# Healthcare Technologies Roadmapping: The Effective Delivery of Healthcare in the Context of an Ageing Society (HCTRM)

JRC/IPTS-ESTO Study

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# Acknowledgements

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The authors are also grateful to the experts invited to participate, who brought together a broad range of expertise on various aspects of healthcare in Europe and thereby helped to define the footprint matrix. Their fostered sense of teamwork and positive constructive inputs from various standpoints avoided duplicating efforts, and stimulated complementarity.


# Participants

Overall direction and guidance for this report was provided by the ESTO partner organisations, the IPTS, EU Commission services, and an invited expert advisory group, representing researchers, clinicians, and industry. A list of participants is given in Annex II.

The mandate of this expert advisory group was, mainly in the context of a problem definition workshop, to provide advice and recommendations in identifying the key technologies and issues to be addressed in the roadmapping process, and to ensure that the resulting roadmap is accurate, relevant and useful to both the European Commission and the European research community.

This steering mechanism allowed industry, research, end user and government representatives to voice their views and the views of the organizations they represent so that the final roadmap presents a balanced picture, in a timely, effective manner. It was not intended that this collaboration impinge on competitive sensitivities; the emphasis was on enabling technologies of interest to the healthcare sector.

# Executive Summary

In order to reduce the current gaps between actual treatment provision and optimal treatment, the need for high quality healthcare technologies has been recognised to a greater extent. There is little doubt that healthcare systems management in many EU countries can be improved in order to improve sub-optimal medical treatment of the European population. Due to the ageing of the population, and the Enlargement of the European Union, the European population is anticipating that more financial resources will have to be invested into the future healthcare system. In order to improve the situation of million of patients without exploding expenditures in the healthcare systems, the provision logistics for healthcare technologies must be discussed in public; healthcare cost-benefit analyses shall be conducted with a longer-term perspective: (including expenditure and added value), adequate co-payment policies must be implemented.

The technology roadmap analyses the options deriving from the current and emerging state of healthcare technologies, if the present policy trends continue. It examines the impact of a range of societal and economic challenges and describes how the "desired future" could be reached in the context of an enlarged and ageing EU.

As demonstrated in two technology matrices, modern healthcare technologies have the potential to extend the life expectancy of patients, 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.

The dominant technologies revolve around three technology clusters: Genetic Technologies (GENTEC), Medical Technologies (MEDTEC) and Information & Communication Technologies (ICTEC), listed in the healthcare technology matrix. Particular applications identified include the following:

- Pharmacogenomics
- Gene therapy
- Genetic diagnosis
- Stem cells
- Telemedicine and telecare
- Minimal invasive surgery

Promising developments over the next few years are expected to include the following:

- Vaccines against infectious diseases
- The ability to predict, delay, prevent and even cure cancer, heart disease, and certain neurological diseases.
- Genetic engineering (e.g. the human genome project)
- Continuing developments in biomaterials for prostheses and advances in robotics.

The Gene technology Cluster has demonstrated that in the future it can be envisaged that the process of patient medical diagnosis and treatment will involve an assessment of the patient's genetics. Appropriate drugs will then be prescribed on the basis of their suitability to a patient's genetic make-up. This is the field of pharmacogenomics, which is likely to be a major healthcare benefit of genetic technology.

The challenges to healthcare systems, and to regulatory systems, in making this a reality, are considerable.

At the *regulatory* level, it will require the recognition that drugs which are ineffective, or even unsafe, in certain individuals may be approved on the basis of their efficacy in a genetically defined group of patients.

At the *general practitioner* level, a new understanding is needed of the relevance of genetic makeup to patient treatment. In addition, some mechanism by which the medical system can be reliably informed of the genetic profile of their patients as it relates to drug suitability. This mechanism may be similar to current systems for determination of blood group, or of sensitivity to penicillin. However, healthcare information systems will also have a major role.

Pharmacogenomics will allow us to relate drug prescription to individual patients rather than to the diseases they suffer. Pharmacogenomics will therefore have significant implications for drug development and regulation, and it will have several overall effects on the healthcare system. It will be a major input into the design and testing of future drugs. However, in this report we are concentrating on the major direct impact of pharmacogenomics on the healthcare delivery system. This impact relates to the ability to define individuals as to their pharmacogenetic status. In other words it can be envisaged that, in the future, the process of treatment will involve a determination of the patient's genetic status. Appropriate drugs will then be prescribed on the basis of their specific suitability to a patient's genetic make-up. This is the field of pharmacogenomics, which is likely to be a major healthcare benefit of genetic technology.

The future impact and significance of genetic diagnostics is expected to be shaped around the politics and findings of the *Human Genome Project* (HGP)[1]. One of the most interesting features in gene testing is predictive gene testing: tests that identify people, whether in the foetus or adult, who are at risk of getting a disease, before any symptoms appear. Tests are already available in research programs for several diseases, and more gene tests can be expected as more disease genes are discovered.

Some of the most serious medical conditions, such as cancer, are due to abnormal cell division and differentiation. A better understanding of the genetic and molecular controls of these processes can yield information about how such diseases arise and suggest new strategies for therapy. A significant use of stem cells is to uncover the secrets behind the signals that turn specific genes on and off to influence the differentiation of the stem cell. Research has looked for ways to use stem cells to generate new cells and tissues to replace those which are damaged or diseased. Due to the very early stage of the science of stem cell biology prediction of the future of stem cell applications is nearly impossible. It is not possible to predict which type of stem cells or which methods for manipulating the cells, will best meet the needs of basic research and clinical applications. Only further research can provide these answers.

In the health and healthcare domains, the Information and Communication Technologies are used in intra- and inter-enterprise healthcare applications and their integration, telemedicine, home healthcare, disease management, eHealth, and health or wellness management or a combination of these.

[1] Human Genome Organisation (HUGO) Ethics Committee: Draft Statement on Gene Therapy Research http://www.hugo-international.org/hugo/genetherapy.htm

Healthcare enterprise applications and their integration comprise a large set of clinical information systems for specific medical domains such as laboratory, radiology, intensive care, and anaesthesia and operating rooms. Within these, are another set of systems such as decision support systems and computer assisted or remotely guided diagnostic and therapeutic procedures based on e.g. virtual reality. The integration of the systems includes interoperability and connectivity at the functional and semantic level, incl. vocabularies and, of course, standards. The Integrated Healthcare Enterprise initiative that started in North America in the late 1990's has since then migrated to Europe and Japan and is gaining momentum as a vehicle to demonstrate interoperability at a practical level. At the process level, it comprises clinical guidelines and pathways, protocol-based care, including evidence based medicine (EBM). It also comprises architectures and middleware solutions for integrating healthcare enterprises and for providing interoperable inter-enterprise environments e.g. in a regional setting. Hardware and software security aspects and privacy of confidential patient data, overall trust of complex systems and the technologies and standards, such as the Public Key Infrastructure (PKI) and smart card technologies also belong to this area.

Telemedicine has been a very popular field of experimentation for the past ten years or so. Today it is mostly seen as a technology enabling the collaboration of healthcare providers over a distance in delivering a service to the customer. This can take place either in a store and forward mode or in real time. Home healthcare is often seen as a modality of telemedicine. Examples include the "home hospital" for episodic and chronic care and follow-up and monitoring of patients after hospital discharge. These operations can be performed with the real or virtual presence of care personnel in the homes. The main characteristics of these two are the extension of the hospital concept towards a virtual hospital (a.k.a. hospital without walls) and that healthcare professionals are clearly in the loop caring for the patients.

eHealth dot.com's were projected to be a response to the interest of the general public in health and wellness. Unfortunately, neither the services offered nor their pricing met the expectations of the customers. Empowering the individual or patient in health and illness management is conceptually a nice idea but its successful implementation is not an easy task. The primary challenge is the development of an application that the individual finds useful and motivating. Equally challenging is its integration into the way healthcare services are provided and reimbursed.

In the field of biomedicine IT applications are a quickly evolving domain. This includes IT tools and methods to improve our understanding and knowledge of biological systems. Examples include bioinformatics, tools for protein sequencing and proteomics, computational biology, biocomplexity and modelling of the physiological system from the gene to organ level, such as the Cardiome and Physiome initiatives. GRID computing (the connection of a large number of computers in a grid through the Internet into a virtual supercomputer) is an emerging alternative to real supercomputers in delivering the computing power needed in these applications.

In considering application of ICT in the health, healthcare and biomedicine domains we need also to be reminded that all the above is influenced by the trends in generic IT and IT development methodologies. How do we design systems that are usable and useful? Today human computer interfacing and usability engineering and component-based software development based e.g. on the Unified Modelling Language and Model Driven Architectures are hot topics. Mainstream IT technologies today are based on the emerging next generation Internet facilities, e.g. standards development activities of the Internet Engineering Task Force (IETF) and the World Wide Web Consortium (W3C) including the semantic web and broadband,

wireless and mobile communication technologies for anytime anywhere access to information.

The Cluster on Medical Technologies demonstrated that medical imaging techniques such as MRI and CT scanning are used routinely in medicine today. They visualize the inner body from the outside and yield three-dimensional pictures of the organs. An important trend in MRI technology is the design of increasingly smaller scanners, with lower capital and operating costs than present-day models. The key to this trend is the development of smaller and less costly magnets. It is therefore expected that the indications for MRI will expand in the future. For example, mini-MRI units may become available for dedicated uses in orthopaedics, neurology, and mammography.

A second development is magnetic resonance neurography (MRN), which can be used to identify the site of damage to peripheral nerves by detecting increased signals at sites of nerve entrapment and trauma. This technique is the first of its kind with the ability to monitor the process of peripheral nerve degeneration and regeneration.

In PET-scanning, the introduction of multi-slice-imaging, 3-mm resolution, and 3-D resolution has revolutionised the field and enhances whole-body imaging for the diagnosis of meta-static and recurrent cancer. In general, the enormous potential of PET in clinical practice and medical research, as well as emerging radionuclide therapies for dispersed and inoperable cancers will lead to a strongly increased demand for radiopharmaceuticals. For example, for recurrent cancer of the head and neck, a notoriously difficult area for imaging using current technology, PET has shown an accuracy of greater than 95 percent in detecting recurrent disease. It is expected that whole-body PET scanning will be faster, less expensive, more widely available, and the most accurate and rapid means of detecting cancer that has either recurred or spread beyond the primary site. Many of these developments are enabled by the collaboration between physicians and nuclear chemists. The short-lived radioactive isotope markers needed for these imaging techniques can be composed in many different ways[2].

For medical applications, the laser has become an indispensable tool for a number of applications, in particular in ophthalmology, gastroenterology, gynecology and urology, with more limited applications in other specialties.

In the past decade, virtual reality (VR) has become a mature technology. While the creation of artificial worlds in the computer was not much more than gaming in its beginnings, today these find real-life commercial applications for simulating purposes. Augmented reality builds on these developments. Here, computer images and real images overlap. Different research teams are working on the integration of these simulation techniques into medical practice and the operating room. In time, the training simulator will enable the beginning orthopaedic surgeon to learn and practice clinical functional tests for the diagnosis of injuries and diseases of the knee. Using such tests, physicians can determine the functionality and stability of the knee joint by manual movement and simultaneous palpation.

The sub-cluster on technological advances in minimally invasive surgical procedures include, for example, the development of new imaging techniques based on MRI-, CT-, and PET scanning, development of new endoscopes and associated tools such as lasers, and the application of virtual and augmented reality in novel clinical procedures and training programmes.

[2] More general information on this issue can also be fond on the website of the EU Institute for Health and Consumer Protection (http://ihcp.jrc.cec.eu.int/)

Although the prediction for the field of Minimally Invasive Surgery as a whole points in the direction of rapid future development, prediction of the diffusion of each single application in individual healthcare systems in the EU is much more complex. Likewise, the assessment of the impact of presently documented and anticipated overall future trends on different actors and key elements of healthcare systems, which is presented in the next section, should be read with some caution.

For example, Himal (2002) predicts that the next 25 years, just as the last 15 years, will be periods of enormous change in general surgery. In general, the most widely held opinion is that the development of new instruments and the refinement of established techniques will lead to the expansion of MIS to new areas. Similar expectations are formulated in more broadly oriented technological foresight studies. In a paper prepared for the Danish Technology Foresight Project on Bio and Healthcare Technology, Jackson (2002) summarized health technology foresight reports of 4 countries and included a number of relevant sources on global technology trends. Based on this combination of sources he predicted that in the coming two decades there will be a rapid development of new devices and instruments for MIS.

Furthermore, the difference between diagnosis and treatment will become more and more difficult to define with the advent of new imaging and scanning techniques that combine diagnosis with therapy, e.g. new therapeutic ultrasound applications. Another development that is listed in the report in relation to MIS is that of laser technology. The interaction of different technological trends in case of MIS is expected from the synergy with nanotechnology, which is predicted to result in micro machines for surgery by the year 2020.

For all technology clusters it was found that there is a need for growing dialogue with stakeholders on conflicting themes: ethical issues (GENTEC), data privacy (ICTEC), etc. There will be a stronger deconcentration through the advances of ICT and individualisation of healthcare through GENTEC - ICTEC) as well as a growth in the importance of networking. It was found that there is a need for more training in technologies for GPs (ICTEC - GENTEC), particularly for the primary healthcare sector, while higher technological investments (ICTEC – MEDTEC) will imply transformations in the organisational structures and in the workforce. Due to better access to information, and the development of innovation networks, secondary healthcare structures will increasingly work in networks.

In the diagnosis area especially the technological innovations for minimal invasive surgery and telecare will be noticeable. The developments in technology clusters (particularly in minimal invasive surgery and telecare) were found to contribute 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.

Achieving a balance between three objectives, equal access to healthcare, high-quality healthcare, and financially sustainable of healthcare systems, poses a major challenge for the overall management of healthcare systems[3].

However, although these healthcare technologies are available in principle for all patients throughout Europe, not everyone receives adequate treatment. There is a huge difference between a (technologically possible) optimal treatment and the treatment delivered to the

[3] European Commission, DG Employment and Social Affairs.

patient. There are also huge differences in the provision of innovative healthcare technologies between the various European countries depending on the national health delivery system.

Broad and equal access to healthcare does not 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 and self-care and self-responsibility in this area is being promoted. If the patient is not able to afford the treatment or is not able to assess the treatment's benefits correctly, then the diffusion of innovative healthcare technologies will be hampered – a fact that applies to all of the three technology clusters.

It was found that particularly the advances in the medical technologies cluster (minimally invasive systems) and in the telecare sector will impact on the potential to evaluate healthcare quality. But it remains open how the quality of healthcare can be unequivocally defined and understood, and how quality can be measured and evaluated. A definition of the efficiency or the 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 healthcare service.

Concerning the financial sustainability of healthcare systems, the major cost factor seems to be skilled labour and its support processes and this is also the major determinant of "the cost" of medical technologies, particularly in the MEDTEC and the GENTEC cluster.

At the healthcare professionals' level, skills, knowledge about healthcare technologies innovation and knowledge about the available treatment options are required to improve quality. Particularly in the area of minimal invasive surgery and telecare it was found that, besides the different organisation of the healthcare system, disparities in financing methods can influence medical practice as well.

The options for healthcare providers were seen in further training and education for better informed encounters with patients and with other care professionals because of easier access to appropriate patient-specific information. Physicians need to be trained in the use of modern healthcare technologies.

Among the options for industry is a pluralistic approach with commitment to a new public-private partnership in strategic thinking and policy development, in order to help the national health authorities to set priorities for care and the rational allocation of resources.

From the advances of healthcare technologies, options for patients can be expect assuming that the procedure is reasonably evaluated and carried out by an experienced surgeon. These include a better assessment, treatment and care that can take place at a time and place of their choice, a greater mobility, a better monitoring, more specific and readily available information about their conditions, a lower mortality rate, reduced postoperative pain, a decreased risk of wound-related complications, and the obvious cosmetic advantages.

The options for society were found to be quite valuable, as modern healthcare technologies will mostly improve the cost-effectiveness of healthcare. The demand for convincing evidence on the effectiveness, but also on the 'value for money' of healthcare is expected to increase in the future as, partly due to the ageing of the population, healthcare will increasingly consume a bigger share of each country's GDP.

Recommendations and requirements for intervention concern many policy areas, and stakeholder, as they comprise, for instance media reporting, fostering patient demand and

physician interest; the availability of respected medical innovators; the ability of physicians to get reimbursement for new procedures in most cases, even if they do not (yet) appear in the benefit package; commercial pressure and information; the availability of appropriate training; maturity of the procedure or technology; policy measures encouraging the diffusion of a procedure, such as the decision not to regulate a procedure, providing convincing evidence of (cost)effectiveness.

# Structure of the Report

The report presents some synergies, barriers, stimuli and uncertainties associated with available and future healthcare technologies and their application. It sets out some preliminary perceptions of the dimensions of this challenge and examines a selection of the types of technological area that are currently - or likely to be - relevant.

The **technology matrix** is able to illustrate on the one hand the major drivers that frame technologies for health-care delivery (e.g. generic "orientations" such as treatment, care and prevention, cost-effectiveness or availability, patient demand for cheaper medicine, faster diagnosis, better quality, new treatments, etc.), and on the other hand the dominant technology clusters. This type of approach is particularly suited to situations where both, technology performance and healthcare delivery dimensions are clustered in specific time periods. In particular, this has entailed the construction of two key matrices:

- a "**footprint matrix**" to display a snapshot of the situation as it pertains today; and
- a "**matrix 2020**" to display baseline projections.

**The technology roadmap** analyses the options and pathways deriving from the current (footprint-matrix) and emerging (matrix 2020) state of healthcare technologies, if the present policy trend continues. It examines the impact of a range of societal and economic challenges and describes how the "desired future" could be reached in the context of an enlarged and ageing EU (e.g. accessibility, quality, financial sustainability of healthcare) along a range of societal and economic challenges.

As the two matrices demonstrate, modern healthcare technologies have the potential to extend the life expectancy of patients, 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.

The **conclusions** tackle the healthcare technologies diffusion in Europe from a technology/economy push perspective (with options for healthcare providers and industry) and from the public health perspective (with options for patients, society, the quality of care).

The **recommendations and requirements** are addressed to the implications from the three technology clusters for the organization of care and for key policy areas for intervention and display options rather than advice for further R&D in healthcare related research areas, as well as technology related research areas that could benefit healthcare.

While the construction of full scale **scenarios** has proved to be beyond the timescale and resources of this project, an epilogue to this report lays out the groundwork for scenario planning and gives a basic description of how to use this report it for strategic planning and visionary stories. It provides a very good basis for further scenario building, indicating the key players and technologies for roadmapping, and the ways towards alternative desirable futures (e.g.: accessibility, quality, financial sustainability). Annex II describes how this information could be used for further vision building and outlines the implications of the project results for further scenario construction. Some ideas, suggestions and visions for potential scenario dimensions are articulated (Government Driven versus Market driven healthcare delivery or Patient-led versus Provider-led delivery).

A comprehensive **bibliography** indicates references to various foresight exercises, roadmaps and other relevant activities that have been used in preparing this report.

As this report is result of is a **pilot study** with rather limited resources, participants' views on the process of constructing the roadmap, and the lessons that may be drawn for future such activities have to be collated.

# Some Key Definitions

The healthcare sector consists of a variety of players - clinicians, hospitals and other healthcare facilities, insurance plans, 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 for-profit or non-profit entities. Although these various players are generally referred to collectively as the "healthcare delivery" system (a term that suggests a non-existent degree of integration) communication, collaboration or planning among these various entities is often limited.

This report uses the term **technology roadmap** for the portrayal of development of healthcare technology and its application in disease prevention and health promotion. However, a single standard definition of technology roadmapping does not exist, and an examination of available roadmaps (see Annex IV) indicates that there are several definitions of what a technology roadmap constitutes depending on the purpose and field of application[4].

The term **Foresight** is employed to describe the process involved in systematically attempting to look into the longer-term future of science, technology, the economy and society with the aim of identifying the areas of strategic research and the emerging generic technologies likely to yield the greatest economic and social benefits.[5] For a more detailed definition, please see Annex I.

**Scenarios** are often used as a management tool to reduce mistakes in executive decision-making. They involve consideration of the wider implications of potential decisions. They might focus, for example, on changes in the structure of industry sectors, political decisions, consumer acceptance, substitute technologies and so on.

[4] Phaal, R., Farrukh, C. and Probert, D. 2001. Technology Roadmapping: linking technology resources to business objectives, Centre for Technology Management, University of Cambridge, http://www-mmd.eng.cam.ac.uk/ctm/

[5] see Technological Forecasting and Social Change, Vol. 60, devoted to technology Foresight.

# Background and Objectives

The Healthcare Technologies Roadmap: the effective delivery of healthcare in the context of an ageing society (HCTRM) is the first of a planned series of six problem-driven roadmaps that will comprise the Science and Technology Roadmaps (STRM) launched in August 2002 by the IPTS and the European Science and Technology Observatory (ESTO).

The objective of the Healthcare Technologies Roadmap was to provide a problem-driven technology horizon-scanning in the area of healthcare technologies.

With this objective, an IPTS/ESTO project team examined the role developing healthcare technologies may play in healthcare delivery, relative to other factors such as the ageing of the population, the Enlargement of the European Union and their likely influence in the future. A key aim of the study is to provide a context for R&D policy developments and contribute to planning by public and private policy makers.

Though the roadmap is technology oriented, it takes into account not only a technical model emphasizing the techno-economic dimension, but also the dimensions of delivery of healthcare services and technologies, and their contribution to disease prevention / health promotion.

The roadmap displays, within a global context, future directions in healthcare and its delivery, a description and analysis of the current (footprint-matrix) and emerging (matrix 2020) state of health technologies in an enlarged EU, taking account of the most important socio-economic factors, (e.g. the shift in emphasis towards age-related issues) and focussing on the interdependence of the multiple factors influencing healthcare utilisation and costs.

# Introduction: Major Drivers of Change

About ten years from now the following drivers of change will have fully emerged and will determine the players and resources in future healthcare.[6]

Rising life expectancy will exert increasing pressure on public pensions and healthcare systems. Population ageing is often accompanied by an increase in non-communicable diseases and mental health problems. As our population ages, medical costs also rise because in general an aging population uses more healthcare services than a younger one.

An increase in the scale and diversity of international migration, for instance due to the Enlargement of the European Union, may create severe problems concerning equal rights to healthcare. With increasing consumer demand by a growing senior citizen and enlarged European population, healthcare costs tend to spiral upward and healthcare systems collapse. Increasing medical costs affect all of us – health insurers, customers and healthcare providers.

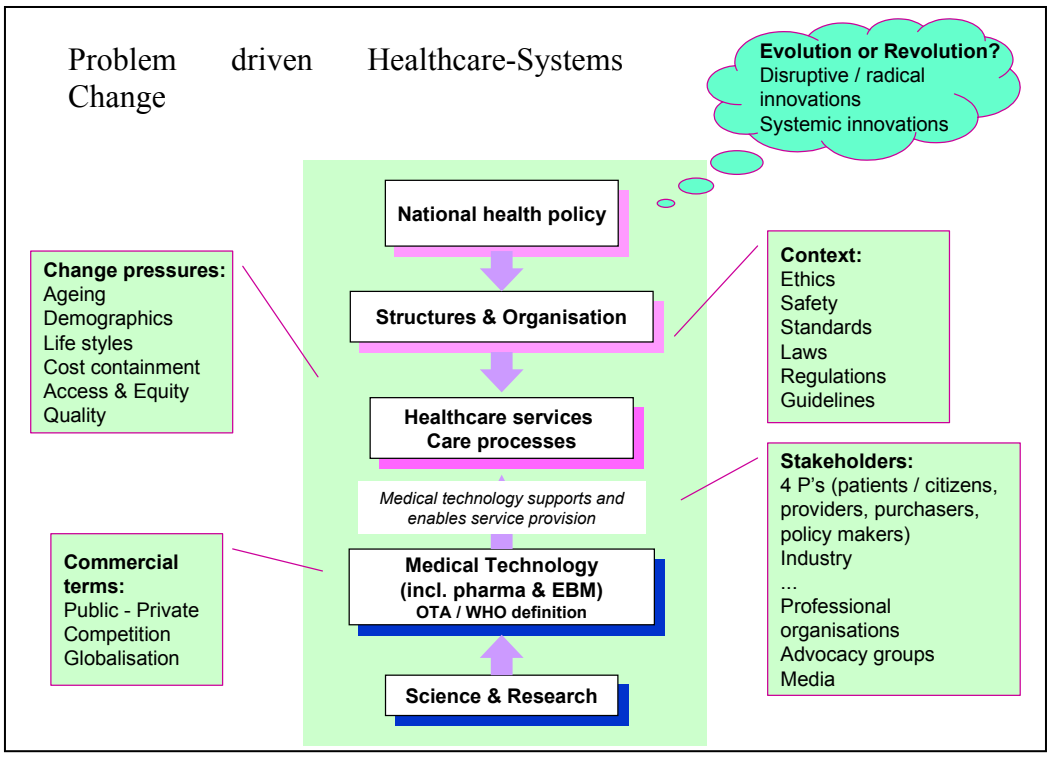
Globalisation and increasing mobility may exacerbate the spread of infectious diseases and, because of overcrowding, lead to anxiety, depression and chronic stress. Globalisation will lead to the emergence of new diseases, and re-emergence of old ones in more virulent form (e.g. legionella, food pathogens, tuberculosis, diphtheria and cholera) as a consequence of the increased mobility of people.

Technology innovation and development will provide new or improved therapies, medical treatments and diagnosis methods and techniques. Apart from genetics, major breakthroughs are expected in other areas such as tissue and organ engineering, surgery and the treatment of disease. Important innovations include the use of computers and robotics, the application of communications and information technology, new diagnostic techniques, genetic engineering, cloning, the production of new classes of pharmaceuticals, and the work now beginning on growing replacement tissues and organs. These developments can contribute significantly to improved health status.[7]

Healthcare systems in the EU member states are under multiple pressures due to a series of factors. Demography, changes in family structures, technological progress, further EU integration and enlargement and higher people mobility and expectations are the most important drivers. At the same time, constraints on national financial resources allocated to healthcare expenditure call for reforming EU systems improving their efficiency and effectiveness while retaining their responsiveness to citizens' needs and expectations as well as an equitable and fair funding basis.

[6] Emerging Thematic Priorities for Research in Europe, IPTS Working Paper, IPTS-JRC Seville, 4/12/2000

[7] The HCT & pharma market today (2001) globally was 600 billion USD, with HCT representing one third and pharma two-thirds. Numbers can be obtained from Eucomed (www.eucomed.org).




## Ageing

Improvements in healthcare and health status have led to a number of demographic changes, such as increased life expectancy, lower mortality rates, rapid population growth, reduced fertility and population ageing. Notwithstanding (and often because of) these improvements, new health challenges for the future are emerging. The population will also be better educated in 2020: 55 percent of the population age 25 years and older will have the equivalent of one year of college. Income disparity -a critical factor in determining health- will increase slightly. Access to care will remain "tiered" and that such a tiered structure will become much more extreme. Only the top tier, the "empowered consumers," have considerable discretionary income, are well educated, and use technology (including the Internet) to get information about their health. These new consumers increasingly will engage in shared decision making with their physicians.

The European population balance is changing as a result of a double demographic development. In most European countries both fertility and mortality are falling: fewer babies are born, and people live longer. The result is 'population ageing', a general trend which has been accelerated by the post-war baby-boom. A European Commission scenario suggests that between now and the year 2025 the European Union will experience:

- A fall in the number of young people under the age of 20 of 9.5 million, or 11% of this age group currently.
- A fall in the population of adults of working age (i.e. in the 20-59 age group) of 13 million, or 6.4% of this age group currently.
- An increase in the population of retired adults (60 and over) of 37 million, or 50% of this age group currently.

Population ageing will have significant socio-economic implications.[8] There are serious concerns about the viability of pensions systems in many countries (particularly where pension payments depend on current contributions from people in work), about public sector budgets (particularly for healthcare), about the care implications of a larger population of frail older people, and about the possibility of a growing marginalised and socially excluded older population. Population ageing is seen as a challenge to the European model of social welfare and protection.

The concerns are justified, but pessimistic conclusions should not be drawn too quickly. This report presents a perspective in which demographic change is seen as a positive opportunity for the European economy. The opportunity lies in innovative technological, social and organisational responses to the challenges of an ageing population. Through innovation it may be possible to not only avert potential economic problems, but also to enhance the quality of life of older people, and develop new business possibilities for European industry.

The future health of the European economy depends in part on how European industry adapts to the changing composition of demand, and whether or not it can produce innovative solutions in response to the actual and potential needs and demands of older age groups. It should be emphasised that many of the goods and services which are likely to emerge can be internationally traded: there will be international competition in the development and supply of such goods. However, adaptation to the new patterns of demand is not simply a private-sector issue – government also has a role to play in the development and diffusion of new technologies and in the creation of markets, through:

- development of relevant technological infrastructures;
- actions to create markets for new age-appropriate technologies;
- development of relevant standards and regulations (both technological and organisational); and
- diffusion of best practice.

## Enlargement of the European Union and Globalisation

Health and poverty are interlinked and many applicant countries are still struggling with the consequences of social, economic and democratic change, social exclusion, the rising numbers of elderly people, and the increase in communicable diseases. The 1990s have been marked by a profound transformation in healthcare systems in the Candidate Countries, and the "free-of-charge services" have turned into medical insurance system allowing patients to be reimbursed for their medical expenses.

Nevertheless it has often been argued that most of the health systems in the Candidate Countries are "still a mess", with a culture of informal payments to doctors according to the principle "Bribe the doctor and you get what you want".[9] There is a risk of an exodus of poorly paid doctors and nurses taking up jobs in the present EU15 with better salaries, working conditions and career prospects which might have serious implications for healthcare in the new Member States.[10, 11]

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[8] Saranummi N., Kivisaari S., Särkikoski T. & Graafmans J. (1996) Ageing and technology. Sevilla: Institute for Prospective Technological Studies, European Commission-JRC (IPTS - Technical Report Series).

[9] Dr Elias Mossialos of the London School of Economics at the OECD conference 23-26 April 2001, http://www.oecdconference.org/material.htm

[10] Belabed, Eva, 2000, www.health.fgov.be/WHI3/krant/krantarch2000/kranttekstjuly/000725m10eu.htm

[11] Belabed, Eva, 2000, Social Impact of the Enlargement

The equal right to healthcare cannot imply unlimited free access to any form of medical treatment or product that one can imagine. The right to healthcare as a social right implies that governments be instructed to become involved through legislation with the structuring and financing of the healthcare system and the maintenance of quality of care. However, more and more it is being acknowledged that there are limits to what can be financed collectively. In order to safeguard solidarity in areas where this is indispensable, a search has started for possibilities to give people greater responsibility in other areas where this can be justified.

Due to the enlargement of the European Union, changes in the utilization of cross-border services will be noticeable to the economy, and the increases will not remain restricted to border regions. It can be presumed that noticeable increases in efficiency can be realized as basically unrestricted cross-border distribution of health services emerges in the course of the development of the internal EU market.

## Technology development

Important technologies such as data processing, lasers, optics, nuclear technology and new materials, have been successfully introduced into healthcare products with one major aim: to improve healthcare delivery. Despite increased interest in cost/benefit assessment techniques, the pace of introducing new technologies is unlikely to slow, and there will be a significant increase in the number of new technologies available in the coming decade.

The autonomy and independence of the elderly will be supported by the development of alternative forms of assistive technologies & home-based nursing care technology, ranging from new forms of home and community care services (home help, day care centres, etc.) to a better housing environment for the elderly. The adoption of sensors, IT and remote care technologies (telecare and telemedicine) will be crucial in increasing functional independence among older people in their homes and provide them friendly diagnostic devices for telemonitoring of chronic illnesses (see the IPTS roadmap on Ambient Intelligence).

New prosthetics techniques and the use of new biomaterials will dramatically improve life conditions of people with handicaps. The treatment of new and re-emerging diseases as well as the treatment of non-communicable diseases is a whole set of research issues that should be dealt with in the next decade.

ICTs will allow remote delivery of healthcare and support services and information to people in their own homes and the remote exchange and delivery of medical diagnosis, consultation and information (doctor-to-doctor and doctor-to-patient). Telecoms will permit remote monitoring of patient's condition or behaviour from a centralised facility. Telecare and telemedicine will be important for providing healthcare services to rural areas at a reduced cost, with consequent positive effect on social cohesion. Integration of ICTs, medical imaging and robotics will include image processing, virtual reality, storage analysis and interpretation, robot-assisted surgery, image-guided surgery and conform radiotherapy. The development of medical decision support systems will be an essential complement to evidence-based medicine, providing information, analysis or options to assist in diagnostic, therapeutic and prescription decisions.

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http://www.ces.eu.int/pages/en/acs/events/16_11/Doc_Belabed_161100_en.PDF

Advances in cellular biology research, in particular in embryonic and adult stem-cells, promise a huge potential of providing a treatment for several diseases caused by non-functioning cells or tissues in the body (diabetes, Alzheimer disease, Parkinson's disease etc). It may be even possible to replace whole organs, thus solving the problem of shortage of donated organs. Through therapeutic cloning or using the patients' own stem cells the problem of rejection of foreign tissue might be overcome. Progress in xeno-transplantation research and the development of artificial organs will contribute to move in the same direction.

Cost effective technological advances, while mitigated by ethical debate, will enhance screening, surveillance, and environmental health. "Cost-effective" medical technologies often spread in cost-increasing ways. Some medical technologies reduce costs if their use is restricted to narrowly defined indications or populations, but increase costs as their use expands. Medical technologies exert their influence through both volume and price effects. Some technologies have a small target population, but a high price tag. Healthcare technologies cannot be separated from the systems in which they are used. Healthcare technology does not increase costs by itself. Rather, the healthcare system and the incentives it contains are critical.

The enlarged EU will need better instruments for disease & epidemic control, risk assessment and management, and harmonisation in technical standards of healthcare equipment. Special attention should be devoted to the development of appropriate IPR regulation for pharmaceutical products.

## Health policies and systems change

In all European countries healthcare is a matter of public policy. This has led to the development of a significant body of legislation and initiatives. Since 1993, there is a specific 'Health' title in the Treaty (Maastricht Treaty), which gave the Community concrete legal competencies on public health. Articles 3 and 129 define the scope and objective of the Community's activities in the field of public health.

In response to the Treaty objective the Commission presented in 1993 a Communication on the framework for action in the field of public health as an initial strategy document to develop work on public health. On this basis eight action programmes were developed: health promotion, cancer, AIDS and certain other communicable diseases, drugs prevention, health monitoring, injury prevention, rare diseases, and pollution-related diseases.

In addition, several other initiatives outside the programmes have also been carried out on a number of important public health areas. This included: legislation on tobacco control, strategy on safety of blood and blood products, establishment of a network for the epidemiological surveillance and control of communicable diseases, electromagnetic fields and a certain number of reports and studies have been produced on the health status and health in other policies.

At the end of the 1990s the general framework of health policy changed due to many factors. The powers of the Community in the public health field had been expanded in the Treaty of Amsterdam through a revised Article and renamed as Article 152. According to Article 152 actions in the public health area should aim at: contributing towards ensuring the attainment of a high level of health protection; improving health; preventing human illness and diseases; obviating sources of danger to health and ensuring that all EC policies protect health. In addition to these objectives Article 152 also includes specific provisions allowing the Community to take actions with a direct bearing on health protection, while respecting the responsibilities of the

Member States for the organisation and delivery of health services. These include: measures in the field of veterinary and phytosanitary legislation; measures setting high standards of quality and safety of organs and substances of human origins, blood and blood derivatives; incentive measures to protect and improve public health.

In addition a number of new challenges and concerns have emerged. While the health of the European Community's population has never been better, serious public health problems remain. At the same time, healthcare systems face new challenges arising from: the rising public expectations creating constant pressure for increased health services; the rapid development of health (care) technologies; and the demographic ageing of the population which creates both additional and different demands at the same time as reducing the proportion of the 'active' population. Moreover the enlargement of the EU raises a number of issues and challenges both for the candidate countries[12] and the European Community.

In this overall context the Commission proposed in May 2000 a new health strategy of the European Community[13]. On the basis of previous experiences, the new strategy promotes an integrated approach to health related-work at Community level towards achieving health objectives. As a key element the Commission put forward a proposal for a new programme of Community Action in the field of public health.

The new public health programme[14] is the key enabling mechanism to implement the EU's overall health strategy. It represents a significant new departure for public health in the European Community. It moves away from the fragmented, diseases oriented approach of the past, where resources were spread thinly over many one-off projects. Its intention is to target key priority areas where added value can be achieved.

The programme will be focused along three main strands of actions enabling the EU to identify and tackle the major health problems it faces:

- Improving health information and knowledge for the development of public health;
- Strengthening the capability of responding rapidly for co-ordinated reactions to major health threats;
- Targeting actions to promote health and prevent disease by tackling the key underlying causes of ill health and addressing the main health determinants.

The programme shall thereby contribute to ensuring a high level of health protection in the definition and implementation of all Community policies and activities. This will be done through the promotion of an integrated and intersectoral health strategy; tackling inequalities in health and encouraging co-operation between Member States. Health technology assessment is one of the cross-cutting issues in the new public health programme.

Health services account for approximately 8.1% of GDP in the EU. Although national health systems vary significantly across countries, on average about half of total expenditures on health are accounted for by hospital. Around 20% is spent on pharmaceutical products, the remainder relating to "other" medical expenditures (including primary care). Over the past decades, real health spending grew at a rapid rate, increasing its share of overall public expenditure and raising concern about the future financing of health services. About 78% of total spending on

[12] Associated Central and Eastern European countries, Cyprus, Malta and Turkey.
[13] COM (2000) 285 final of 16.5.2000
[14] OJ L 271/1 of 9.10.2002, Decision 1786/EC.

health is covered by public insurance systems. The decade of the 90s saw major changes in health systems aimed at further increasing the overall efficiency of these services (i.e. reducing the cost while maintaining and if possible increasing the quality of the services and the accessibility to all). Important changes in the regulatory environment have either recently been implemented or are going to be realised in the near future. All actors in this sector will have to adapt to these changes, however, national health insurances and national health services can be regulated/restructures on EU level only by unanimous decision (which becomes increasingly difficult in a Community with 15, and soon even more members.)[15]

Healthcare reform had been overdue but too often its unfolding in the last decade has been at the expense of investment in infrastructure and has failed to achieve real reform of obsolescent methods of accounting and analysis. Faced with fiscal exigency, governments at all levels have looked to achieve savings by reducing capital spending on plant, information systems and technology. This has been short-sighted. Industry in general had long ago come to understand that these were key strategic investments if a business was to maintain competitiveness. Unfortunately, that lesson has often not been incorporated into healthcare policy development.

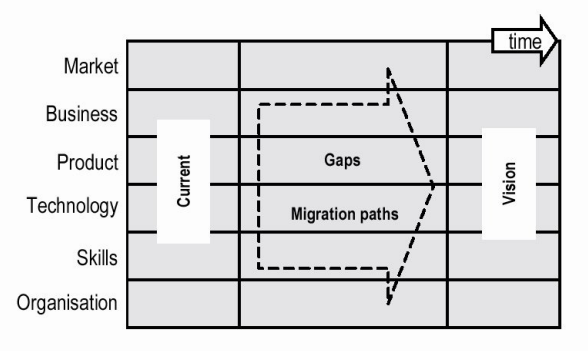
Cutbacks in training positions of five years ago are now coming to be seen as short-sighted as human resource shortages are compounded by the decaying technological infrastructure that makes recruitment and retention difficult.

[15] http://www.ehfg.org/website98/englisch/9.htm

# Prevailing Healthcare Technologies and their Delivery Dimensions: The Footprint Matrix

## The Methodological Approach

Technology roadmapping has become a widely used technique during the past decade from the perspectives of both individual companies and entire industries.[16] The term "roadmap" conveys the main purpose of this technique, namely to chart an overall direction for technology development or usage. However, a standard definition of technology roadmapping does not exist, and an examination of roadmaps that have been created indicates that roadmapping is a very flexible approach, depending on the purpose and field of application[17]. Broadly, a technology roadmap approach is used in this project to *place specific new technologies into their larger context for healthcare* technology development and its application for health prevention and promotion.




source: adapted from Phaal 2001a

The roadmap format was developed using a matrix-based approach in order to illustrate on the one hand the current situation and on the other hand to focus on the development of a vision of the future situation. This type of approach is particularly suited to situations where both, technology performance and healthcare delivery dimensions are clustered in specific time periods. In particular, this has entailed the construction of two key matrices:

a "**footprint matrix**" giving a snapshot of the situation as it pertains today; and
a "**matrix 2020**" to display baseline projections.

Based on these, the final technology roadmap analyses the options deriving from the current (footprint-matrix) and emerging (matrix 2020) state of healthcare technologies, if the present policy trend continues. It examines the impact of a range of societal and economic challenges and describes how the "desired future" could be reached in the context of an enlarged and ageing EU. The underlying criterion was that these technologies will be broadly accessible, of high quality, and financially sustainable.

For the definition of the matrix framework, the key issues identified by the IPTS/ESTO team were exposed to wider, informed opinion in order to incorporate as many as possible stakeholders´ positions. This was to ensure that the resulting roadmap is accurate, relevant and useful to both the European Commission and the European research community. A broad team

[16] See Annex IV for a bibliographic sample.
[17] Phaal, R., Farrukh, C. and Probert, D. 2001. Technology Roadmapping: linking technology resources to business objectives, Centre for Technology Management, University of Cambridge, http://www-mmd.eng.cam.ac.uk/ctm/

of experts[18] elaborated a more detailed description of issues as well as factors that attend, enhance, stimulate, hinder, or block the issues and described important positive and/or negative impacts that are connected with it, such as the technology orientation (economic push), the public health orientation (consumer/patient demand pull) and the R&D/policy maker/regulative orientation. This entailed the following working steps:

- Generation and classification of issues: the broad generation/mapping of existing and potential emerging technologies/applications (impacts and/or concerns) and issues over the short and medium term (the next 10-20 years);
- Discussion of "issues" against the "drivers";
- Identification of Barriers to and stimuli of these issues;
- Determination of synergies and uncertainties associated with these issues;
- Prioritisation and ranking of issue along the care delivery dimensions[19];
- Clustering of Healthcare technologies and definition of "spots" for the HCT Matrix.

## The Matrix Architecture

The operational form of the roadmap is a healthcare technologies matrix, which illustrates:

- **The major drivers** that frame technologies for healthcare delivery (e.g. generic "orientations" such as treatment, care and prevention, cost-effectiveness or availability, patient demand for cheaper healthcare, faster diagnosis, better quality, new treatments);

- **The dominant technologies** as Gene & Biotechnologies (GENTEC), Information & Communication Technologies (ICTEC) and Medical Technologies (MEDTEC).

The matrix should be the framework for spots of the various dimensions of healthcare technologies that have a strong impact on the future structure and organisation of EU healthcare systems and services. In this way, the Healthcare technology matrix can be used as a tool to display the overall direction of healthcare technology development and their ability to support disease prevention and health promotion and to indicate future issues and potential gaps in healthcare related systemic, socio-economic and R&D policy plans.

The concept of the HCT-Matrix

| | Key dimensions of delivery | | | | | |
|---|---|---|---|---|---|---|
| Healthcare Technologies | Promotion | Prevention | Diagnosis | Treatment | Monitoring | Aftercare |
| GENTEC (Subcategories) | | | | | | |
| ICTEC (Subcategories) | | | | | | |
| MEDTEC (Subcategories) | | | | | | |

[18] See Annex II

[19] E.g.: Are some of the issues the same or very similar? Can they be merged to one issue? Do all of the issues have the same relevance, etc...

The matrix should display for each cell, spots representing the dimensions of the development of key technologies.

For the elaboration of the footprint matrix, the key drivers for the access to future healthcare technologies (identified in a first attempt by the IPTS/ESTO team) were exposed to comment from a wider group of healthcare stakeholders. Their opinion has been incorporated in order to incorporate as many as possible stakeholders' positions and in order to ensure that the resulting roadmap is accurate, relevant and useful to both the European Commission and the European research community.

**Healthcare Delivery Dimensions**

The delivery of healthcare services can be illustrated in terms of the following series of key dimensions: Promotion, Prevention, Diagnosis, Treatment, Monitoring, and Aftercare. Within each of these, specific technologies have a range of potentially significant impacts. These dimensions of healthcare delivery can be seen as the major drivers that frame technology development (such as patient demand for cheaper medicine, faster diagnosis, better quality, treatments, etc.). The aggregation of those generic delivery qualities into a set of delivery qualities helps to incorporate complex issues as drivers/application areas for healthcare technology development into the matrix (roadmap).

***Prevention*** – the adoption of measures to prevent the spread and development of diseases is divided into three parts: primary, secondary and tertiary prevention. While lifestyle improvements are mainly linked to primary prevention, secondary prevention may include use of pharmaceuticals/vaccination and tertiary further medication or other measures.

Gene screening will allow the identification of people predisposed or at risk to certain health problems. This will provide a strong basis on which to advise patients as to the consequences of different lifestyles on their health. Knowledge of genetics may also provide other forms of information on disease susceptibility that can prevent diseases. The development and delivery of pharmaceutical and nutritional products will therefore be increasingly linked to progress in genetic screening.

***Promotion*** – health promotion should assist people to change their lifestyle, to move toward a state of optimal health. Optimal health is defined as a balance of physical, emotional, social, spiritual, and intellectual health. Lifestyle change can be facilitated through a combination of efforts to enhance awareness, change behaviour and create environments that support good health practices. Of the three, supportive environments will probably have the greatest impact in producing lasting change.

- Physical: Fitness. Nutrition, Medical self-care, Control of substance abuse.
- Emotional: Care for emotional crisis, Stress Management
- Social: Communities. Families, Friends
- Intellectual: Educational, Achievement, Career development

***Diagnosis*** - there will be further development of methods for early diagnosis to reduce the severity of disease, the extent of treatment, and the consequent resources required while under care. As diagnosis becomes easier and faster, it can be more widely and easily applied, again with the concomitant benefits of increasing therapeutic efficiency, and reducing the need for treatment through earlier identification.

There are also implications for human resources, as the development of new diagnostic tests enables conditions to be identified, that would otherwise rely on tacit professional knowledge. Similarly technologies for self-diagnosis, or for expanding the range of diagnostic possibilities by primary carers, again facilitate earlier diagnosis and reduce the need for the involvement of secondary healthcare professionals.

***Monitoring health*** – regular and more accurate checks and tests on health can forestall the development of serious conditions, and inform the formulation of preventative measures or minimise treatment; changing patterns of family life mean that increasing numbers of elderly people live alone and may not have relatives to informally monitor their health, or assist them, particularly when mobility may be limited, to seek the advice or attention of a medical professional. This is compounded by constraints on health service delivery which could reduce routine and special home visits.

***Treatment*** – in the area of the delivery of treatment, there is considerable scope for technology to resolve problems. In the area of surgical treatments, the development of less invasive surgical procedures can reduce the risk of secondary infection, can reduce healing time and improve patient quality of life. Improvements in wound healing technology can also contribute to quicker recovery.

Improvements in various prosthetic and implant technologies can help rehabilitation after surgery, and with a longer lifetime for prosthetics the need for replacement is reduced. In the domain of medical treatment, advances in pharmaceuticals and other therapies provide alternatives both to surgical and other medical treatments. One specific area of improvement considered is pharmacogenomics, i.e. the ability to define better drugs for patients based on their genetic make-up. Drugs optimised for specific individuals will be more effective and significantly benefit healthcare.

***Aftercare*** – follow-up to treatment. The recovery process does not end when an individual completes rehabilitation programs. Continuing support upon completion of treatment is the key to a healthy recovery from disease. Treatment is just the beginning of a lifelong process of growth and recovery in all areas of life that have been affected by illness and long-term maintenance is a critical feature of rehabilitation. Patients require support from their healthcare team, family, and friends to continue the lifestyle changes they implemented during the rehabilitation period.

For each of these dimensions, the major drivers of change raise particular issues, where there are opportunities and challenges for technologies to provide assistance in resolving them.

## The Healthcare Technologies Clusters

Since the matrix should allow for spots of the various dimensions of HCTs that have a strong impact on the future structure and organisation of EU healthcare systems and services, three technology clusters were built: GENTEC, ICTEC, and MEDTEC, which can be displayed against their key dimensions of delivery.

## *The GENTEC-Cluster: Genomic and proteomic technologies, gene and antisense therapies*

The GENTEC Cluster comprises all technologies that are based on the application of genetic or genomic information. The increase in genetic information is arguably the great scientific advances of our time, and its application will have major consequences for healthcare provision. For instance:

Prevention: genomics will provide the information which will relate how we live to heath status. We can then use this information to enhance healthy living. Knowledge of the genetics of pathogens (viruses, bacteria etc) will enable target viral and other diseases with highly specific vaccines; it may allow us to correct aberrant gene expression, compensating for loss of gene function or selectively blocking adverse specific genes.

Diagnosis: Knowledge of the genetics of pathogens (viruses, bacteria etc) will allow us to better diagnose diseases and to find sources of pathogens before they become hazardous. It will also allow us to define the genetic make-up of patients as a prelude to defining optimal treatment.

**Drugs**: The field of drug development is being completely revolutionized by genetic technology at all phases. At the discovery stage the emphasis will increasingly be on targeted discovery. Historically, most drugs have been developed as a result of chance observations that certain compounds affect certain conditions. Genetic technologies and associated molecular biological techniques have vastly increased our ability to understand disease. This understanding allows us to use our knowledge of disease genes and proteins to design new therapeutics to redress disease or its affects. This targeted discovery is already revolutionizing drug research.

At the stage of drug validation, a huge range of technologies are now becoming available to rapidly and simply facilitate the process of assessing the efficacy and safety of potential drug leads.

At the manufacturing stage, an increasing proportion of drugs will be manufactured using genetic expression. This is partly a result of fact that a majority of new therapeutics will be biological in origin. Production of products by genetic engineering will have effects on the costs and quality of drugs. The basis of production of these drugs is also likely to become more diverse, with production in live animals and in plants becoming possible. These novel manufacturing possibilities will also present opportunities for novel delivery of therapeutics in foods. Oral delivery of genetically engineered paediatric vaccines in bananas and milk are among a wide range of possibilities. This will affect the economics of drug production, although it will also create new challenges for the regulatory process.

There are however, considerable ethical and hazard related issues that has to be addressed regarding manufacturing drugs in plants and animals. E.g. one of the main concerns is the risk of new and unknown epidemics based on disease transmission from animals to man (zoonosis) and from man to animals. Another concern is the risk of gene flow from gene-modified plants to the wild fauna as well as conventional crops.

**Drug Prescription:** In parallel with the changes in the nature and diversity of drugs, our increasing knowledge of individual genomes will produce more information about individual differences in ability to metabolise drug products. Our current treatment paradigm is one in which one disease is treated by a narrow range of drugs. The efficacy of these drugs is judged based on a population basis. However, there are major variations in metabolic ability between

different individuals. Thus while the majority of the population will benefit from these drugs, others will not. Equally the effectiveness of dosage or mode of administration will also vary among individuals.

- Multidisciplinary functional genomics approaches to basic biological processes
- Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches
- Development of new diagnostics
- Development of new in vitro tests to replace animal experimentation
- Development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders) and immunotherapies
- Innovative research in post-genomics, which has high potential for application

## *The ICTEC-Cluster: Information and communication technology*

The ICTEC Cluster comprises all information and communication technologies relevant for the healthcare sector, as for instance: Surgery Assisted By Computer, Minimally Invasive Systems for Diagnosis and therapy, Integrating IT, Medical Imaging and Robotics, Telecare and Telemedicine/Health Telematics, Decision Support Systems, Bio-Informatics, E-health/Public Health Information/Services and tools for Independent Living and Security. For instance:

- **Surgery assisted by compute**r: it enables a less invasive surgery, carried out by minimum-access robotic techniques, but also it allows to optimise the surgery itself and to reduce its risks by simulations. Information technology development will contribute to that process increasing the availability of *health information* among citizens and consequently the opportunities for self-diagnosis, self-care and self-treatment.

- **Integrating IT, medical imaging and robotic**s, including image processing, virtual reality, storage analysis and interpretation, robot-assisted surgery, image-guided surgery and conform 7 radiotherapy. A less invasive surgery will have a positive impact reducing both the risk of failure and the length of stay in the hospital (reducing consequently the total number of beds required).

- **Telecare and telemedicine,** including remote delivery of health, care and support services and information to people in their own homes, over the new high-speed digital telecommunication infrastructure, and the remote exchange and delivery of medical diagnosis, consultation and information (doctor-to-doctor and doctor-to-patient). Telecoms will allow remote monitoring of patient's condition or behaviour from a centralised facility. Furthermore, telecare and telemedicine will be crucial for providing healthcare services to rural areas at a reduced cost, with consequent positive effect on social cohesion.

- **Health Telematics:** Information and communication technologies will be an important enabler of diagnosis and preventive medicine, providing a range of sensor, imaging, computational, data-storage and data-retrieval, and other capabilities for activities ranging from diagnosis and treatment to far more efficient management of medical records. The application of these technologies in the healthcare sector is usually referred to as “health telematics”, “telehealth” or ‘e-health”. Health telematics means the remote delivery of healthcare and support services and information to people in their own

homes, over the new high-speed digital telecommunication infrastructure. It comprises also "telemedicine" for the remote exchange and delivery of medical diagnosis, consultation and information (doctor-to-doctor and doctor-to-patient).

- **Decision support systems** (DSS), including systems to provide information, analysis or options to assist in diagnostic, therapeutic and prescription decisions, and assist in organising treatment plans. DSS will be an essential complement to evidence-based medicine and to medical information systems, improving use of available information on diagnosis, prognosis, studies, prescriptions and treatment options. Future diffusion of smart cards with full health history of individual patients.

- **Bio-informatics** is the science that uses biological data and knowledge stored in computer databases. There will be diffusion of databases containing gene sequence data and protein sequence data. Furthermore, connections of healthcare centres to national electronic information networks for patient records and information will provide accurate diagnosis, treatment and outcomes.[20]

## *The MEDTEC-Cluster: Medical devices and tissue engineering*

The Cluster of other Medical Technologies comprises: Innovations in Smart Materials, Nanomaterials, Therapies and Drug Development, Tissue Engineering, Hybrid and artificial organs, Xeno-Transplantation, miniaturisation and integrated Microsystems, prosthetics, gerontechnology, etc....These include:

- **Gerontechnology**: Less Invasive Surgical Procedures, Wound Healing Technology, Prosthetic and Implant Technologies, Rehabilitation-Technology, Assistive Technologies & Home-Based Nursing Care Technology.

- **Innovative problem solving materials:** Materials technology will produce products, components, and systems that are smaller, smarter, multi-functional, environmentally compatible, more survivable, and customizable. These products will not only contribute to the growing revolutions of information and biology but will have additional effects on manufacturing, logistics, and personal lifestyles. Increases in materials performance for power sources, sensing, and actuation could also enable new and more sophisticated classes of robots and remotely guided vehicles, perhaps based on biological models.

    - **Agile Manufacturing**: Smart Materials, Nanomaterials, innovative problem solving materials Novel Nanoscale Computers, Food- and Nutrition-Technologies, Medical devices and tissue engineering, Diffusion of bio-artificial organs, smart prosthesis, xenotransplants and biosensors.

    - **Nanofabricated Semiconductors**: Nanomaterials such as semiconductor "quantum dots" could begin to revolutionize chemical labeling and enable rapid processing for drug discovery, blood assays, genotyping, and other biological applications.

[20] Finnish Ministry of Trade and Industry and Tekes (National Technology Agency), On the way to technology vision, http://www.vn.fi/ktm/eng/2ktm_etu.htm and Life 2000 - Biological Functions 2000-2002, http://www.tekes.fi/eng/technology/tekno_tiedot.asp?id=205

- **Implants of medical devices, Hybrid organs and tissue engineering** (the latter may totally replace and make obsolete the former): human tissues or organs (e.g., autologous or allogeneic tissues), animal tissues or organs (e.g., transgenic animals or xenotransplants), processed, selected or expanded human or other mammalian cells (e.g. stem/progenitor cells, genetic and somatic cellular therapies), with or without biomaterials, totally synthetic materials of biomimetic design, diffusion of bio-artificial organs, smart prosthesis, xenotransplants and biosensors.

- **Minimally Invasive Systems for Diagnosis and Therapy:** Integrating information technology, medical imaging and robotics will revolutionise the future of surgery. A wider diffusion of image processing, virtual reality, storage analysis and interpretation, robot-assisted and image-guided surgery will strengthen existing minimally invasive techniques. They usually result in less pain, scarring and recovery time for the patient (particularly important for elderly people) as well as reduced health-care costs. These techniques will have a direct effect on healthcare systems structure due to the reduction of the length of stay in the hospital for recovery and consequent reduction of the total number of beds required, and through performance of operations on an outpatient. Furthermore, techniques for non-invasive tissue microscopy and tissue architecture visualisation will be particularly critical for diagnosing diseased tissues.

## The footprint matrix: prevailing Healthcare Technologies and their delivery dimensions

| Key dimensions of Healthcare delivery | Prevention | Promotion | Monitoring health | Diagnosis | Treatment | Aftercare |
|---|---|---|---|---|---|---|
| GENTEC | Many diseases are genetically determined either directly through genetic defects, or indirectly through making the bearer more susceptible to disease. This susceptibility may be affected by diet, age, stress or other lifestyle conditions. Vaccines will also be developed using genetic technologies. In addition, it is highly likely that future vaccines will be live organisms engineered to express a range of antigens aimed at different diseases. Another approach at vaccine production will be the use of live pathogens from which the genes for pathogenic action have been deleted. These vaccines have a high immunogenic action.[21] | The increasing knowledge of functional genomics will vastly increase our knowledge of the relationship between genes and disease. This will allow us to develop personal lifestyle guides for people with propensities for different diseases, thus reducing the incidence of certain diseases. | GENTEC will enable a paradigm shift to a heavier concentration on preventive medicine and reduce the frequency of misdiagnosis and reduce societal costs for treatments based upon these diagnoses. | The above genetic knowledge will also facilitate highly accurate genetic diagnostic testing to determine genetic defects, indicators of disease propensity etc. It will also allow diagnosis of the metabolic status of patients, which will have a major relevance to the ways in which patients are treated for certain illnesses. This is further discussed below in relation to pharmacogenetics. However, a number of challenges and problems are related to genetic diagnostic testing of healthy individuals. Firstly, it is important to secure the right of citizens who prefer "not to know". Secondly, it is anticipated that the increasing number of genetic tests will result in an increased need for counselling.<br>In addition to greater understanding of man's genetic makeup, the genetics of human pathogens will also be elucidated. One outcome of this will be the identification of highly specific methods for identification of specific bacterial, viral and protozoan pathogens. This technology will be applied to high-spec, rapid identification of human pathogens. This will also allow earlier and more specific intervention by clinicians. | The specific are of genetic disorders has potential for treatment by a range of 'gene therapy' technologies. These therapies aim to compensate for the lack of a protein by delivering the missing protein at the specific locus of appropriate expression. Examples include current research aimed at delivering proteins to the lungs of cystic fibrosis patients, or to the eyes of Retinitis patients. These therapies are complex because they require both the identification and the genetic capability of producing the protein, and also a mechanism for local delivery. To date there is no approved example of this technology, but it is likely that they will emerge (SCID).<br>To date there is no approved example of this technology, but it is likely that they will emerge.<br>Early high hopes of applying this technology or treatment have been replaced by more cautious assessments, but gene therapy is nonetheless seen as holding important promises for treatments. In addition to therapies which are directly based on genetic technology, gentec will also have a significant impact on other healthcare technologies. Antibody-based drugs, for instance, which are a rapidly growing group of therapies, will be produced by genetic expression, and the targets for their operation will also be identified through the use of genetic mechanisms. | Improved Drugs and Drug prescription |

[21] New vaccines are being developed by using genomics. Vaccines are developed against both communicable diseases such as tuberculosis and malaria as well as chronic non-communicable diseases.

| | | | | | | |
|---|---|---|---|---|---|---|
| ICTEC | Self-care (maintaining wellness), better access to care (provision of care when/where it's desired, reduced need for travelling), improved encounter with care service (speedier), empowerment (encounter is more of a dialogue), reduced readmission into the system, improved social inclusion and independence. | Optimisation of resource use, scale economies, better use of public health information (e.g. dissemination of health promotion information), reduction of inappropriate readmission, more highly skilled workforce. | I&CTEC will be an important enabler of diagnosis and preventive medicine, providing a range of sensor, imaging, computational, data-storage and data-retrieval, and other capabilities for activities ranging from diagnosis and treatment to far more efficient management of medical records. Imaging at cellular and sub cellular level will be particularly critical for diagnosing diseased tissues. | ICT can provide tools to support decision making, knowledge management. | ICT can facilitate provision of the right information at the right time.<br>Easier access to appropriate patient-specific information, easier access to general professional information, appropriate use human resources, decision-support (including access to additional expert opinion). | ICT is a backbone of telecare/smart homes to support independent living. |
| MEDTEC | Protecting against disease by preventing or reducing the risk of its occurrence or reoccurrence, or limiting its security, e.g., vaccine-delivery devices, prophylactic devices, and sterilisers. | Enabling patients to lead a fuller and more comfortable life, often outside the hospital environment and often returning to full time employment, for example by means of ambulatory infusion pumps and monitoring equipment | Screening: detecting a disease or abnormality, or risk factor associated with these in asymptomatic populations, e.g., mammography for breast cancer, prostate-specific antigen testing for prostate cancer, and colorectal cancer screening devices and tests. | Identifying the cause and nature or extent of disease, e.g., CT for head injuries, angiography for atherosclerosis, and glucose monitoring tests for diabetes. | Restoring maintaining, or improving health, including cure of acute disease, care of chronic conditions, palliation to relieve or alleviate when cure is not possible, or avoidance of deterioration, e.g., drug delivery systems, prosthetic joints radiation therapy for cancer, bio artificial organs and laparoscopy for minimally invasive surgery. | Rehabilitation: restoring, maintaining or improving an impaired person's ability to function, e.g., ambulatory aids, incontinence and ostomy aids, sensory aids, and assistive devices for speech impairment |

# Critical Healthcare Technologies of the Future: Matrix 2020

From the footprint matrix, only those technology sub-categories have been further explored that were categorized as major scientific advances within the next 15 years, from expert judgement and national foresight exercises (see Annexes I and II). The priority technologies identified in this respect were:

- Pharmacogenomics, Gene therapy, Gene diagnostics, and Stem Cells in the GENTEC-Cluster;
- Telecare and Telemedicine in the ICTEC-Cluster; and
- Minimally invasive systems (MIS) in the MEDTEC-Cluster.

Since the matrix 2020 indicates potential foreseeable implications based on progress and directions in current science and technology (S&T) and does not attempt to predict or forecast exact events and timetables, trends were gleaned from existing outlooks, testimonies, and foresights, providing collective opinions and points of view from a broad spectrum of individuals.

The matrix 2020 focuses on these issues as sub categories of the Technology clusters and provides a view toward 2020 in the absence of any new policy initiatives in the EU. If no policies are developed, it can be foreseen that in 2020 the actual situation will still be far from ideal. The ideal can be defined as equal access to cost-effective, high quality technologies in a wide range of specialties in a wide range of indications, as part of a healthcare system which' organization has been adapted to (and ideally has helped to shape) technological developments.

## The GENTECH-Cluster

## Sub-category: Pharmacogenomics

### *History and development*

Pharmacogenomics is the study of the relationship between human genetics and pharmaceutical action. In simple terms, it is the study of why drugs don't have the same effects in all patients. The major factor in this 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 and thus tailor drugs to individual needs.

Pharmacogenomics is one of the many areas of knowledge which has been made possible because of the genome screening programmes. While it has been long known that patients vary in their response to drugs, the ability to determine the genetic causes was absent. Recent studies with twins suggest that 80% of observed variability in response to drugs is related to genetic make-up.

Pharmacogenetics evolved in the 1950's in research efforts to explain genetic differences that cause people to metabolize drugs differently. Before technology allowed isolation of individual genetic variation, pharmacogenetics and its predecessors were based on gross ethnic variation. Allelic or genotype variance between people was inferred based on gross ethnic differences between the three major ethnic groups: the Negroid, Mongoloid and Caucasoid. These could be further narrowed by loose classifications based on geography, anthropology, language, and race.

Many of these studies were chance observations, or curiosity-driven studies of drug response in different races. Eventually the collected data showed that ethnic difference was a significant factor, which should be a standard part of any drug development process.

The critical genetic variations between patients can affect many metabolic pathways, but in general terms they mainly affect drug pharmacokinetics, i.e. drug ingestion, absorption, metabolism, clearance, and excretion. All drugs are taken in by the body, assessed for usefulness and then broken down and excreted. The metabolic apparatus for accomplishing these tasks are different in many of us, with the result that drugs may be rapidly broken down and excreted, or may be present in the body for a long period.

The cytochrome P450 (CYP) family of enzymes is primarily involved in drug metabolism and is the subject of much research in this respect. The CYP2D6 enzyme (and numerous variants) is involved in the metabolism of 30-40 commonly used drugs. Because of genetic differences, some people metabolise drugs slowly, and others rapidly. The former may be exposed to the active drug for longer rapid metabolisers. Conversely, ultra-rapid metabolisers may have long exposure to the metabolite and only a short exposure to the administered medication. These differences will result in very different patient responses.

The other potential basis for difference is in pharmacodynamics, i.e. by variations in the way in which the drug has its effect. Some drugs act on cell receptors that have different structures (polymorphisms) in different patients. These differences may also affect the effectiveness of the drug. The overall effectiveness of a drug in any individual may be a combination of variations in systemic drug levels and receptor polymorphisms.

Physicians and pharmacists have long been aware of different patient responses, but have had no accurate way to predict them. Currently, genomic and genetic research provides the capability to genetically type individuals which includes information as to how individuals metabolise drugs. It has significance in many areas but particularly in drug development and patient treatment.

## *Organization of the field*

The field is as yet developing and most of the activity is of a scientific rather than a clinical nature. The major areas of interest and activity are:

- Drug development research
- Genomic screening of patients
- Research on factors of relevance to drug metabolism

***Drug Development***: As yet, pharmacogenomics is mainly of interest to the drug development industry and associated research and service providers. Establishing a relationship between the patient's genetic make-up and their response to a particular drug is clearly important in understanding drug efficacy and safety. Many of the large drug companies therefore have major activities in this field. In addition, the clinical research organisations that service this industry are also interested in genetic screening of subjects being enrolled for drug trials.

***Genome Screening***: There is significant activity worldwide in screening populations to seek genes relevant to particular diseases. In addition, when specific genes are found, there is interest in establishing variations between individuals within these genes. This activity is mainly carried out by genomic companies, many of which specialise in particular disease areas. Some of these companies specialise in pharmacogenetic factors. However, most of their output will be sold to diagnostics companies, or to the drug developers. The output will take the form of strategic

information (e.g. patents) linking specific genetic sequences or genes with specific pharmacogenetic activity.

***Functional Genetic Research:*** There is also a significant body of research at a more basic scientific level looking at the genetic factors that affect variations in drug metabolisation. The genes involved can affect either pharmacokinetic or pharmacodynamic factors. Pharmacokinetic effects will affect the way in way in which the drug is absorbed by the body or the mechanism or rate at which it is broken down or excreted by the body. If the drug does not reach the target organ, or is not delivered in the intended dosage or duration, it will have obvious consequences for the efficacy of the drug. Pharmacodynamic factors are those which affect the specific mechanism of action of the drug. For instance, if the drug is targeted to a particular receptor or enzyme, some patients may have small variations which result in these targets not being recognised by the drug.

### *Current status*

Pharmacogenomics is currently at the research phase. However, it is already very clear that genetic factors are a major determinant of drug efficacy, and that there are significant genetic variants between patients. Therefore both the drug development community and the regulators of drugs are actively involved in the monitoring and development of the field.

There are also major programmes of research in progress worldwide. These programmes include both clinical disease researchers which are using genetics as a mechanism, and also geneticists who are applying their expertise to the identification of genes of relevance to a particular disease. These programmes are rapidly elucidating information on the genetic factors affecting the action of particular drugs or drug classes. In addition to extensive commercial and nationally funded activities within the EU, the Sixth Framework Programme for Research and Technological Development also has a significant area of activity in "*Rational and accelerated development of new, safer, more effective drugs including pharmacogenomics approaches.*"[22]

## Sub-category: Gene therapy

### *History and development*

Gene therapy is a potential method of treating genetic disorders which is the subject of extensive research and trials worldwide. Genetic disorders are caused by a defective or deficient gene which results in the lack of an essential protein and/or in the expression of a defective protein with adverse effects. About one in ten people suffer from an inherited genetic disorder. Many of the serious disorders are currently untreatable and a significant proportion can be fatal.

The theoretical mechanism of gene therapy is to treat the disorder by delivering a 'working' gene for the missing protein at the specific locus of appropriate expression in the body. Gene therapy does not correct the defective gene, but it fulfils the same function by an alternative means. The 'therapeutic' gene may be contained in a virus or other vector but is not a part of the patient's own genetic make-up. This external gene expresses a protein which takes the place of the protein which is missing due to the genetic disorder.

[22] Calls for proposals for indirect RTD actions under the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" OJ C 315/1 of 17/12/2002

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"[23] The advantages of this therapy are the local delivery of the protein to a specific tissue, and the on-going nature of the delivery.

An example of a disease target is cystic fibrosis, which is caused by the lack of a protein which metabolizes mucus in the lungs. Absence of this protein causes severe lung congestion in cystic fibrosis patients. One gene therapy approach has been to introduce a virus, genetically modified to produce the missing human protein, into the lung. The concept is that the patients cells (using the DNA inserted by the virus) will continually produce the missing protein throughout the lung.

Many other genetic disorders have potential for treatment using 'gene therapy' technologies. The major targets to date include: Cystic Fibrosis, Severe Combined Immunodeficiency Syndrome (SCID), and Retinitis Pigmentosa.

About one in ten people has an inherited genetic disorder, and approximately 2,800 specific conditions are known to be caused by defects (mutations) in just one of the patient's genes. Some single gene disorders are quite common - cystic fibrosis is found in one out of every 2,500 babies born in the Western World - and in total, diseases that can be traced to single gene defects account for about 5% of all admissions to children's hospitals.

Techniques in development are also aimed at correcting defective genes. This is accomplished at the transcription stage rather than within the chromosome. These techniques are still in early development.

## *Current status*

The technical obstacles to development of these therapies are very significant. An effective Gene Therapy must deliver a specific protein in appropriate dosage and frequency at a specific location in the body. This pre-supposes the identification and production of the missing protein, and also the availability of a mechanism for local delivery. The usual experimental mechanism for protein delivery in trials to date has been the use of benign viruses; and the disease targets have so far been those affecting the more accessible tissues e.g. the lungs of cystic fibrosis patients, or the eyes of Retinitis Pigmentosa patients. Possibly the greatest challenge, however, is to make the therapeutic gene express the protein reliably and at clinically beneficial levels in the target tissue.

The first trial of a gene therapy took place in Sept. 1990 and there have been over 400 since then. In the USA there have been 300 Investigative New Drug (IND) notifications of gene therapies in development. However, these trials have been very disappointing. Trials have been halted on several occasions due to the death, and illness, of trial patients. Even those trials which have been technically successful in demonstrating the technology have fallen far short of therapeutic efficacy[24]. To date no market approval of a gene therapy has been given by any regulatory authority. However, it is likely that effective therapies will eventually emerge and the technical problems confronting the field continue to be overcome.

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[23] HUGO Ethics Committee: Draft Statement on Gene Therapy Research http://www.hugo-international.org/hugo/genetherapy.htm

[24] Gene therapy has proven to be effective in children with SCID, and it is being done in many cases already, though there is a risk of cancer

## Sub-category: Gene diagnostics

### *History and development*

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 hereditary diseases. Such diseases are either the result of chromosomal abnormalities, which can be visualised by conventional microscopy, or of mutations in DNA. 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.

Genetic diagnostics also has a wider relevance to healthcare as it is also a highly effective means of detecting microbial pathogens at extremely low levels, and can also differentiate between pathogenic and other strains of micro-organisms, which is difficult for immuno-diagnostic technology. The emphasis in this paper is on genetic disease applications of this technology.

Molecular genetics was originally applied in medicine to map and identify the major single gene disorders, such as cystic fibrosis and polycystic kidney disease. Focus is now to reveal the genetic basis of the more common diseases, most of which are caused by the interaction of several genes. With the help of samples from very large, families suffering from well-characterised diseases, genetic linkages for some of the major causes of morbidity and mortality in Western populations have been identified. Large-scale genotyping, increasingly integrated genetic and expressed sequence maps, and large scale sequencing programmes have all contributed to this remarkable evolution in our understanding of how genes might modify our susceptibility to disease, however many questions still need to be answered.

### *Current status*

According to The National Health Museum, Washington DC[25] the most widespread type of genetic testing is newborn screening where infants have blood samples tested for abnormal or missing gene products. Some tests look for abnormal arrangements of the chemical bases in the gene itself, while other tests detect inborn errors of metabolism by verifying the absence of a protein that the cell needs to function normally.

Carrier testing can be used to help couples to learn if they carry - and thus risk passing to their children - a recessive allele for inherited disorders such as cystic fibrosis, sickle-cell anaemia, or the lethal Tay-Sachs disease. Genetic tests - biochemical, chromosomal, and DNA-based - also are widely available for the prenatal diagnosis of conditions such as Downs's syndrome. In clinical research programs genetic tests are used to identify telltale DNA changes in cancer or pre-cancerous cells. Such tests may facilitate early detection, diagnosis, prognosis, and treatment.

## Sub-category: Stem Cells

### *History and development*

Stem cells are cells that have the ability to differentiate into other types of cells and potential use for cell-based regenerative therapies. All cells in the body continually regenerate themselves and therefore all tissues have a set of cells from which all of these new cells arise. These are the

[25] www.nationalhealthmuseum.org, visited 25.01.2003

tissue stem cells. On the same basis, every embryo has stem cells from which all of the tissue stems cells originate. Their proliferative capacity combined with the ability to become specialized makes stem cells unique.

In the 1960s, it was recognized that certain mouse cells had the capacity to form multiple tissue types, and the discovery of bona fide stem cells from mice occurred in 1971. Understanding of embryo stem cells developed from the beginnings of *in vitro* fertilization (IVF), when oocytes were matured and fertilized in vitro in the early sixties.

Moving to clinical work involved aspirating fully mature human oocytes. These oocytes could be fertilized in vitro, and grew through cleavage stages to blastocysts, and then a large embryonic disc. Embryo transfers to the uteri of infertile patients were initially unsuccessful, but in 1978 the first IVF baby was born in Britain.

## *Current status*

The ultimate (toti-potent) stem cell is the fertilized egg, from which derives a hierarchy of gradually specifying stem cells that form the tissues and organs of the foetus and support growth and repair in the newborn and adult individual. These cells can give rise to another embryo and thus all tissue types. Once the fertilized egg has developed to the early blastocyst stage, pluri-potent embryonic stem cells develop in the so-called inner blastocyst cell mass. These cells have the potential to form all tissues in the body, but cannot develop into a new living foetus. The embryonic stem cells soon differentiate into lineages of multi-potent stem cells, destined to form the various tissues and organs in the foetus. Tissue-specific stem cells are abundant in foetal tissues and organs, and remain present in reduced numbers in the newborn and later in most, if not all, tissues and organs of the adult individual. The tissue-residing "adult" stem cells are the basis for growth and repair of tissues throughout life. But tissues differ in this respect with good repair of skin, but poor or insufficient repair of brain and spinal cord or pancreatic insulin-producing cells (Rasmussen, 2003).

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.

Ten laboratories in the United States, Australia, India, Israel, and Sweden reported that they have derived stem cells from 64 individual, genetically diverse blastocysts that meet the US criteria for use in federally funded human embryonic stem cell research. Several genetically diverse stem cell lines exist due to private research, however, only few companies have pursued the commercial use of stem cells as therapies so far. The majority of these are based in the US.

Limited types of stem cell therapies are already in use. The most well-known therapy is the stem cell transplant (a form of a bone marrow transplant) for cancer patients. In this therapy, stem cells that can give rise to blood cells (red and white).

## *Organization of the field*

The technological field is characterised by an early stage of development. There is a lack of coordination of stem cell research activities across governments, non-government agencies, and

the private sector in the EU as well as in the US.

## ICTECH-Cluster

## Sub-category: Enabled home care delivery[26]

In this report we make a distinction between *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 healthcare workers communicate amongst themselves more effectively). Telecare and telemedicine are each a component of eHealth, a much broader definition of ICT-driven activities which are transforming the delivery of healthcare (Richardson et al. 2002).

Our main focus here is on *telecare.* This is because of its potential importance 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 (Tang et al. 2000; Bradley et al. 2003). Effective integration of care and support services, including the widespread use of telecare, could therefore improve the quality of life of citizens by enabling safer independent living and increased social inclusion.

Telecare has already been deployed in numerous pilot projects and small-scale trials across Europe and elsewhere (Curry et al. 2002). A range of telecare equipment is currently available, including:

- passive devices to detect falls, wandering and other hazards such as fire or gas and trigger a human response or shutdown of equipment
- electronic prompts and memory aids
- lifestyle[27] and physiological monitoring systems[28]
- specialised telephones and videoconferencing.

There is also a range of 'assistive technology' (equipment or system that assists people who have difficulties, due to the natural frailties of age or a disability, in carrying out everyday activities) currently available, some of which has the potential to be integrated with telecare applications[29]. Electronic assistive equipment is available for use in the home by people who have such severe physical disabilities that their needs cannot be met by conventional home adaptations. A system will typically be operated by a single switch and a scanning selection unit, or with a sensitive programmable keypad or by voice control. Functions include control of visitor access, door opening and closing for the wheelchair-mobile user, personal alarm

[26] Other sub-categories: Pervasive healthcare (anytime, anywhere access …), generic ICT (for eHealth, eProfessionals / eWork, eLearning, eReach, eTeams), DSS / EBM: in light of chronic and degenerative diseases, safety, ethics, cost-effectiveness reimbursement, integration, organisation of care, see also the IPTS Roadmap on Ambient Intelligence.

[27] Lifestyle monitoring is a relatively new concept and entails the continuous or intermittent gathering and interpretation of data relating to the movement, activity and behaviour of people in their homes.

[28] Medical physiological monitoring systems have been in use in hospitals and GPs' surgeries for several years. These are now available in ruggedised forms suitable for patient use in their own homes. This extension of medical monitoring to the home or community is sometimes referred to as community telemedicine.

[29] The term assistive technology covers simple items such as walking sticks, bath seats and grab rails, as well as electro-mechanical equipment (e.g. powered wheelchairs), electronic aids (e.g. digital hearing aids and environmental controls), or equipment used by carers such as lifting aids. There is a fuller discussion of the scope of assistive technology in Marshall (2000) and in Cowan and Turner-Smith (1999).

functions, control of furniture and beds, control of the ambient environment and operation of home entertainment and communications equipment.

Telecare services and 'smart homes' – homes in which ICT has already been installed to help control a variety of functions and provide communication with the outside world – also share a common ICT base. Smart homes and telecare services are natural companions, since both product (smart home) and application (telecare) entail similar technology, and core functions of smart homes are potentially of great benefit in assisting in home care provision[30] (Fisk 2001; Tang and Venables 2000; Woolham and Frisby 2002). For example, the monitoring equipment for telecare would probably already be installed in a smart home thus avoiding the need for retrofitting. A basic and widely accepted parameter for smart homes systems is that they should be modular, i.e. with the ability to add functionality as needs arise. The implication for telecare is that changes in a patient's health and social care status can easily be accommodated by installing or removing modules as appropriate.

The challenge for the next decade is to provide customisable packages of telecare (including assistive technology) which can be easily deployed in individuals' homes according to their evolving needs. This will be facilitated by developments in a range of core enabling technologies, notably:

- Communications (e.g. Internet/broadband connectivity, mobile and fixed telecommunications, digital interactive TV (DiTV), Bluetooth).
- Digital interfaces (e.g. information presentation, touch screen technology).
- Database and data mining technologies (e.g. data fusion, smart cards, expert systems, decision support systems).
- Sensors and actuators (e.g. wearable/implantable vital signs sensors, biochemical sensors, environmental control sensors).

These core technologies can potentially be of great benefit in complementing and extending existing care service delivery. Their development has not been targeted at health and social care but at bigger mass markets where there are financial returns available to offset the development costs. However, the demand for the introduction of telecare is likely to be high in the next two decades, driven by the ageing population, healthcare budgetary constraints and a growing acceptance that care at home is, for most people, more desirable than care in an institution. The short term is likely to see the introduction of new telecare products, making use of these core technologies, which facilitate the extension of an increasing number of hospital services to the home.

# MEDTECH

## Sub-category: Minimally invasive surgery

### *History and development*

Minimally invasive surgery (MIS) is today a very broad category of medical technologies using an even larger set of HCT. One of the main ideas is that the integration of different modalities will continue resulting in more complex hybrid systems comprising nanotechnologies / MEMS all the way to 3-/4-D multimodality imaging systems. The market for MIS related HCT is also becoming segmented with the already established less costly MIS devices and at the high end

[30] In this context smart homes are sometimes referred to as 'safe' or 'caring' homes.

the R&D / experimental systems.

In parts MIS 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. Nowadays, nearly every organ system in the body can be approached by these technologies. Fiberoptic endoscopes allow visualization of the entire gastrointestinal tract (esophagoscope, gastroscope, duodenoscope, enteroscope, and colonoscope), the urinary tract to the kidney (cystoscope and ureteroscope), the abdominal organs, including the internal female sexual organs (laparoscope, applied through a small incision in the skin of the abdomen), the interior of the uterus (hysteroscope), many of the joints (arthroscope), and much of the lung through the breathing passages (bronchoscope) and via the chest (thoracoscope). In addition, the colposcope is used to visualize the lining of the cervix and the vagina. Tools have gradually been incorporated into these scopes. Miniature forceps, scissors and tools for tying ligatures were first, and they are still being improved.

Within the last 30 years, other advanced tools, including lasers, heater probes, electrocoagulation devices, and cryotherapy devices, have also been incorporated into these scopes. Catheterization, based on developments in cardiac catheterization, has been a diagnostic tool for more than 50 years. More recently, it became the basis for innovative treatment procedures. New imaging techniques are also important in MIS. Imaging techniques have two purposes which interact with each other. One purpose is to identify and characterize a lesion requiring treatment. The other purpose of imaging is to assure that the treatment modality is in the correct location and to monitor the treatment. Imaging makes other contributions to MIS. For example, in CT scanning, radiologists have recognized that biopsies could be guided by such imaging. Later, CT scanning and ultrasound were used to guide therapeutic procedures, such as draining abscesses in the abdomen. Drugs can also be installed in certain parts of the body by guided needle. The newer endoscopes are in themselves imaging devices. Perhaps the most important fact about endoscopes is that their images can be projected onto colour monitors, resulting in a situation where high quality images can be seen in the operating room, and can be observed by participants simultaneously (Banta 1993a).

In the past, surgery was exclusively done by large open incisions which gave good visualization of a potential problem and also sufficient room to remove a problem such as a tumour, to tie blood vessels, and so forth. However, already before the advent of MIS, surgery gradually changed. People did and do not like to have large surgical scars on their bodies. In addition, open surgery is associated with serious short- and long-term complications. New instruments made it possible to do surgery through smaller incisions. Surgeons became more skilful. Therefore, surgical incisions became smaller and surgical techniques changed. Examples of such less invasive surgery include lumpectomy instead of mastectomy and rectum-saving operations in colon cancer surgery.

The pace of change, however, has dramatically increased due to the advent of the technologies just described (Banta 1993a). Because MIS has fundamentally changed surgery, its development has been characterized as a ‘seminal shift in philosophy’, a ‘revolution’ (Wickham 1993, Himal 2002), and a ‘paradigm shift’ (Mack 2001). For patients, it holds the promise of improved outcomes manifested as improved survival, fewer complications, and more rapid recovery resulting in quicker return to functional health and productive life (Mack 2001). For the healthcare sector, MIS holds the promise of increased cost-effectiveness of care. As a consequence, there may be benefits as well for society as a whole.

## *Current status*

In the late eighties it was felt that an attempt should be made to bring together diverse strands of interests into one recognizable society. The key groups seemed to be surgeons interested in MIS, interventional radiologists, and the instrument manufacturers. A number of interested parties inaugurated the first meeting of the new society in London in 1989, where the group, in order to accommodate radiologists, agreed to the term 'minimally invasive therapy' instead of choosing 'minimally invasive surgery' (Wickham 1993). One year later a new journal was established, entitled 'Minimally Invasive Therapy and Allied Technologies'. In 2000, the Society was formally changed to 'Society for Medical Innovation and Technology', acknowledging the fact that an increasing range of technological innovations plays a role in the development of MIS.

Since then, a myriad of societies have emerged, both national and international in scope. Of particular relevance may be the International Society for Minimally Invasive Cardiac Surgery[31], as technological development in this field is extremely rapid. One of these developments results in reducing the invasiveness of coronary artery bypass surgery by allowing the surgeon to operate on a beating heart, eliminating the need for a heart-lung machine (Mack 2001). The ISMICS was formed in Paris in 1997, following a World Congress of Minimally Invasive Cardiac Surgery. A journal was established in 1998, entitled 'The Heart Surgery Forum'. Virtually all societies organize annual meetings, either nationally or alternating between Europe and the USA.

Concurrently, in a number of countries regional centres for minimally invasive surgery have been established that provide opportunities for training and research in a variety of specialties. Sometimes these centres also act as a source of public information, e.g. the Centre for Minimally Invasive Therapy in Leeds (UK)[32]. From these activities it can be inferred that those who have an interest in MIS have adequate platforms for being informed on the state of the art in highly specialized fields and, increasingly, to receive appropriate training.

## *Diffusion of MIS in the US and the EU*

Data from the United States show that MIS has become widespread in the late nineties in at least 7 specialties: general surgery, gynaecology, urology, plastic surgery, thoracic surgery, cardio thoracic surgery, and vascular interventional surgery (Mack 2001). Of the 25 indications listed in these specialties, there were 8 in which MIS was performed in the majority of patients. Of these, the most frequently applied procedures are laparoscopic fundoplication for reflux esophagitis (95% of cases), laparoscopic removal of the gall bladder (laparoscopic cholecystectomy; 85% of cases), and selected applications in pediatric urology (80% of cases).

In the EU, in the early nineties a study was carried out on the diffusion of ten cases of MIS in five countries: the United Kingdom, Denmark, France, Germany and the Netherlands (Banta 1993a). The study showed that most cases had diffused slowly, with the exception of laparoscopic cholecystectomy, extra-corporeal shock wave lithotripsy and percutaneous lithotripsy, and catheter-based treatment of coronary artery disease, e.g. PTCA (Banta and Vondeling 1993) A detailed study comparing the diffusion of laparoscopic cholecystectomy in Denmark and the Netherlands showed a rapid and virtually complete diffusion of this procedure at the hospital level in both countries (Poulsen et al., 2001). In a September 1992 Dutch newspaper article, it was stated that laparoscopic cholecystectomy is applied in about 75% of cases in The Netherlands. This figure was deemed representative of other European countries

[31] ISMICS, home page http://www.smit.de/organization.html
[32] http://www.limit.ac.uk/limit.htm

(Scholtens 2002). Laparoscopic appendectomy, however, is only carried out in 8% of cases in The Netherlands, compared to 60% in Belgium. Other common laparoscopic procedures are estimated to be carried out in 20 to 30% of cases in Belgium and France, compared to a few percent of cases in The Netherlands, which is ascribed to budgetary- and personnel problems (Scholtens 2002). These data indicate marked differences in the diffusion of different MIS procedures in individual EU countries.

At the hospital level, there is a trend towards the organization of MIS procedures in different specialties in a single dedicated suite, the first of which was operational in 1993 (Kenyon et al., 2001). Three companies play a major role in this development of which the biggest, located in the US, has sold 900 suites worldwide since 1992, 700 of which are located in the US[33] (). There are at least two European manufacturers producing suites like these, Storz and Wolf/Bechtold. Anecdotal evidence suggests that such dedicated suites are still rather uncommon in the EU. For example, to date only one hospital in Denmark operates a MIS suite, while a few other hospitals are in the negotiating phase (R. Juul-Larsen, personal communication). In The Netherlands a hospital in the north of the country recently claimed to be the first of its kind to start operating a fully equipped MIS suite[34].

It can be concluded that the field of MIS has become firmly established since its inception in the 80s, but at the same time it is likely that there are marked differences between the US and the EU, with more widespread diffusion and more intense use of MIS in the US. In addition, there are significant differences between Western-European countries. The diffusion of MIS in other EU countries, including the ten new members, is undocumented. Overall, the diffusion of dedicated MIS operating rooms seems in its initial phase in the EU.

### *Drivers*

According to the home page of the Society for Minimally Invasive Therapy and Allied Technologies[35], the leading driving factor is considered to be health(care) technologies of laparoscoendoscopic and endoluminal surgery, interventional radiology, cardio thoracic surgery, surgical robotics and image guided surgery. Of these, the application of robotics in minimally invasive endoscopic procedures is relatively new (Mack 2001). The implications of robotics for surgical procedures are discussed in more detail elsewhere in this report (ICTEC).

Other new technologies that are relevant for MIS include new materials, micro systems, tissue engineering, and the MIS suites, more generally formulated as ‘the operating room of the future (OR 2000+)’. One could infer from this that the development of MIS is primarily defined by a ‘technology push’. However, a study on the diffusion of MIS in The Netherlands, carried out in the early nineties as part of a study on the diffusion of MIS in five European countries, demonstrates that the diffusion of each individual application of MIS can be understood as the result of a combination of factors that stimulate or impede this process. In each case, specific combinations of factors determine the diffusion pattern in the healthcare system (Vondeling et al., 1993).

Factors that may slow diffusion of MIS include:

- budgetary pressures on hospitals, which make them reluctant to undertake new, capital-intensive procedures or procedures that require extra time or personnel

[33] http://www.strykerendo.com, visited 22-01-03
[34] http://www.chirugen-leeuwarden.org/endosuite01.htm, visited 23-01-03
[35] http://www.smit.de/organization.html, visited 21-01-03

- 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

Factors that may facilitate diffusion of MIS are:

- media reporting, fostering patient demand and physician interest
- the availability of respected medical innovators
- the ability of physicians to get reimbursement for new procedures in most cases, even if they do not (yet) appear in the benefit package
- commercial pressure and information
- the availability of appropriate training
- maturity of the procedure or technology
- policy measures encouraging the diffusion of a procedure, such as the decision not to regulate a procedure
- convincing evidence on (cost)effectiveness

Combining the Dutch study with data of the other countries in the EU-study, it was concluded that the payment system perhaps is the most important (impeding) factor in diffusion of MIS (Banta and Vondeling 1993). All countries examined in the study had some sort of budget caps or prospective budgeting system for hospitals intended to limit hospital expenditures. Most of these have been implemented in the 1980s (Abel Smith 1992), and have not been recalled. As mentioned earlier, the budget system is still regarded as a major impeding factor for MIS in e.g. Dutch hospitals (Scholtens 2002)

The most important force facilitating the diffusion of MIS is patient demand, as was documented in several case studies in the EU study, e.g. on laparoscopic cholecystectomy, ESWL and PTCA. Press reporting in these cases has fostered patient demand and physician interest, often to good effect, but not always, as patients are often unaware of the fact that the best results can only be achieved by well-trained surgeons (Hunter 2002).

Furthermore, the EU study showed that evaluation plays little role in choices in healthcare (Banta and Vondeling 1993). In a recent editorial in Surgical Endoscopy on clinical trials and

the development of lapraroscopic surgery, it was concluded that proper evaluation in randomized controlled trials and subsequent meta-analysis has by en large only been carried out in three indications: laparoscopic cholecystectomy, laparoscopic appendectomy, and laparoscopic inguinal hernia repair (Hunter, 2002). Likewise, as a consequence, evidence on cost-effectiveness is not a significant factor influencing diffusion either (Banta 1993b). High quality evidence is still extremely scarce in this area, although there seems to be consensus that laparoscopic procedures increase hospital costs, with a varying impact on total healthcare sector costs, depending on the specific procedure (Hunter 2002).

Mack (2001) lists a number of factors that further increase insight in differences in the speed of diffusion of individual MIS procedures, based on the distinction of three classes of complexity of surgical procedures. The first class covers excisional procedures, in which a structure is removed (e.g. appendectomy, cholecystectomy). The second class covers ablative procedures, in which tissue is destroyed (e.g. cryosurgery of hepatic tumours), and the third class is reconstructive, in which structures are joined and connected (e.g. bowel or Fallopian tube anastomosis). Excisional or ablative procedures are easier to perform than reconstructive procedures and are, according to this author, more easily adaptable to endoscopic techniques. Perhaps, as the most relevant ablative and excisional procedures are realized today, the relative complexity of reconstructive procedures can be regarded as a diffusion-impeding factor.

## The Matrix 2020: Critical Healthcare Technologies of the Future

| | Prevention | Promotion | Monitoring Health | Diagnosis | Treatment | Aftercare |
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| **GENTEC** | **Pharmacogenomics**:<br>Knowledge of human genetics will have significant benefits for disease prevention. However, pharmacogenomics is most relevant to the process of matching patients to appropriate drugs using genetic information. While the use of appropriate drugs will have a preventive effect in offsetting more severe disease, the major application of this technology will be in treatment or in design of future treatments.<br><br>**Gene therapy**:<br>To some extent gene therapies can be viewed as preventive. They do not prevent the genetic disorder, but they prevent the adverse consequences of the disorder.<br>Gene diagnostics: The most striking feature of these techniques is that they make it possible to foretell the presence of future pathologies, whether in the foetus or adult, long before symptoms are expressed. DNA testing for multi-factorial disorders often is followed by preventive measurements such as operations or life-style changes for which clinical geneticists have to rely on other professionals.<br>Human Genome Project and | **Pharmacogenomics**:<br>Pharmacogenomics will not have a major relevance to health promotion.<br><br>**Gene diagnostics**:<br>Individual counselling and personal life style guides for people with propensities for different diseases may reduce the incidences of certain diseases. | **Pharmacogenomics**:<br>Pharmacogenomics will not have a major relevance to health monitoring.<br><br>**Gene diagnostics**:<br>Monitoring of patients in whom symptoms are to be expected (in the absence of therapy) at some point in the future, e.g. in Huntington's disease. | **Pharmacogenomics**:<br>Pharmacogenomics will not have major relevance to disease diagnostics. However, diagnostics will have a very significant role in developing the concept of pharmacogenomics. Identification of patients with specific genetic traits will be required to determine suitability of drug options for patients. This will probably be done by genetic diagnostics. There is likely to be a niche within the diagnostics market for diagnostic products to determine genetic traits relevant to pharmacogenomics analysis.<br><br>**Gene therapy**:<br>No major impacts of Gene Therapy on diagnostics. However, accurate diagnosis of genetic defect will be a fundamental prerequisite in establishing the need for gene therapy.<br><br>**Gene diagnostics**:<br>Gene tests can make diagnoses on abnormal arrangements of the chemical bases in the gene itself, while other tests detect inborn errors of metabolism by verifying the absence of a protein that the cell needs to function normally.<br>Carrier testing can be used to help couples to learn if they carry - and thus risk passing to their children - a recessive allele for inherited disorders such as cystic fibrosis, sickle-cell anaemia, or the lethal | **Pharmacogenomics**:<br>In the future it can be envisaged treatment will involve a preliminary determination of the patient's genetic status. An appropriate drug will then be prescribed on the basis of their suitability to a patient's genetic make-up. This is a significant change from current practise and amounts to a customization of drug therapy to each patient.<br><br>**Gene therapy**:<br>Gene Therapy holds the promise of treating genetic diseases which are currently untreatable. Because of the way in which gene therapy works (see above) the diseases focused by gene therapy researchers have been single-gene disorders. The complexity of multi-gene disorders means that they are unlikely to be treatable by means of this technology for the foreseeable future. On the way to the clinical use of genetic therapy, significant problems have to be solved, especially in developing gene delivery vectors. One concern is that the use of virus may involve a risk of inducing or transmitting infections.<br><br>**Stem cells**:<br>Some of the most serious | **Pharmacogenomics**:<br>Pharmacogenomics will not effect major changes in aftercare other than the impact on drug prescription noted above.<br><br>**Gene therapy**:<br>Of their nature, genetic therapies will be lifelong. There will therefore technically be no aftercare.<br><br>**Stem cells**:<br>Replacement of damaged or malfunctioning cells can avoid costly medical treatment of chronic diseases, but no special new type of aftercare may bee expected after stem-cell based therapies.<br><br>**Gene diagnostics**:<br>Counselling and lifetime psychological support of patients with incurable diseases. |

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| | new diagnostic techniques may lead to advances in understanding the complex interactions between genetic, social, environmental and psychological factors by 2020. The HGP is expected to generate an explosive increase in the knowledge of the structure and function of human genes. Mapping will then, it is widely thought, lead towards new treatments and preventative possibilities. 'At risk' individuals can be presented with complex reproductive decisions aimed at limiting the inheritance of pathologies. | | | Tay-Sachs disease. Genetic tests - biochemical, chromosomal, and DNA-based - also are widely available for the prenatal diagnosis of conditions such as Down syndrome. | medical conditions, such as cancer and birth defects, are due to abnormal cell division and differentiation. Stem cells hold the most promise for those diseases where cells are damaged or malfunctioning, and might be replaced; for example, Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, juvenile diabetes, stroke, spinal cord injuries, and heart muscle damage following heart attack.<br>The ultimate goal is to grow new neurones and entire organs, at first outside the body but eventually in the body.<br>Human stem cells could also be used to test new drugs. For example, new medications could be tested for safety on differentiated cells generated from human pluri-potent cell lines.<br><br>**Gene diagnostics**:<br>The next stage beyond diagnosis is the use of the genetic data to improve treatment, (se sub category pharmacogenetics) and to make changes to an individual's genes (see sub category genetic therapy). | |
| **ICTEC** | **Primary role in HC delivery:**<br>Information provision, providing channels for public education – promotion of well-being (e.g. generalised health advice) | Health and social providers are able to deliver far more targeted care promotion messages and evaluate their effectiveness. | **Role in HC delivery**:<br>Supporting the shift towards home-based monitoring and community care and rational use of hospital services.<br>Supporting independent living | Care professionals have access to sophisticated tools that can support the diagnostic process, e.g. the rapid transmission of physiological parameters, automatic image analysis. | An expanding range of treatments take place outside institutional settings – these are currently limited to chronic disease management (e.g. COPD) and rehabilitation (e.g. | The introduction of telecare and telemedicine allows aftercare to be provided in the settings that patients want.<br><br>Role in HC delivery: |

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| | **Enabling technologies**: Internet, broadband connectivity, 3G / GPRS telephony, mobile/fixed telecommunication technology, DiTV, touch screen technology, database/data mining<br><br>**Issues for implementation:** Access issues: people should be helped to gain access and to understand use of new channels. The risk of exacerbating disparities between individuals/groups must be considered (e.g. access to information limited to few groups)<br>Need for multiple delivery channels – from paper to new technologies.<br>Resources to provide high quality content and tools for validating quality of information.<br>Acceptance of increased individual responsibility for own health and better understanding of individual health risks. Strategies for involving patients in their own care need to be developed.<br>Integration of services with mainstream care delivery system – depends on type of information being provided; how much feedback; data protection/confidentiality.<br>Availability of robust tools for demonstrating cost and clinical effectiveness – drivers for investment. | Role in HC delivery: Supporting public health – monitoring population health related behaviour. Distribution of information to appropriate stakeholders to facilitate methods to inform public policy. Promoting public debate and eliciting public views Facilitating public engagement in discussion of health matters. Documenting responses to treatment and gathering information on new disease threats and adverse effects of interventions<br><br>**Enabling technologies**: Knowledge management, advanced data warehousing (e.g. database/data mining); computing power (parallel processing).<br><br>**Issues for implementation:** Skilled resources to analyse data and quality of analytical tools.<br>Integration of services with primary and secondary care system – quality of information from providers.<br>Anonymity issues | – acquiring information on health and social status to inform health and social care professionals and to allow them to intervene appropriately.<br><br>**Enabling technologies**: Mobile and fixed telecoms, networked sensors, data handling, Digital interfaces: Info presentation, knowledge management, wearable devices, wireless<br><br>Issues for implementation: Public and professional acceptance of increased monitoring and new roles and responsibilities (move towards continuous rather than ad hoc monitoring of individuals health status). Support for professional and non-professional carers; Resources (skills + finance) Data protection; Availability of robust tools for demonstrating cost and clinical effectiveness – drivers for investment; Integration of services with mainstream care delivery system; Functional integration of technological systems (interoperability and connectivity) | **Role in HC delivery**: ICT has a role prior to/during/ and post diagnosis. Pre- and during diagnosis: Changing triage forms/ points of entry/contact with the system (e.g. virtual physician)<br>Enabling better access to information to support decisions and tools to optimise the process of decision-making.<br>Enabling a more rational use of services (e.g. improving the consultation process by supporting collaboration between professionals / professionals and professionals / patients).<br>Enabling tele-diagnosis (service delivery where and when it's needed) and the centralisation of complex and expensive diagnostic services.<br>Supporting the improved understanding of biological triggers/causes of disease.<br>During and post-diagnosis: Facilitating the analysis of medical decision-making to identify critical points where errors may arise and prevent them.<br>Supporting practice underpinned by evidence (Evidence Based Medicine)<br><br>**Enabling technologies**: Telecoms – mobile/fixed, Internet, Digital Interfaces – acquisition and presentation of information (e.g. PACS). Database/data mining, EPR/EHR, data fusion (linking pathology, radiology and other diagnostic information through an institutional network so that results can be obtained and analysed easily), Smart Cards, Decision-making tools (expert systems, decision support | speech therapy).<br><br>Role in HC delivery: Improving communication from diagnosticians to specialists delivering the treatment, and between specialists delivering the treatment (e.g. better feedback on clinical effectiveness of treatments).<br>Greater role for remote treatment (more for patient / therapist interaction than remote surgery).<br><br>**Enabling technologies:** Decision-making tools (expert systems, decision support systems), advanced data warehousing/mining, EPR, Wireless, Mobile/Fixed telecoms(remote surgery – tactile feedback, robotisation of surgery …), Internet, data fusion, smart cards, computing power, networked systems, Bluetooth technology.<br><br>**Issues for implementation:** Professional and public acceptance of new approaches to clinical intervention (consultation / surgery) and ability to adapt to new circumstances. It must be ensured that appropriately trained staff can use technologies to access and adapt to a changing knowledge base<br>Integration of services with other levels of the healthcare delivery system | Supporting chronic disease management and independent living – monitoring health and social status; intervention to provide care (e.g. assistance with medication regimen, rehabilitation). Facilitating automation of repetitive tasks. Supporting carers (formal and informal) through the provision of information.<br><br>**Enabling technologies:** Internet, broadband connectivity, 3G / GPRS telephony, DiTV, touch screen technology, database/data mining, networked sensors/actuators, wearable devices, biochemical sensors (for near patient testing), ubiquitous computing.<br><br>**Issues for implementation**: Public and professional acceptance of new methods of service delivery. Motivators must be put in place so that there are incentives to change; Integration of services with mainstream care delivery system; Data protection/confidentiality; Skills/resources for infrastructure procurement and systems integration; Availability of robust tools for demonstrating cost and clinical effectiveness – drivers for investment; Provision of commercial incentives for the industry (prolonged patent protection etc) to become involved in provision. |

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| | **Secondary Role in HC delivery**:<br>Support for healthcare regimens – customised around individual needs (e.g. specific advice and guidance about a health condition).<br>Enabling technologies: Internet, broadband connectivity, 3G / GPRS telephony, DiTV, touch screen technology, advanced data warehousing, (database/data mining).<br><br>**Issues for implementation**:<br>Acceptance of increased individual responsibility for own health, willingness to act on information provided and facility to act.<br>Availability of robust tools for demonstrating cost and clinical effectiveness – drivers for investment.<br>Some issues over validation of information.<br>Integration of services– depends on how much feedback. Data protection/ confidentiality. | | | systems), Computing power. Bluetooth technology.<br><br>**Issues for implementation**:<br>Professional and public acceptance of new approaches to consultation and ability to adapt to new circumstances. Motivators must be put in place so that there are incentives to change. It must be ensured that appropriately trained staff can use technologies to access and adapt to a changing knowledge base.<br>Reorientation of professional education training and continuous updating of skills – technical and clinical; Functional integration of technology (interoperability and connectivity between existing and new technologies)<br>Standardisation of terms and procedures used. | Reorientation of professional education training and continuous updating of skills – technical and clinical.<br>Real time issues and scale economies important for remote surgery.<br>Functional integration of technology (interoperability and connectivity between existing and new technologies) | (especially for procedures with limited application elsewhere).<br>Strategies for involving patients in their own care need to be developed. |
| **MEDTEC** | MIS is, and in 2020 still will be unimportant in case of prevention. In the US, an exception may be the use of gastrointestinal endoscopic procedures for taking biopsies, in the context of GI cancer screening programmes. The prospects for this indication in the EU are undocumented. | Irrelevant in case of MIS, now and in 2020 | Irrelevant in case of MIS, now and in 2020 | MIS is highly relevant for the diagnosis of disease. MIS procedures will become one of the mainstays of diagnosis of disease in 2020, mainly due to its non-invasiveness, e.g. on the basis of scanning and ultrasound techniques, and because diagnosis in many cases can immediately be followed by treatment. | At present MIS is used in the majority of cases in 8 conditions in 7 specialties in the US, with a somewhat more limited diffusion and use in Western-European countries. It is expected that the number of MIS procedures will increase in the decades to come, with rapid short-term developments in particular in spinal surgery and cardio thoracic surgery. | As MIS becomes more and more the norm, the procedures will become more complex and patients in day surgery will be sicker. This will require more attention to patient selection and after care. Aftercare and its organization is very important for the success of treatment of MIS procedures, because after-care related to MIS is increasingly |

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| | | | | | | given in the home. This requires a different type of community care, involving, for example, nurses and general practitioners. MIS then, is a force encouraging integration of the healthcare system, which is the major future expectation in this respect. Despite promising initiatives in several countries (transmural care, shared care, integrated care. managed care, etc.) this development may go very slow, due to lack of permanent funding of new arrangements and the general inertia of healthcare systems. In technological terms, MIS may benefit from developments in home care technology and monitoring technologies. |

# The Healthcare technologies roadmap: financially sustainable and equal access to high quality healthcare technologies in of the future

The following technology roadmap analyses the options deriving from the current (footprint-matrix) and emerging (matrix 2020) state of healthcare technologies, if the present policy trend continues. It examines the impact of a range of societal and economic challenges and describes how the "desired future" could be reached in the context of an enlarged and ageing EU.

As the two matrices demonstrate, modern healthcare technologies have the potential to extend the life expectancy of patients, 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.

The desired future would bring about a broad diffusion (accessibility) of high quality technologies contributing to financial sustainability.[36] Achieving a balance between the three objectives (equal access to healthcare, high-quality healthcare, and the financial sustainability of healthcare systems) poses a major challenge for the overall management of healthcare systems[37].

However, although these healthcare technologies are available in principle for all patients throughout Europe, not everyone receives adequate treatment. There is a huge difference between a (technologically possible) optimal treatment and the treatment delivered to the patient. There are also huge differences in the provision of innovative healthcare technologies between the various European countries depending on the national health delivery system.

## Influential factors ruling the broad access to financially sustainable high quality healthcare technologies of the future

Among the most important factors for the diffusion of innovative healthcare technologies are the cost of development & provision, skills, the technical development, the organisation health delivery system, ethics, the cost of use/reimbursement, R&D and evaluation. These seven different influential factors have been identified as the most important factors governing the access to high quality, financially sustainable healthcare technologies from the three examined technology cluster. They are strongly interrelated but most of these are not patient related factors, but rather healthcare provider related, industry related, system related or policy related factors.

## Broad and equal access to healthcare

The broad and equal access to healthcare does not imply unlimited free access to any form of medical treatment or product that one can imagine. The right to healthcare as a social right implies that governments be instructed to become involved through legislation with the structuring and financing of the healthcare system and the maintenance of quality of healthcare. However, more and more it is being acknowledged that there are limits to what can be financed collectively. In order to safeguard solidarity in areas where this is indispensable, a search has

[36] Diffusion of Medicines in Europe Oliver Schöffski Friedrich-Alexander-Universität, Erlangen-Nürnberg Lehrstuhl für Gesundheitsmanagement www.lif.se/Nyheter/Diffusion_Medicines.pdf -
[37] European Commission, DG Employment and Social Affairs.

started for possibilities to give people greater responsibility in other areas where this can be justified. In many countries decision-makers do not favour coverage of expensive new healthcare technologies and rather promote self-care and self-responsibility in this area.

Due to financial restrictions more and more people in Europe have to pay for goods and services on their own. But not everyone can afford innovative healthcare technologies. This is a situation that is questionable from an ethical point of view. If the patient is not able to afford the treatment or is not able to assess the treatment's benefits correctly, then the diffusion of innovative healthcare technologies will be hampered – a fact that applies to all of the three technology clusters.

Beside the patients themselves, healthcare professionals play a major role in utilisation of innovative treatments. In principle, doctors should be free to choose the best technologies available for their patients. In reality they are under huge pressure from all other players in the healthcare system (e.g. patients, insurance funds, health politicians).

The advances in healthcare technologies, especially in genetics, are raising deep ethical concerns among the citizens. The use of genetic testing is perceived as a possible source of gene-based discrimination in areas like employment, insurance and other aspects of social integration and acceptance (chances to get married, for example). The possibility of applying new technologies to modify the gene content of future generations is also regarded with apprehension by some who fear these changes could have an impact on the future of humanity. Again the shadow of genetic discrimination in the form of a new eugenics, the search for the genetic improvement of the human race, is regarded with certain anxiety. Another major ethical issue is the use of stem cells from human embryos for research and future therapeutic applications. Some citizens reject the use of human embryos on the basis that it is against the dignity of life itself. Even more distressing are the worries of those who object to the process of human cloning that the technique to develop tissue for auto-transplantation entails. Though this process is not meant for reproductive purposes, the mere idea of generating a human clone is disturbing for a part of society.

It was found that, particularly the developments in the telecare sector affect both information and provision of healthcare. But who protects health information online and how is it done? How much confidence do consumers have in the privacy of their health information? Issues around public perceptions and intellectual property arise particularly in the GENTEC and related field, where there is scope for improvement. But how can these be addressed? How will concerns about genetic information affect the development of the GENTEC Cluster? What are the likely regulatory trends in the future? Who should be involved? How will current ethical concerns be assimilated?

## High quality healthcare delivery

At the patient level the recent discussion on the consumer empowerment mirrors the discussion about the inappropriate diffusion of information. At the level of healthcare professionals, skills**,** knowledge about healthcare technologies innovation and knowledge about the available treatment options are required.

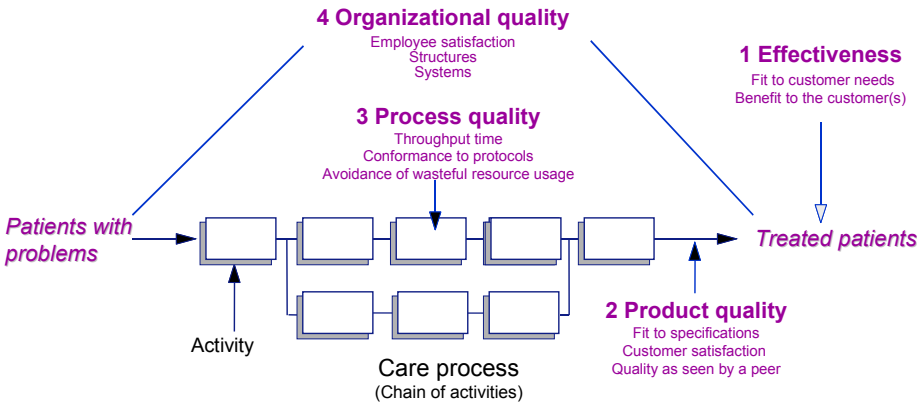
In most European countries there is a need for better technology education in medical schools. Sometimes students do not learn enough about the latest healthcare technology innovations. A much bigger problem is ongoing provision of this kind of information after leaving medical

school. Healthcare professionals should also know the correct use and application of innovative healthcare technologies.

Technical development is the key to the economic development of a nation and the improvement of the quality of life of its citizens, and successful nations are those that have a culture of and infrastructure for innovation. Over the last twenty years, new drugs and surgical therapies have greatly improved the quality of life for patients. Innovation in healthcare technologies enhance the quality of and prolong life (organ transplants and artificial organs) and to make diagnosis easier (Magnetic Resonance Imaging machines). The current dominant technologies with technology development as an enabling or driving issue are found in the MEDTEC and the GENTEC cluster.

Without the accomplishments in healthcare R&D Europe´s public health system would not be what it is today. Research investment is the basis for the development of novel methods in healthcare technologies that are put to use to the benefit of the population, of people's health and for the improvement of their quality of life. In order to further keep up the high level of general healthcare in Europe, the European Commission supports research projects in companies, at universities, at technical colleges, and at other research institutions. S&T must be embedded in the medical surroundings, and has to be integrated into medical research. This is why the EU not only supports the development of so-called key technologies such as micro-system technology, material sciences, information and communication technology, etc., but also their application in medicine.

How is the quality of healthcare defined and understood? How is quality measured and evaluated? A definition of the efficiency or the 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 healthcare service. Is it health? In that case, no healthcare system has ever been productive according to the definition of "health" by the World Health Organisation. Is it an improvement in health or the absence of deterioration of health? How could this ever be substantiated or measured? There is no measurement of the status of a person's health. On the other hand there are qualitative and quantitative indicators for medical technologies and their instantiations in healthcare, as the following figure indicates.




It was found that particularly the advances in the MEDTEC (MIS) and the telecare sectors will impact on the potential to evaluate healthcare quality.

## Financial sustainability of healthcare systems

Healthcare technologies are goods. Markets exist for these goods, and suppliers in these markets seek competitive advantages to increase market share and profitability. The major cost factor is (skilled) labour and their support processes and this is also the major determinant of the cost of a given medical technology, particularly in the MEDTEC and the GENTEC cluster. Technology and pharma products actually drive down the costs of well-established, effective medical technologies. But usually the clinical indications to use a certain medical technology tend to change over time thus diluting the effect of technology. Parallel to this new medical technologies are created widening the possibilities to treat medical problems and also the increasing "medicalisation" of everything adds to the workload. The costs which result from progress in healthcare technologies are extremely difficult to forecast, as past developments have not yielded findings with any strong statistical basis.

The industry has a very clear interest in selling their products at a good price, following the profit principle. In general it is assumed that the market principle leads to more research and development of new healthcare technologies than a public organisation of this sector. Innovative healthcare technologies, therefore, do not only have to overcome resistance within the health insurance funds, but also from competing companies. There is no doubt that healthcare manufacturers have a responsibility for the health of individuals and for the operability of the healthcare system, like every player in this sector.

However, the debate on the future of healthcare in our society is dominated by the fact that healthcare is not a sector of economic activity like all others. It has its own particular characteristics, which make that the market economy can not operate here in the same way as in other sectors of the economy. In the first place there is the important fact, that the right to health is recognised as a basic human right, which has to be implemented by the national governments. This requires from the national governments a policy and legislation providing for availability and accessibility of healthcare services for all citizens. These matters can not be left simply to market forces, which by their very nature would provide services according to the consumers' ability to pay.

The basic market mechanism, according to which demand goes up when prices go down and vice versa, seems not to work, or work in the opposite way, when it comes to healthcare. To this should be added the serious problem of asymmetry of information. This problem is widely recognised in all areas of economic activity, but in healthcare it plays a very special role. There is, of course, the obvious problem of the lack of medical knowledge on the part of the patient.

A lot of general conditions limit the diffusion of healthcare technologies. Some of these conditions are within the healthcare system and others are outside. Particularly in the area of minimal invasive surgery and telecare it was found that, besides the different organisation of the healthcare system, disparities in financing methods can influence medical practice as well. With the increasing convergence of healthcare provision across Europe, it is desirable that the population gets the same or at least similar healthcare and has an equal access to healthcare. The insurance status or the place of residence should not be the reason for whether or not a patient receives appropriate treatment.

Can the organisation of European healthcare ensure the required standards of safety, quality and efficacy of new healthcare technologies? How can healthcare be regulated on European level, with what type of regulation?

As healthcare represents a significant proportion of public spending, the monitoring of Public Finances by the European Union is also significant. The Ageing sub-Group of the Economic Policy Committee has undertaken financial projections of future public spending on health and long-term care for the elderly. Subsequently, the issues were introduced into the European Social Agenda and the work of the Social Protection Committee. [38] The European Commission has published a Communication in December 2001. This Communication examined the demographic, technological and financial trends that present challenges to Europe's future ability to maintain high levels of social protection. The report concluded that health and long - term care systems in the European Union face the challenges of ensuring the three objectives: access for all regardless of income or wealth, high levels of quality and financial sustainability. It is now widely recognised that these three core principles - accessibility, quality, financial sustainability - represent a good framework for policy exchange and information gathering.

The Barcelona European Council in March 2002 asked for a more thorough examination of issues related to access, quality and financial sustainability. For this reason the Social Protection Committee submitted a questionnaire to the Member States to gather information about health and long term care for the elderly. The replies this questionnaire will shortly be made public on the Directorate General for Employment and Social Affairs web pages. A final Joint Report, drawing on the main conclusions from the national replies and proposing future steps, will be delivered to the Spring European Council in March 2003.[39]

**Influential factors ruling broad access to financially sustainable high quality healthcare technologies of the future:**

| Desired Future | Issues | Diagnosis | Treatment | Monitoring | Aftercare |
|---|---|---|---|---|---|
| Broad and equal access to healthcare | Ethics | | ● | ● | ● |
| | Cost of use / reimbursement | ● ● | ● ● | ● | ● |
| High quality healthcare delivery | Skills | ● | ● ● | ● | ● |
| | Technical development | ● | ● ● | | |
| | R&D | | ● | | |
| | Evaluation | ● ● | | ● | ● |
| Financial sustainability of healthcare systems | Cost of development & provision | ● | ● ● | | |
| | Organisation | ● ● | ● | ● | ● ● |

● = MIS ● = Telecare ● = Gentech

[38] Commission of the European Communities, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: The future of healthcare and care for the elderly: guaranteeing accessibility, quality and financial viability Brussels, 05.12.200, Com (2001) 723 final.

[39] Commission of the European Communities, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: Proposal for a joint report on Healthcare and care for the elderly: Supporting national strategies for ensuring a high level of social protection, Brussels, 3.1.2003, COM(2002) 774 final

In the diagnosis area especially the technological innovations for minimal invasive surgery and telecare will be noticeable. The developments in technology clusters (particularly in minimal invasive surgery and telecare) were found to contribute 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.

For all technology clusters it was found that there is a need for growing dialogue with stakeholders on conflicting themes: ethical issues (GENTEC), data privacy (ICTEC), etc. There will be a stronger deconcentration through the advances of ICT and individualisation of healthcare through GENTEC - ICTEC) as well as a growth in the importance of networking. It was found that there is a need for more training in technologies for GPs (ICTEC - GENTEC), particularly for the primary healthcare sector, while higher technological investments (ICTEC – MEDTEC) will imply transformations in the organisational structures and in the workforce. Due to better access to information, and the development of innovation networks, secondary healthcare structures will increasingly work in networks.

# Conclusions

## Healthcare technologies diffusion in Europe: the technology/economy push perspective

Healthcare technologies are goods. Markets exist for these goods, and suppliers in these markets seek competitive advantages to increase market share and profitability. The proprietary nature of much medical technology, together with the high costs of innovation, has created world markets for many technologies - particularly pharmaceuticals and imaging and surgical instrumentation.

Without the accomplishments in medical technology, Europe's public health system would not be what it is today. Technical advance is the basis for the development of novel methods in medical technology that are put to use to the benefit of the population, of people's health and for the improvement of their quality of life. In order to further keep up the high level of general healthcare in Europe, the European Commission supports research projects in companies, at universities, at technical colleges, and at other research institutions.

As the term "medical technology" already implies, not only the technical but also the medical side plays an important role. Technology alone is not enough. Research in technology must be embedded in the medical surroundings, meaning it has to be integrated into medical research. This is why the EU not only supports the development of so-called key technologies such as micro-system technology, material sciences, information and communication technology, etc…, but also their application in medicine.

This way, the patient profits directly from developments in medical technology. On the other hand, medical technology also has a great significance for Europe's economy and for the securing of export-oriented jobs. Particularly in products of medical technology, the proportion of export is relatively high. With this roadmap, we hope to give some insight into the variety of healthcare technology in Europe.

In public health, medical technology already plays a significant role today, and will be increasingly important based on the future demographic development. Besides, the population's legitimate wish for a higher quality of life, either during illness or with old age, cannot be met without the developments in medical technology. Medical technology is not only important for public health but also for industrial development in Europe. The market for products in this area is a global, growing market: in the industrial nations it is growing at an annual rate of five to seven percent.

Small and middleclass companies are most represented among the medical technology industry. The innovative products and methods in the field of medical technology are subject to special legal stipulations and conditions that originate in the public health system. New products and methods have to be implemented not only legally, but also in consideration of the ancillary conditions that concern cost reduction in public health and the medical market. This puts considerable pressure on a medical technology company in terms of time and costs. Generally, the market in medical technology is characterized by fast product innovations.

## Options for healthcare providers

### *Options for healthcare providers arising from Gentechologies*

Implementation of pharmacogenomics will require major changes at different levels of the healthcare system:

***Healthcare practitioners***: At the general practitioner level, it will require a new understanding of the relevance of genetic makeup to patient treatment. Ensuring that the GP population gains this understanding is not an inconsiderable task given the age structure of GP populations in the EU. Many GPs graduated at a time when molecular genetics were not a part of the medical curriculum. Education of GPs on the novel concept involved in pharmacogenomics will be an important task for a healthcare system. Some lessons have been learnt in this area by experience in introducing tests for foetal genetic disorders to obstetrics/gynaecological practitioners.

In addition, it will also be necessary to develop systems which can reliably inform the GP, the pharmacist, and others in the healthcare system, as to a patients 'genetic status' or pharmacogenomics make-up. Healthcare information systems will also have a major role in solving this information issue. Given that full implementation of a pharmacogenomic treatment regime for even one disease is unlikely for at least 10 years, is entirely possible that this issue will be solved by the eventual availability of integrated systems carrying data on individual patients.

***Regulatory System:*** The regulatory system currently operates on the basis that a drug must be safe and efficacious in all patients if it is to be approved. (There are obvious exceptions for certain illnesses, but this is the general principle). If pharmacogenomics is to be used as a basis for healthcare improvement, the regulators must adopt the principle that drugs which are ineffective, or even unsafe, in certain individuals may be approved on the basis of their efficacy in a genetically defined group of patients. This will create new requirements for the way in which drug trials are conducted, patient recruitment etc. and the terms on which these drugs are approved.

It is likely that gene therapies will be more complex to administer than drugs, and there may be a need for frequent involvement of clinicians in the therapeutic process. This, however, will depend on the particular therapy. There are many approaches in development.

Physicians in the primary care sector will have increasing responsibility for using genetic tests. Educational programmes will need to be implemented to improve the knowledge of genetics to ensure prudent use of technology in the primary care sector not only for physicians but also for other healthcare workers.

As it is the case with other healthcare applications of gene technology**,** healthcare providers need more educational focus on genetics and genomics, and in molecular and cellular biology (see sub category Pharmacogenomics).

### *Options for healthcare providers arising from Information & Communication Technologies*

In the future health and social care providers can expect an increase in support services available to support care professionals in their routine tasks and an expectation that they will use them, an increase in better informed encounters with patients and with other care professionals because of

easier access to appropriate patient-specific information, routine tasks, such as daily blood pressure or blood sugar measurement, to be removed thus enabling better use of resources.

### *Options for healthcare providers arising from Medical Technologies*

MIS has important implications for physicians and nurses, who need special training. Physicians need (especially) to be trained in the use of endoscopes and the associated instruments. Anaesthesiologists need to be trained in the use of regional and local anaesthesia, and need to be oriented to avoid general anaesthesia wherever possible. Nurses need to monitor the status of the patient after the therapy, but also to promote early ambulation and early eating (Banta, Schersten and Jonsson 1993). It is expected that physicians, when confronted with wishes from their well-informed 'empowered' patients, will be prone to seek the necessary training to be able to compete and offer their patients with the latest endoscopic techniques (Worrell, 2002). In the future, combining the implications for patients and the implications for providers, it is expected that the latter will increasingly be confronted by patients who will act as consumers of healthcare, and part of their demand will be related to MIS.

## Options for industry

### *Options for industry arising from Gentechnologies*

Pharmacogenomics has major implication for the drug development industry, and for the diagnostics industry. Until now patient populations could not be classified on the basis of their suitability for particular drugs other than in very gross ways (age, pregnancy status, other medication). Pharmacogenomics provides a mechanism to accurately determine patient groups which differ in regard to their susceptibility to particular drugs. This has consequences for the effectiveness of current drugs and the design of new ones. It is a 'two-edged sword' for the industry as pharmacogenetic data may determine that current drugs are ineffective in certain patients. This could reduce sales of drugs. On the other hand, a clear indication that a specific drug is effective in a defined population group could increase sales if that defined group is large enough.

This potential has led to many mergers and/or business agreements between genomic companies and the major drug manufacturers. Drug companies have been quick to get access to the technologies which can provide genomic and genetic data. Many liaisons have now been formed between genomics companies or institutions and big Pharma companies and most of them now have associates or in-house expertise necessary to provide them with the pharmacogenomics information they require on their target diseases.

Pharmacogenomics also has consequences for the drug regulation process, as drug trials must take patient status into account in assessing drugs for market approval. This will also have an impact on industry as it could potentially limit the market for which certain drugs are approved. Equally, it may allow drugs which have been refused approval for wide patient groups to be approved for patients with a specific genetic status. In addition, it creates a new opportunity for genetic diagnostic products aimed at diagnosing patient status with regard to drug efficacy.

There is significant commercial activity in the area of gene therapy, with over 135 companies worldwide developing therapies or technologies relevant to the therapies.[40] The goal of the therapy development companies is to develop and obtain market approval for gene therapy

[40] Gene Therapy Players: Financial Times BioFrontiers Rept. (1999)

products aimed at specific diseases. FDA defines Gene Therapy products as*: 'products that introduce genetic material into the body to replace faulty or missing genetic material, thus treating or curing a disease or abnormal medical condition.'* The major area of promise for gene therapy is in monogenic inherited diseases.

Initiation of gene therapy trials is more difficult in Europe and fewer trials have been allowed to proceed than in the US. Out of approximately 110 gene therapy applications submitted to two EU authorities, only about half have been allowed to proceed. Not only is this a novel therapy, but there is also more concern over the use of genetically modified organisms in Europe than in the US. In France, for example, these trials are regulated by laws on drugs, genetically modified organisms and gene therapy, requiring review by three regulatory bodies in addition to the Ethics Committee.

Another difficulty in starting clinical trials in Europe is the lack of a centralized approval procedure for clinical trials, making country-by-country submissions a necessity. The new Clinical Trial Directive (2001/20/EC) should make it less cumbersome to start clinical trials in Europe, but implementation of this Directive will not occur until at least May 2004. Once ratified by Member States, this Directive will provide a centralized procedure for clinical trial applications. The new Directive allows for a 90-day review of gene therapy applications that can be extended by another 90 days in the event of consultation and thus generally will be slower than in the US. The new centralized procedure should be quicker than the current process and will ease the burden on gene therapy companies with respect to performing clinical trials in Europe.

A centralised EU procedure is currently available through the Committee for Orphan Medicinal Products (COMP). This Committee would cover many gene therapy trials for rare, single gene mutation diseases. To obtain orphan drug status for a specific product and indication, a company must file its clinical trial application as a centralized procedure. COMP will provide advice on application and trials to be performed. This is an effective method and avoids filing in multiple countries.

Overall, harmonizing regulations within Europe will help the initiation of trials and advance the progress in the field.

Gene therapy techniques are also one of many therapies being developed for cancer treatment. For cancer therapy, the vector is designed to express their protein at the location of tumour cells. These proteins could be immunomodulator molecules which stimulate a local immune reaction to the tumour. Alternatively the vector can express an enzyme which reacts with an injected pro-drug to create an anti-cancer agent which is only active at the site of expression of the protein.

Health industry experts predict that the market in genetic tests will expand rapidly over the next few years. For example**,** development and sale of over-the-counter genetic tests is expected to be subject to commercial interest. Fears *et al.* (2000) has provided the following list of expected future implications of gene diagnostics for the pharmaceutical industry:

- Increased efficiency of R&D
- Segmentation of products into smaller markets
- Pricing premium for effectiveness
- Need to provide R&D incentives for less profitable indications (orphan diseases, international health)
- Convergence of technology with informatics

Furthermore due to competition between long term objectives and short term patient care initiatives Fears *et al.*, suggest a pluralistic approach, with commitment to a new public-private partnership in strategic thinking and policy development to help the national health authorities to set priorities for care and the rational allocation of resources.

Although public funds have been expended in support of adult stem cell research, most advances in human embryonic and foetal germ cell research have come from the private sector in the hope that products can be developed for medical therapy. However, results are mixed for companies pursuing the use of stem cells as therapies. The reason is primarily the early stage of research presented today. For embryonic stem cells to be applied in clinical procedures, years of trials in monkeys will be necessary. The less ethically problematic multi-potent adult stem cells appear to differentiate like embryonic stem cells into a host of cell types, and may even be better at making some tissues, but this work is at an even earlier stage.

Although Stem cells seem to be a promising technology for the future**,** comprehensive basic research is required to address the many fundamental questions that need to be answered before claims can be made about the commercial potential.

## *Options for industry arising from Information & Communication Technologies*

Future opportunities for industry include:

- Construction of smart homes and the retrofitting of existing stock
- Supply of sensors and sensor systems
- Compilation and maintenance of large, searchable databases
- Possibilities for greater involvement in the overall care process, through outsourcing of specific services such as call management and response

## *Options for industry arising from Medical Technologies (MIS)*

The development of MIS has had a stimulating impact on the medical device industry. The industry producing instruments for MIT is highly diverse. Traditionally, profitability is particularly high in the cardiovascular market, and in the large-sized market for diagnostic imaging equipment such as CT-scanners and MRI equipment. In the early nineties, according to Gelijns and Fendrick (1993) in an analysis of the dynamics of innovation of MIS, the possibilities for the industry were somewhat better in the United States than in Europe. In the mid-nineties, analysts predicted that the economics of the medical device industry would lead to market concentration in a few giant manufacturers, in an analogous pattern to the pharmaceutical industry (An. Frost & Sullivan/Market Intelligence reports 1996, p 91). Nowadays in the US, the MIS industry is regarded mature (Worrell, 2002). In this country, growth rates for the four most important laparoscopic applications (cholecystectomy, appendectomy, fundoplication and inguinal herniorrhaphy) are expected to be modest in the years to come, ranging from 1.5 to 8.6% in the period 2002-2006. In contrast, volumes of bariatric surgery for the treatment of morbidly obese, and endoscopic spine surgery are expected to increase between 35 and 50% annually in this period (Worrell 2002). The former indication illustrates the growing importance of lifestyle-related demand for treatment. The potential demand for such treatment is enormous, allowing new companies to enter the market in specific niches, while in most other market segments, conform earlier predictions, firms may consolidate their position e.g. by mergers.

In 1995, the United Kingdom Parliamentary Office of Science and Technology published a report on minimally invasive therapy and its implications (Parliamentary Office of Science and Technology 1995). In this report four types of significant recent developments were distinguished: in imaging systems, robotics, surgical instruments and micro engineering. The combination of developments in separate fields, according to the authors, may offer most potential for future clinical applications. Developments in surgical instruments and micro engineering are briefly reviewed. The report anticipates that surgical instruments for MIS will become more sophisticated. Among the most difficult procedures are those involving needle and thread (suturing, ligation, etc.) and these are likely to be replaced by tissue welding techniques using microwaves or radiofrequency heat energy in the near future. Laser tissue welding could probably play a role here as well. Other advances include high-speed drills and ultrasound systems which can be used for tissue maceration outside the body, and allow the removal of large organs or tissues through small holes through the body. Advances in micro engineering have resulted in the construction of microscopic electric motors less than 1 mm in size. Such motors could power tiny surgical instruments such as forceps and scissors, and could be introduced into body cavities or organs to conduct operations that are not possible using existing techniques (Parliamentary Office of Science and Technology 1995). A more recent prediction is that in the future, advancements in microchip and wireless technology may allow the development of e.g. swallowable cameras, and magnetically controlled implants that can be navigated remotely. According to Mack (2002), the technology is here, the potential is enormous, and the path is minimal. And at an aggregate level, the design of customized MIS operating suites will become increasingly sophisticated and it use is predicted to become increasingly common (Herron et al., 2001).

## Healthcare technologies diffusion in Europe: the public health perspective

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

Against the background of an ageing society, and EU enlargement with unequally distributed chances of health, there is the danger of the ‘health gap’ widening between the various social groups and classes. Health education and training can help to correct a potential imbalance at an early stage.

It is likely that in the future the usage of self-medication products as a treatment for minor ailments will increase, with consumers self-medicating rather than visiting a doctor. Self-medication is already used widely and appropriately for many ailments and is a hidden asset to the primary healthcare system. However, 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 including national authorities, the industry and the clinical professions.

The provision of information on, and the advertising of, medicines to the public is a highly sensitive issue, since information to patients should be objective, comprehensive, readable, accurate and up-to-date. It is made more difficult by the lack of a clear definition of the

distinction between advertising and information, and the growth in the use of the Internet.

The equal right to healthcare does not imply unlimited free access to any form of medical treatment or product that one can imagine. The right to healthcare as a social right implies that governments be instructed to become involved through legislation with the structuring and financing of the healthcare system and the maintenance of quality of care. However, more and more it is being acknowledged that there are limits to what can be financed collectively. In order to safeguard solidarity in areas where this is indispensable, a search has started for possibilities to give people greater responsibility in other areas where this can be justified. In many countries decision-makers do not favour coverage of expensive new medical and healthcare technologies and rather promote self-care and self-responsibility in this area.

The challenge is to ensure high quality of life for the entire lifespan of the individual and for all social groups. Preventive measures can contribute greatly to attaining this goal.

## Options for patients

### *Options for patients arising from the Gentec Cluster*

The implication for patients is a greater certainty that the drugs prescribed will be effective. This applies in several respects: it will provide a means of ensuring that the clinician can select from among existing drugs using patient data as a basis for choice. In addition, development of future drugs will be made with an enhanced knowledge of patient needs. However, if it is to be effective, health systems will need to conduct promotion campaigns to patients to ensure that they understand the concepts involved, and the need for genetic analysis as a precursor to drug prescription. It can be envisaged that patients will be classified on a basis similar to current systems for determination of blood group, or of sensitivity to penicillin. Nevertheless, there are potential privacy issues. Will an individual who is not susceptible to certain drugs be less able to obtain insurance, or to pursue certain occupations?

**Gene therapy** represents the only current therapy in development for many genetic disorders. It is very likely that therapies will be customised for particular disorders, although some common technical features (e.g. vectors) may arise. Therefore progress may be significant for one disorder and have no significance for others. In addition it is likely that the disease targets will be determined by commercial reality and therefore the more common disorders will be of more interest to the companies active in the field.

**Gene diagnostics** will have major social, ethical and legal implications for patients and healthy individuals subject to diagnostic tests. Analyses of DNA/RNA will increase the knowledge concerning genetic predisposition for development of diseases later in life. At the same time such analyses are likely to establish a new paradigm, allowing for genetic counselling that is far more individualised than we know today. Individual counselling and personal life style guides for people with propensities for different diseases may reduce the occurrence of certain diseases. However, a number of challenges and problems are related to genetic testing of healthy individuals (Danish Ministry of Science, 2002).

- 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".

Stem cells hold the most promise for those diseases where cells are damaged or malfunctioning, and might be replaced. A better understanding of the genetic and molecular controls of cell division and differentiation processes can yield information about how such diseases arise and suggest new strategies for therapy. The ultimate potential of stem cell is to grow new cells (e.g. neurones), tissues and entire organs, at first outside the body but eventually in the body.

The American Association for the Advancement of Science and Institute for Civil Society has listed the following examples of potential stem cell applications (AAAS and ICS, 1999):

> *"Type 1 Diabetes in Children. Type 1 diabetes is an autoimmune disease characterized by destruction of insulin producing cells in the pancreas. Current efforts to treat these patients with human islet transplantation in an effort to restore insulin secretory function (obtained from human pancreas) are limited severely by the small numbers of donated pancreas available each year combined with the toxicity of immunosuppressive drug treatments required to prevent graft rejection. Pluripotent stem cells, instructed to differentiate into a particular pancreatic cell called a beta cell, could overcome the shortage of therapeutically effective material to transplant. They also afford the opportunity to engineer such cells to effectively resist immune attack as well as graft rejection.*
>
> *Nervous System Diseases. Many nervous system diseases result from loss of nerve cells. Mature nerve cells cannot divide to replace those that are lost. Thus, without a "new" source of functioning nerve tissue, no therapeutic possibilities exist. In Parkinson's disease, nerve cells that make the chemical dopamine die. In Alzheimer's disease, cells that are responsible for the production of certain neurotransmitters die. In amyotrophic lateral sclerosis, the motor nerve cells that activate muscles die. In spinal cord injury, brain trauma, and even stroke, many different types of cells are lost or die. In multiple sclerosis, glia, the cells that protect nerve fibres are lost. Perhaps the only hope for treating such individuals comes from the potential to create new nerve tissue restoring function from pluripotent stem cells. Remarkably, human clinical experiments have demonstrated the potential effectiveness of this approach to treatment. Parkinson's patients have been treated by surgical implantation of foetal cells into their brain with some benefit. Although not completely effective, perhaps owing to lack of sufficient numbers of dopamine secreting cells, similar experiments using appropriately differentiated stem cells should overcome those obstacles. More complex experiments have already been successfully conducted in rodent models of Parkinson's. Similar approaches could be developed to replace the dead or dysfunctional cells in cortical and hippocampal brain regions that are affected in patients with Alzheimer's.*
>
> *Primary Immunodeficiency Diseases. Pluripotent stem cells could be used in treatment of virtually all primary immunodeficiency diseases. Presently, there are more than 70 different forms of congenital and inherited deficiencies of the immune system that have been recognized. These are among the most complicated diseases to treat with the worst prognoses. Included here are diseases such as severe combined immunodeficiency disease (the "bubble boy" disease), Wiskott-Aldrich Syndrome, and the autoimmune disease lupus. The immune deficiencies suffered as a result of acquired immune deficiency syndrome (AIDS) following infection with the human immunodeficiency virus are also relevant here.*

*These diseases are characterized by an unusual susceptibility to infection and often associated with anaemia, arthritis, diarrhoea, and selected malignancies. However, the transplantation of stem cells reconstituted with the normal gene could result in restoration of immune function and effective normalization of life span and quality of life for these people.*

*Diseases of Bone and Cartilage. Stem cells, once appropriately differentiated, could correct many diseases and degenerative conditions in which bone or cartilage cells are deficient in numbers or defective in function. This holds promise for treatment of genetic disorders such as osteogenesis imperfecta and chondrodysplasias. Similarly, cells could be cultivated and introduced into damaged areas of joint cartilage in cases of osteoarthritis or into large gaps in bone from fractures or surgery.*

*Cancer. At the present time, bone marrow stem cells, representing a more committed stem cell, are used to rescue patients following high dose chemotherapy. Unfortunately, these recovered cells are limited in their capacity to restore immune function completely in this setting. It is hoped that injections of properly differentiated stem cells would return the complete repertoire of immune response to patients undergoing bone marrow transplantation. Complete and functional restoration will be required if, for example, immune/vaccine anticancer therapy is to work. More importantly, success would permit use of very toxic (and effective) chemotherapeutic regimens that could not currently be utilized for lack of an ability to restore marrow and immune function."*

In addition to this**,** human stem cells could also be used to test new drugs. For example, new medications could be tested for safety on differentiated cells generated from human pluripotent cell lines. Other kinds of cell lines are already used in this way. Cancer cell lines, for example, are used to screen potential anti-tumour drugs. But, the availability of pluripotent stem cells would allow drug testing in a wider range of cell types. However, to screen drugs effectively, the conditions must be identical when comparing different drugs. Therefore, scientists will have to have knowledge to control the signals responsible for the differentiation of stem cells into the specific cell type on which drugs will be tested.[41]

## *Options for patients arising from the ICTEC Cluster*

In the future patients can expect:

- As far as possible, all assessment, treatment and care to happen at a time and place of their choosing ;
- Loss of mobility will not be an inevitable consequence of old age or infirmity – use of mobile telecoms will facilitate monitoring when and where it is needed;
- Specific information about their condition will be readily available to allow them to have an informed discussion with their care provider;
- Greater control through self-management of their condition using near patient testing.

## *Options for patients arising from the MEDTEC Cluster*

Perhaps the most important implication of lasers and MIT is for patients. For patients, assuming that a procedure is reasonably evaluated and carried out by an experienced surgeon, these procedures offer great advantages. These include a lower mortality rate, reduced postoperative

[41] An in-depth discussion of the future for stem cell research can be found in a special issue of Nature vol. 414, 2001.

pain, a decreased risk of wound-related complications, and the obvious cosmetic advantages. The patients recover faster and the period of post-operative disability is reduced. This allows patients to return to work or normal activities early (Banta, Schersten and Jonsson1993, UK Parliamentary Office of Science and Technology 1995, Mack 2001).

Welan, analyst at the US-based firm Frost and Sullivan, quoted by Worrell (2002), predicts that what we are going to see in the future is that patients will have more power in determining what procedures are performed on them and how they are performed. In his words, patients will become more educated and will know about their alternatives, so they will know if their procedure can be performed minimally invasive or not, and they will usually prefer that alternative. This opinion is echoed in a number of related publications (e.g. Jackson 2002, Hunter 2002, Himal 2002)

Worrell also considers that the ageing of the population is likely to result in an increase in the demand for medical procedures requiring endoscopes in nearly every medical specialty (Worrell, 2002). In other words, due to both the ageing of the population and stronger expression of patient preferences, patient demand for MIS will increase in the future.

## Options for society

### *Options for society arising from the GENTEC Cluster*

"Underdosing, overdosing, and misdosing of medications cost the United States more than one hundred billion dollars a year, and can be considered a leading cause of death." [42] Pharmacogenomics could dramatically decrease the cost of healthcare provision by improving drug safety. Similarly, the ability of clinicians to administer drugs that are known to be effective will also save the costs which might have been incurred by prescribing ineffective drugs. On the other hand, pharmacogenomics could increase healthcare costs if each patient requires tailor-made drugs.

A further issue is that certain groups may be shown not to have effective therapies for certain diseases. The concept of pharmacogenomics is that variations in patient genetics create a need for variation in drug solutions. It is therefore logical to presume that genetically different populations within the EU may have different needs for pharmaceuticals directed to particular diseases. It is entirely conceivable, for instance, that a particular drug may be ineffective in a significant proportion of, for example, Dutch patients, while being highly effective in Spanish patients. This will create a demand for alternative drug solutions within these populations.

The willingness of the pharmaceutical industry to develop an effective drug for this genetic group will depend on the market size. This demand may only be met using orphan drug or equivalent measures to encourage research on solutions for defined patient groups.

A further issue for society is that future drugs could be developed specifically for a target genetic group and have adverse effects in other genetic groups. It will therefore become even more important to educate the public on drug safety and on the principle that drugs which are effective in one person, e.g. a family member, may be ineffective, or even hazardous, in another person.

[42] Valdes, R. Introduction. Pharmacogenetics in Patient Care conference by American Association of Clinical Chemistry (AACC), Nov. 6, 1998.

The other issue presented by pharmacogenomics is the wider issue of genetic data and privacy. If a clinician is to define effective drug solutions it will be necessary to have information on the patient's genetic data. The issues presented by this need are well known and are represented by the following quote:

> *"It should someday be possible to sequence a person's entire genome and put that information on a computer chip or disc, and to merge this genomic information with the person's medical record. Who should have the authority to make such a disc? Who should own it? How can we guarantee its treatment as particularly private and sensitive medical information? These are questions that must be addressed, as we become able to influence to a large extent our own evolution."*[43]

The major impact on society is the ability to treat disorders which are currently fatal and untreatable. There are significant ethical issues associated with gene therapy, and it is one of the areas where ethical debate long preceded the advent of a working technology. In considering ethical issues, it is necessary to first distinguish between therapies aimed at somatic cells and at germ-line cells. Somatic cells are the normal working cells of the body; whereas germ-line cells are those which constitute the reproductive functions. Gene therapy on reproductive cells is therefore ethically more complex than on somatic cells because of the potential that the therapy might have consequences for the next generation. However, to date the major interest has been in therapies for somatic cells. Many organisations have issued statements regarding the ethical conduct of gene therapy research and trials including HUGO [44] (genetic enhancement possibilities of germ line gene therapy, potential for manipulation, and some fear lack of control might end up with scientists playing God).

The frequency of genetic disorders differs between different countries and population groups may also prove to be an issue in prioritization of genetic disease programmes between EU countries.

Finally, these therapies are life-long, technically complex, and require frequent monitoring and intervention by healthcare providers. They are likely to be very expensive as a result, although this may differ dramatically between therapies. The impact of these complex therapies on healthcare budgets is likely to be significant and must be included as a factor in any assessment of healthcare futures.

Barriers and uncertainties for future genetic technologies are generally expected, especially in the societal acceptance, regulation and infrastructure for the technologies. Especially genetic testing without demonstrable clinical benefit can have consequences that reach beyond the individual to their families and communities. The social and cultural aspects of genetic testing must be investigated and debated (Burgess, 2001). Reports of discrimination[45] based on genetic test results have been documented since the early 1990s primarily in the insurance and employment contexts and its consequences are now widely recognised (Otlowski et al., 2002)

The problems are largely concentrated around ethical considerations on the use of embryonic stem cells. The use of spare embryos as a source of 'raw material' (in this case, stem cells) is controversial. By some, the concept is fully rejected. Others, on the contrary, feel that the very

[43] Professor B. Dallapiccola Genetics & the Future of Europe' Forum 2000. see http://europa.eu.int/comm/research/quality-of-life/genetics/en/02.html

[44] http://www.hugo-international.org/hugo/genetherapy.htm

[45] Problems of "genetic determinism" and eugenic fears: If pre-implantation and pre-natal screening get out of hand, people fear new genetic racism.

fact that these embryos exist and are stored independently of any parental plan, and given the high hopes they raise for treating certain diseases, makes their use ethically acceptable[46].

Primitive germinal cells seem to divide less readily than embryonic stem cells, although the available scientific data are scant. These cells also present an unresolved scientific problem: are they genetically viable? They are taken from foetuses that have been obtained from therapeutic abortions. Some scientists point out that the reason for the abortion may have been a serious malformation or disease caused by a genetic defect, which cell lines isolated from the aborted foetus would be likely to carry. The germinal cells approach is also criticised by opponents of abortion.

The attitude towards research in embryonic stem cells represents an ethical value conflict that places society against a choice between two possibilities both having inevitable moral consequences and costs. Such perspectives demand an ongoing, open and broad debate and a definition of a political position (Danish Ministry of Science, 2002). In agreement with this OECD has declared that a social consensus is needed before opposition to such research overwhelms the common good it provides. Therefore, dissemination and translation of research findings is absolutely essential if the public is to understand, support and ultimately benefit from the research effort (OECD, 2002 p. 133).

The US National Committee on the Biological and Biomedical Applications of Stem Cell has stated that public funding of basic research on stem cells is necessary if progress toward medical therapies should not be hindered. Public funding helps ensure that many scientists can pursue a variety of research questions and that their results are made widely accessible in scientific journals.

### *Options for society arising from the ICTEC Cluster*

In the future society and government can expect improved social inclusion and independence, clearer links between health and care outcomes and other societal problems and more integrated policy making at national and international level.

### *Options for society arising from MEDTEC Cluster*

For the broad society, MIS is potentially quite valuable, as it will mostly improve the cost-effectiveness of healthcare. Early return to work or normal activities is beneficial to the broad society and for individuals (Banta, Schersten and Jonsson 1993). The demand for convincing evidence on the effectiveness, but also on the 'value for money' of MIS is expected to increase in the future as, partly due to the ageing of the population, healthcare will increasingly consume a bigger share of each countries' GDP (Jackson 2002).

## Options for the quality of care

### *Options for the quality of care arising from the GENTEC Cluster*

**Pharmacogenomics** has major potential benefits for the quality of care. There is little doubt that many of the drugs currently prescribed have no effect on a proportion of the patients to whom they are given. This development would effectively customise drugs to patients.

[46] see e.g http://www See ccne-ethique.org/english/start.htm, visited 25.02.2003

There may be an intermediate stage where pharmacogenomics will make it more evident that certain drugs are ineffective in certain patients. It may even possibly expose the fact that there are particular genetic groups for which there are no effective treatments for certain conditions. However, this simply exposes a current reality and will have a long-term benefit. In the case of Gene therapy, it is not so much a case of increasing the quality of care, but rather of providing the possibility of effective care to those who currently have none. Almost all gene therapies are directed against fatal genetic disorders which are currently untreatable.

As noted above in relation to the impact on healthcare providers, communication between different practitioners within the healthcare system will be important to ensure a correct match between drug treatments and genetic profile. The development and use of electronic communication systems and electronic patient records, which could facilitate such communication is discussed in another section of this report.

Due to the sensitive information that genetic information may hold this should be accessible only for the individual or with proper authorisation. Not only will this demand major security measures but also the way this information is delivered is a crucial matter.

The UK's Human Genetics Commission (HGC) has recommended that genetic tests should be regulated by legislation similar to those governing conventional medicines. If this is enough to prevent genetic discrimination and other consequences of individual genetic information is doubtful as long as the rapid advancement inside electronic exchange and accessibility of information is unconsidered.

## *Options for the quality of care arising from the ICTEC Cluster*

In the future the quality of care will improve due to the facility to measure, record, and analyse (i.e. audit) outcomes over long periods of time and reinforce best practice, and due to better knowledge management, the understanding of how knowledge is created, utilised and transferred in complex undertakings like health and social care delivery.

However, the future deployment of telecare and telemedicine will be influenced by a number of factors. These include:

- ***Accessibility***. This takes two forms: *patient* accessibility (ease of use) and *service* accessibility (access to the underlying ICT infrastructure and skills). It will be important not to either reinforce existing social divisions in access to healthcare because 'digital divide' issues have not been overcome or new divisions have been created.
- ***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.
- ***Systematic evaluation of telecare /telemedicine outcomes.*** This needs to occur both at the individual patient level and at the whole system level. There will be a need to adopt new robust evaluation methodologies that can overcome healthcare professionals' concerns over the lack of randomised control trials and demonstrate both cost and clinical effectiveness (Barlow et al. 2003).
- 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 telecare and telemedicine and the reinforcement of unsuitable care models. There may be a need to support the emergence of a new type of ***care professional***, the 'telecarer', who has an understanding of both telecare/telemedicine and the context in which it can be provided. Without better dissemination of results of telecare/telemedicine trials, there is a danger of piecemeal, uncoordinated adoption of unsuitable models.

Whether telecare deployment should be planned at a ***local or national level*** will depend on the viable scale for the particular service. For instance, common conditions would be best dealt with locally while rarer conditions might benefit from a national perspective.

## *Options for the quality of care arising from MEDTEC Cluster*

A routine system of ongoing monitoring of quality of care of MIS is extremely important because of the lack of supervision of the patient after discharge. The starting point for such a system is making the goals of care explicit. Decision rules can be formulated based on these goals. The data system should include information on the patient's condition at the time of pre-assessment, information about the operation (or therapy), information on nursing after the procedure, information about home-care (follow-up), including information on complications, and information on satisfaction of complaints of the patient. Ideally, the professionals involved in the care would then use this information to improve their own care. Evaluation and learning, of course, feed back into the standard-setting process (Banta, Schersten and Jonsson. 1993). The most important expectation for the future in this respect is that quality assurance systems will become increasingly sophisticated and commonplace in healthcare systems around the EU, while increasingly focusing on outcomes (Scrivens, 2002),

The development of MIS requires new forms of communication between patients, physicians, other healthcare providers, and management. The main reason is that MIS procedures have reduced stays in hospital, partly because the patient recovers at home. Therefore, the most important communication is that for the patient to provide feedback on the results of the procedure after he or she goes home. Besides the hospital, which should know the outcome of therapy, general practitioners and community nurses should also be part of the communication system when they become involved in the care before the procedure and care in the home after the procedure (Banta, Schersten and Jonsson 1993). The development and use of electronic communication systems and electronic patient records, which could facilitate these developments, is discussed elsewhere in this report.

# Recommendations and requirements

## The organization of care

## Implications from the GENTEC Cluster

The major implication from the GENTEC Cluster for the organisation of care is the very specific need for patient genetic data by general and specialist practitioners, and pharmacists. By some means, these groups must be able to determine the genetic status of the patients they treat. Given that pharmacogenomics is still in its early development, it is conceivable that integrated informatic systems for patient data will be available within all EU healthcare systems by 2020. In this case, the genetic information will simply be a further field of information to be held within these systems.

Alternatively, use of smart-cards with patient genetic data could be envisaged. These could be carried by the patient.

There are no major implications for the organisation of care. All of these therapies will be life-long and will require constant monitoring. Many, if not all, will require that the gene vector is periodically re-introduced into the patient. This re-introduction may be simple through injection or minor surgery, or more elaborate depending on the progress made in developing these therapies. The frequency with which this is necessary is likely to be high, but is again dependent on technical progress in the field.

Genetic diagnostics and associated diagnostic kits will allow for testing in the primary sector close to the patient's home. However, the prescription and management of gene tests by health professionals will increase the workload in the healthcare sector especially the primary sector.

Closed network boundaries e.g. due to competition between different specialties could hinder the multi-disciplinary co-operation necessary for future innovative capacity (see also drivers in section on minimally invasive surgery in this report).

The ultimate potential of stem cells (the ability to grow new neurones and entire organs to substitute damaged or malfunctioning organs) requires new tools to measure the in vivo development of replacement organs and tissues. Also it may be expected that regenerative therapies can be a realistic alternative to pharmaceutical therapy.

## Implications from the ICTEC Cluster (Telecare)

The major implication from the ICTEC Cluster for future healthcare organisation will be to:
Be delivered in the community and sheltered housing settings

- Focus on chronic disease management
- Support patient self management
- Avoid inappropriate admission, long stays and readmission into the acute sector as far as possible
- Collect information on the activities of daily living of patients so as to build up profiles and make appropriate interventions when health or social status decline

## Implications from the MEDTEC Cluster (MIS)

As a consequence of the developments outlined above, the hospital will increasingly become a place where high-technology medicine is practiced, and the conventional surgeon may become a rare species. In more general terms, as MIS is done more and more without hospital admission, it will foster changes in the organization of care both in and outside the hospital (Banta, Schersten and Jonsson 1993).

The most important change inside the hospital may be the shift from specialty specific operating rooms to the organization of MIS procedures in different specialties in a single dedicated suite, a development that is already ongoing (Kenyon et al., 2001). Perhaps it only makes sense for larger and/or academic hospitals to build dedicated, customized endoscopy operating room suites where the technology is built into the facility (Worrell 2002). Whether or not these facilities are invested in, most procedures in MIS nowadays are carried out as either day surgery or requiring relatively short hospital stays. MIS has and is expected to continue to reduce the need for hospital beds and is changing patterns of specialization and practice. This trend has been reinforced due to the fact that conventional procedures also tend to improve, allowing reduced lengths of hospital stay. An example is the development of mini-laparotomy for laparoscopic cholecystectomy. This has resulted in a situation where an increasing number of the planned operations to be replaced by minimally invasive procedures are carried out as a day-case, resulting in reduced differences in length of stay of conventional versus MIS procedures (Hirsch and Hailey 1995, Parliamentary Office of Science and Technology 1995). As the trend towards day-case conventional surgery may have been stimulated by the advent of MIS, both trends provide a cumulative stimulus for the reduction of beds, a trend that is expected to continue.

Specialties will change as a result of MIS. But how and to what extent is rather speculative. According to Banta, Schersten and Jonsson (1993) general surgery has gradually lost much of its work through technological changes and shifts to other specialties. As the volume of surgery falls, and as some procedures are done by other specialists, surgeons may find themselves in a difficult position. In the long run, according to these authors, these developments seem sure to change patterns of specialization and practice (Banta Schersten and Jonsson1993). Has this early prediction been confirmed? In a review of trends, Treacy et al. (1995) suggested that the field of MIS would widen, including to, for example, coronary revascularization, endoluminal graft repair of aortic aneurysms, and solitary axillary node biopsy in place of axillary clearance for breast cancer (Treacy and Johnson 1995). This trend is confirmed by more recent authors, e.g. Mack (2001) indicating that through the inclusion of robotics and other technological quantum leaps the field of cardiovascular surgery has become a fruitful field for new applications of MIS. Focusing on other specialties, Organ and colleagues (1996) expected MIS to expand with the addition of splenectomy, lymph node biopsy for haematological disorders, adrenalectomy, repair of perforated ulcers, staging of abdominal malignant neoplasms, and diagnostic laparoscopy combined with ultrasonography (Organ et al 1996). Most of these developments have been realized in the meantime, and although general surgeons may indeed have lost some of their work to other specialties, it seems that general surgeons more and more embrace MIS, perhaps slowing the trend described by Banta, Schersten and Jonsson in 1993.

Furthermore, complete abandoning of conventional surgery for specific indications seems unwise, as it is occasionally necessary to shift from a minimally invasive procedure to a conventional procedure.

After-care related to MIS is increasingly given in the home. This requires a different type of community care, involving, for example, nurses and general practitioners. MIS then, is a force

encouraging integration of the healthcare system, which is the major future expectation in this respect. As MIS becomes more and more the norm, the procedures will become more complex and patients in day surgery will be sicker. This will require more attention to patient selection and after care (Banta, Schersten and Jonsson 1993). In many countries, concepts of care that increase coordination between general services and specialized services are emerging or have been established, e.g. transmural care in the Netherlands, shared care in the UK, and managed care in the US. This development, albeit slowly, is expected to continue.

## Key policy areas for intervention

## Implications from the GENTEC Cluster

It is arguable that the major potential benefits for **pharmacogenomics** will not be realized without the development of an accepted means to inform healthcare providers as to the genetic status of patients. Some system will therefore have to be developed by liaison with all of the parties concerned. A trade-off must be sought between the potential of pharmacogenomics and the needs of patient privacy.

Europe has already been significantly behind the US in establishing regulatory processes in several news areas of biotech products. Europe should begin the process of developing and agreeing protocols which will facilitate the approval of drugs for specific genetic groups.

Following on 2 above, a process of education and liaison with pharmacists and clinicians will be needed to prepare for the introduction of drugs which are directed at specific genetic groups

**Gene therapies** are a highly desirable treatment for inclusion in Europe's healthcare arsenal and should be promoted. At this stage the major mechanism is through research funding to overcome the technical barriers which have affected its clinical success. While there are real concerns arising from the experiences of clinical trials to date, the benefits to healthcare are such that a continuation of justified trials is essential. In this respect Europe should ensure that it does not create trial conditions which either impede EU companies developing these technologies, or delay the availability of such therapies to EU patients. The costs of gene therapies are likely to be very high because of their complexity, life-long nature and the probable need for significant clinical involvement. The consequences for healthcare providers will be major. At least one genetic disease, treatable with a self-injected conventional injectable enzyme product, costs €200.000 per year. The added complexity of gene therapies may mean that they cost substantially more. Some policy initiatives on how healthcare providers will deal with such situations may be warranted.

As noted earlier, the future impact and significance of genetic diagnostics will increasingly be shaped around the politics and findings of the Human Genome Project (HGP). In anticipation of the findings, it is essential to lay down a harmonised regulatory framework, recognised in all parts of Europe, providing clear-cut rules to guarantee quality practices of genetic diagnostics throughout Europe. Such quality assurance scheme would encompass not only development, but also scientific and technological procedures, including guidelines on good laboratory, clinical and industrial practice. This is addressed in the ESTO study: "Genetic Testing Services – Quality Assurance and Harmonization in the EU: Technical needs and options".

The further diffusion of stem cell technology in both EU and the US is strongly dependent on a definite political attitude towards the ethical dilemmas on performing research on embryonic stem cells. None the less a public debate has only taken place in a small number of the EU

member states and mainly among the "old" EU member states. The major concern is whether the possibility of developing new medical treatments can outweigh the ethical doubts related to the isolation of stem cells from the embryo.

The EU has announced a delay in financing of human embryo and stem cell research until the end of 2003**,** allowing time to address the contentious issue of funding research using embryonic material. National governments will not be bound by the EU's decision; they are free to spend domestic research budgets as they choose.

Some other nations appear ready to allow embryonic stem cell research to move forward, including somatic cell nuclear transfer (SCNT, another name for cloning but more descriptive as it refers to the actual process of transferring a somatic cell into an enucleated cell). For example, a government-appointed ethics committee in Singapore has newly released recommendations that scientists in that country be allowed to create human embryos through cloning for certain research projects.

It appears clearly that public regulatory initiatives in the field are very diverse and incomplete, making the operational climate for innovative healthcare companies unsettling. According to Norus (2002), is it important that EU regulation keeps up with future global trends. Otherwise it can be expected that biotech enterprises will move to other parts of the world where their activities can be undertaken. This is due to the fact that the biotechnological field of enterprises consist of a number of overlapping and flexible environments built on very specific knowledge networks in the form of transnational strategic alliances, research collaboration etc.

The revision of the legislation currently taking place in most countries is monitored for example by the European Science Foundation (ESF, 2002).

Progress in stem cell technology is of great importance to ageing research and clinical practice. Therefore a desired scenario of the future application of stem cells needs to be visualised.
As stem cell research is relatively new it is important to build a scientific foundation in order to explore the potential of the technology and overcome the technical barriers. This includes confined experiments on cells obtained from embryos as well as on cells obtained adults in parallel. Ethical doubts related to the isolation of stem cells from the embryo need to be discussed in public in order to prepare a definite political attitude in the EU. The rapid development in stem cell research defies current regulatory frameworks and existing regulations need to be revised for stem-cell research. Public research inside stem cell research needs to be upgraded in order to secure long term goals and societal needs.

## Implications from the ICTEC Cluster

Without appropriate government policies, mainstream development of telecare and telemedicine is unlikely to occur (Barlow et al. 2003). Key areas for policy intervention include:

- The legal framework (e.g. data privacy, ethics, legal liability)
- Mechanisms for reimbursement or payment for services.
- Mechanisms to foster learning across projects and localities and develop a more coherent knowledge base.
- Refocused support from R&D and single-project funding towards support for the inclusion of telecare and telemedicine in mainstream care delivery.

Policy makers should not be overly prescriptive about the use and implementation of telecare and telemedicine, but develop an institutional framework which allows care providers to use it

as an option when appropriate. Policies will, however, need to reflect *national* differences. The introduction of telecare and telemedicine needs to fit into the specific national ways in which care is funded and delivered. A technology-driven 'one size fits all approach' will neither be able to meet the needs of vulnerable individuals nor be appropriate for the different European societies.

ICT facilitates, improves and creates linkages between different dimensions of the care delivery process. An effective care system is reliant on informed professionals treating informed patients. Benefits to key stakeholders include:

- *Patients*: Self-care (maintaining wellness), better access to care (provision of care when/where it's desired, reduced need for travelling), improved encounter with care service (speedier), empowerment (encounter is more of a dialogue), reduced readmission into the system, improved social inclusion and independence.
- *Health and social care professionals:* Easier access to appropriate patient-specific information, easier access to general professional information, appropriate use human resources, decision-support (including access to additional expert opinion).
- *Care system:* Optimisation of resource use, scale economies, better use of public health information (e.g. dissemination of health promotion information), reduction of inappropriate readmission, more highly skilled workforce.
- *Future prospects*:
    - increased mobility; use of GPRS/3G etc to facilitate care delivery when/where it's needed;
    - shift from human intervention to machine intervention - ICT controlling processes;
    - near patient/personal testing.

## Implications from the MEDTEC Cluster

The following recommendations are mainly addressed to national governments and national and regional health systems and healthcare payers, but they could also be implemented in some cases by policy bodies such as medical societies.

- *Guidelines* - Therapeutic guidelines should be established for those MIS procedures where there is convincing evidence of effectiveness and cost-effectiveness. The clinical guideline initiative of the European Association for Endoscopic Surgery (EAES) deserves full support. Data on the cost-effectiveness of treatment alternatives should, as far as possible, be integrated in the guidelines.

- *Training and safety requirements* - Training and safety requirements should be worked out and could be coupled to reimbursement systems as a means of 'steering' practice, in countries where the reimbursement system makes such coupling feasible.

- *Knowledge centres* For the sake of all interested parties (doctors, hospital administrators, government agencies, and industry) clearing houses (data banks) for exchange of available information need to be established on a national and/or international level The clearing house should be user oriented and should accumulate information on technical developments, safety, clinical applications, and evidence of effectiveness and cost-effectiveness of minimally invasive surgery procedures

- *Centres for minimally invasive surgery* - Healthcare authorities (and financers) should

actively support the establishment of regional centres for minimally invasive surgery that could act as reference centres (combining basic research, clinical research, treatment of patients, and possibly also technical research). These centres may generate, collect and disseminate knowledge on specific procedures and set up multi-centre trials involving other centres (e.g. the Leeds Centre for Minimally Invasive Therapy).

- *Reimbursement and funds* - In a number of countries the healthcare financing system (global budgets, reimbursement system) actually seems to block the development of appropriate, cost-effective use of minimally invasive surgery procedures in clinical practice. There is a need for proper reimbursement of minimally invasive surgery procedures which are proven to be cost-effective in order to stimulate diffusion of such procedures. Secondly, specific funds could be set up for capital investment in cases where the technology appears to be cost-effective.

- *Technology assessment* - Technology assessments (effectiveness, cost-effectiveness, life-cycle studies) in the field of minimally invasive surgery are valuable as a tool for health policy decision making. Many applications are still in the phase of clinical experiment or of unproven effectiveness. The results of such studies can be used to encourage appropriate diffusion and application of these procedures.

- *Consumer information* - A concerted effort could be made to improve lay knowledge of health practices, so that people will have a better basis for choice. The lay media could be actively involved in such efforts.

- *Implementation*- International organizations, such as the EU and WHO, should support and encourage the implementation of these recommendations in individual countries. Exchange of information developed by technology assessments is a particular priority.

Due to the overall limited evidence on effectiveness and cost-effectiveness of MIS procedures and due to a relatively low intensity of use, sharing of systems between specialties and a purchasing strategy based on the size of a hospital and the characteristics of the adherent patient population seem the most straightforward ways to prevent both under-use of installed systems and unwarranted adoption and use of new systems.

## A plea for further R&D

The provision of optimal health innovation and delivery systems across Europe has become much more complex. The general trends that we can see are:

- an increasing blurring of boundaries between public and private sector organisations in the health RTD and delivery systems;
- a growing emphasis on the prevention of ill-health;
- the growth of a variety of initiatives designed to move healthcare from expensive intramural settings (e.g., hospitals) into extramural settings and the community itself;
- the move towards developing trans-European R&D capacity and healthcare provision;
- the development of new tools and strategies to control (aggregate) expenditure on healthcare.[47]

[47] Moses B., University of Patras, Greece, Societal Change and Healthcare-Oriented Technologies

As a result of these trends, the roles and responsibilities of the institutions, practitioners and even users that formed the traditional market for health technologies are changing. We need to understand how these different actors perceive and respond to these transformations and so construct the socio-economic terms on which health innovations are mobilised and managed.

The future of public health service delivery will be shared among the local public health agencies, the community's private healthcare providers and organizations, and community based organizations and leaders. The science of epidemiology will continue to be one of public health's most useful guides and will extend beyond biomedical applications to evaluate innovative and comprehensive public health prevention strategies. It was argued that **cost-**effective prevention and treatment technologies embrace basic, applied and developmental research and, as such, necessitate cooperation and partnerships between academic institutions, national research institutes and industry. Future research topics could include for instance the following aspects:

## Healthcare related research areas

- Healthcare Terminology(data infrastructure)
- Reference terminology and terminology server development as a unifying element of an integrated CPR. Adoption of a common vocabulary for describing patient conditions and healthcare services.
- Artificial Intelligence Tools for Screening and Alerts
- Workflow, Rules, and notification engines that can automatically search clinical data to alert physicians to certain conditions that are present in a patient record.
- Quality Measurement
- Better definition of what constitutes quality healthcare, how to measure it, and how to affect change (relates to IOM reports on medical errors and proposals for how to improve the situation).
- Expert systems for Decision Support
- Individual health agents

## Technology related research areas that could benefit healthcare

### *GENTEC Cluster*

- The need to investigate and debate social and cultural aspects of genetic testing
- Boundaries for collaboration between different healthcare disciplines should be eliminated to secure provision of test capacity as well as the multi-disciplinary co-operation necessary for future innovative capacity
- In order to avoid conflicts between long term objectives and short term patient care and commercial initiatives (i.e. new products and services) public-private partnership is essential to set priorities for care and the rational allocation of resources
- The policy regarding challenges and problems related to genetic testing of healthy individuals need**s** to be defined
- A harmonised regulatory framework, providing clear-cut rules to guarantee quality practices of genetic diagnostics needs to be established throughout the EU

## ICTEC Cluster

- Voice/Speech Recognition
- Utilize speech to capture data and computer commands.
- Text Parsing
- Automatically parse text to extract structured data such as medications, results and patient conditions. Translate the data into structured database fields (concepts, terms, and, codes) that can be accessed and manipulated.
- Artificial Intelligence Tools for data mining
- Tools to automatically analyze data, discover patterns and present the results to non-technical users.
- Mobile Devices
- Mobile devices that can be easily used by physicians and other healthcare workers to interact with a computer system during the patient care process.
- Grid Computing
- Relevant to achieving better forms of healthcare delivery, distributed systems, and component use and reuse.
- Nanotechnology
- The convergence of nanotechnology and biotechnology

## MEDTEC Cluster

*Treatment monitoring systems*
The goal of research in this area is to enable the surgeon to monitor e.g. ablative treatment as part of the procedure in order to increase selectivity of tissue destruction. The advantage of sensitive monitoring systems is that the desired effect can be maximised, and that unwanted effects can be minimised.

*Delivery systems*
Further development is needed for steering systems and delivery systems, e.g. for distributing laser light within the target organ. Two main groups of technologies are needed:

- multifiber systems for interstitial treatment
- modified delivery systems to optimize laser light distribution within body cavities (e.g., hollow organs or blood vessels)

*MIS systems and accessories with minimal use of disposable materials*
Development and assessment of durable materials is needed. Such an assessment needs to include the perspectives of manufacturers, users, and society. The research can focus on:

- better quality of endurable materials
- design of accessories to optimize sterilization
- reliability of sterilization (especially with respect to AIDS)
- consequences of non-disposable accessories for working routines of healthcare staff
- less polluting disposables

Cost-effectiveness analysis can be used to guide technical development in this area. Hospitals should use technology assessment to guide investment decisions in minimally invasive surgery procedures, and in particular on the establishment of Endosuites.

Minimally invasive procedures in treatment of tumours have great potential and further research could lead to benefits for a large number of patients.

Further research is needed on the role of competing treatment modalities in a single minimally invasive surgery procedure or as part of minimally invasive surgical treatment strategies compared to conventional surgery in areas where evidence is lacking and where there is substantial doubt on patient benefits.

Meta-analyses should be carried out in particular field in minimally invasive surgery where a sufficient number of RCTs have been done, and long-term follow-up studies of MIS procedures should be reported.

Registries should be created including all randomized controlled trials prior to initiation, involving minimally invasive surgery procedures. A separate registry could list the RCTs alongside which an economic evaluation is carried out.

A small set of core guidelines for economic evaluation should be actively promoted and taught to researchers, in particular to clinicians and other non-economists assessors in the field of MIS.

A determination of how existing institutional, regulatory, and policy domains in the European health-care system are effecting and being affected by the new markets for innovative health technologies.

An examination of processes of 'interactive learning' across networks of firms, government, health intermediaries, and users that determine the negotiation over and eventual innovation trajectories that are followed; through consideration of the interaction between these institutions to identify instances where particular arrangements have facilitated or constrained innovation processes;

An evaluation of the impact that new health technologies have on inter-organisational relations (both public and private) in the healthcare system through the development of simulation techniques that can model the co-evolution of institutional and technological change, especially in relation to managing the tension that may arise between economic development and societal objectives

A determination of whether new health technologies are more, or less, demanding of health delivery systems, markets and producer-user relations and how the changes they create might be managed more effectively, to both enhance their potential for health improvement and by implication foster both personal and collective forms of social security.

# Epilogue: Potential for a Scenario Approach

The following indications suggest how to use the information from this roadmap for further vision building and outlines the implications of the project results for further scenario construction. Some ideas, suggestions and visions for potential scenario dimensions are articulated.[48]

The aim of a potential scenario analysis should be to calculate, for a distinct environment, two or three scenarios which are maximally consistent, maximally different from each other and are most likely. For these scenarios, appropriate considerations could be made in order to confront, with adequate planning, possible developments, which were originally unexpected.

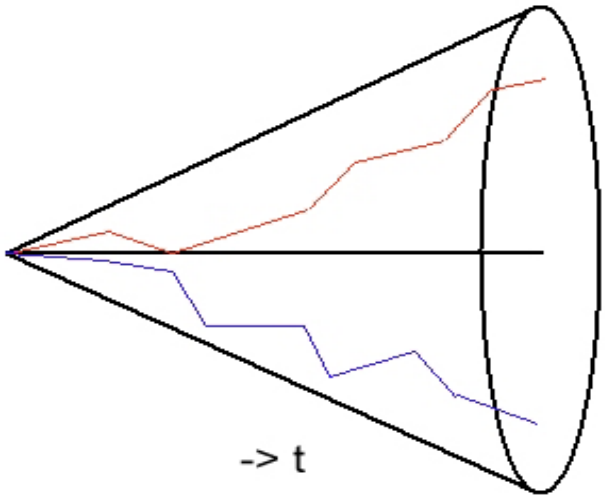



Illustration 1: Future Cone

This "Future Cone" encloses, starting from the present situation on the left, the sum of all possible developments. From the starting point, a possible development zigzags linear and unchanging in the future (central axis), every other comprehensible development must manoeuvre within the cone, happenings outside the cone can not enter and with increasing t, the cone will expand further. The results of a scenario analysis could be the red and blue marked scenarios in the picture which are very different from each other and are far enough away from the central axis (the present situation) to get new recognition.
A scenario consists not only of the end point in the basis of the cone but especially the route marks from the “point to the base,” which will be shown later, this path is the sum of individual development tendencies which a scenario defines.

## Step 1 - List of possible influential factors

Firstly a list of those factors which characterise the potential of the considered environment should be created. These so-called influential factors could be sorted into influential areas in order to structure the theme complex for consideration. This arrangement can also serve to

[48] This approach is based on a method applied by VDI- Future Technologies Division, Germany. For further detail, please contact braun_a@vdi.de.

organise an environment in a hierarchical way and uncover the field over successive refinements. In our concrete example, "Annex II," new influential areas with altogether 33 influential factors were obtained, whereby this list depending on the field under consideration, can occupy 50 or more single elements.

## Example: Extract Influential areas and factors

1 Prevention
1.1 Prevent the Spread and Development of Disease
1.2 Lifestyle Improvement

2 Promotion
2.1 Enhance Awareness,
2.2 Support Good Health Practices

3 Monitoring Health
3.1 Accurate Check and Test Health Status
3.2 Forestall the Development of Serious Conditions

4 Diagnosis
4.1 Identification of Conditions for Disease
4.2 Description of Medical Action

5 Treatment
5.1 Medical Care
5.2 Delivery of Healthcare

6 Aftercare
6.1 Follow-Up to Treatment
6.2 Rehabilitation

7 Gentech
7.1 Treatments for New and Re-Emerging Diseases

Illustration 2: Influential factors

## The combinational Problem of Scenario-analysis

This output list of influential factors in a two-fold perspective is too rough. Firstly influential factors were mentioned with great certainty which will only insignificantly influence the final scenarios – in this sense these factors can only be characterised as unimportant and therefore will be neglected for the further calculations (belonging to this are also influential factors which have clear development tendencies); secondly it relates to the actual process of scenario calculation in a problem class which can only be characterised in the computer science succinct as "difficult". The calculation time which is necessary for solving the problem, does not increase polynomially instead exponentially with the number of influential factors to be considered.

Should one wish to calculate scenarios with 50 influential factors theoretically, $7x10^{23}$ scenarios would be possible. Even a high power computer which can calculate more than 100 million scenarios per second would be occupied for the next 500 years.

Since the complex nature of the problem cannot be changed, and neither a faster computer or better algorithms can reduce the duration to an acceptable cubic or even quadratic dimension, it is necessary to reduce the cardinality of the entered amount therefore the number of the influential factors, and in this way simplify the large output problem to a smaller problem with approximate identical explanatory power.

This reduction will be made subsequently by the influence analysis, with the aim to reduce every user-defined entered amount to a manageable measure of maximum 23 factors (internal simulations have shown that for the calculation of scenarios existing from 23 described elements approximately six hours calculation time must be applied. Every additional influential factor would increase the duration by about factor 2,5. This means that with only 27 factors already over one week calculation time would be assumed).

## Step 2 – Influence analysis

The criteria for reducing the entry list in the frame of the influence analysis are the influence strengths. The question must be pursued, which factors of the original list have a great influence on the remaining elements and which, which is more important for us, only exercise a little or no influence on one another. Concerning this, the linear list is brought in quadratic form and the individual factors are evaluated in a matrix manually, in relation to a fixed scale, by pairs regarding their influences on one another (asymmetric).

Afterwards the individual influential factors are organised algorithmically on the basis of the *influence matrix* based on their (direct) influence and in order to uncover hidden cohesions or indirect influences a further process is used to compare the results from both cycles. Previous attempts have shown that the results of both operations in their entirety differ insignificantly but in detail there are substantial differences. Approximately 20% of the influential factors point to an indirect connection to each other which in subsequent scenario building processes could produce significant differences. The user in this case can exert significant influence on the content-related progress of the analysis process since the algorithms in this case make key factors available.

## Example: extract partial influence matrix

| | 1.1 Prevent the Spread and Dev | 1.2 Lifestyle Improvement | 2.1 Enhance Awareness, | 2.2 Support Good Health Practic | 3.1 Accurate Check and Test He | 3.2 forestall the Development of | 4.1 Identifcation of Conditions fo |
|---|---|---|---|---|---|---|---|
| 1.1 Prevent the Spread and Development of Dis | x | 3 | 0 | 0 | 1 | 1 | 0 |
| 1.2 Lifestyle Improvement | 1 | x | 0 | 1 | 0 | 1 | 1 |
| 2.1 Enhance Awareness, | 2 | 1 | x | 3 | 2 | 2 | 1 |
| 2.2 Support Good Health Practices | 3 | 1 | 1 | x | 2 | 3 | 3 |
| 3.1 Accurate Check and Test Health Status | 3 | 1 | 1 | 1 | x | 3 | 3 |
| 3.2 forestall the Development of Serious Conditi | 3 | 2 | 0 | 0 | 1 | x | 3 |
| 4.1 Identifcation of Conditions for Disease Befor | 2 | 2 | 1 | 2 | 1 | 3 | x |

Illustration 3: Influence Matrix

One recognises here the evaluation spectrum ("0" – no influence to "3" - maximum influence) and the paired asymmetric evaluation of the influences.

## Step 3 - Prognosis Creation

The list which was reduced in step 2 contains those factors – the so-called key factors – which a scenario describes in its rough structure. This rough structure must be further refined in which the user allocates appropriate development tendencies (characteristics) to the individual key factors. With this a few key factors could occupy two or (maximum) three characteristics.

## Example: extract prognosis

1. Lifestyle Improvement
 a) strong: for all
 b) unbalanced: only for a few
 c) only marginal

2. Support Good Health Practices
 a) through government health policies
 b) through private health services
 c) through media, press and the internet

3. Identification of Conditions for Disease before they Progress to ...
 a) remains the same
 b) is faster and better

4. Rehabilitation
 a) becomes more important
 b) is no longer affordable
....

Illustration 4: Prognosis of the key factors

## Step 4 – Consistency matrix

In order to calculate the entire compatibility of a scenario it is important to determine the individual consistencies of characteristic pairs. This determination is symmetric and orientates itself along a predetermined five step scale (spectrum from "eliminates itself" to benefits itself").

For the later consistency analysis this matrix will then be used in order to assess the entire consistency of a scenario. As was already mentioned the consistency value of a scenario, thus the computability of a determined scenario in its entirety respectively the components of scenarios among themselves is strong criteria for the ascertainment of the desired "extreme scenarios".

## Example: extract consistency matrix

Illustration 5: Consistency matrix

| -2 = schließt sich vollständig aus<br>-1 = ist irgendwie möglich<br>0 = neutral<br>1 = veträgt sich<br>2 = sehr veträglich / begünstigt sich gegenseitig | | 1. Lifestyle Improvement | | | 2. Support Good Health P | | | |
|---|---|---|---|---|---|---|---|---|
| | | a) strong: for all | b) unbalanced: only for a few | c) only marginal | a) through government healt | b) through private health ser | c) through media, press and t | a) remains the same |
| 1. Lifestyle Improvement | a) strong: for all | 0 | 0 | 0 | - | - | - | - |
| | b) unbalanced: only for a few | 0 | 0 | 0 | - | - | - | - |
| | c) only marginal | 0 | 0 | 0 | - | - | - | - |
| 2. Support Good Health Practices | a) through government health | 2 | 1 | 1 | 0 | 0 | 0 | - |
| | b) through private health servic | 2 | 2 | 1 | 0 | 0 | 0 | - |
| | c) through media, press and the | 2 | 1 | 1 | 0 | 0 | 0 | - |
| | a) remains the same | 1 | 1 | 1 | 0 | 0 | 0 | 0 |

## Step 5 – Span analysis

Also within this adjustment special factors could be exposed which significantly influence possible tendencies of a scenario. Those scenarios could be of such outrageous importance, that it is necessary to contemplate the later tendencies of these individual factors and consider all combinations of these characteristics in the building of scenarios. Generally in this step those two key factors (occasionally three) are determined which will most strongly influence the later building process and will most clearly alter the tendency of the scenarios. Additionally the possibility will be given to the user to strongly influence the "marching direction" of the scenario generation. When one considers again illustration 1 it can be clearly stated that the determined key factors correspond exactly to those "breaking points" in the path within the cone, which effectively lead the scenario path away from the middle axis.

## Example: Extract Span analysis

```
Span  34 with Descriptor   1: '1. Lifestyle Improvement'
Span  31 with Descriptor   5: '5. Biomaterials, Molecular Manufacturing '
Span  26 with Descriptor   6: '6. Genomic and Proteomic Technologies ...
Span  26 with Descriptor   9: '11. Tissue Engineering/Hybrid and Artificial ...
Span  23 with Descriptor 10: '12. Miniaturization and Integrated Microsystems'
Span  22 with Descriptor   4: '4. Rehabilitation'
Span  19 with Descriptor   3: '3. Identification of Conditions for Disease ...
```

Illustration 6: Span

## Step 6 – Consistency analysis

A scenario consists ultimately of a set choice of characteristics. A scenario with three factors and each with two characteristics would look like the following for example: 1a - 2b - 3a (thus for the influence factor 1 the first characteristic "a" would be chosen, for factor 2 the development tendency "b" and so on)

The difficulty exists in assigning those characteristic occupations so that the entire scenario acquires the highest possible consistency value (the problem of the combinatorial analysis was already discussed above).

Various considerations which clearly reduce the duration are displayed by our algorithms in this case. For example during the calculation those scenes which display the many partial inconsistencies or also the few total inconsistencies are ignored.

The result of the consistency analysis delivered a reduced amount of scenarios which distinguish themselves by a high consistency. This amount can be further reduced by the criteria of differentiation. Only those scenarios are thus interesting which are highly consistent as well as maximally different from one another. Also the entire possibility of a scenario as completion criteria can clearly reduce the number of scenarios further (thus there are scenarios which have a high consistency but are improbable or uninteresting. Simulations have shown that the probability criteria filter out those scenarios which correspond to the significant means of the current status of the environment under consideration or also those which approach an optimal but improbable occupancy).

## Example: extract result scenarios

1. Lifestyle Improvement:
  a) strong: for all

2. Support Good Health Practices:
  a) through government health policies

3. Identifcation of Conditions for Disease before they Progress to more Serious Stages:
  b) is faster and better

4. Rehabilitation:
  a) becomes more important

5. Biomaterials, Molecular Manufacturing :
  a) available and accepted by the population/legislation

6. Genomic and Proteomic Technologies /Use of Stem Cells / Cloning:
  a) broadly used to transform the implications of ageing

7. Personalized Pharmaco-Genomics:
  b) is broadly available

8. E-health / Public Health Information / Services and tools for Independent Living and Security:
b) broadly used for information only

9. Tissue Engineering/Hybrid and Artificial Organs/Xeno-Transplantation. :
a) is broadly available

10. Miniaturization and Integrated Microsystems:
a) is broadly available and promotes treatment

11. Smart Materials, Nanomaterials, Innovative Problem Solving Materials:
a) is broadly available and promotes treatment

12. Preventative Health Care:
c) increases

13. Healthcare Management & Healthcare Systems:
a) based on governmental health policy concepts

Illustration 7: End scenario

## The scenario analysis in figures

33 factors characterised at the beginning of the considered field whereby in the "worst case" approx. $5x10^{15}$ Scenarios are conceivable.
Through the reduction of 33 influence on 13v key factors the number of possible scenarios could be reduced to approx. 316.000.
The span analysis leads to a scenario framework from nine rough scenarios and their missing characteristic occupancies per consistency analysis were determined.
From 316.000 possible scenarios thus the nine most consistent scenario suggestions were determined.
From these nine suggestions finally the two scenarios which were most different from one another were chosen, whereas the probability criteria here were not applied.

In conclusion the results of the scenario analysis must be interpreted and be prepared descriptively.

## Example for two alternative scenarios

These key issues could be used to develop health-sector-specific scenarios within the context of the macro-scenarios, such as the "Globalization" vs the "National-Fortress" scenarios.

## The "Globalization" scenario

Macro Scenario: In line with global trends and opportunities, EU governments embrace global liberalisation, and facilitate private-sector empowerment to respond to global market forces, leading to market liberalization, with initially good economic growth.

Innovations in medical technology are responsible for a large share of the improvements in health care that result in procedures which are both more efficient and less invasive. In addition, it improved the quality of care provided and made it more effective. International developments in the medical devices industry are characterised by progressive miniaturisation, the increased use of information and telecommunication technologies, the development of new, better-tolerated biocompatible materials and the integration of biologically engineered methods.

In this scenario there is increased economic growth, but government spending on health care decreases, with an increased reliance on the private health-care system. This leads to a decline in services and academic medicine.

Health-care policies are developed on European level, but there is limited implementation, with the result that diseases of lifestyle and poverty increase. Healthcare Management & Healthcare Systems will be completely liberalized and based on free market and private service supplies. Preventive Health Care becomes more difficult (increasing stress / allergies /..etc) and the support of good health practices is mainly undertaken by private health services. Rehabilitation becomes more important.

Exclusive private health-care services cause antagonism between public and private health-care systems.

Services are available for those who can pay; hence the overall lifestyle improves only for a few.

The benefits and innovations emerged through the development of smart materials, nanomaterials, innovative problem solving materials, miniaturization and integrated microsystems, tissue engineering/hybride and artificial organs/xeno-transplantation are only available for specific target groups.

Foreign technology is imported and health-care options are increased, with a private academic health sector developing.

The identification of conditions for disease before they progress to more serious stages is faster and better, and biomaterials, molecular manufacturing will be available – however, the broad application either not accepted or not allowed. There are only limited applications for genomic and proteomic technologies /the use of stem cells / cloning because of legal bans, but personalized pharmaco-genomics is available for specific target groups. E-health / public health information / services and tools for independent living and security are broadly used for information purposes.

## The "National Fortress" scenario

Macro Scenario: Building on the S&T skills base and knowledge generates comparative advantage and a competitive edge regionally and globally. The regional identity is strengthened, although some national identity is lost. Initial economic growth will be slow. The incremental social development leads towards a shared regional vision. National and selective regional policies are developed and implemented. The ethos of caring grows, with a greater commitment to accountability. Increased economic growth leads to greater spending in the public health sector, as well as an increase in the private health-care sector, which have an increased focus on external markets. The development of local technology is encouraged.

In this scenario healthcare management & healthcare systems are based on governmental health policy concepts. Preventive health care increases, and good health practices are supported through government health policies. E-health / public health information / services and tools for independent living and security are broadly used for personal information. Overall there is a strong lifestyle improvement for all with faster and better diagnosis. However, also the diseases of lifestyle do increase. Rehabilitation becomes more important as people age and biomaterials are available and accepted by the population/legislation.

Genomic and Proteomic Technologies /Use of Stem Cells / Cloning broadly used to transform the implications of ageing, Personalized Pharmaco-Genomics is broadly available,

Tissue Engineering/Hybride and Artificial Organs/Xeno-Transplantation, Miniaturization and Integrated Microsystems, Smart Materials, Nanomaterials, Innovative Problem Solving Materials are broadly available and promote treatment. Hence it seems that rather this scenario is the technology-friendly approach.

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# Annex I: Results from international Foresight studies

Numerous science and technology Foresight exercises have been carried out around the world. Most of these have been national Foresight exercises and some have focused on sub-national and regional levels. There have also been a few that have been international in scope (in particular by the European Commission and the APEC Centre for Technology Foresight based in Thailand) or that have involved international collaboration (e.g. between Japan and Germany).

There is always a strong element of uncertainty when projecting technological progress and implications for the future. Since the matrix 2020 indicates potential foreseeable implications based on progress and directions in current science and technology (S&T) and does not attempt to predict or forecast exact events and timetables, trends **were gleaned from existing outlooks, testimonies, and foresights, providing collective opinions and points of view from a broad spectrum of individuals.**

The goal was to obtain a balanced perspective of current trends and directions, yielding ranges of possibilities rather than a single likely future to give a rich feel for the many possible paths that are being pursued. Such ranges of possible futures include both the optimistic and conservative extremes in technology foresights as well as the range of optimistic and pessimistic implications of these trends.

| Foresight Exercises from Country: | Inventory and Exploitation of International Foresights and Forecasts | | |
|---|---|---|---|
| | GENTECH | ICTECH | MEDTECH |
| Australia | DNA Technology<br>Gene machines to make new proteins<br>Sequence banks for proteins & nucleic acids<br>Complete maps of genomes of economically important organisms<br>Gene detection<br>Specific DNA probes<br>Detection of genetic health disorders<br>Gene/ enzyme replacement<br>Gene therapy<br>Genetic and proteomic engineering transforming new genes into organisms/ microbes<br>Improved waste water management<br>Disease and pest resistant strains<br>New anti-cancer drugs<br>Bio-sensors<br>Improved safety and monitoring in food & chemical industries and the environment<br>Crop engineering<br>Integrated systems<br>Bio- materials and bio-sensors<br>Home (health) diagnostic systems, daily check- up<br>Home artificial intelligence- based elderly and handicapped support device<br>Sensors connectable to sensory nerves<br>Production & processing of organic food<br>Medical & supportive technologies for | | |

| | | | |
|---|---|---|---|
| | elderly mobility & transport | | |
| Brazil | Bio- mapping<br>Bio- materials<br>Biotechnologies<br>Bacteriology<br>New biotechnology products<br>Transgenic crops<br>Bio- informatics<br>New cancer diagnosis techniques<br>DNA recombination<br>Gene therapy<br>Bio- safety<br>Diabetes Diagnosis techniques<br>Genome<br>Proteome<br>Aging control techniques<br>Telecare | | |
| Canada | Gene therapy<br>Genome-based therapeutics<br>Multi-transgenic animal models for human diseases<br>Humanized animal for organ transplants | Biochips for microsystems technologies | Nanotechnology identifying genes or proteins<br>Identify disease-related gene(s) or protein(s)<br>Biological and medical analytical device technologies<br>New pharmaceutical products & individualized health care<br>Nutraceuticals (transgenic and non-transgenic)<br>In-home identification of transgenic vs. Organic foods<br>Bio-electronics & biosensors<br>Artificial organs for therapeutic & industrial use<br>Biological components to provide molecular devices (nano-motors, hybrid |

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| | | | bio/semiconductor computers)<br>Portable, advanced biochemical analysers for health monitoring & diagnostics |
| Finland | Biosciences-prevention of cancer metastasis<br>Genetically modified food | | |
| France | Transgenic crops<br>Molecular design/modelling<br>Bacteriology<br>Tissue engineering<br>Gene detection<br>Gene therapy<br>Proteome<br>Biotechnology<br>Bio-processing<br>Biosensors<br>Bio-pharming<br>Nutraceuticals<br>Bio-safety<br>Bio-mapping<br>Bio-pesticides | Image technology for disease control<br>Functional diagnostic imaging<br>Bacterial/viral detection/Screening | Biocompatible materials<br>Aging control techniques<br>Monoclonal antibody production<br>Protein engineering<br>Pharmaceutical research using molecular techniques |
| Germany | Molecular biotechnology<br>Biological production systems<br>Bionics<br>Bio-mimetic materials<br>Renewable resources (biomass and agents)<br>Environmental biotechnology | | |
| Hungary | Functional genomics<br>Food safety technologies<br>Biomedical research – molecular biology | Telematics for intelligent transportation systems<br>Telemedicine | New methods of health preservation & prophylactics<br>Pharmaceuticals research with molecular techniques<br>Research in social hygiene |
| Ireland | Biotechnologies | | Integration and miniaturisation technologies |

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| | Genomics<br>New diagnostics<br>Gene chip technology<br>Drug delivery<br>Bioinformatics<br>Biosensors<br>Transgenics<br>Biomaterials<br>Combinatorial chemistry<br>Bioremediation<br>Robotics<br>Proteomics<br>Novel instrumentation technology<br>Food processing (food safety & quality technologies, biotech)<br>Biotechnology (disease detection, bio-screening marine organism, food processing)<br>Application of biotechnology in crops, animal production & food processing (diagnostics, genetic & breeding technologies, environmental impact assessment, risk analysis methodologies) | | (digital cameras – electronics & materials for manufacture of screen-integrated circuits, medical devices, sensors)<br>Food safety, quality production & processing (ingredient technology; food micro-structure, flavour and quality; minimal processing technologies; pathogen control systems; high pressure technology; food irradiation; robotics, IT)<br>Market intelligence (development of consumer behavioural models to project future food demands) |
| Japan | Use of stem cells for treatment<br>Identification of genes related to diabetes, hypertension etc.<br>Identification of multiple genes related to cancer<br>Protein engineering<br>Gene therapy against malignant tumours | Ambulance-hospital data communication systems<br>Biometric security systems | Bio-micromachining for drug delivery to cancer etc.<br>Elucidation of carcinogenic mutation mechanisms<br>Improvement in survival rate for cancer<br>Elucidation of cancer metastasis mechanisms<br>Scientific guidelines for adult disease-preventing lifestyles<br>Chemotherapy for digestive organ cancer with low drugresponsiveness |

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| | | | Elucidation of arteriosclerosis contraction mechanisms<br>Overcoming drug resistance of malignant tumours<br>Effective methods against cancer metastasis<br>Drugs to cure viral liver disease<br>Origins of Alzheimer-type senile dementia<br>Biological & immunological therapy effective for cancer<br>Effective methods of preventing Alzheimer's<br>Cure for allergic diseases<br>Development of HIV vaccine<br>Prevention of diabetic complications<br>Elucidation of individual ageing mechanisms<br>Anti-AIDS therapy<br>Early cancer diagnosis based on biochemical examination<br>Technique to eliminate viruses from blood<br>Effective means to prevent metastasis of cancer<br>Drugs to prevent certain types of cancer<br>Anti-cancer agents targeting manifestation functions of cancer genes<br>Bioplastics using microorganisms and plants<br>Cure for senile dementia of Alzheimer type<br>Improves photosynthesis to increase food production<br>Development of implantable artificial kidney<br>Organ regeneration through multiplication of own cells |

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| | | | Artificial organs incorporating human cells & tissues |
| Peru | Genetically modified plants & food<br>Bio-mapping<br>Biotechnology products<br>Bio-pharmacos<br>Biotechnology production of antibiotics & enzymes using micro-organisms | IT systems for health diagnosis | New transplant techniques and technologies<br>Health diagnosis techniques |
| South Africa | Biotechnology/food improvements<br>Bio-mapping<br>Gene therapy<br>Bio-pharming | Telemedicine<br>E-health | Development for HIV/AIDS and malaria vaccines<br>Prophylactics for TB/ hypertension<br>Microdosing<br>Human machine interfaces (bio-metrics, voice recognition |
| Spain | Genomics, Proteomics | Telemedicine | Health technologies |
| United Kingdom | Genetics & health risks<br>Stem cell research<br>Gene therapy<br>Interaction of genotype, lifestyle & environmental risk | Smart homes/telecare<br>Cyber health system<br>Health/bio-informatics | Biomedical research on prevention of dependency in later life<br>Longitudinal databases on health status & dependency<br>Assistive technologies for aged<br>Interaction of food/diet, genes & health<br>Brain development, brain function, learning & memory<br>Socio-economic determinants of mental ill-health<br>Home-based medical care<br>Medical image/signal analysis, synthesis & interpretation<br>New/cheaper vaccines for developing countries<br>Xenotransplantation<br>Tissue engineering<br>Advanced (e.g. functional, neuro-) imaging |

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| | | | Lifestyle medicines (e.g for anxiety, phobias) |
| US | Bioprocessing<br>Drug design<br>Genetic engineering<br>Biotechnology<br>Monoclonal antibody production<br>Protein engineering<br>Recombinant DANN technology<br>Biopharming<br>Gene transfer techniques<br>Gene therapy<br>Bio-molecular<br>Biomedical engineering<br>Combinatorial chemistry | Bioelectronics<br>E-health | Neutraceuticals<br>Tissue and organ engineering<br>Biocompatible materials<br>Functional diagnostic imaging<br>Bacterial/viral detection/screening<br>Advanced human-machine interfaces<br>Cellular-level sensors<br>Fibre optic probes |
| APEC | DNA technology<br>Complete genome maps of economically important organisms<br>Gene detection<br>Gene/enzyme replacement<br>Gene therapy<br>Genetic engineering<br>Bio-sensors | | |

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## Definition

Technology foresight addresses information, viewpoints, controversies etc. covering different knowledge dimensions (economy, technology, environment, society, policy, and values).

Foresight can be carried out by a broad set of analytical and participatory methods ranging from desktop research, expert groups, and stakeholder involvement to interactive brainstorming processes or broad participatory arrangements. Different approaches and methodological traditions have been established for long-range strategic outlook in such uncertain futures. One tradition has been established around corporate strategy, with focus on management of emerging technologies and on firms' future strategic environment. Godet (1987) and Day and Schoemaker (2001) are examples of this tradition. In this tradition Richard Slaughter (1998) defines technology foresight as: "*the ability to create and maintain a high-quality, coherent, and functional forward view and to use the insights arising in organisationally useful ways, for example, to detect adverse*

*conditions, guide policy, and shape strategy and to explore new markets products and services".*

Another tradition has been established within policy-making at governmental level seeing science and technology as important locomotives in national systems of innovation. Therefore, different types of technology foresight studies have attracted renewed interest during the 1990's, aiming at strengthening the national systems of innovation (Grupp and Linstone, 2000). Within this tradition, Martin (1995) has defined technology foresight as "*the process involved in systematically attempting to look into the longer-term future of science, technology, the economy and society with the aim of identifying the areas of strategic research and the emerging generic technologies likely to yield the greatest economic and social benefits*". Here, both adaptation of changes and creation of new changes are on the agenda.

The rationale behind the ESTO road mapping is located in the last of these two traditions.

Forecasting can be defined in according to Jantsch (1967) as a probabilistic statement, on a relative high confidence level, about the future. Technology forecasting is the probabilistic assessment, on a relative high confidence level, of future technological transfer or development. The literature on technological forecasting make a distinction based on intent. Kappel (2001) has identified that most forecasting falls into the category of exploratory forecasting, or making predictions about technical achievements in the future. An alternative is normative or goal oriented, forecasting that adds to predictions the resource constrains and allocations that make that progress happen.

Important to keep in mind is that technological forecasts do not take technological jumps in to consideration and to have a relative high confidence level it need to be based on a empirical data that can be traced back at least for decades. In other words it only make sense to exercise technological forecasting on mature technologies where the future development is dominated by incremental innovation.

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# Annex III: Technology Roadmap Bibliography

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