicrobial resistance and bioterrorism, and develop strategies for preventing and responding to communicable disease (e.g. influenza preparedness and protection against intentional epidemics) and non-communicable disease threats. It also addresses issues related to the quality and safety of substances of human origin (e.g. blood, tissues and cells, and organs), as specifically referred to in Article 152 of the EC Treaty, in order to prevent the transmission of pathogens by these therapeutic materials.⁴⁷

Further, the Commission has brought together Health Ministers from across the Union with representatives of patients, professionals, providers and purchasers of healthcare and the European Parliament in a high level reflection process which agreed a wide-ranging report in December 2003.⁴⁸ The key result of the reflection process was the recognition of the value of European cooperation in helping Member States achieve their health objectives.

The EU Commission has set out a response to this report in a Communication issued in April 2004. In parallel, the Commission has adopted a separate communication on extending the "open method of coordination" to healthcare and long-term care.⁴⁹ This broad approach was approved by the Council in October 2004, and the first statements from the Member States on the challenges they face on these issues should be provided within 2005.⁵⁰

One of the key requirements for progress in this area was to establish a High Level Group on health services and medical care, which began work in July 2004. In its first

⁴⁷ http://europa.eu.int/comm/health/ph_threats/threats_en.htm.

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<http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/1678&format=HTML&aged=0&language=EN&guiLanguage=en>

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<http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/04/508&format=HTML&aged=0&language=EN&guiLanguage=en>

⁵⁰ http://europa.eu.int/comm/health/ph_overview/Documents/pr_20041025_en.pdf

report to the Council in December, it set out an ambitious agenda for work for 2005, structured around seven main areas⁵¹:

- Cross-border healthcare purchasing and provision⁵².
- Health professionals⁵³
- Centres of reference⁵⁴
- The establishment of a European health technology assessment network. ⁵⁵
- The use of new information and communication technologies
- Extending health impact assessment to cover health systems. ⁵⁶
- Patient safety. ⁵⁷

The Legal Base

The Public Health programme is based on Article 152 (4) of the Treaty establishing the European Community. The programme is an 'incentive measure designed to protect and improve human health', 'excluding any harmonisation of the laws and regulations of the Member States'.⁵⁸

⁵¹ Speech of Commissioner Markos Kyprianou, Member of the European Commission, responsible for Health and Consumer Protection, The European Voice conference "Healthcare: Is Europe getting better?". Brussels, 20 January 2005.

⁵² This covers issues such as looking in greater detail at the financial impact and sustainability of cross-border healthcare, and the availability of information to patients: on the quality, safety and continuity of their care, as well as on patients' rights and responsibilities, and data on the extent of cross-border healthcare.

⁵³ This concerns issues beyond the formal legal framework for the recognition of professional qualifications. Rather, the Group is working on wider issues, such as how to ensure continuing professional development to ensure the provision of high quality service.

⁵⁴ Certain principles have been developed regarding what European centres of reference could be. These cover elements such as the role of such centres in tackling rare diseases or other conditions requiring specialised care.

⁵⁵ Such a network should address methods for developing common information packages, ensuring that assessments can be transferred and used between different health systems, and sharing methodologies and expertise.

⁵⁶ The European Union's impact on health takes place largely through policies other than those specifically related to public health. Other policies will have to take account of their impacts on health in general.

⁵⁷ Health care interventions, although intended to benefit patients, may in some cases cause harm. By pooling expertise within Europe and working with the WHO, best practice could be spread throughout all Member States and minimise a serious problem for health.

⁵⁸ The Constitutional Treaty includes political reinforcement of the importance of health. It includes promoting "the well-being of its peoples" as one of the three fundamental aims of the Union. The treaty also includes rights to health care and The two strands to the future agenda for EU healthcare priorities are hence: cooperation at European level to help health systems work together, and support to reform and investment by Member States themselves to adapt to current and future challenges. Article 152 of the Amsterdam Treaty stipulates that: "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care." Because of this legal constraint, there have been no EU initiatives to date to develop specific legislation concerning health systems delivery in the Community. According to the Amsterdam Treaty however, the organisation of health services and medical care remain the responsibility of Member States, with the community having a role to play in ensuring that the wider European

It constitutes one of the Community actions foreseen by Article 152 in the field of public health, together with the promotion of co-operation and co-ordination between Member States and other legislative measures: setting up of high standards of quality and safety of tissues and blood, measures in the veterinary and phytosanitary fields which have as direct objectives the protection of public health or Council recommendations. All these actions shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The financial envelope of the public health programme for the period 2003- 2008 is € 312 million.⁵⁹ According to the annual work plan the budget available for 2004 is € 61,3 million. This amount is divided into the 'operational budget' of €53,7 million, which will be used by awarding grants for projects and by issuing calls for tender, and resources for technical and administrative assistance and support expenditure of €7,6 million.

Consumer Protection and Patient empowerment

Confident, empowered consumers can be a motor for European competitiveness as they seek out the best deals regardless of borders, rewarding the EU's best and most innovative businesses. Consumer spending is a key driver for growth and economic integration in the EU: purchases made by individual consumers account for 60% of turnover in the Union's internal market.

Ensuring consumer protection in national law is of little value to ordinary consumers unless the rules are properly enforced. Creating and maintaining consumer confidence requires consistent respect for, and enforcement of, consumer rights across all Member States. It means ensuring all national authorities play their part in watching out for dangerous products and services in the EU's Internal Market – and that when dangerous goods are found they are taken off the market quickly and efficiently. It also means proper cooperation between Member States in stamping out cross-border scams, where a fraudulent trader in one Member State targets consumers in another

Better datasharing between Member States' enforcement authorities and between consumer organisations around the EU could help to achieve these objectives. In order to take forward this agenda of consumer confidence and empowerment, there is a need for:

environment is supportive of optimal health promotion and health protection. Hence, all European level initiatives are currently expressed in non-binding terms. The same article gives the European Community a mandate which none of the health authorities of the member states have: "A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health ... by promoting ...health information and education".

⁵⁹ Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities, OJ No L 248, 16.09.2002.

Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities, OJ No L 357, 31.12.2002.

- Sustained capacity-building among consumer organisations to help to bridge the gap between Member States that enjoy effective consumer protection activism and those that do not.
- Empowerment of the individual consumers, especially the young, through education projects based on existing education networks and through targeted information campaigns.
- Consumer safety in Europe to be enhanced by better cooperation between Member States' authorities, and between EU and interested supplier countries.
- EU-wide collation and analysis of data on consumer issues to guide consumer policy priorities and raise the quality of EU decision-making.
- Reviewing consumer laws to the extent necessary to make them more consistent so that consumers are faced with a more predictable legal environment.

The Current Policy

The aim of promoting the interests, health and safety of consumers in the EU is enshrined in articles 153 and 95 of the Treaty establishing the European Community.

On 7 May 2002, the European Commission adopted a new Consumer Policy Strategy specifying its overall political approach for the five year period, 2002-2006.⁶⁰

It has three key objectives:

- A high common level of consumer protection

This means harmonising, by the most appropriate means (e.g. framework directive, standards, best practices), not just the safety of goods and services, but also those economic and legal interests that will enable consumers to shop with confidence anywhere in the EU and by whatever means. The main initiatives envisaged are addressed in the Green Paper on EU Consumer Protection and on the safety of services.

- Effective enforcement of consumer protection rules

There is no good law if it is not properly enforced. In practice, consumers should be given the same protection throughout the EU, and also in an enlarged EU. The priority actions are the development of an administrative co-operation framework between Member States and of redress mechanisms for consumers.

- Proper involvement of consumer organisations in EU policies

For consumer protection policies to be effective, consumers themselves must have an opportunity to contribute to the development of policies that affect them. Consumers and their representatives should have the capacity and resources to promote their interests on a similar footing as other stakeholders.

The main actions consist of a review of mechanisms for consumer organisations to participate actively in EU policy making and to the setting up of education and capacity-building projects. These three objectives are designed to help achieve integration of consumer concerns into all other EU policies, and to maximise the benefits of the single market for consumers.

The Legal Base

⁶⁰ http://europa.eu.int/comm/consumers/overview/cons_policy/index_en.htm

Decision No 20/2004/EC of the European Parliament and of the Council of 8 December 2003 establishes a general framework for financing Community actions in support of consumer policy for the years 2004 to 2007.

The objectives and actions in the consumer policy strategy should steer the allocation of funds for actions implemented under this framework. In addition, activities intended to integrate consumer interests into other areas of activity in accordance with Article 153 of the Treaty should be given high priority together with the three key objectives of the consumer policy strategy.

The financial framework for the implementation of this Decision for the period from 1 January 2004 to 31 December 2007 is set at €72 million, of which €54 million shall cover the period until 31 December 2006.⁶¹

The Food Chain and Food safety

Food production, food retailing and international trade in food together make the EU the world's biggest food importer – and one of the biggest food exporters. Our regulations affect trading partners worldwide and often lead regulators elsewhere.

DG SANCO policies loom large in the World Trade Organisation (WTO) and in the bilateral trade relations with many countries. Food issues are high on the EU's domestic agenda. Europe's citizens expect their food to be safe, and safety concerns carry a high political and financial cost. Following the crises of the late 1990s – in particular bovine spongiform encephalopathy (BSE) and dioxin in chicken – the EU has put in place a comprehensive reform of our food safety legislation.

The need to safeguard the EU against animal diseases remains a priority. Plant diseases, often overlooked at EU level, also require careful attention. The challenge for the coming years will be to make this new legislation work. This means major reforms for national food safety systems and food chain operators (including smaller bakers, restaurants, etc).

The central goal of the European Commission's food safety policy is to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products, whilst ensuring the effective functioning of the internal market.

The Commission's guiding principle, primarily set out in its White Paper on Food Safety of January 12, 2000⁶², is to apply an integrated approach from farm to table covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.

The White Paper on Food Safety sets out the plans for a proactive new food policy: modernising legislation into a coherent and transparent set of rules, reinforcing controls from the farm to the table and increasing the capability of the scientific advice system, so as to guarantee a high level of human health and consumer protection. The main types of intervention classified within this category would be as follows:

General food law, animal nutrition, labelling and nutrition, biotechnology, novel food, biological safety, chemical safety, surveillance networks, community reference laboratories, official controls, trade and certification requirements, including bilateral veterinary agreements with some third countries.

⁶¹ http://europa.eu.int/comm/consumers/overview/cons_policy/index_en.htm

⁶² europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf

The Current Policy

The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. The implementation of this approach involves the development of legislative and other actions:

To assure effective control systems and evaluate compliance with EU standards in the food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU;
 To manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health;
 To manage relations with the European Food Safety Authority (EFSA) and ensure science-based risk management. 63

Plant and Animal health and welfare

The European Commission's activities in this area start with the recognition that animals are sentient beings. The general aim is to ensure that animals need not endure avoidable pain or suffering and obliges the owner/keeper of animals to respect minimum welfare requirements: on the farm and in particular laying hens, calves and pigs, during transport and at slaughtering.

The EU supervises the sale and use of plant protection products, or pesticides and sets standards to monitor and control pesticide residues. It implements preventative measures to guard against the introduction and spread of organisms harmful to plants or plant products within the EU.

It also ensures quality conditions for the sale of seeds and propagating material within the EU.

The Current Policy

The objective of EU animal legislation is to protect and raise the health status and condition of animals in the Community, in particular food-producing animals, whilst permitting intra-Community trade and imports of animals and animal products in accordance with the appropriate health standards and international obligations.

The main Community legislations focussed on control measures, to be taken as soon as the presence of a disease is suspected, eradication and monitoring programmes, for the diseases that are already within the Community.

The main types of intervention classified within this category are: eradication programmes, safeguard clauses, import measures, veterinary fund, community reference laboratories, trade and certification requirements, including bilateral veterinary agreements with some third countries. 64

The main objective of EU plant health legislation is to protect the safety of food derived from plants and to secure the health and quality status of crops in all Member States. It also regulates the trade of plants and plant products within the EU as well as imports from the rest of the world in accordance with international plant health standards and obligations

⁶³ http://europa.eu.int/comm/food/index_en.htm

⁶⁴ http://europa.eu.int/comm/food/animal/index_en.htm

EU legislation also covers the intellectual property rights granted to plant varieties, as well as the conservation and use of genetic resources.

The main types of intervention classified within this category would be as follows: harmful organisms, property rights, genetic resources, seeds and propagation, genetically modified plant and seeds, solidarity and liability programmes, safeguard clauses, trade and certification requirements, including bilateral veterinary agreements with some third countries.

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⁶⁵ http://europa.eu.int/comm/food/plant/index_en.htm

5. Analysis of European Strengths, Weaknesses, Opportunities, and Threats

An analysis of European strengths, weaknesses, opportunities, and threats (SWOT) suggest that the European strengths concern, for instance, the general open mindedness towards healthcare technologies among the older population segments and the huge and attractive Market for Healthcare Technologies in the future. From a supply perspective, Europe can capitalise on a well developed healthcare deliveries infrastructure. From a policy-oriented perspective, the EU-wide knowledge base has significantly been strengthened over the last decade through extensive public funding of RTD projects.

<p>Strengths</p> <ul style="list-style-type: none"> • Huge and attractive Market for Healthcare Technologies • General open mindedness towards healthcare technologies among the older population segments. • Well developed healthcare deliveries infrastructure • The EU-wide knowledge base has significantly been strengthened over the last decade through extensive public funding of RTD projects. • There is a strong awareness of the potential advantages of using and comparing national measurements and policy approaches; • There is consent among almost all European Health Ministries that harmonization of systems is a high priority issue. • Significant RTD activity and accumulated skills and knowledge in care- and accessibility-related healthcare technologies • 	<p>Weaknesses</p> <ul style="list-style-type: none"> • Research findings have in many cases not been successfully transferred into marketable products and services and there is lack of co-ordination between EU policies and national policies. • Inadequate shape of national/regional/European healthcare systems and regulation. • Market potentials have not yet been adequately addressed by industry. • A lot of diversity still exists in the methods and approaches of the national R&D policy activities within the EU; • National R&D policy activities are not fully coordinated on a transnational or European scale (in some cases, even on a national scale) and data measurements are not compatible; • Coordinating data collection on an international scale is time consuming and difficult to organise; • Healthcare information is still very scattered and citizens sometimes lack guidance in their search; • The diversity of healthcare systems makes the set-up and exploitation of healthcare innovation in Europe more complex and thus expensive. • Insufficient education and training of healthcare professionals.
<p>Opportunities</p> <ul style="list-style-type: none"> • High ICT capacity needed to manage the increasing complexity of healthcare processes; • Novel healthcare solutions are applicable to many healthcare delivery processes at affordable prices; 	<p>Threats</p> <ul style="list-style-type: none"> • Enlargement of the European Union - structural, cultural and economic diversity and the risk of an increased gap between the haves and the have-nots; • The foreseen shortage of medical staff in the

<ul style="list-style-type: none"> • Communities of patients are becoming stronger, creating a self-help mentality; • Web technologies - intranets, extranets, and the Internet - will serve as a low-cost, rapidly deployable platform for disseminating information across vertically and horizontally integrated healthcare organizations; • The diversity of technology solutions already available presents a rich learning opportunity. • Improvement of European collaboration in order to support standardisation, assessment and market creation. • Appropriate technology assessment methodologies should be developed for the different health industry sub-segments and technologies. • Stimulate and support exploitation and technology transfer through national and corporate RTD programmes and innovation/enterprise support programmes • Three demographic trends which are driving technological advances in healthcare: <ul style="list-style-type: none"> • longer life expectancy (particularly in developed countries); • increasing proportion of older people in the population; and • o decreased fertility and delayed reproduction. 	<p>next 5-10 years;</p> <ul style="list-style-type: none"> • Current S&T developments in healthcare are being held back by lack of confidence in the scope and stability of the national health systems on the part of some specialist healthcare suppliers; • Current risk averse and adversarial procurement procedures are also hampering innovative solutions for healthcare; • Maintenance and updating of information services has many hidden costs; • The question of data protection and certification is not fully addressed. • Potential Japanese and US dominance in the medical technologies market; • Asian dominance in R&D on biotechnology
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The current dominant application clusters with technology development as an enabling or driving issue are found in information and communication technologies, nanotechnologies, materials technologies, genetics and biotechnologies and energy technologies. An increasing convergence of nano-technology biotechnology, information technology and cognition science is expected, with , again, huge application opportunities in the health sector, for instance, in neuroscience or cardiovascular and metabolism illnesses. 66

The technological strength and options will be most promising in the diagnosis area, where technological innovations for minimal invasive surgery and telecare will be noticeable. The developments in minimal invasive surgery and telecare are expected to contribute also to a strong improvement of treatment. Innovation in Information and Communication Technologies will further improve telecare particularly for the health monitoring. Particularly the advances of telecare and to a certain extent from minimal invasive surgery are important for the health aftercare and rehabilitation.

⁶⁶ Swedish Technology Foresight; Teknisk Framsyn (2004) and NBIC 2002.

Options and challenges for broad and equal diffusion of healthcare technologies

Bio- and Gentechnologies:

It is important to secure the right of citizens who prefer „not to know“. It is anticipated that the increasing number of genetic tests will result in an increased need for counselling.

Offering these tests outside the authorised or established medical laboratories or clinics might in some cases fail to attend the proper counselling as a prerequisite for testing.

Other concerns relate to the risk of those who have - either through screening or diagnosis - been identified as carrying genetic disorders, which may - or may not - result in illness in later life. This might cause “discrimination fears” and social “genetic determinism”.

Telecare and telemedicine

Accessibility. This takes two forms: patient accessibility (ease of use) and service accessibility (access to the underlying technology infrastructure and skills). It will be important not to either reinforce existing social divisions in access to healthcare or to create new divisions.

Acceptance of technology. This comprises both professional acceptance of technology and of new relationships and work practices, and secondly public acceptance of technology in new care settings.

A lack of standards. There is a need to develop standards relating to interoperability and compatibility of technical systems, and standardisation of operational systems.

Data protection. Concerns over unauthorised data mining and protection of personal data confidentiality may require new definitions of patient consent to be developed.

Ethical issues. These include the need for ‘informed consent’, i.e. patient involvement in decisions over their own treatment, potential invasion of privacy through automatic monitoring of lifestyles, danger of removing choice and control from the user, and substituting technology for more personal forms of care and support.

Poor understanding of the social context into which technology is placed may lead to inappropriate investment in health technologies and the reinforcement of unsuitable care models.

New skills: There may be a need to support the emergence of a new type of care professional, who has an understanding of both technology and the context in which it can be provided.

Medical Technologies and minimally invasive systems (MIS)

Budgetary pressures on hospitals, which make them reluctant to undertake new, capital-intensive procedures or procedures that require extra time or personnel/Financial incentives on hospitals, which make shorter stays disadvantageous.

The absence of reimbursement of a new procedure, or a tedious procedure of reimbursement. The fact that MIS procedures are often more time-consuming than the traditional procedure, at least until the ‘learning curve’ time is over.

Payment to physicians no higher than for the standard procedure, giving a disincentive if the new procedure is more time-consuming.

Lack of convincing evidence on (cost)effectiveness.

Difficulties in organizing studies demonstrating effectiveness, including logistical problems, lack of funds, lack of interest in the profession, resistance of patients to entering clinical trials, and regulatory requirements (especially) to assure that the study is ethical.

Lack of MIS procedures in present medical education, and a lack of training courses to bring skills to acceptable levels.

Physician, especially surgeon conservatism (that is, comfort with traditional procedures used in open surgery).

Competition between different specialties in several areas.

Resistance to commercial pressures.

Rapidly evolving new procedures

Policy measures, aimed to restrict the annual number of procedures or the total number of devices.

However, a lot of general conditions limit the diffusion of healthcare technologies. Some of these conditions are within the health care system and others are outside (for instance the availability of skilled labour and its price).

Concerning the European weaknesses, market potentials have not yet been adequately addressed by industry. This concerns for instance cultural and language barriers but also the diversity of care and social systems currently in place. As regards publicly funded RTD projects that have targeted older and disabled people as a specific user group, research findings have in many cases not been successfully transferred into marketable products and services and there is lack of co-ordination between EU policies and national policies.

Among the challenges (options and threats) for the next decade, is a better co-ordination of all EU Commission services involved in activities to which healthcare relates, notably DG AGRO, RTD, SANCO, ENTR, COMP, EMPL and others, in order to making Europe attractive to the best researchers and innovators. A major issue will be further promotion of European collaboration in order to support standardisation, assessment and market creation.

Patients, users and industry should be an integral part in designing and implementing future health policies. Appropriate technology assessment methodologies should be developed for the different health industry sub-segments and technologies. Alternative ways of financing healthcare should be considered, as well as the need to break away from traditional structures in healthcare provision and related budgets. The need for high quality health information to patients should be addressed

6. Forward Look: Healthcare Technologies Roadmap

The last decade has seen a propagation of Foresight exercises across Europe, which seem to constitute a new area in which policy and investment decisions are discussed and in which "futures" are contested. The health-statements and visions made in national foresight exercises are here summarised into a "roadmap", in order to portray the larger context for healthcare developments of the future and to exploit how health acquires its identity and legitimisation in foresight exercises.

Foresight is understood in the European Commission as a tool for policy design and policy shaping with the major strategic function of priority setting in European Union policy making. Results from existing foresight exercises can help to gain a better understanding of the expectable evolution of the demand side of healthcare during the next two decades, and see whether foresight exercises can serve to quantify and qualify the future potential of healthcare technologies in the context of an ageing society in an enlarged European Union.

In the light of the strategic function foresight has gained in the European Commission⁶⁷, the following healthcare technologies roadmap aims at displaying the results from existing foresight initiatives⁶⁸ and foresight meta-analyses ⁶⁹ in order to

⁶⁷ The foresight unit in the European Commission (www.cordis.lu/rtd2002/foresight/home.html) has recently established a European platform for cooperation in foresight. www.efmn.net.

⁶⁸ National and international (technology) foresight exercises, such as:

- Japanese Delphi Study; NISTEP (2001). The Seventh Technology Foresight - Future Technology in Japan toward the Year 2030. NISTEP Report 71. Science and Technology Foresight Centre, National Institute of Science and Technology Policy (NISTEP), Ministry of Education, Culture, Sports, Science and Technology. <http://www.nistep.go.jp/achiev/ftx/eng/rep071e/idx071e.html>.

- Swedish Technology Foresight; Teknisk Framsyn (2004): Choosing Strategies for Sweden. A synthesis report from the Swedish Technology Foresight. Uppsala. URL: <http://www.tekniskframsyn.nu>

- British Foresight Programme; Office of Science and Technology (Hrsg.) (2000): Foresight. Making the future work for you. Department of Trade and Industry. URL: www.foresight.gov.uk

- Delphi '98; Cuhls, K.; Blind, K.; Grupp, H. (Hrsg.) (1998): Delphi '98 – Studie zur globalen Entwicklung von Wissenschaft und Technik, Karlsruhe. URL: <http://www.isi.fhg.de/ti/Projektbeschreibungen/Cu-delphi.html>

- Danish Technology Foresight; Ministeriet for Videnskab, Teknologi og Udvikling (2003): Åbenhed. Teknologisk frem-syn om bio- og sundhedsteknologi. Copenhagen. URL: <http://www.teknologiskfrem-syn.dk/406.html>

- Futur; BMBF (2003): Eine erste Bilanz. Futur: Der Deutsche Forschungsdialog. Bonn. URL: www.futur.de

- RAND: Anto, P.S.; Silbergliitt, R.; Schneider, J. (2001): The Global Technology Revolution – Bio/Nano/Materials Trends and Their Synergies with Information Technology by 2015. Santa Monica, Arlington. URL: www.rand.org

- NBIC: Roco, M., C.; Bainbridge, W., S. (eds.) (2002): Converging Technologies for Improving Human Performance. NSF/DOC-sponsored report. Arlington. URL: http://www.wtec.org/ConvergingTechnologies/Report/NBIC_report.pdf

quantify and qualify the future potential of healthcare technologies in the European Union and to gain a better understanding of the expectable evolution of health during the next two decades.

- New Zealand Futurewatch - Biotechnologies to 2025, Report to the New Zealand Government Agencies by the Ministry of Research, Science and Technology, January 2005. Part 2: Health and wellbeing. <http://www.morst.govt.nz/uploadedfiles/biotechnology/futurewatchbookfull.pdf>.

⁶⁹ Metaanalyses such as:

- Reiß T.; Cuhls, K.; Hafner, S.; Zimmer, R. (2004), Metaanalyse aktueller Zukunftsstudien zu international beobachtbaren Trends und Themen im Bereich Gesundheit, Bericht an die Helmholtz-Gemeinschaft Deutscher Forschungszentren, Karlsruhe.
- Seiler, P., Holtmannspötter, D., Albertshauer, U. (2004), Internationale Technologieprognosen im Vergleich, Übersichtsstudie (Band 52), Hrsg.: VDI Technologiezentrum GmbH.
- Braun, A. (2004): Roadmap für die e-Health-Entwicklungen der Zukunft, The IPTS Report - Issue 81 - February 2004, <http://www.jrc.es/home/report/english/articles/vol81/EDI1E816.htm>
- Braun, A. et al (2003): Healthcare Technologies Roadmapping, <http://esto.jrc.es/docs/HealthcareTechnologiesRoadmapping.pdf>.
- Braun, A.; Constantelou, A.; Karounou V.; Ligtvoet A.; Jean-Claude Burgelman, JC ; Cabrera, M. (2003), Prospecting ehealth in the context of a European Ageing Society: Quantifying and qualifying needs. IPTS/ESTO Report, Seville.

Healthcare Technologies Roadmap⁷⁰

Roadmap for trends in the field of the nervous system

Neurological diseases

2005	2010	2015	2020+
Morbus Parkinson's and other basal ganglion illnesses are understood so that therapy eliminates all symptoms (shaking, balance and orientation problems) - German Delphi '98			
Accurate dosage of drugs at targets in brain - Japanese Delphi Study			
Individualised therapy combating stroke - British Foresight Programme			
Tissue engineering to produce nerve tissue - British Foresight Programme			
Neuroimplants and artificial limbs; linking of technical systems with brain function; artificial inner ear, retina, thought control of individual muscle groups (after stroke, paraplegia) - German Futur			
Alzheimer understood and treatable - Japanese and German Delphi			
	Therapy of prion-induced diseases is possible - Japanese and German Delphi		
	Everyday use of cell therapies, including stem cells for Parkinson's Multiple Sclerosis, Alzheimer, regeneration after stroke, spinal		

⁷⁰ summary of expert estimations in foresight exercises, based on

- Braun, A.; Barlow, J.; Borch, K. et al. (2003). Healthcare Technologies Roadmapping: the Effective Delivery of Healthcare in the Context of an Ageing Society (HCTRM). Seville: IPTS- Institute for Prospective Technological Studies. <http://esto.jrc.es/docs/HealthcareTechnologiesRoadmapping.pdf>.

- Braun, A.; Constantelou, A.; Karounou V.; Ligtoet A. ; Jean-Claude Burgelman, JC; Cabrera, M. (2003), Prospecting ehealth in the context of a European Ageing Society: Quantifying and qualifying needs. IPTS/ESTO Report, Seville.

- Braun, A. (2004): Roadmap für die e-Health-Entwicklungen der Zukunft, The IPTS Report - Issue 81 - February 2004, <http://www.jrc.es/home/report/english/articles/vol81/EDI1E816.htm>

- Seiler, P., Holtmannspötter, D., Albertshauer, U. (2004), Internationale Technologieprognosen im Vergleich, Übersichtsstudie (Band 52), Hrsg.: VDI Technologiezentrum GmbH.

- Reiß T.; Cuhls, K.; Hafner, S.; Zimmer, R. (2004), Metaanalyse aktueller Zukunftsstudien zu international beobachtbaren Trends und Themen im Bereich Gesundheit, Bericht an die Helmholtz-Gemeinschaft Deutscher Forschungszentren, Karlsruhe.

cord injuries, clinical trials (Parkinson's) - Japanese Delphi Study, British Foresight Programme

Roadmap for Trends in the field of the nervous system, continued

Mental disease

2005	2010	2015	2020+
Functional surgery (selective division of functional channels) in brain deployed with certain illnesses (for example, Angst, depression) Therapy combating depression or brain injury by magnetic stimulation of selected brain sectors - British Foresight Programme			
	pathogenesis of mental diseases (such as schizophrenia or manic-depressive psychosis) can be solved at molecular level; availability of therapy for total convalescence based on these insights; deployment of new Drug-Delivery-Systems - British Foresight Programme, Japanese and German Delphi		

Brain function

2005	2010	2015	2020+
Development of brain-support-systems making human decision-making processes, abilities, knowledge, experience available for others to use or for learning processes ("uploading") - NBIC, Japanese Delphi Study.			
Neuromorphic engineering Use of architecture and design principles drawn from the nervous system to develop biomimetic autonomous robotic systems; important principles here: analysis and interpretation of high dimension sensor data in complex natural scenarios, asynchronous dynamics, fault tolerance, insensitivity to unclear input signals, distributed representation, associative data			

processing pulse-coding versus analogue integration, adaptation. -RAND, German Futur.		
Electronic inner ear implants eliminate deafness - RAND		
Non-invasive "neuroimaging processes (similar to CT) with resolution of 1 mm to combat stimulus conditions in brain. - Japanese Delphi Study		
Understanding of reciprocal regulation mechanisms of the immune system, nervous system and endocrine system and the therapeutic use of these insights - German Delphi		
	New personal sensors extend human sensory areas improving sensory and communication abilities. Here principles of sensor transformation (e.g. the conversion from a visual perception to an odour perception) will be used to transmit data about social and physical surroundings. - RAND	
		Use of neuro-imaging processes in the visualisation of various brain processes at cellular level (e.g. visualisation of thoughts) and in the administration of drug therapies (targeting) - Japanese Delphi Study, British Foresight Programme.
		artificial retina and artificial eyes as electronic implant restore sight, using direct electric link to nerve and brain cells - Japanese Delphi Study, RAND, British Foresight Programme.
	"Human Cognition Project" analogous to the "Human Genome Project": multidisciplinary co-operation research structure, means of function and potential increases in performance of the human brain. Complete mapping of links in the brain; analysis of the nature of culture and personality; uploading human personality to computers and robots. - NBIC.	
	Understanding of complex brain functions; memory, learning, feelings, logical thinking, language, sleep, dreaming, etc. and the use of these insights too for "neuromorphic engineering" - Japanese and German Delphi, RAND, German Futur.	
		Development of computers with new logical architecture simulating brain function; data encoding according to biological principles Biocomputers using networks of cultured neurons Artificial neural networks with learning ability drawing from linking principles of the cerebral nervous system. - Japanese Delphi Study, German Futur.
		Use of human(brain)/computer interfaces, also for artificial sense organs - Japanese and German Delphi
		Understanding of molecular mechanisms for the creation of neuronal networks - Japanese and German Delphi - German Futur.

Roadmap for trends in the field of transplantation

2005	2010	2015	2020+
With xenotransplantations, time periods up to a year can be survived until suitable donor organ becomes available - German Delphi			
Early diagnosis of defence mechanisms with organ and tissue transplants in everyday use - Japanese and German Delphi			
Mechanism of tolerance reaction completely understood so that transplatation of internal organs is completely under control - Japanese and German Delphi			
		Long-term conservation and cultivation techniques for organs used so that organs can be made available trouble-free world-wide. - Japanese and German Delphi	
		Xenogenic transplantation therapies using internal organs of transgenic animals are widespread - Swedish Technology Foresight, RAND	

Roadmap for trends in the area of artificial and bioartificial organs

2005	2010	2015	2020+
Connection of artificial organs to nervous system and brain (artificial cochlea, retina, thought controlled movement of muscle groups), Danish Technology Foresight, RAND, German Futur			
Auto-adaptive intelligent artificial legs are widespread - Japanese Delphi Study,			
Development of artificial breathing organs which can be completely implanted - Japanese Delphi Study,			
In-vitro development of mammal embryos possible in artificial placenta - Japanese Delphi Study,			
		Implanted biosensors monitor function of implanted artificial organs or co-ordinate muscle movements - Japanese Delphi Study, British Foresight Programme	
		Artificial tissue from biocompatible multifunction materials replace damaged tissue - British Foresight Programme - Swedish Technology Foresight, Japanese and German Delphi	
		Permanent implantable organs integrated in human cells and tissue are in practical use - Japanese and German Delphi	
Artificial organs are developed with functions that outperform biological organs and tissue - Japanese Delphi Study,			
Development of artificial intelligence by fusion of IT and living cells,			
Direct computer based monitoring and co-ordination of artificial body members independent of nervous system - Japanese Delphi Study			
			Development of artificial muscles - Swedish Technology Foresight, - Japanese and German Delphi
			Development of technology to produce artificial cells that assume cell functions such as cell membrane transport, ion and

			energy exchange - Japanese Delphi Study,
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Roadmap for trends in the field of comparative genome research

2005	2010	2015	2020+
Using extensive DNA and protein sequence databases and further developed software programmes it is possible to pathfind new protein functions. - Japanese and German Delphi			
Complete understanding of molecular mechanisms in the cell cycle of higher animals - Japanese Delphi Study,			
Knock-out make possible the analysis of the interdependency of certain genetic functions with the whole organism possible - RAND			
New therapeutic approaches made possible by the genetic modification of known receptors, ion channels, enzymes or other proteins in intra-cellular signal transmission. - German Delphi			
Establishment of methods decoding data to modify DNA (e.g. methylation) for the complete human genome - Japanese Delphi Study,			
Availability of quick and cheap sequencing for the analysis of the complete genome including single nucleotide polymorphisms; used for diagnosis and individualised therapy - Japanese Delphi Study,			
	Monogene diseases to be cured by genetic diagnostics and Gene Therapy; broad use of genetic diagnostics (predisposition to cancer, diabetes, cardiovascular diseases); consideration of ethical implications - Swedish and British Technology Foresight Programme		
		Understanding of transcription and signal transduction processes in embryo development, giving understanding of differentiation and function development in at least one model organism; corresponding understanding in humans - Japanese and German Delphi	

Roadmap for trends in the field of stem cells and tissue engineering

2005	2010	2015	2020+
Human embryo and adult stem cells can be isolated precisely and in desired quantity,- RAND, Japanese Delphi,			
Tissue and organ creation using tissue engineering is a biotechnological alternative to today's transplantations/ artificial organs, Swedish Technology Foresight			
Biologically smart matrix systems make better biocompatibility and cell regulation possible, British Foresight Programme, - RAND, British Foresight Programme			
			Regenerative healing methods for damaged organs using embryo stem cells widely in use and stem cells can be transplanted on all areas of tissue damage precisely, - Japanese Delphi, Swedish and Danish Technology Foresight

Roadmap for trends in the field of cardiovascular disease

2005	2010	2015	2020+
	Availability of multifunctional endoscopes (in miniature, high resolution, remote controlled by magnetic fields, with intelligent stent, plasma oxygen carriers and remote controlled release of anticoagulants or angiogenesis factors) - British Foresight Programme		
	Use of system biology (virtual heart simulation by Noble) as complementary approach for clinical tests, RAND		
	Wide deployment of non invasive methods for the diagnosis of phase and degree; Discovery of molecular genetic causes of arteriosclerosis, Gene Therapy in practical use - Japanese and German Delphi		
	Use of artificial blood and functional blood purifiers - Japanese and German Delphi		
	Deployment of various cell therapy methods (allogenic transplantation, autogenic adult stem cells) to treat diseased myocardial tissue, for example, after a heart attack - Japanese and German Delphi, British Foresight Programme		
		Production of functional heart tissue by tissue engineering, British Foresight Programme, RAND	
		Investigation of thrombosis and vascular pathology by means of 3-D-tomography: recording of flow, circulation, distribution of oxygen and endothelium function Implementation of remote controlled micro-instruments with thrombosis and embolism Implantation of bio materials for blood inspection	

		- Japanese and German Delphi, British Foresight Programme	
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Roadmap for trends in the field of metabolic diseases

2005	2010	2015	2020+
Non invasive methods for measuring blood sugar on the basis of sensors on the body surface in everyday use - Japanese Delphi			
Prevention measures (e.g. immune suppressives) for diseases based on glucose metabolism widespread German Delphi			
Availability of oral insulin - Japanese and German Delphi			
Establishment of new method of diagnosis for kidney diseases which supersedes renal biopsy - Japanese Delphi			
Kidneys (and most endocrine organs) are replaced by tissue engineering, xenotransplantations with kidneys transplanted from transgenic pigs in clinical tests - British Foresight Programme			
Medicinal treatment on viral liver diseases is widespread - - Japanese and German Delphi			
External artificial livers for permanent and continuous use - Japanese Delphi			
Gene Therapy for inherited high cholesterol levels widely used - Japanese Delphi			
Liver replacement with tissue engineering. Cellular therapy (allotransplatnation) for liver diseases - British Foresight Programme			
	Gene Therapy for diabetes developed Fully implantable artificial pancreas in everyday use - Japanese Delphi		
	Genes for diabetes, hypertension and arteriosclerosis identified and molecular		

	causes for the disease found - Japanese and German Delphi		
		Cell therapy with embryonic and adult stem cells is successfully deployed on diabetes mellitus - British Foresight Programme	

Roadmap for trends in the field of environmental health disorders

2005	2010	2015	2020+
Understanding of the influence of specific techniques deployed in food production and processing (e.g. genetic engineering, irradiation, microwave treatment) on human health - German Delphi			
Sensors for consumer user specific measurement of allergenic substances or those endangering health in foodstuffs.- - German Delphi			
Understanding between environmental pollution and allergies is expected makes possible clear reduction in the number of those suffering from allergy - Japanese Delphi,			
Avoidance of disease based on modulation of the interdependency of environmental factors with genetic risk factors - British Foresight Programme			
	New sensors make possible to determine the chemical formation of people's immediate surroundings, contributing to improvement in safety, productivity and health - NBIC		
		Development highly precise impact-assessment technologies for carcinogenic and endocrine water contamination in the slightest concentrations; understanding of the health effects from long term consequences of these substances; development of biomonitoring systems for environmental hormones - Japanese Delphi,	
		Understanding of environmental factors and regulation mechanisms of immune reactions in the case of various make complete control of these illnesses possible - Japanese Delphi, British Foresight	

Roadmap for trends in the field of cancer research

2005	2010	2015	2020+
With types of tumour where viruses play a role, the emergence of cancer can be prevented by vaccination German Delphi			
Early diagnosis of almost every form of cancer on the basis of blood tests is widely applied - Japanese Delphi,			
		Clarification of the emergence and pathogenesis of cancer: genetic factors, environmental factors, interaction of these factors, molecular mechanisms of apoptosis, mechanisms of metastases - Japanese and German Delphi,	
		Use of methods distinguishing cancer cells from normal cells for systematic medicinal treatment by means of missile drugs, which react to certain signals Development of radiosensitisers to fight cancer Widespread immunotherapy against cancer, development of drugs that do not inhibit blocking infection, thus precluding opportunistic infections Metastasis can be prevented effectively Widespread Gene Therapy against cancer By controlling signal transduction in cancer cells, re-differentiation of cancer cells in normal cells can be achieved Drug resistance in case of cancer can be overcome, bowel cancer with low drug responsiveness can be treated completely - Japanese Delphi,	
		Strategies to prevent cancer disease are widespread: Availability of drugs which protect against certain types of cancer, Risk estimation of the disease on the basis of genetic constitution by means of bioinformatics and use of this information for prevention schemes. - Japanese Delphi,	

Roadmap for trends in the field of infectious disease, immunology

2005	2010	2015	2020+
Analysis of further viral agents (polio, measles) makes vaccines superfluous- Japanese Delphi			
Understanding of molecular mechanisms of malaria attacks and development of treatment methods on this basis - Japanese Delphi,			
Medicines combating acute virus hepatitis widespread German Delphi			
Automatic identification of bacteria and quick (<1 hour) assessment of their antibiotic-sensitivity - Japanese Delphi,			
complete recovery from HIV-infection; availability of vaccines combating HIV, gene therapy combating sexually transmitted immune deficiency- Japanese and German Delphi,			
		Understanding of pathogenesises in autoimmune diseases (including molecular mechanisms in the mechanisms of adhesion molecules) and development of therapies and prevention measures to combat against autoimmune diseases - Japanese and German Delphi,	
		Therapeutic approaches eliminating viruses from the blood in everyday use - Japanese and German Delphi,	
		Everyday application of effective drugs combating polyresistant bacteria; development of new drugs will be available that cause no resistance- Japanese Delphi,	

		Quick early warning measures (e.g. on genetic basis) making swift identification of new pathogens possible based on global monitoring systems; development of vaccines Swedish Foresight
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7. Outlook: Options and Choices

It is assumed in general that greater emphasis on prevention and care will lead to encouraging the growth of a new service industry, the "health business". Technological development supporting this trend include various medical instruments, monitoring equipment, and large centralised data systems, which make cableless communication possible between homes, service companies and hospitals.

An important precondition for the further development of prevention strategies is the review, quality control, evaluation and the management of health data, hence the public **health monitoring** facilities. For this, new diagnosis and early recognition systems with low statistical distribution, data authentication in respect to patients, telemetric data entry as well as the development of an intelligent data evaluation for combined data from the fields of genetics, proteomics and metabolomics area all required.

Huge potential is expected for telemedicine, used for distance monitoring and diagnosis of body functions, which includes image and data transmission between ambulance and hospitals for emergency cases or also the further development of tele-operations systems. These trends are already being realised and will get stronger in future: freely programmable machines, which are to be deployed for care in homes and hospitals, the development of technology for old age and sick care at home, which can be adapted to suit diverse constraints in terms of space and environment, as well as the broad use of care robots.

The internet will make an international knowledge network for patients and care personnel possible. With better level of information for patients, the quality of medical care gets better too.

Healthcare crosses the boundaries between the provision of a public good, S&T and business, as well as invoking legal, organisational, political and economic issues. If this cross-disciplinary field is to progress at any level (local, regional or EU-wide), there should be close cooperation between the responsible administrative authorities, most notably DG SANCO, DG INFSO, DG RTD, DG AGRO and DG EMPL.

Strategic goals at all levels (local, regional, national and EU-wide) might be:

Legislative issues:	Current European laws should emphasize the confidentiality and protection of the patient data, while norms for ehealth system security are adopted: Set clear policies for healthcare Develop a consensus model which brings all stakeholders into the operational policy level Decompose strategic initiatives to a manageable level Define policy objectives for health applications, and create favourable framework conditions that foster health applications;
Infrastructure development:	Develop a better understanding of the drivers of innovation for the health services and applications Strengthen and integrate health services and applications; Build and strengthen a well-coordinated approach among national and regional authorities;
Human skills development:	Develop an infrastructure of user friendly interoperable systems for health education, disease prevention and medical care

	Create resources to help citizens and medical practitioners assess the quality and authenticity of health information on the Internet
R&D priorities:	Support R&D related to long-term healthcare goals Focus funding on key gap areas for healthcare Encourage independent technology assessment to guide purchaser decision making Continue to support the availability of user-friendly healthcare solutions. Identify and disseminate best practice.
Promotion and encouragement :	Facilitate effective participation of consumers in health networks; Increase widespread availability of low cost access to health services Reduce social inequalities related to healthcare issues;

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