

OPPORTUNITIES AND THREATS OF MODERN BIOTECHNOLOGY

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This future scan is part of a broader initiative of the Dutch government to investigate the opportunities and threats of modern biotechnology for society. The present scan focuses on the potential effects of biotechnology on the organization of healthcare and healthcare services. Changes in the medical paradigm will eventually be reflected in the way medical care is delivered and organized. At present healthcare is still strongly based on the sequence of symptoms, consultation, diagnostics, cure and care. Prevention is a relatively minor part of healthcare as is self-management by the patient. Biotechnology is a broad scientific and industrial area that encompasses many aspects of health and healthcare. A pragmatic division of biotechnology in four areas, namely food, diagnostics, therapeutic interventions and 'replacement medicine' will be the base for the subsequent analyses.

Among all other developments the humane genome project is probably the most appealing. We discuss the hopes and expectations which surround biotechnology. However, the road from genetic variation to effective medical treatment is a long and winding one, indeed a double helix. From functional genomics the road leads to proteomics, metabolomics to epidemiological knowledge of emerging pathology and intervention strategies. These developments will fundamentally change the way one will address health and illness and may thus affect the healthcare system.

In the international literature only few authors have given thoughtful considerations on the effects biotechnology might have on the organization of healthcare delivery. Apart from more pure technological aspects, privacy, patient rights and protection as well as the role of medical professionals receive most attention.

The future scan on the potential effects of biotechnology takes place in times of increasing turbulence. What seemed utopia yesterday, may appear reality in experiments tomorrow. Such developments readily get characterized by the metaphor of a revolution: 'the biotechnology revolution, the genetic revolution, the healthcare revolution'. Although there is every reason to speak of the age of biotechnology, it is by no means sure that this will result in an age of re-creation. We argue why we abandon the metaphor of revolution and how the scenarios can be used to evoke debate and to widen the horizon. This may result in a draft of potential policy assignments.

Subsequently the report describes trends and possible consequences of modern biotechnology with regard to food, diagnostics, therapeutic interventions and replacement medicine.

Food and healthy feeding habits improve health significantly. Biotechnology has opened new avenues regarding food and health(care). Knowledge of the humane genome supplies insight into the risk and protective factors. The manipulation of organisms used in food processing adds a new dimension. Resistance against genetic manipulated food products increases, although new products may in the long run improve state of health. This would require a change in attitude. As citizens have always been responsible for their own feeding habits, there is no reason to change this in the age of biotechnology, i.e. medicalization should be avoided. Quality control and public information, however, remain typical

government tasks. We do not deem it likely that biotechnological innovations of food will rapidly and profoundly change the organization of healthcare.

An extensive evaluation is made of changed diagnostic processes due to biotechnological advancements. New areas of application and the resulting uncertainties are identified. The consequences for daily medical care, for the present and the future patient, for screening and predictive medicine are sketched. A vast increase in diagnostics may lead to a shift towards preventive medicine and will result in many non-symptomatic patients requiring medical attention. Opportunities and threats are weighed, with a special focus on how screening could be affected by a biotechnologically driven diagnostic boom.

Therapeutic interventions based on modern biotechnology could result in a vast increase of therapeutic options, both for rare and common disorders. Specific attention is given to pharmacology as this seems one of the most promising areas. Risk reduction, new targets and increased efficacy will increase the possibilities for cure. Clinical development will still be a rate limiting step. Treatment possibilities may benefit from gene therapy, which is seen as a truly different way of healing. However, the discrepancy between experimental investigations and clinical application is wide and only substantial investments could reduce this gap. Cellular therapy is another form of highly individualized medical care, especially for cancer treatment. Both aforementioned areas require special investments in facilities and knowledge. Finally we touch upon the potential importance of biotechnology in the (renewed) battle against infectious diseases.

The growing waiting list for organ transplantations increases the pressure to find alternative solutions. Xenotransplantation is viewed as one of those solutions. Modern biotechnology has reframed the theoretical cadre by which transplantation rejection problems need no longer form an unsolvable obstacle. For the next fifteen years xenotransplantation does not seem to be the solution for shortage of donor organs; simply too many questions need to be answered and urgent problems solved. Instead of organ transplantation other developments emerge such as tissue engineering and stem cell manipulation. Especially stem cell manipulation could lead to a shift in the area of tissue replacement and repair of damaged organs. Whether this will have substantial effects in the next 15 years remains elusive. Both developments – xenotransplantation as well as embryonic stem cell research – evoke emotional ethical discussions.

Evaluating the effects of biotechnology at a higher level of integration, we pursue the issues of healthcare systems and the medical paradigm. Perhaps more than any other technology, biotechnology will affect individual healthcare by its emphasis on DNA. Scientific progress has not solved many ethical and societal dilemmas of healthcare but rather seems to have magnified existing questions. Goal and ends of medicine have to be reshaped. So far existing policies have stressed a healthcare system that is equitable, of high quality and thus contributes to social coherence and stability. Biotechnological changes have both stabilizing and destabilizing effects on the present system. One of the major challenges for the future is a healthcare system that proves to be 'biotechnologically sustainable'.

Most people receive medical help in a similar fashion. A simple model is formulated in which the various aspects are aligned. The usual entrance into the healthcare system is the occurrence of symptoms. Diagnostics, cure and care usually follow. Modern biotechnology – by accentuating diagnostic profiling of risk factors – could substantially change present 'logistics' of healthcare. This may result in a major increase of preventive medicine. One example is used to illustrate this shift in paradigm. Based on a number of considerations, we outline a first draft of a

biotechnology paradigm of healthcare. The issues emerging from this model are explored.

Due to the comprehensive nature of biotechnology, panoramic views are scarce. We therefore use hypercholesteremia as an example to illustrate the many facets regarding biotechnology, illness and medical care. Although biotechnology plays a principle role, it is by no means the only acting principle. High cholesterol levels are associated with coronary and heart diseases and form a major threat for public health. Familial hypercholesteremia (FH) is a hereditary form in which fat metabolism is disrupted. However, not every carrier of a mutation is at risk for cardiovascular disorders and an unexplained variation between genotype and phenotype is under investigation. Apart from a genetic predisposition, endogenous and cellular factors play a role in the development of disease, while lifestyle and environmental factors also contribute to pathological changes. Cholesterol-lowering treatment (especially statins) is effective, although a subgroup of patients does not benefit. Moreover, diet and exercise reduce cholesterol levels. FH is an almost prototypical example of the complex interaction between genes, environment and behaviour. Genes are important but not necessarily decisive. The knowledge acquired for the FH patients will also affect the public in general as most people with high cholesterol levels do not suffer from a mainly genetic disturbance. The role of prevention will increase, for all groups of patients. Prevention with a strong emphasis on effective self-management by people at risk. The care need will probably increase and it cannot be excluded that pharmacological treatment is used to compensate for lifestyle. Organization of care and treatment for hypercholesteremia thus illustrate the delicate balance between genetics and behaviour.

Having analyzed the main trends and uncertainties the Foundation for Future Health Scenarios (STG) made a choice regarding the forces and uncertainties that may shape the future. Based on a combination of uncertainties and potential impact, we motivate our choice for three scenarios that depict plausible futures for healthcare in 2015. Biotechnological progress and reactions of the public result are different in the scenarios The Expanding Universe, The Big Bang and The Lonely Planet. The complete scenarios are given in chapter 12, but do not lend themselves for a summary.

Scenarios are stories. They are drafts of plausible future, but do not address specific policy issues. The consequences of the three scenarios are further analyzed from the perspective of the government. For food, diagnostics, therapeutic interventions and replacement medicine a separate analysis is made. Seven themes have been chosen to make the consequences of the scenarios explicit in terms of policies and options to anticipate. Themes that are relevant for the government include quality, access to care and costs. Other themes pertain the consequences for the system of care, the professionals, the attitude of citizens and the safeguards for the society. The aim of this exercise is to explore policy options of the different scenarios.

Despite the differences between the scenarios, the advance of biotechnology will result not only in diverging trends and effects. The common consequences require a pro-active policy so that challenges are anticipated and opportunities are fully exploited. A first attempt was made to clarify main future issues. Although scenarios have to be used for the 'art of strategic conversation', more concrete issues also have a right of their own. Policy makers have to prioritize and to anticipate in order to avoid reactive measures. The task at hand is to guarantee the sustainability of the healthcare system and to improve health for all citizens, a tremendous task indeed.