

From Bio to NBIC convergence – From Medical Practice to Daily Life

Report written for the Council of Europe,
Committee on Bioethics



Rinie van Est, Dirk Stemerding, Virgil Rerimassie, Mirjam Schuijff,
Jelte Timmer, Frans Brom

drugs kennis
veranderen
interactie
debat
techniek
wetenschap
onderzoek
wetenschap
wetenschap
wetenschap

Rathenau Instituut

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Preface Rathenau Instituut

In the Summer of 2013 the Rathenau Instituut was invited by the Committee on Bioethics (DH-BIO) of the Council of Europe to explore what kind of new emerging technologies exist that may raise ethical and legal challenges from the perspective of human dignity and human rights.

The Council of Europe's initiative reflects a growing international interest to map and anticipate potential disruptive societal effects of new emerging technologies. One of the first events to trigger such interest was the workshop "Technological convergence for improving human performance", which was organized in 2001 by the American National Science Foundation. The workshop put to the fore the growing interaction between nanotechnology, biotechnology, information and cognitive technology. This so-called NBIC convergence was thought to be disruptive, in particular with regards to the question of what it means to be human in the 21st century.

Strongly inspired and motivated by the above event, the Rathenau Instituut has become deeply involved in exploring the societal meaning of NBIC convergence. Over the last decade we have studied a variety of emerging technologies like synthetic biology, robotics, persuasive technology, and brain stimulation technologies. In particular on the European level we have studied NBIC convergence in a more comprehensive way. This is exemplified by the 'Making Perfect Life' project, which was commissioned by the STOA (Scientific and Technological Options Assessment) bureau of the European Parliament.

Based on the assessment of four fields of bioengineering – body, brain, living and intelligent artefacts – the 'Making Perfect Life' project concluded that there was a strong need to broaden the bioethical debate in our society in response to NBIC convergence. The European Commission was advised to take a more prominent, integral and pro-active role in stimulating research, public awareness and debate in Europe on the ethical, legal and social aspects of bio-engineering in the 21st century.

Clearly the initiative of the Council of Europe to explore the ethical and legal challenges raised by technological convergence resonates with the recommendations of the 'Making Perfect Life' project. The Rathenau Instituut is glad, therefore, that it was asked by the Council of Europe to cooperate in this exciting endeavor.

Our study "From bio to NBIC – From medical practice to daily life" highlights three technological trends which might be very relevant for the Committee on Bioethics. First of all, new types of developments are observed within the medical domain: from neuro-modulation techniques to molecular medicine. Our study further shows that NBIC convergence enables the application of biomedical technologies outside the professional medical domain. Finally we see, as a result of this development, an increasing use of biomedical tools and bio-data for non-medical purposes, like gaming, entertainment, marketing, coaching, and human or social enhancement.

Jan Staman

Director Rathenau Instituut

Preface Committee on Bioethics

In the past decades a variety of developments in the field of biomedicine have been addressed by the Council of Europe. While recognizing these developments as a potential benefit for human health and welfare, the Council also realizes the possibility of abuse as a reason for concern from the perspective of human rights and human dignity. On the basis of the common framework provided by the European Convention on Human Rights and Biomedicine, or Oviedo Convention (1997), the Committee on Bioethics of the Council of Europe (DH-BIO) has considered various ethical and legal challenges raised by the applications of biology and medicine.

In recent years innovations in the biomedical field are more and more emerging from the convergence of developments in different domains, including nanotechnology, cognitive science and information technology. As a result of this convergence, we can observe an increasing interaction between the life sciences and the engineering sciences. This interaction and convergence between different scientific and technological fields also raises new questions about the implications of these developments for human rights and human dignity.

For DH-BIO there is a clear need to look into these new developments as a basis for possible future activities focusing on the ethical and legal challenges raised by new forms of technological convergence. As a first step in this process, DH-BIO invited the Rathenau Instituut to give an overview of this complex and wide variety of developments and to identify the ethical challenges raised, in particular with regard to the protection of human rights.

Earlier drafts of this report have been discussed with invited experts and during a plenary meeting of the Committee on Bioethics. As the lively debates during these meetings have made clear, this study offers an excellent starting point for further activities planned by the Committee, aiming at more in-depth analysis of the ethical issues raised by the developments that are discussed in this study.

Anne Forus

Chair DH-BIO
Council of Europe

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1 Introduction

The Committee on Bioethics of the Council of Europe has played an active role in anticipating new emerging technologies. In line with this tradition, the Committee has asked the Rathenau Instituut to explore what kind of new emerging technologies exist that may raise ethical and legal challenges from the perspective of human dignity and fundamental human rights.

This report provides a specific perspective on emerging technologies, namely NBIC convergence. NBIC convergence refers to the convergence of nanotechnology, biotechnology, information technology and cognitive technology. We believe the perspective of NBIC convergence can be helpful in clarifying which techno-scientific developments the Committee has already extensively considered and which developments do not yet appear on the 'radar' of the Committee but may be of interest to the Committee in the coming years. Our exploratory study aims to enable an informed discussion within the Committee about which technological developments especially might deserve further study.

1.1 Summary of our argument

In chapter 2 we have described the role and activities of the Council of Europe in the field of science and technology as a starting point for our own work. In this way we wanted to develop a fuller understanding of the way the Committee on Bioethics has dealt with advances in biology and medicine and to get a clearer idea of how to define the focus of our report. In chapter 3 the perspective of NBIC convergence is presented. We use this perspective on new emerging technologies to pinpoint some technological megatrends and to indicate to what extent, if at all, the Committee has already dealt with these developments in the past. We conclude that the Committee has focused in its work on developments in the field of biotechnology, in particular genetic technologies. The NBIC perspective provides three other complementary perspectives. These three perspectives – (cognitive) neurotechnology, nanotechnology, and information technology – are discussed in chapters 4, 5, and 6. In our discussion of the neuro- and nano-perspectives we address in particular various new types of interventions being introduced in the human brain and body that may be of interest to the Committee on Bioethics to further explore over the next few years. In our discussion of the info-perspective we focus on the rapid proliferation of intelligent artefacts that have or will become intimately integrated into our lives and which can be used to monitor our mental and physical health conditions or actively stimulate and coach us to adopt a healthy lifestyle. In chapter 7 we discuss how this new wave of technologies may transform a variety of socio-technical practices, causing humans and technology to become increasingly entangled. As a result, the human condition is more and more becoming a techno-human condition. This implies that biological and biomedical technologies are increasingly applied in multiple ways outside the practices of professional health research and health care. In chapter 8 we conclude that through the increasing NBIC convergence we are moving from well-known terrains of (bio)ethical debate to potentially new terrains, which will raise new ethical and regulatory challenges. The principal question is whether the fora for ethical reflection and debate that are institutionally linked to the practices of professional health research and health care will be able to take up the challenge to explore the ethical issues raised by the developments outside the medical domain.

1.2 Note on our methodology

The request for this study by the Committee on Bioethics included the following items:

- Overview of current scientific developments in the field of emerging technologies
- Focus on developments which may raise bioethical issues, in particular with regard to the protection of human rights
- Special attention to the neurosciences, genomics and other ‘omics’ technologies, and to nanotechnologies
- Identify the main ethical (and regulatory) challenges raised by these developments (without going into their in-depth analysis)

The starting point for this study was a number of previously published studies about converging technologies in which the Rathenau Instituut has participated (Nordmann 2004; Berloznik et al. 2006; Van Est et al. 2010; Van Est & Stemerding 2012). We further included in our discussion the founding study on converging technologies published by the US National Science Foundation and Department of Commerce (Roco & Bainbridge 2002).

The focus in this report is on developments in the fields that are relevant from the three perspectives – neuro, nano, and info – that complement the bio-perspective as already familiar terrain for the Council of Bioethics. Genomics and other ‘omics’ technologies we refer to as a subject in our discussion of the nano-perspective (chapter 5). We did not discuss synthetic biology as a converging technology in this study, because it is mainly involved with research on the microbial level and as such does not raise bioethical issues that are relevant from a human rights’ perspective.

In writing this report we also greatly benefited from the opportunity to discuss draft versions of this study in an extended Bureau meeting of the Committee on Bioethics, involving a number of invited experts from different fields and countries (Paris, 30 October 2013) and subsequently in a plenary meeting of the Committee on Bioethics in Strasbourg in November 2013.

2 Role and activities of the Committee on Bioethics

Science and technology and human rights are strongly intertwined. On the one hand, science and technology may strengthen human rights and human dignity. Developments in medicine have contributed to healthier and longer lives and ICT has provided new means for personal development and interaction, to name but two examples. On the other hand, science and technology may give rise to risks and ethical issues and therefore threaten human rights and human dignity. Consider, for instance, the atrocities committed against human test subjects in the so-called pursuit of scientific knowledge, the physical hazards of new chemical substances, or the privacy issues inherent to the coming of the digital age. Indeed, science and technology and human rights have a delicate relationship in need of close attention.

In order to combat the downsides of science and technology, the European Convention on Human Rights – the treaty that forms the backbone of the human rights framework of the 47 member states of the Council of Europe – evidently forms a first line of defence. However, in acknowledgement of the delicate relationship between science and technology and human rights, the Council felt the need to explicitly engage with science and technology. In the words of the Council, it wanted to strike “the necessary balance between progress and respect for human dignity”.¹ Ever since its establishment in 1985, its Committee on Bioethics (formerly Steering Committee on Bioethics) has demonstrated remarkable foresight for emerging S&T and has facilitated the Council’s member states towards the codification of fundamental principles and values in the face of S&T. Correspondingly, it helped in establishing ethical thresholds that were not to be passed.

The core of the aforementioned legal instruments is evidently the European Convention on Human Rights and Biomedicine or Oviedo Convention (1997).² The purpose of the Oviedo Convention is laid down in article 1: “Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine”. The Oviedo Convention contains provisions regarding:

- consent;
- private life and the right to information;
- the human genome, including predictive genetic tests, interventions in the genome, and non-selection of sex;
- scientific research, including on embryos in vitro;
- organ and tissue removal;
- the prohibition of financial gain and disposal of a part of the human body.

1 <http://hub.coe.int/web/coe-portal/what-we-do/health/bioethics?dynLink=true&layoutId=78&dlgroupId=10226&fromArticleId=>

2 Currently, twenty-nine member states of the Council of Europe have ratified the Oviedo Convention. Six member states have signed the treaty, but not (yet) ratified it. See: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=18/12/2013&CL=ENG>

In terms of structure, the Oviedo Convention is intended to set out only the most important principles. Additional standards and more detailed questions are to be dealt with in additional protocols. The Convention can therefore be seen as the starting point for an ever-growing human rights framework dedicated to developments in science and technology. Relatedly, the Explanatory Report to the Oviedo Convention reads as follows: “the Convention as a whole will thus provide a common framework for the protection of human rights and human dignity in both long-standing and developing areas concerning the application of biology and medicine” (Explanatory Report to the Convention on Human Rights and Biomedicine, No. 7). In succession to the Oviedo Convention four additional protocols have been adopted so far. They deal with the following topics:

- cloning of human beings (1998);
- transplantation of organs and tissues of human origin (2002);
- biomedical research (in particular, rights of participants) (2005);
- genetic testing for health purposes (2008).

In addition to the Oviedo Convention and the additional protocols, the Council of Europe has adopted a number of non-legally-binding recommendations, such as those regarding xenotransplantation (2003), persons with a mental disorder (2004), and research on biological materials of human origin (2006).

In sum, the Council of Europe has a long-standing history of coping with the downsides of science and technology in the face of human rights and human dignity. These efforts have culminated in a number of legal instruments, largely dedicated to developments in the biomedical sphere. On the one hand, these instruments relate to fundamental principles – like the right to a private life – that are laid down in other (previous) legal instruments of the Council of Europe. On the other hand, they also contain newly formulated common standards, as far as the consensus among European countries allowed (Andorno 2005).

In order to protect the individual's dignity and fundamental rights with regard to the applications of biology and medicine, the Committee on Bioethics, over the years, has addressed ethical and legal challenges raised by developments in the biomedical field. Amongst others, the Committee has focused on biomedical research, human genetic testing and screening, cloning of human beings, xenotransplantation, transplantation of organs and tissues of human origin, and biobanks. These developments relate to advances in biology and medicine and mainly concern technologies that intervene in the human body.

3 The NBIC perspective on new emerging technologies

The Committee on Bioethics of the Council of Europe wants to explore what kind of new emerging technologies exist that may raise ethical and legal challenges from the perspective of human dignity and fundamental human rights. This chapter provides a perspective on emerging technologies and aims to delineate the subject of our study and to clarify which developments might need special attention. Whether those developments indeed require the attention of the Council of Europe in the coming years is of course for the Council to debate and decide on. Accordingly, this report will not address that question, but aims to provide input to the Council so that it may address that discussion.

The perspective we use to get to grips with a broad spectrum of new emerging technologies is *technological convergence*, in particular so-called NBIC convergence. NBIC refers to four key technologies: nanotechnology, biology, information technology, and cognitive sciences. The mutual interplay between these four key technologies is denoted as NBIC convergence (Roco & Bainbridge 2002).

3.1 NBIC convergence³

Technological convergence – simply combining different technologies – has always been an important source for innovation, because technological breakthroughs often take place on the boundaries between technologies and industrial sectors. In particular, the convergence of information technology into a wide range of scientific disciplines and industrial and service processes, and actually in every aspect of society, characterizes the information revolution (Castells 1996). It is no surprise that the term ‘convergence’ was used more and more in the IT sector during the 1980s. An example of such convergence in those years is mechatronics, i.e. combining IT and production technologies. A decade later the Internet resulted from the convergence between IT and communication technologies. During that period, the Human Genome project also provided a prime example of technological convergence: between biology and IT (so-called BI convergence). The mapping of the human genome is strongly dependent on computer power. Vice versa, developments in and concepts from biology also inspired the IT community, as illustrated by notions such as neural networks, swarm intelligence, and DNA computers.

At the start of the 21st century an even broader view on technological convergence was first promoted in the closed world of military and space research in the United States. For example, an influential study by RAND foresaw that bio/nanomaterial trends and their synergies with information technologies would create a global technology revolution (Antón et al. 2001). In a similar vein, the NASA Ames research centre introduced the triangle of nanotechnology, biology, and IT – thus, NBI convergence – to its mission. Inspired by these optimistic signals, Roco and Bainbridge of the National Science Foundation (NSF) organized the workshop ‘Converging technologies for improving human performance’ at the end of 2001. Roco and Bainbridge introduced the term NBIC convergence there; it was a name for the intended integration between nanotechnology, biotechnology,

3 This section is mainly based on Berloznik et al. 2006.

information technology, and cognitive sciences. The expansion of the NBI-triangle to the NBIC tetrahedron recognized the rapid emergence of the cognitive sciences and the comeback of artificial intelligence.

Not a neutral but a fruitful concept

NBIC convergence is not a neutral concept. Most trends are perceived and set with a certain goal in mind, because trends observed can be changed into *visions* that suggest particular actions (Van Lente 1993). This phenomenon is called performativity; visions are necessary tools to mobilize minds and resources, create incentives, formulate goals, set the research agenda, and raise political and public awareness, etc. Accordingly, the NSF workshop was organized to mobilize people and resources. The workshop put forward two radical ideas. The first was the utopian vision that NBIC convergence will lead to a fantastic new wave of innovations, that is, a prosperous 'Era of transitions' (cf. Gingrich 2001). According to the NSF, breakthroughs in the areas of ICT and nanotechnology will make large-scale developments in the areas of biotechnology and the cognitive sciences possible. This will lead to a technological development which will increasingly focus on the control of animals' and humans' bodies. This leads us automatically to the second radical idea: introducing transhumanist thinking into publicly funded research. The NSF workshop proposed a broadening of the objective of scientific research from curing ill people to improving the physical and mental performances of healthy people. It is expected that it will become technically possible to improve human performance via machine intelligence (e.g. brain implants) or modification of the human body and that these technical improvements will provide adequate means of solving present social, political, and economic conflicts.

Both radical ideas that were communicated through the NSF report led to international attention in small circles. For example, the European Commission set up a high-level expert group (HLEG) Foresighting the new technology wave. The HLEG rejected the desirability of improving physical and mental performances in humans. However, the relevance of the notion of NBIC convergence as a way to frame, signal, and anticipate new emerging technologies was embraced. NBIC convergence was thought to be crucial for the successful development of new areas such as molecular medicine, service robotics, ambient intelligence, personal genomics, and synthetic biology. According to the HLEG, this joint set of engineering fields promised a "new technology wave" (Nordmann 2004). It was also empirically shown that convergence between various NBIC key technologies was taking place (Compañó 2006). Moreover, it was acknowledged that the convergence of technologies and scientific disciplines was a normal aspect of technological and scientific development. The NBIC key technologies themselves all arose from the convergence of underlying disciplines, such as "physics, chemistry and electronic engineering (nanotechnology), biology, chemistry and medical sciences (biotechnology), electrical engineering, mathematics and physics (information technology), ... and psychology, linguistics, informatics, philosophy and anthropology (cognitive sciences)" (Berloznik et al. 2006, p. 49).

To conclude, NBIC convergence is a fruitful way to signal new emerging technologies. This way of framing new emerging technologies can also be used to reflect on the technological terrains that might be of special relevance to the Council of Europe. Up till now the Committee on Bioethics has mainly focused on biotechnological and biomedical interventions in the human body (see the light-green cell in Table 3.1). Through NBIC convergence, the number of ways to intervene in the human body will greatly increase, not only by means of biotechnology (B) but more and more also by way of nanotechnology (N) and information technology (I) (see the yellow cell in the third column and the second row in Table 3.1). Moreover, due to the advent of cognitive technologies our minds will more and more be the object of intervention (see the yellow cells in the third row in Table 3.1).

Table 3.1 Examples of new bio-tech-based and info-tech-based interventions in human bodies and brains (based on Van Est & Stermerding 2012, p. 29). The Committee on Bioethics has extensive experience with the technologies in the green-coloured cell, and far less experience with those in the yellow cells.

	Bio-tech-based interventions	Info-tech-based interventions
Human body	<ul style="list-style-type: none"> - Genetic engineering: - Gene therapy - Artificial chromosomes in gametes - Stem cell therapy 	<ul style="list-style-type: none"> - Smart e-pills
Human brain	<ul style="list-style-type: none"> - Stem cell therapy - Nanomedicines crossing the brain barrier 	<ul style="list-style-type: none"> - Brain-computer interfaces (BCIs) - (Non-)invasive neuromodulation - Persuasive technology

3.2 NBIC as a new kind of convergence⁴

One might conclude from the above that NBIC convergence is ‘more of the same’ in the sense that innovation is normally driven by technological convergence. However, there is something qualitatively new about NBIC convergence. Namely, a significant part of the new converging developments is taking place at the boundary between life and artificial life, that is, between human and machine, in which thought and artificial thought, and intelligence and artificial intelligence are contained. This has to do with the essence of NBIC convergence.

The key characteristic of NBIC convergence is the fact that it points to the gradual dissolving of the narrow borders between the physical and the biological sciences. Traditionally, the physical sciences studied non-living systems, while the biological sciences studied living organisms. NBIC convergence implies their convergence. This merger goes both ways, and each way represents a bio-engineering megatrend that may be denoted with the catchphrases ‘biology is becoming technology’ and ‘technology is becoming biology’ (cf. Arthur 2009).

Biology is becoming technology

On the one hand, the physical sciences (nanotechnology and information technology) enable progress in the life sciences, such as biotechnology and cognitive sciences. Above, we saw that this type of technological convergence has created a new set of engineering ambitions with regard to biological and cognitive processes, including human enhancement. One might say that developments in nanotechnology and information technology boast of the dream that complex living systems, such as genes, cells, organs, and brains, might in the future be bio-engineered in much the same way as non-living systems, such as bridges and electronic circuits, are currently being engineered. In this respect, the ongoing influx of the physical sciences into the biological sciences seems to go hand in hand with a growing influence of an engineering approach to life. The ‘biology becoming technology’ trend, therefore, implies and promises a strong increase in *new types of interventions* into living organisms, including the human body and brain.

Technology is becoming biology

On the other hand, the life sciences – insights into biological and cognitive processes – inspire and

⁴ This section is mainly based on Van Est & Stermerding (2012).

enable progress within the physical sciences, such as material sciences and information technology. The trend ‘technology is becoming biology’ implies that technologies are acquiring properties we associate with living organisms, such as self-assembly, self-healing, reproduction, and intelligent behaviour. ‘Technology is becoming biology’ is about bringing elements of life-like systems into technology. Bedau et al. (2009) therefore speak about ‘living technology’. This development relies heavily on so-called biomimicry, or biomimetics. The basic idea behind biomimetics is that engineers can learn a lot from nature. Engineers want to emulate nature to enhance their engineering capabilities. The ‘technology becoming biology’ trend embodies a (future) increase in bio-, cogno-, and socio-inspired *new types of artefacts*, which will be applied in our bodies and brains and/or intimately integrated into our social lives. Examples of bio-inspired artefacts are biopharmaceuticals, engineered tissues, stem cells, and xenotransplantation and hybrid artificial organs. Animalistic or humanoid robots, avatars, softbots, persuasive technologies, and emotion-detection techniques are examples of cogno- and socio-inspired artefacts.

We may conclude that the Committee on Bioethics has a lot of experience with technologies that fall within the ‘biology is becoming technology’ trend. Moreover, the Committee also has a lot of experience with bio-inspired artefacts to be used in the human body (see the green column in Table 3.2). The Committee has far less experience with the cogno- and socio-inspired artefacts that fall within the ‘technology is becoming biology’ trend (see the yellow column in Table 3.2).

Table 3.2 Examples of new types of bio-, cogno-, and socio-inspired artefacts (based on Van Est & Stermerding 2012, p. 30). The Committee on Bioethics has ample experience with the technologies in the green coloured cells, and far less experience with those in the yellow cells.

Source of inspiration	Bio-inspired artefacts	Cogno- and socio-inspired artefacts
Human	<ul style="list-style-type: none"> - Biopharmaceuticals - Engineered tissues (hybrid materials with living ingredients) - Stem cells (e.g. growth of human mini-brain) - Hybrid artificial organs 	<ul style="list-style-type: none"> - Humanoid robot - Avatar - Service robots and softbots - Social robots - Ambient persuasive technology

3.3 From bio to NBIC convergence

Nordmann (2004) commented on the ethical debate surrounding NBIC convergence as follows: “If these various technologies created controversies and anxiety each on their own, their convergence poses a major challenge not only to the research community, but from the very beginning also to policy-makers and European societies.” As society has experienced over the last few decades, the life sciences, and in particular genetic engineering, present a politically and ethically sensitive area of technology development (Bauer & Gaskell 2002).

Because of the increased interaction between the biological and physical sciences, NBIC convergence is radically broadening the bio-debate (Van Est et al. 2010). Besides genetic interventions, the societal aspects of info-tech interventions in the bodies and brains of animals and human beings will take centre stage in the political and public debate. But also the ‘technology becoming biology’ trend is expected to lead to various controversial issues. Society has already discussed many issues

related to bio-inspired artefacts, such as cloning, xenotransplantation, and stem cell therapy. But society will also experience an increase in cogno- and socio-inspired artefacts. These technologies will also raise many ethical issues as they become intimately integrated into our social lives.

When studying our own human condition, the two engineering megatrends can be conceived in terms of three tendencies (Van Est 2014). First, human beings are more and more seen as machines. Man as a machine is not a new idea. As far back as the 17th century, René Descartes introduced a mechanistic world view. NBIC convergence is revitalizing the engineering ambition to be able to permanently restore and improve the human body. But outside the official field of science, plenty of experimentation also goes on. For example, a company called Foc-us has put a headset on the market that makes use of transcranial direct current stimulation (tDCS), which should enable gamers to incite their prefrontal cortex (Lee 2013). Moreover, members of the biohacking movement literally try to hack their own body, for example to acquire new tactile or visual senses. Second, machines become more and more humanoid – or at least engineers have the ambition to build in human traits so machines can detect and portray social and emotional behaviour and start shaping our behaviour. And, third, interactions between people change, precisely because machines are increasingly penetrating our privacy and social life. This might make us think of the arrival of smart phones and social media and the widespread use of sensors embedded in all kinds of web-connected consumer products – from ‘intelligent’ shoes to mobile phones. Businesses and members of the quantified-self movement thrive on the opportunities provided by this process of ‘sensorization’ (Kwang 2013) to collect massive amounts of biological data. Consequently, NBIC convergence is creating a historic tipping point in which the distance between technology and ourselves rapidly decreases (Van Est 2014). We let technology *into us*; we let it into a position *between us*. And as a result, the technology increasingly gathers information *about us* and can even operate *just like us*, that is, mimicking facets of our individual behaviour. In short, man and machine are able to fuse to an extensive degree, so that it is hardly a metaphor to say that we are becoming more intimate with technology. This makes it clear that the use of medical devices and technologies and the collection and analysis of biological data is no longer reserved as the practice of medical research and health care.

What could the implications of the NBIC perspective on new emerging technologies be for the agenda of the Committee on Bioethics of the Council of Europe? As we said before, this report aims to provide input to the Committee so that it can address this question in an informed manner. Our analysis shows that the Committee in the past has paid a lot of attention to getting to grips with trends in the field of biotechnology. Tables 3.1 and 3.2 show that the Committee paid a lot of attention to both biotech-based interventions in the human body and bio-inspired artefacts. The NBIC perspective provides three other complementary perspectives to capture new types of interventions in the human body and brain, and new types of artefacts that may have a profound influence on human beings. Besides the *bio*-perspective on new techno-scientific developments, the other three perspectives are: (cognitive) *neuro*technology, *nano*technology and *information* technology. These three perspectives will be used in the remainder of this report to illustrate new types of interventions in the brain and human body and to describe the development of new types of cogno- and socio-inspired artefacts. In particular, we would like to use these three perspectives to show how new emerging technologies might transform current health care practices. Moreover, and maybe even more importantly, we want to highlight the increased use of medical technologies and the collection and usage of biodata outside professional health care settings.

4 The neuro-perspective

4.1 Introduction

The human brain is a highly complex organ that is vital for our functioning and well-being. To this day, this 'grey matter' is not completely understood. Physicians, psychologists, philosophers, and (cognitive) neuroscientists all try to understand how the brain works, what the mind is, or how neurological or psychiatric conditions can arise and be treated. The *neurosciences* constitute a highly interdisciplinary field, and research into the brain has seen an exponential growth over the last few decades. Several technological developments are (part of the) driving forces behind this growth.

Before the advent of brain imaging (such as MRI) that made it possible to study the human brain *in vivo*, scientists had to rely on studying the human brain *post-mortem* or use animals. Neuroimaging techniques (such as (f)MRI, PET, or CAT) are helpful in studying the brain, but also in the clinic for diagnostic purposes (e.g. MRI or EEG). Neuroimaging remains an important tool to increase knowledge about the brain, but more and more attempts are being made to also alter or assist the functioning of the brain by means of technology (neurodevices, drugs, and, on the horizon, even neural stem cell technology). We call this *neuro-engineering*. The goals of neuro-engineering are providing better treatments for neurological or psychiatric conditions as well as gaining a better understanding of the brain. Engineering the brain through interventions is one approach that can be seen in the neurosciences. Another approach in studying the brain is reverse engineering (Van Keulen & Schuijff 2010). In reverse engineering, models of (parts of) the human brain are artificially built in order to understand the brain better or to make better computers.

In this chapter, we focus on *neurodevices* as the area in the neurosciences (and related disciplines) where the convergence of biology and technology is most advanced. It is expected that the market for neurodevices will grow in the near future (predicted growth of neurodevices market is 11.3% annually between 2008 and 2015 to an expected value of \$4 billion by 2015⁵ or even \$11.61 billion in 2021⁶). Moreover, insights and technologies from the neurosciences are increasingly used in *non-medical* domains and practices.⁷ Neurodevices are becoming of interest for the entertainment sector (particularly gaming) and for people seeking to boost their performance or mental well-being for personal reasons (doing better at exams by reducing exam anxiety) or professional reasons (monitoring cognitive overload). In all these emerging practices, we see the use of medical or functionally equivalent technology by healthy people for non-medical purposes.

5 [http://www.researchviews.com/healthcare/medical/neurologydevices/ResearchInformation.aspx?sector= Neurology%20 Devices](http://www.researchviews.com/healthcare/medical/neurologydevices/ResearchInformation.aspx?sector=Neurology%20Devices), accessed on 15-12-2013.

6 http://www.science20.com/newswire/global_neuromodulation_devices_market_will_be_worth_1161bn_2021_says_visiongain-83375, accessed on 15-12-2013.

7 Examples of domains where neurosciences or knowledge from the brain is becoming more important are education, food, and the law.

4.2 Engineering the brain using neurodevices

The main goals of engineering the brain are to treat disease, such as the alleviation of symptoms of Parkinson's disease, or to help people with disease or impairment to function better, for example by helping paralysed patients to communicate via brain-computer interfaces. The neurodevices used in engineering the brain, resulting in modification of behaviour or cognition, can be *non-invasive* or *invasive*. Many of these technologies need further exploration and development to define for which medical purposes they can be used, to establish treatment protocols, and to reduce side-effects, etc. (see Van Keulen & Schuijff 2012).

Non-invasive neurodevices

EEG or fMRI neurofeedback. Neurofeedback uses real-time recorded and displayed brain activity to let someone learn to adjust his or her own brain activity to match a reference or optimal brain activity, which is also displayed. For example, two bars are shown: one representing the desired brain activity and the other the measured activity. The person then needs to train him- or herself to adjust the second bar (representing measured brain activity) to the first (reference) bar. The brain activity can be measured with EEG (electroencephalography) or fMRI (functional magnetic resonance imaging). EEG neurofeedback is offered in commercial clinics as a treatment for ADHD and various other conditions. Only for the treatment of ADHD, however, is there evidence of efficacy.

Transcranial magnetic stimulation (TMS). TMS devices generate a magnetic field above the skull, which influences the electric activity of the neurons to a depth of approximately 3.5 cm into the skull, altering cognition or motor function. TMS is used for the treatment of refractory depression and off-label for other conditions such as stroke. TMS is also used as a diagnostic tool and in research settings. There is some evidence that the technology can possibly be used for cognitive enhancement (Luber & Lisanby 2014). *Transcranial direct current stimulation (tDCS)* is another important transcranial stimulation technology. tDCS uses small electrodes to deliver a low current to the brain, and has medical as well as potential enhancement applications.

Non-invasive *brain-computer interfaces (BCIs)* are devices that record brain activity and translate it into signals operating external devices. The effects of this control can be fed back to the user of the system, which can lead to further use. BCIs can therefore be used to “enable a new real-time interaction between the user and the outside world” (Daly & Wolpaw 2008). For example, when paralysed patients are able to control a wheelchair or communicate via a computer, this allows them continued communication or control of their surroundings. The brain activity can be recorded with (portable) EEG or with (non-portable) fMRI. In non-invasive BCIs, training is necessary for the patient to learn to operate the BCI and to fine-tune the translation algorithm to the individual patient. One of the aims of BCIs and BCI research is to give paralysed or even locked-in patients methods of expressing themselves or influencing their surroundings (via computer commands). In the case of a *passive* BCI, brain activity may be recorded for reasons other than medical ones, for example to monitor a cognitive state (for example to monitor the alertness of those in highly demanding jobs).

While non-invasive neurodevices are being experimented with, or even already offered in clinics, more work to explore the full potential of these technologies is needed. However, even with further development, not all of these technologies will reach a broad market. fMRI neurofeedback and fMRI BCIs will always require an expensive and immobile MRI machine. Such systems may be especially useful in offering completely paralysed people a means to communicate or control their surroundings.

EEG neurofeedback and TMS have more potential to become widely used as they are much less expensive than MRI equipment. They are also mobile, so they can be used in various locations and even in patients' homes. EEGs traditionally used in the clinic or research laboratory require the application of the (several to over a hundred) electrodes by a technician or practitioner. Nowadays, there are EEG headsets (with up to fourteen electrodes) commercially available that can be used by consumers or patients at home (see box 1). This new development in EEG technology makes the shift from medical to non-medical uses easier. To make applications inside and outside the clinic successful, more research is needed into the efficacy, safety and protocols for the use of these technologies without professional supervision.

Box 4.1 EEG neurofeedback-based technology for enhancement and entertainment

In the clinic and laboratory, EEG neurofeedback technology is being offered and being studied as a (possible) treatment for conditions such as ADHD or insomnia. This technology, however, has also drawn attention outside the medical realm. Several neuroheadsets using EEG technology to record brain activity can be purchased to monitor one's own alertness or relaxation or to play games based on brain activity. For example, the firm Emotiv offers an EEG headset that can be used in the clinic, but also for neurofeedback or mindfulness meditation as well as games.⁸ The firm Neurosky offers a neuroheadset that can be used to visualize one's own brain activity, and which can also be used for games and brain training. Brain training with EEG neurofeedback is often aimed at improving focus.⁹ A few EEG neurofeedback clinics also offer their services for healthy consumers, such as sports people seeking to increase their putting accuracy in golf.¹⁰

If EEG neurofeedback devices are brought on the market with a non-medical goal (such as gaming or promotion of relaxation), they are not seen as *medical* devices and do not have to comply with the existing medical devices regulations. However, since the technology of EEG neurofeedback for gaming, improvement of focus, and relaxation is similar (or even equivalent) to that of clinically used EEG neurofeedback technology, it is to be expected that the same side-effects and risks can occur. Side-effects include headache or difficulty falling asleep after the use of EEG neurofeedback. Also, it is possible to induce epileptic seizures, particularly when EEG neurofeedback technology is used wrongly, although it is not clear how often this occurs (Stockdale & Hoffman 2001). This leads to questions about the safety of the technologies, especially when operated by people who have not had adequate training.

8 On Emotiv's homepage (<http://emotiv.com/store/app.php>, > app store > neurofeedback) several apps are advertised that "stimulate and optimize brain activity".

9 Neurosky (<http://store.neurosky.com/products/neurocoach>) offers the NeuroCoach as a "sophisticated brain-training app designed to interactively help improve your brain fitness, in health, well-being, performance and learning".

10 The Dutch company Brainclinics studied whether the use of EEG neurofeedback can increase the putting efficacy of golfers (<http://www.brainclinics.com/neurofeedback-resources-nl>). On their website however they offer EEG neurofeedback only as a treatment for conditions such as ADHD or sleep problems. The German company TopFocus seems to offer EEG neurofeedback to boost athletic performance, although their website has not been updated recently (<http://www.boeschtraining.com/homedeutsch.htm>). In the Netherlands, the Corpus Health clinic also offers EEG neurofeedback to boost inner peace, clarity of thinking, and concentration (<http://www.corpushealth.nl/therapieen/neurofeedback>). These are some examples. We did not carry out a systematic survey of the number of commercial clinics offering EEG neurofeedback for medical and/or non-medical reasons.

Invasive neurodevices

In *deep brain stimulation (DBS)*, electrodes are placed deep inside the brain in order to alter brain functioning. The electrodes are connected to a pulse generator via leads (wires), both of which are also implanted in the body. The pulse generator is placed under the clavicle or in the abdomen. DBS is mainly used to treat the symptoms of Parkinson's disease, and is experimentally used for psychiatric conditions such as obsessive–compulsive disorder or depression. DBS only treats the symptoms of the disease and does not cure the illness. Because of the risks and side-effects involved, DBS is a last-resort therapy. Potential enhancement effects of DBS have also been reported.

Box 4.2 Deep brain stimulation raises deep questions

Deep brain stimulation (DBS) can successfully treat the tremor symptoms of Parkinson's disease and essential tremor. In the lab and clinic, the use of DBS to treat patients with treatment-resistant depression, obsessive–compulsive disorder (OCD) and other psychiatric conditions is on the rise. In treatment for motor disorders and experimental treatments for psychiatric disorders, incidental findings have led to interesting questions related to the body, the mind, and behaviour. A man became manic as a consequence of his treatment with DBS for Parkinson's disease, which led him to (amongst other things) start an affair with a married woman, spend his savings on parties and clothes, buy multiple houses (including an estate), and write his memoir (Leentjes et al. 2004). These activities were not in character with this man's previous behaviour and got him into legal and financial trouble. There were no settings which reduced the symptoms without the manic state, so the patient chose (when the devices were switched off) to be admitted to a mental hospital while on stimulation. A woman with OCD did not experience a reduction in her symptoms, but did experience a feeling of happiness (Slob 2007). A man who received DBS therapy as an experimental treatment for obesity reported an improved autobiographical memory (Hamani et al. 2008).

Obviously, electrical stimulation of the brain can lead to unexpected, cognitive side-effects. The latter two examples also show potential non-medical applications of DBS: enhancement of mood (to happiness) and memory (more detailed recollection). These effects on the mind raise all kinds of questions, such as psychological or psychiatric questions exploring the extent to which our emotion and cognition can be manipulated and philosophical questions about the nature of the mind and the consequences for free will. Ethical and legal questions include issues such as autonomy, accountability, and liability, and whether one should be allowed to use DBS for non-medical reasons.

Brain computer interfaces (BCIs) can also be invasive, with the brain activity recorded inside the skull – either on the outside of the cortex or inside the brain tissue, using electrocorticography or single neuron recording or grid recording. Invasive BCIs generally work better and faster than non-invasive BCIs, but they are riskier and their longer-term efficacy is unclear. A related field of research is *neuroprosthetics*, ranging from well-established cochlear implants to artificial limbs controlled by the brain, which are still in their early research stage.

A novel group of technologies for invasive engineering of the brain are *neural stem cell therapies*. Neural stem cell therapies aim to replace neurons lost due to illness (Parkinson's, Alzheimer's disease) or injury (e.g. a stroke or an accident). Some approaches to neural replacement therapy using stem cells are close to, or have already entered, the clinical trials phase of research. Stem cell therapy of the brain is difficult and not without risks. The new neurons should grow enough to

integrate into the brain. If they do not develop properly, they could, for example, cause epileptic seizures or pain. On the other hand, they might also grow too well and develop into a tumour (Nuffield Council 2013).

Optogenetics is a recently developed technology that is often used in combination with imaging or recording technologies. In optogenetics, neurons are selectively made sensitive to light using genetic modification. When specific types of neurons are made photosensitive, light can be used to excite or inhibit only these neurons. This means that researchers can study the effect of neurons in unprecedented, precise ways. Optogenetics is an invasive neurotechnology, as it requires genetic modification of neurons as well as the implantation of the device that provides the light. Optogenetics as a research tool has only been used on animals so far. Clinical use in humans is predicted, for example in combination with deep brain stimulation (Deisseroth 2010).

Invasive neurodevices are in diverse stages of development from being experimented with in the lab to being an established practice. DBS is an established treatment for motor neuron diseases but in the experimental stage for psychiatric conditions. Neuroprosthetic limbs are far from being a mainstream treatment, but cochlear implants have already been used for over 20 years. Invasive neurotechnologies can be effective, but they are by their invasive nature always riskier than non-invasive technologies. If the efficacy is similar, non-invasive technologies will be preferred. However, improved safety and reduction of risks and side-effects may lead to a growing clinical demand for invasive neurodevices. Non-medical use of invasive neurodevices might be a theoretical option, but there are no indications that this will become reality in the near future.

4.3 Reverse engineering the brain

Reverse engineering of the brain can be defined as the analysis of existing brains or parts thereof in order to uncover its design principles by means of creating representations of the system in another form. Reverse engineering is therefore trying to rebuild a brain with artificial means (a computer model, for example) in order to understand the brain better. Advances in the field of reverse engineering of the brain may lead to a better understanding of the healthy (or sick or impaired) brain and potentially to novel treatments for patients, but also to better computers. As reverse engineering approaches often try to simulate the brain using software or hardware, the neurosciences closely collaborate with information and computing sciences to do so. There are three main forms of reverse engineering: narrow reverse engineering, neuromorphic engineering, and in vitro engineering.

Narrow reverse engineering refers to simulating the brain in software. Data about the (human or mammalian) brain are used to create virtual representations of (a small part of) the brain. For example, the Blue Brain project¹¹ tried to simulate a working (rat) brain. The first step was to reconstruct a neocortical column at the cellular level. An IBM supercomputer was needed to create this representation. The next step was to recreate something brain-like by making more of these columns and linking them together, as they would be in a real brain. To do so, the Blue Brain project joined

11 <http://bluebrain.epfl.ch/>

forces with many other institutes in the Human Brain project.¹² This recently announced FET Flagship project of the European Commission,¹³ The Human Brain project,¹⁴ also includes narrow reverse engineering, focusing on simulating the human brain based on all current knowledge about it in order to improve understanding of the healthy and diseased brain. The Human Brain project should run from 2013 to 2023 and the costs are approximately €1.19 billion. Another large-scale reverse engineering project is the American National Institutes of Health (NIH) Human Connectome project,¹⁵ which maps the neural pathways that underlie the functioning of the human brain.

In *neuromorphic engineering*, the focus lies on building (physical) representations of the brain: building brain-like (or inspired by a part of the brain) hardware. The goal of neuromorphic engineering is to combine the best of both worlds to make better computers: for example, the programmability from computers and the capacity to learn and adapt from the human brain.

In vitro engineering is a wetware approach that uses in vitro, cultured, or living neuronal cells and neural networks. Since this approach uses the neural cultures as representations of the brain, it is considered to be a reverse engineering approach. The main goals are to understand the information processing with (in vitro) neuronal networks and to discover the underlying principles of neuronal learning, memory, plasticity, and connectivity (Cohen et al. 2008).

4.4 In focus: Non-medical use

Although EEG (or fMRI) neurofeedback, TMS, and DBS nowadays are mostly used in medical or research practices, these neurodevices may also potentially be used in a non-medical context for human enhancement, entertainment or other purposes. Human enhancement can be defined as the use of medical technology to improve the performance, looks, or well-being of healthy, normal individuals for non-medical purposes (Schuijff & Munnichs 2012; Coenen et al. 2009). Medications like methylphenidate (Ritalin) and beta blockers are currently being used by healthy people to boost concentration and reduce performance or exam anxiety. Such enhancers may also be used by individuals for professional reasons, as for example pilots taking modafinil (a drug to treat narcolepsy) in order to stay alert longer. Finally, enhancement might not only be attractive for individual consumers of professionals, but also be considered as a useful option by employers or governments to improve the functioning of groups.

Generally speaking, all neurodevices discussed in this chapter are supposed to potentially enhance focus or mood. Currently, there are some indications for their effectiveness, but it is not clear to what extent and for whom they might be effective (for everybody or only those who have certain charac-

12 The Blue Brain project represents an essential first step towards achieving a complete virtual human brain. "The researchers have demonstrated the validity of their method by developing a realistic model of a rat cortical column, consisting of about 10,000 neurons. Eventually, of course, the goal is to simulate systems of millions and hundreds of millions of neurons" (<http://jahia-prod.epfl.ch/page-59963-en.html>, accessed on 17-12-2013). To do so, the Blue Brain project "recently joined with many other partners to propose the Human Brain Project – a very large 10 year project with brain simulation at its heart" (<http://jahia-prod.epfl.ch/page-58067-en.html>, accessed on 17-12-2013).

13 There are only two Flagship projects. The other one is about grapheme. The EU funds these two large-scale research projects because it is expected that they will provide a "strong and broad basis for future technological innovation and economic exploitation in a variety of areas, as well as novel benefits for society" (<http://cordis.europa.eu/fp7/ict/programme/fet/flagship/>, accessed on 17-12-2013).

14 <https://www.humanbrainproject.eu/nl>

15 <http://www.neuroscienceblueprint.nih.gov/connectome/>

teristics?) or what protocols are needed for enhancement purposes (neurodevices such as EEG neurofeedback and TMS require multiple sessions to reach lasting effects).

Given the requirements for equipment, neurodevices for non-medical use will often be commercially available only in a clinical context. EEG neurofeedback is indeed being offered in this way for enhancement of cognitive, athletic, or artistic capabilities. However, EEG neurofeedback or systems based on similar technology are also being developed for use in a non-clinical entertainment context. The use of neurodevices in entertainment is particularly interesting for gamers as it offers them an (additional) neural control of a game. In a game, EEG neurofeedback could, for example, change the looks of the player's avatar based on his emotion and therefore be an additional way of controlling the game (in addition to a joystick or a keyboard). This is still in the early stages of development (Van Erp et al. 2012). Companies might also be interested in using neurotechnologies, such as fMRI technology, for neuromarketing, which is a method of assessing how consumers make choices, which may help firms to better market their products.

Also in regard to brain computer interfaces, there are non-medical usages that might be interesting for healthy persons. In this case the BCI is not intended to be used by the subject to control an external device; the brain activity is only monitored. A potential application would be to detect cognitive overload in jobs such as air traffic controllers. Another possibility might be to objectify the gut feeling ("something is wrong") of police officers, using BCIs to train them to better recognize this subconscious feeling themselves (Van Erp et al. 2012). Although many applications of BCIs are envisioned or speculated about, BCI technology for medical as well as non-medical purposes is currently still in its infancy.

If we look at neuroimaging or other brain-recording technologies, even more possibilities arise. It has been claimed that fMRI can be used to detect in the brain whether someone is a paedophile (Ponseti et al. 2012). Governments might consider the employment of this technique to prevent paedophiles from working in certain jobs, for example in a children's home. There are also claims that lies can be detected with fMRI.¹⁶ Or that 'guilty knowledge' can be seen in the brain with an EEG¹⁷: by a spike in an EEG signalling a subconscious recognition of information only the perpetrator could have known – regardless of whether the person being interviewed admits to recognizing it. However, doubts remain about the reliability of these tests and thus whether they can really be used in legal or other practices (Nature Neuroscience editorial 2008; Greely 2009).

Even more speculative are possibilities for the application of neuromodulation by governments in the context of *social enhancement*, defined as the use of biomedical technologies by the government for the common good (De Jong et al. 2011; Academy of Medical Sciences et al. 2012). Neurodevices might be employed so that civil servants can work more effectively and/or relax better, and as such might help to prevent burn out (Goebel 2011). fMRI neurofeedback could make people more empathic, which offers possibilities for the rehabilitation of certain criminals (Goebel 2011). It has also been speculated that deep brain stimulation might be used to rehabilitate criminals (Denys 2011).

16 For example, the American company No Lie MRI (<http://www.noliemri.com/>) offers MRI-based lie detection.

17 See for example, the American company Brainwave Science (http://www.governmentworks.com/bws/how_it_works.asp)

4.5 Possible ethical, legal, and socio-economic questions about neurodevices

This chapter shows how neuroscience as an interdisciplinary research field has converged with developments in the field of information technology, which opened new possibilities for imaging the brain and for new kinds of interventions in the brain. At the same time, developments in computer and information technology are creating new possibilities for mimicking the brain in software and hardware models. The new engineering approaches to the brain have been developed in a medical context, but also offer opportunities for non-medical use and for practices of enhancement. This involves new possibilities for intervention in individual behaviour and thus creates new regulatory and ethical challenges.

One issue that needs to be examined is the safety of the use of neurodevices outside the medical domain, as for example EEG technology in gaming, which might induce seizures as a (worst-case) side-effect. When is a technology that can safely be used by medical professionals also mature enough to be used by lay people? What about questions of liability in this context?

In addition to these regulatory questions there are also more fundamental and far-reaching issues to consider. Neurodevices raise multiple questions related to autonomy. What does the possibility that people who have deep brain stimulation become manic or happy mean for our autonomy or even for the concept of free will? Will the use of neurodevices for human enhancement pressure other people to enhance themselves too? If the government would like civil servants, or other groups, to use neurotechnologies, are they able to refuse this? Should we consider the use of neurodevices for social enhancement a valid option, or an undesirable technology fix for social problems?

5 The nano-perspective

5.1 Introduction

Nanoscience and nanotechnologies comprise a broad field of multidisciplinary research which is characterized by increasing collaboration between physicists, chemists, biologists, and engineers and in which different traditional scientific disciplines converge at the molecular and atomic level. Nanotechnologies offer new instruments for observing the operation of living cells that may be considered as complex, highly functional 'machines' at the nanometre scale (Health Council of the Netherlands 2006). Since the 1990s, developments in nanotechnology have made it possible for biomedical scientists to observe human bodily functioning at the molecular level, for example, by using novel imaging techniques or lab-on-a-chip technology (Boenink 2009). The interest in the medical applications of nanotechnology has led to the emergence of a new field called *nanomedicine*, which fits into a long tradition of medical science that searches for biological mechanisms of disease at deepening physiological levels (Freitas 2005; Riehemann et al. 2009; Walhout et al. 2010).

We can describe developments in the field of nanomedicine in terms of two broad and related trends. On the one hand, nanotechnology makes it possible to focus in the study of the human body on *biomarkers* that can be identified at the molecular level, including DNA, RNA, and proteins which may signify basic biochemical processes in healthy or diseased cells. The idea is that at this molecular level it will not only be possible to develop a better understanding of health and disease, but also to use biomarkers as a tool to detect diseases as early as possible, even to the point of detecting single defective cells or biomarkers predicting the onset of disease. On the other hand, nanotechnology contributes to a trend of progressive *miniaturization* of devices that will, more and more, enable the regular and even continuous monitoring and adjusting of the bodily functioning of individuals, both *in vitro* and *in vivo*. Both trends are not only enabled by nanotechnology but also strongly rely on information and communication technology (ICT) for capturing data, data analysis, modelling, and data sharing (Compañó 2006; Boenink 2009; Nanomedicine European Technology Platform 2009; Walhout et al. 2010).

Nanomedicine also creates new opportunities for medical treatment, involving the use of nano-encapsulation for improved and targeted drug delivery and the use of nanoparticles for less invasive therapies or as more effective medicines. Another prospect is reconstructive (regenerative) nanomedicine, which aims at tissue repair and the restoration of bodily functions by using 'smart biomaterials' and by the use of stem cells as agents for cell-based therapies (Nanomedicine European Technology Platform 2009; Walhout et al. 2010). However, in the following description, we will highlight the potential development of the *diagnostic capabilities* of nanomedicine, characterized by the two broad trends indicated above, that may facilitate early diagnosis and may lead to increasing opportunities for continuous health monitoring and thus may interfere more and more with the personal sphere of the life of individuals.

5.2 Molecular understanding of health and disease

Biomarkers are identified by molecular epidemiological research (often enabled by huge biobanks) which looks for relationships between specific molecular characteristics and the occurrence of

disease. Human genome research is only one source of emerging biological information that has the potential to inform health care. Other molecular data (such as epigenetic, proteomic or metabolomic data) will also need to be incorporated (National Research Council 2011; European Commission 2013).

Ideally, biomarkers may be used to reconstruct what is called the 'molecular pathway' or 'molecular network', the series of biochemical reactions in a cell, which in turn may be the starting point for the reconstruction of a 'disease pathway', that is, the chain of events leading to symptoms and complaints. 'The implicit model of disease underlying this endeavour to reconstruct complete disease processes is that of a *cascade*: molecular changes in the cell lead to changes at the cellular level, transforming the functioning of tissues and organs and meanwhile causing symptoms, signs, and subjective experiences of non-wellbeing. In this way, in a series of steps quite small changes may lead to ever larger changes that in the end have very serious consequences for someone's health. Such a cascade model of disease conceives of disease as a process evolving in time as well as gradually extending in bodily space. It therefore strongly suggests the need for early intervention, as a freely flowing cascade is very difficult to stop' (Boenink 2009: 249).

As the manifestations of disease become increasingly connected to biomarkers indicating particular disease pathways at the molecular level, such biomarkers may be used as predictors of increased risk and may enable the regular monitoring of health status across the life course of an individual. An example illustrating this approach has been recently reported, describing how a series of molecular measurements (including genomic, proteomic, and metabolomic data) collected at multiple time points in a single individual were used to generate a dynamic biomarker profile. 'The subject was an apparently healthy individual and the collection of an enormous volume of data over a 14-month period allowed information to be obtained on the individual's dynamic state of health. Firstly, whole-genome sequencing revealed evidence of increased risk for diseases including type-2 diabetes. On-going monitoring further revealed the onset of type-2 diabetes with a sharp increase in blood glucose, which was paralleled by complex changes in other biomarker profiles. According to the authors of the study, this approach will allow data pertaining to a specific individual to serve as a baseline for identifying pathological changes and indeed for monitoring health' (Chen et al. 2012, quoted in ESF 2012: 22).

5.3 Diagnostic nanotechnologies

Early diagnosis of disease is enabled by two types of diagnostic nanotechnologies (Walhout et al. 2010):

- *In vitro* tests to identify molecules associated with a specific disease (biomarkers) using biosensors;
- *In vivo* measurement of specific molecules associated with a specific disease (biomarkers) using imaging techniques or sensors incorporated in the body.

In vitro tests

One of the biggest successes in the field of nanotechnology is the diagnostic *lab-on-a-chip*: a laboratory the size of a stamp with microscopic channels to conduct chemical and physical analysis of a drop of blood. Such analysis can easily be done with a handheld diagnostic device that gives a result within a few minutes. The development of nano-scale sensors, either mechanical, electrical, or optical, and their integration into micro-scale devices offers enormous potential for cheap and

portable *point-of-care devices* that can be used outside the laboratory or hospital by doctors in their offices or by individuals at home using them for self-care. Nanotechnology plays a crucial role in this trend of decentralization by contributing to the miniaturization of technology and the development of smart environments. In this way, it also contributes to increasing possibilities for the *lifelong monitoring of individual health* (Compañó 2006; Riehemann et al. 2009; Boenink 2009; Walhout et al. 2010).

Box 5.1 Lab-on-a-chip in vitro diagnostics

The Magnotech technology developed by the Philips company is an example of an in vitro diagnostic lab-on-a-chip platform, which is based on the use of magnetic nanoparticles to concentrate, separate, and detect target molecules.¹⁸ Philips is developing this technology into a 'Minicare system', a handheld testing platform which will allow detection of several target molecules in a single measurement and which has the potential to provide blood test results within minutes at the point of care. One possible application is the fast measurement of cardiac markers indicating that a patient has had a heart attack, which may assist clinicians in time-critical decision making when dealing with acute cardiac patients and thus shorten 'discovery to treatment' time. The development of this point of care in vitro diagnostics is also seen as serving a future trend in which more and more care will take place outside the hospital.

An example which clearly illustrates this trend is the 'MiniLab', a lab-on-a-chip platform that has been recently launched by the start-up company Medimate.¹⁹ It has been designed to measure lithium levels or other substances from one drop of blood in a few minutes. It is marketed as a point-of-care test for people suffering from bipolar disorder (manic depression). Many of these patients use lithium as a medication, which has to be closely monitored to limit the risk of lithium poisoning. In the current situation, patients have to visit the hospital four or five times a year to have their lithium levels checked in the lab. As the Medimate website makes clear, the company believes in *self-monitoring*, and their device makes it possible to shift the point of care from the clinic to the patient's home. However, who should use the device in which situation is still an unsettled question (Krabbenborg 2013). Both psychiatrists and patient organizations are calling for the use of the Minilab in professional settings, while some patients express their desire to use the device at home. The issues raised in this context relate to the question of who should be in control, the risk of losing face-to-face contact with the psychiatrist, and the role of insurance companies in reimbursing the costs of self-monitoring at home.

Current lab-on-a-chip technology also enables *single cell* analysis. One possible application is the measurement of sperm cells. Scientists in the lab are working on a small device which measures the motility of sperm cells with electrical current in order to provide a do-it-yourself fertility test for men that can be used in the private environment at home.²⁰ Research is also being done on a system which is able to electrically detect whether a sperm cell contains an X- or Y chromosome and to subsequently sort the cells into two fractions. The aim of this research is to improve established methods in animal husbandry for performing artificial insemination with sex-sorted semen. However, such a system might also open new technical possibilities for sex selection in the context

18 <http://www.business-sites.philips.com/magnotech/technology/index.page>

19 <http://www.medimate.com/nl/node/233>

20 http://www.utwente.nl/ewi/bios/research/Emerging%20research%20topics/Sperm_onchip.pdf

of human reproduction. The use of the techniques of medically assisted procreation for the purpose of choosing a future child's sex has been ruled out by the Oviedo Convention (article 14). But what would happen if relatively effective and cheap lab-on-a-chip procedures for sex selection became commercially available in the *non-medical domain*? If some people might indeed wish to use this option, wouldn't it drive us to reconsider the reasons for prohibiting sex selection in the light of established rights to reproductive choice in our society (Verbeek 2012)?

In vivo imaging and sensing

Molecular imaging is an example of in vivo measuring based on the use of nanoparticles as contrast agents which bind to specific biomarkers that in this way can be made visible in the body. Molecular imaging with MRI, SPECT, PET, and other techniques provides a much better resolution and sensitivity than traditional imaging methods. It is expected that in the future these techniques will enable early diagnosis of cancer and neurological as well as cardiovascular diseases. Another example of in vivo testing is the development of so-called wet sensors to be introduced in the body or the brain of patients. At present it is already possible to check the pulse and measure temperature and blood glucose through a chip placed under the skin which transmits its information wirelessly to an IT unit (Riehemann et al. 2009; Walhout et al. 2010).

Box 5.2 Lab-on-a-chip in vivo sensing

An example of a lab-on-a-chip platform that can be used for in vivo sensing is the so-called nano-pill currently in development for the early detection of colorectal cancer.²¹ By fitting the nano-platform inside a pill that can be swallowed, markers indicating cancer can be detected in vivo and it becomes possible for people to perform the test at home. The pill passes the body through the gut and microscopic wires in the pill can detect DNA fragments from cancer cells long before any tumour becomes visible. This is still a future scenario, but the developers of the nano-pill believe it is possible that this technology will become available within five years.

The nano-pill is conceived as a tool with which people can monitor their health and engage in a preventive practice. However, this practice may still be conceived in a variety of ways (Lucivero 2012). In one version the nano-pill is seen as a *self-test device*. It is supposed to show a positive outcome of the measurement through the release of a blue dye colouring the stool, making the individual performing the test also the witness of the result. A future possibility that is explored in this context is to make the pill a component of the Prevention Compass, a web-based support system for personalized prevention that has been developed in the Netherlands to facilitate self-management.²² Currently, researchers envision another version of the pill, emphasizing its potential role in the context of a national programme of *population screening* and including a broader vision of health monitoring supported by wireless network communication.²³ Accordingly, the pill is being designed as

21 <http://www.utwente.nl/onderzoek/themas/health/en/lab-on-a-chip/lab-on-a-chip/nanopil/>

22 <http://www.preventioncompass.com/>

23 This vision has been forcefully expressed by the famous American systems biologist Leroy Hood: 'New technologies will generate a hand-held device that will be able to analyze a fraction of a droplet of blood for 1,000 or more proteins and these will be a window into health and disease. This will be done twice a year. The information will be fed into a cell phone and then to a server, and then it will be analyzed and the patient and their physician will get an e-mail that says: "You are fine; do this again in six months." Or, "You should see your oncologist.'" (Hood, cited by Boenink 2009: 251).

a radio signalling device, transmitting its measurements directly to the doctor via a mobile phone. Whereas the first blue-dye-colouring version of the pill emphasizes values of autonomy and user empowerment, the second version emphasizes values of efficiency and comfort, relieving future participants in a screening programme of the unpleasant task of collecting and submitting stool samples.

This diversity of visions and values also involves different concerns around a future nano-pill, including concerns about users testing themselves in the private space of their home without the assistance of a care practitioner and fear about the ways in which a radio signalling version of the pill might endanger the patient's privacy. Moreover, as a tool grounded on the promise of molecular diagnostics, the nano-pill enables detection of disease at a much earlier stage, thus manifesting and reinforcing a trend towards health monitoring and medicalization and also suggesting new moral responsibilities towards ourselves and society at large (Lucivero 2012).

5.4 New emerging forms of body monitoring

With the development of ever smaller and more efficient computer chips and battery technology, nanotechnology will also further increase the means for wireless body monitoring, thus making a 'smart environment' possible. The Belgian research institute IMEC, for example, is developing a body area network (BAN) of sensors and actuators that can be worn on the body, monitor many health parameters, and communicate with the outside world via a mobile network. IMEC has already developed such a device for heart and brain activity measurement with wireless ECG and EC, respectively (Walhout et al. 2010).

The development of BANs is justified by a vision of health care moving out of the hospital to 'care at a distance' (Krabbenborg 2012). The explosive growth of social networks may further strengthen this development in the *non-medical domain* (National Research Council 2011; see also chapter 6). 'Citizens and patients are increasingly taking advantage of social media and new technologies to share information about their own health and lifestyle. Many citizens are already using a wide variety of technological tools (e.g. smartphone applications) to generate and analyze health-related information. Patients are also taking advantage of new media and ICT opportunities to organize themselves not just to share experiences and support but also to exchange data on health status and outcomes. The company PatientsLikeMe, for instance, has established an electronic platform with the goal of helping patients to "share and learn from real-world, outcome-based health data". Groups such as Quantified Self provide a platform for citizens to collect data about themselves, including lifestyle factors such as eating habits and exercise, etc., physiological variables such as heart rate and blood pressure, and emotional state. The potential power of these and similar initiatives is their capacity to generate large volumes of data on individual lifestyle, environmental, and sociocultural variables, as well as on self-reported outcomes, symptoms, and quality of life for those with illnesses' (ESF 2012: 29).

5.5 Ethical issues arising from these developments

This chapter shows how nanotechnology is converging with information technology while creating new possibilities for the study and understanding of biological phenomena at the molecular level. In this process nanotechnology offers new options for intervention in the body based on nano-scale devices, but even more so supports new forms of large-scale data generation which open new possibilities for permanent monitoring of individual health states and for early diagnosis of disease.

Nano-based diagnostic devices may reach the market earlier and more easily than nanomedicines, given the higher regulatory hurdles for the development of pharmaceuticals. The introduction of these devices at the 'point of care' will stimulate practices of screening, but also raise questions about the predictive value of early detection of disease markers and options for prevention. Undesirable medicalization lies in wait for this development. Extending practices of health monitoring will interfere more and more with the personal sphere of the life of individuals. When does empowerment of individuals change into coercion from a health perspective?

As nano-based diagnostic devices may increasingly be used at home as self-tests, these technologies will also challenge the doctor–patient relationship and will entail new roles and responsibilities for individual patients and health consumers. This raises questions about both the support and the protection of users in dealing with health information from self-tests.

The increasing exchange of large volumes of data through wireless networks that enable health monitoring can also be used to collect and analyse individual health data without proper consent. This may result in unprecedented possibilities for identifying, classifying, and evaluating individuals on the grounds of increasingly refined data (see chapter 6 for further discussion).

6 The info-perspective

6.1 Introduction

Information technology by its nature cuts through domains. As a tool it has become central to the work of virtually every profession, and as a medium it has shaped the way we interact and socialize. Information technology is not just technology; its processors and software codes are becoming part of ever more intimate circles of human life. *Affective computing* studies how computers can interpret and express emotion. *Artificial intelligence* is reaching new insights about how the human mind can be modelled. *Ambient intelligence* and *persuasive technology* aim to create smart systems that can motivate people to change their behaviour (Verbeek 2009). Information technology is everywhere: it's pervasive and as such it is an integral part of the personal, social, and mental life world (Greenfield 2006).

The integration of information technology into intimate human interaction can be seen as part of a convergence of information technology with biotechnology and the cognitive/behavioural sciences: a technological megatrend also described as 'technology becoming biology' (van Est & Stermerding 2012). Information technology incorporates the science of how we think and behave, while at the same time, through unprecedented data collection and new means of data analysis, contributes to new knowledge about human biology and behaviour.

These developments can be roughly split into two related and reinforcing trends. First, digital data on health and human behaviour have exploded over the past years – something that has garnered much attention under the term 'big data' (Mayer-Schonberger & Cukier 2013). Information technology enables a hitherto unknown scale and depth of analysis of human biology and behaviour. Macro-level analysis of these large quantities of data from multiple sources is delivering new kinds of knowledge about ourselves. This feeds back into the second trend, the development of information technology which is incorporating insights from cognitive and behavioural science to develop systems that better 'understand' human psychology and are able to interpret, interact, and influence it.

6.2 Data on behaviour and biology

Over the past few years we have witnessed an exponential growth of the digital universe (IDC 2013). Increased storage capacity and processing power and the pervasiveness of information technologies have led to the creation of digital data on many aspects of behaviour and biology. Social networks such as Facebook and Twitter have created an unfathomable database on social interaction. Google is charting how knowledge is created through its knowledge graph. Digital medical records could provide a wealth of information on diseases and treatments. The virtual worlds of computer games serve as a laboratory for developing virtual engagement (Reeves & Read 2009). Every movement or record in the digital universe can be used as a data point for analysis. The availability of these large data sets has sparked interest in the potential knowledge to be derived from them. New tools and methods for storing and analysing data have emerged that enable the study of these large data sets, which would not have been possible using traditional methods of data storage and analysis (VINT 2013).

These developments in data storage and analysis enable research at the level of an entire population, rather than using a sample of the population. Driving these developments is the idea that, on a macroscopic level, different insights will become apparent that would not have emerged on a more microscopic level. This offers promises, for instance for the medical sector to identify new factors relevant in the development of diseases, but also for behavioural sciences to identify new patterns in (online) behaviour. The correlations identified through the process of analysis can be employed in predictive models. Such predictive analytics, or data-driven models, offer possibilities for businesses to predict what choices consumers are likely to make, for law enforcement bodies to identify high risk zones for crime, or for decision-support systems in the medical world to integrate data sources from the patient with medical information to establish a diagnosis of a patient's condition (Mayer-Schönberger & Cukier 2013).

The ambition displayed is to use data to develop new kinds of knowledge and models about human behaviour and biology. Data-driven models can be put to myriad uses. To increase efficiency, enable prediction, and improve or directly assist in decisions about business, health, mobility etc.

Box 6.1 People analytics: Big data analysis of behaviour

The emerging field of *people analytics* offers a perspective on how large-scale data analysis is changing human resource management. By using data gathered through social networks, e-mail records, web-browsing behaviour, instant messaging, games, and other digital systems, analyses can be run on who should be hired, who will be successful innovators, and who is on the brink of leaving a company.

The talent acquisition company Gild tracks down successful programmers by searching the web for any open-source code they have written. They analyse how the code is written and documented, how long it took to write it, and how other programmers have adopted it. Their analysis also factors in the online behaviour of the programmers on forums, social media, and other websites. This enables Gild to rate the skills of these programmers, but also to create elaborate behavioural profiles of the online activity of successful programmers. Using these profiles, Gild can rate the skills of programmers who *have not* written open-source code by analysing how their online behaviour matches with these profiles of successful programmers. The company uses its data on programmers to match them with employers looking for a certain type of coding expertise (Peck 2013). This shows how the process of selecting the person best equipped for a certain function is automated on the basis of digitized records of behaviour in the past.

Research at the MIT Media Lab shows how the analysis of work-related behaviour can be taken a step further. Researchers developed a system that tracks employee interactions through 'badges' capturing information on formal and informal conversations: their length, the tone of voice used, non-verbal communication signals, and more (Wu et al. 2008). The data on social interaction can be used to predict productivity or creativity, for instance in successfully predicting the winning team in a business pitch contest (Olguín Olguín & Pentland 2010). Furthermore, the researchers claim to have discovered the data signature of natural leaders, called "charismatic connectors" (Pentland 2010). The spin-off from the research is a company, Sociometric Solutions. The confidentiality of sensitive user data is acknowledged as a matter of concern (Olguín Olguín & Pentland 2010), but these developments also raise questions about supervision of decision-making software, automated exclusion, and the social consequences of these profiles (Dwork & Mulligan 2013).

6.3 Technologies incorporating cognitive and behavioural knowledge

The knowledge developed through studying behaviour in digital environments can be fed back into the design of the technologies we interact with in the virtual and physical world. Merging information technology with behavioural and cognitive sciences provides opportunities to improve the interaction between man and machine.

A defining characteristic of these new systems is the ability to respond to users and environments. Small and cheap sensor technology enables continuous measuring of behaviour and physiology, integrated into all kinds of devices or environments. Through advances in computing power and ubiquitous network connections, the data can be analysed (either on devices or in the cloud) and shared with other applications. Technologies equipped with this kind of 'ambient intelligence'²⁴ can use this information to adapt to users and their interactions (Verbeek 2009). The fluidity of information technology furthermore enables monitoring of these interactions and real-time adaption to optimize the user interaction.

These capabilities enable integration with behavioural and cognitive insights. Science might inform design in terms of how choices and information should be optimally presented; how a certain presentation will stimulate the choice of a preferred option (Fogg 2003); how patterns in physiology or behaviour represent emotional states (Hoque 2013); and how feedback can be delivered directly or via ambient feedback mechanisms requiring less conscious cognitive processing efforts (Maan et al. 2010). Thus combining these possibilities of information technology with insights into behaviour and cognition enables the optimization of interaction between humans and information technology and creates the possibilities for computer systems to analyse, advise and influence the behaviour of its users.

Box 6.2 E-coaches: Behavioural perspectives incorporated in technology

Box 6.1 illustrated the data-driven approach to analysing behaviour. Here we focus on the way in which behavioural knowledge is influencing the development of information technology. The company Empatica focuses on improving mental health and well-being in work environments by monitoring stress in relation to activities on the shop floor. The user wears a bracelet that measures heart rate, movement, indoor location, skin conductance, and temperature to deduce the stress level of the user. These signals are then sent to the user's smartphone and computer and are combined with data about work-related activities, such as appointments, to provide insight into stress factors.²⁵

The goal is to deliver insight into the circumstances that cause an undesirable state (of stress) to emerge and to provide advice and persuasive feedback to improve how users deal with these situations. The smartphone app suggests behavioural interventions such as going for a walk or doing a breathing exercise to improve dealing with stress. This mimics aspects of cognitive behavioural

24 Aarts and Marzano (2003) define ambient intelligence as: embedded, aware of its environment, personalized, adaptable, anticipatory.

25 <https://www.empatica.com/>

therapy in trying to identify maladaptive patterns in behaviour and providing strategies to deal with them. These applications of information technology to support better or healthier personal lifestyles are also described as *e-coaches* (Kool, Timmer & van Est 2013). While these applications could empower users to deal with mental challenges, such as stress, they also pose new challenges with regard to privacy, purpose limitation, and ownership of the data collected; the extension of the control of employers to non-work-related behaviour such as personal lifestyle and fitness behaviours; and the appropriateness of the evidence base for advice delivered by these devices.

6.4 Two fields of application: Affective computing and persuasive technology

As more data on biology and behaviour is digitally collected and analysed, smarter information technology systems emerge. These systems are becoming more 'human' in terms of interpreting human behaviour and influencing human interaction, as part of the aforementioned trend of 'technology becoming biology'. We will focus on two particular fields of application of such technologies, persuasive technology and affective computing, although these are of course but two of many relevant technological developments.

The field of *affective computing* studies how computers can interpret human emotions (Picard 2003; Hoque 2013). This technology can be considered a clear example of the integration of cognitive science into information technology. Through the use of various types of sensors, facial pattern recognition, emotional speech recognition, and physiological monitoring of galvanic skin response and/or heart rate, data is generated and analysed to assess the emotional state of the user. One motivation for the research is the ability to stimulate empathy in computer systems, creating computer systems that respond appropriately to the emotional state of the user. Other current applications for emotion recognition systems range from assisting and training people with autism-related disorders (Hoque 2013) to assessing consumers' emotional response to products (Loijens et al. 2012). As these systems develop into more sophisticated and reliable modules, these technologies can be incorporated into other solutions. The soon-to-be released 'Google Glass', with its augmented reality possibilities, could be a platform for emotion recognition and augmentation apps.

With *persuasive technology*, the integration of behavioural insights into information technology takes on another form. Persuasive technology describes systems designed to influence choices or the behaviour of its users (Fogg 2003). Persuasive technology builds on insights derived from psychology and behavioural sciences as well as from (computer) design practices. Large-scale data collection on online behaviour can be used to analyse how users make their choices, which enables the design to adapt to this. By designing choices and the interaction with technology, users can be stimulated to make certain choices. Persuasive technology can be employed to help people make better choices, for instance personal health systems designed to persuade people to exercise more, using motivating feedback, social cues, personalized arguments, and competitiveness (Kool et al. 2013).

In the interaction of information technology and psychology, new forms of technological persuasion are arising as well. Through persuasion profiling (Kaptein 2010), a personal profile of the type of argument the user is susceptible to is defined, and a persuasion strategy is chosen according to the

given profile.²⁶ Ambient persuasion (Maan et al. 2011) uses low-cognitive signals such as ambient light feedback to influence users without claiming conscious cognitive attention.

6.5 Ethical issues arising from these developments²⁷

This chapter shows how data-driven developments in the field of information technology are creating unprecedented opportunities for data mining and analysis leading to new understandings of human behaviour and to new possibilities for the prediction of and intervention in human interactions. As a result of this development, information technology can be designed in sophisticated ways as smart systems interfering as a coach in the life world of individuals, both within and outside the domain of health.

Via sensors built into consumer products, massive amounts of biological data such as heart rate, emotions, and sleep patterns can be collected. How do we maintain our own physical and mental integrity in such a sensor-filled society? Will we maintain ownership of our biological information, or are we going to hand it out, unwittingly, for free – as we do with our social data – to big companies?

Furthermore, specialists are working hard on emotion recognition technology and apps able to recognize faces and link them to Facebook profiles. If all three of these options were to be available in Google Glass in the future, every user might see who we are, what we do, who our friends are, and how we feel. Companies can marshal this information to draw our attention, to give us specific information, and influence our behaviour. This raises issues about autonomy and freedom of information; how do we maintain a grip on the information we receive? Do we have the right not to be measured, analysed, and coached, and how do we proceed to protect privacy in a world of social media, cameras, and other sensors?

Technologies with human features, such as digital coaches, realistic avatars, and robots yield the ability to influence human behaviour. How can we avoid being manipulated? Robots can be used to perform various human tasks at a distance and with an ever-increasing degree of autonomy, ranging from performing health care responsibilities to killing people. Which social tasks can we humanely delegate to machines, and which not?

The aforementioned questions already exist or may soon be coming into play. The fast pace at which information technology is integrated into intimate human interaction challenges policymakers to develop frameworks in a timely way to socially embed this development. This could be done by drawing from experiences of dealing with the questions of privacy and ethical issues in biomedical technology. That experience is vital as IT is becoming increasingly intertwined with the life and behavioural sciences, causing all sorts of biomedical technologies to be used in the public domain.

26 A user susceptible to authoritative arguments might be presented with the information that the national health council says its beneficial to exercise twice a week, while a person more motivated by social influence will be presented with the social media statuses of his friends all exercising.

27 This subsection is based on Van Est and Rerimassie 2014.

7 Challenging practices within and beyond the medical domain

7.1 Introduction

In the foregoing chapters we have described NBIC convergence from three different perspectives: the neuro-, nano- and info-perspectives. We focused on technological developments which allow new types of intervention in the human brain, using infotech-based neuro-engineering tools, and in the human body, based on a new molecular understanding of life. In addition, we have described the development of new types of cogno- and socio-inspired intelligent artefacts enabling the influencing of human behaviour. These developments illustrate two major bio-engineering trends: biology is becoming technology and vice versa. Although the realization of these two megatrends is in many ways a long-term development, we have identified and highlighted several concrete examples, showing how these different developments are currently emerging in a variety of practices.

New technologies may be applied in multiple social practices. Such practices may be both shaped and transformed by new technologies and will also influence the societal challenges these technologies raise (Van Est & Stermerding 2012). In order to get to grips with the ethical and regulatory challenges raised by these new technologies, it is crucial therefore to identify the sociotechnical practices in which these technologies will become embedded. This chapter will first identify various emerging practices *within the medical domain* in which new technologies might raise various bioethical issues. We will argue that the Committee on Bioethics has already dealt with a variety of these developments, but new fields that might be of interest are also identified. Second, we will point to a whole range of new emerging practices *outside the medical domain* in which biomedical technologies and/or biodata are being used. These new practices provide almost unknown terrain for the Committee on Bioethics.

Table 7.1 gives an overview of established and new sociotechnical practices within and beyond the medical domain, and guides the argument made in this chapter. It is important to note that this table uses the NBIC perspective – or, put better, the N, B, I, and C perspectives – to categorize various developments. It therefore gives a schematic representation of a diversity of practices. Developments are more diffuse and complex, though, since these perspectives and practices often coevolve and impact each other in multiple ways. That is exactly what the notion of NBIC convergence implies, and its impact is both a convergence and a dispersion of practices in which biomedical technologies are applied.

Table 7.1 Established and emerging sociotechnical practices within and outside the medical domain. The Committee on Bioethics has extensive experience with the technologies in the green coloured cells and far less experience with those in the yellow coloured cells.

NBIC perspective	Inside medical research and health care	Outside medical research and health care
Bio-perspective	<ul style="list-style-type: none"> - Interventions in the body - Using bodily material to intervene in the body 	<ul style="list-style-type: none"> - Human and social enhancement - Direct-to-consumer genetic testing
Neuro-perspective: invasive and non-invasive neurodevices	<ul style="list-style-type: none"> - Interventions in the brain 	<ul style="list-style-type: none"> - Consumer use of non-invasive neurodevices for improving performance, gaming, relaxation - Use of invasive devices to extend senses (biohacking movement)
Nano-perspective: molecular medicine, smaller & cheaper devices, sensorization	<ul style="list-style-type: none"> - Understanding and monitoring disease at molecular level - Early diagnosis and intervention 	<ul style="list-style-type: none"> - Home use of medical devices, such as lab-on-a-chip - Biosensor devices in consumer products, such as smart phones and shoes
Info-perspective: big data science, persuasive technology	<ul style="list-style-type: none"> - Large-scale biomedical research resources (bio-banks) - Increasing intensity of biomedical data collection, linking, analysis, use and retention (big data science) 	<ul style="list-style-type: none"> - Increasing volumes of (open access) biological and lifestyle data (e.g. user-generated / self-published data / Quantified Self movement / social networking data / biosensor networks)
	<ul style="list-style-type: none"> - E-health, mobile health, e-coaching, tele-monitoring and tele-care, health care robotics 	<ul style="list-style-type: none"> - Persuasive technology, e-coaching

7.2 Challenging practices within the medical domain

The green cells in Table 7.1 show areas of technological development within the medical domain which the Committee on Bioethics has focused on. These developments concern technologies that intervene in the human body, including the use of bodily material, and the related practice of trafficking in human organs. Moreover, the Committee has considered the ethical issues raised by the deployment of biobanks.

This report aims to identify potential new areas of development which might earn the attention of the Committee. By using the neuro-, nano-, and info-perspectives we can spot various challenging developments within the medical domain (see yellow boxes in the second column of Table 7.1). This approach corresponds with the idea that “developments in genomics and associated areas, nano-technology and imaging techniques, in combination with developments in bioinformatics, computer science and, not forgetting (the use of) the internet, will have a decisive impact on what happens in the future” (Health Council of the Netherlands 2008, p. 46). Our study shows that the rise of neuro-engineering and nanotechnologies is creating new possibilities for introducing technology within our brains and bodies. Large-scale biomarker research is opening up new ways to generate information about our individual health states. The expectation that motivates this development is that this type of research will enable early detection of risk factors for and related prevention of all kinds of diseases.

The trend towards personalized, predictive, preventive, and participatory health care can also be spotted in the research priorities mentioned in the work programme for 'health, demographic change and wellbeing' of the European Horizon 2020 Framework Programme, which include: the clinical validation of biomarkers and translation of 'omics' into stratified approaches; early risk detection and intervention; piloting personalized medicine; self-management, citizen engagement, and patient empowerment supported by ICT; and decision-support systems based on predictive computer modelling used by the patient him- or herself (European Commission 2013). These developments depend on the ongoing miniaturization of devices and on making diagnostic tests increasingly available for use at 'the point of care', that is, at the bedside, in the consulting room, and also at home. As diagnostic devices are becoming smaller, cheaper, faster, and smarter, they will, more and more, allow people to test themselves and may even be incorporated in the body or brain. New types of information and communication technologies also enable the arrival of tele- and mobile health care practices. ICT thus enables the monitoring and organizing of health care outside hospital settings.

The above-described emerging practices are still, to a large extent, established and controlled by professionals within the medical domain. Our study shows that NBIC convergence enables all kinds of advances in biology and medicine that can be applied in practices outside the medical domain as well. These types of application are thus no longer guided by the professional know-how, ethical norms, and regulatory frameworks that define the medical domain.

7.3 Challenging practices outside the medical domain

The increased application of biomedical technologies outside the medical domain is driven by various developments. Without aiming to provide a complete picture, we just name a couple of relevant trends. From a political perspective, we see a move in many countries from government-regulated to more market-driven forms of health care. This market approach addresses individuals more and more as consumers of health care, emphasizing the need for individual empowerment, individual responsibility for a healthy lifestyle, and the ability to choose. The increased use of biomedical technologies in the public domain is also promoted from the bottom up by several groups within society. We may think of members of the quantified-self movement, biohackers, and transhumanists, who are experimenting with technologies and advocate the right to monitor their bodies and lifestyles, to intervene in their bodies, and to enhance their physical and mental performances and extend their senses. The availability of small, easy accessible and relatively cheap technologies enables this movement, and the prospect of the technological wave promised by NBIC convergence encourages it. Moreover, this movement is strengthened by the explosive growth of social networks, which citizens use to share information about their health and lifestyle (ESF Forward Look 2012). Industry seizes the opportunities created by these trend-setting consumers, or better health and lifestyle prosumers, by making available an ever-greater variety of biomedical diagnostic, screening, and enhancement tools on the free market. This lowers the threshold for people to diagnose and intervene in their own bodies, an activity which, for a long time, has been strictly bounded to the highly professionalized medical domain. To close the circle, some politicians embrace these bottom-up societal and market developments as viable ways to reduce the rising costs of the current health care system.

Our study shows that biomedical tools are not only employed in the public domain for medical purposes. Neurofeedback technologies are, for example, used in gaming. Neurodevices might also be attractive to governments, who might find useful applications for their civil servants and soldiers

and for the rehabilitation of convicted criminals or the prevention of crime. Companies might be interested in using neurotechnologies, such as fMRI technology, for neuromarketing, to better assess consumer choice in order to improve their marketing. In addition, the convergence between IT and cognitive and biological technologies is creating two reinforcing trends. First, the collection of digital data on health and human behaviour has exploded over the past few years – the so-called big biodata. Information technology enables a hitherto unknown scale and depth of analysis of human biology and behaviour. Macro-level analysis of these large quantities of data from multiple sources is delivering new kinds of knowledge about ourselves. This feeds back into the second trend, the development of information technology which is incorporating insights from cognitive and behavioural science to develop systems that better ‘understand’ human psychology and are able to interpret, interact with, and influence people’s behaviour.

These developments outside the professional medical domain imply a blurring of boundaries between professional practices of cure and care and public and commercial practices of entertainment, lifestyle, social media, and enhancement. As a result of these developments, humans and technologies are becoming more and more intimately entangled. In chapter 3 we have characterized this entanglement as a process in which technology, more and more, is nestling itself within us and between us, increasingly compiles information about us and can act just like us (Van Est 2014).

8 Conclusion: From medical practice to daily life

Our study shows that NBIC convergence is enabling a new wave of emerging technologies. Even though many of these developments are still highly uncertain and might only materialize in the near or more distant future, questions are already arising from these developments that may be highly challenging in the light of current ethical frameworks and regulatory regimes. These emerging technologies raise all kinds of well-known ethical and social issues, such as safety, privacy, autonomy, responsibility, physical and mental integrity, informed consent, and access to technology. But lesser-known issues and phenomena were also reviewed, such as human enhancement, social enhancement, ownership of biological data, freedom of information, consumers' competences, and medicalization. Moreover, various intriguing questions were raised, such as: should we have the right to enhance ourselves via technology, do we have a right not to be measured, analysed, and coached, how do we avoid being manipulated by human-like technologies, which social tasks can we humanely delegate to machines, and what knowledge, skills and financial means does an individual need to adequately use certain biomedical technologies in daily life?

The central question of course is how can and should democratic society deal with these issues? And how can it strike the necessary balance between technological progress and human dignity? Section 7.2 summarized various challenging technological developments within the medical domain which might over the coming years gain the attention of the Committee on Bioethics. These new types of developments – from neuromodulation techniques to molecular medicine – come into view when the perspective on technologies is widened from bio- to NBIC. Europe has built up a tradition in dealing with the sensitive ethical issues raised by the use of biomedical technologies within the professional medical domain. In fact governance approaches developed and used in Europe regularly serve as worldwide models. In European societies, public and political debates about biomedical and biotechnological interventions in the human body have already been going on for decades, supported by the activities of national and European ethics bodies and regulatory initiatives. As we have discussed in chapter 2, the Council of Europe and its Committee on Bioethics have traditionally played an active role in these debates.

Section 7.3, however, shows that NBIC convergence also enables the increased application of biomedical technologies outside the medical domain. Moreover, driven by the fact that IT has become increasingly intertwined with the life and behavioural sciences, biomedical tools and biodata are not only employed in the public domain for medical purposes, but also, more and more, for gaming, entertainment, marketing, coaching, and human enhancement and social enhancement purposes. This raises the crucial question of whether we have the governance machinery in place to deal with the ethical and social issues raised by the increased usage of biomedical technologies in the private world. More specifically, it raises the question of whether the institutions, including ethical and regulatory bodies, that take part in dealing with ethical and social issues within the medical domain should assume a role and responsibility in dealing with all these issues creeping out of the biomedical domain into the domain of daily life. Or, more generally, to what extent can the experience with the governance of ethically sensitive technologies in the medical domain (amongst others, in terms of regulatory frameworks and institutions) help us to address the ethical and regulatory challenges related to the application of biomedical technologies in daily life?

Governing the use of biomedical technologies in the professional medical domain versus the public domain presents a whole different challenge. Outside the confined regulated medical domain so-called regulatory wastelands often exist or do emerge (Van Est et al. 2008). We saw, for example, that the use of EEG neurofeedback within the medical domain presented a minor regulatory challenge, while its use for gaming, to a large extent, goes on uncontrolled. Employing biomedical technologies outside the medical domain presents various difficult challenges. For example, what kind of knowledge do citizens need to use these technologies in an appropriate way? And with respect to safety, how can risk be monitored? And if certain laws exist are clear regulations in place to enforce those laws. For example, with regard to gene doping, it is conceivable that professional athletes will in the future be tested on whether they use gene doping, but, in principle, amateur athletes can use such doping unnoticed. When reflecting on the question of how to deal with these unregulated practices, it is important to realize that new developments are often unregulated to start with. Regulatory wastelands, therefore, might also function as social experiments and/or playgrounds for new types of emancipatory movements. In fact, we have spotted a number of these movements, in particular the quantified-self and transhumanist movements, which are actually both technologically and politically promoting the use of biomedical technologies in the private domain.

To sum up, through the increasing NBIC convergence we are not only facing new types of interventions in the body and the brain, but also new intertwinements between information technology and the life and behavioural sciences. As a result, we are moving from well-known terrains of (bio)ethical debate to potentially new terrains both within and outside the biomedical domain. In particular, the increased application of biomedical technologies in daily life raises new questions about the role and responsibilities of actors and institutions – both at the national and at the European level – with regard to developments on these new terrains. Without new forms of governance, the dynamics of these developments will be left to a variety of techno-scientific drivers and market forces. Obviously there is a need to deal with the multifaceted ethical and regulatory challenges that are arising from these developments. This need implies an inclusive process of *societal learning*, involving professional, public, political, and ethical deliberation. In this process, intergovernmental committees and public (bio)ethics bodies, like the Committee on Bioethics of the Council of Europe and the European Group on Ethics, may have important roles to play. A first step could be to put these developments on their own agendas. This could have an important impact on the process of putting NBIC convergence and the ethical and social issues it raises on the European political and public agenda.

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Who was Rathenau?

The Rathenau Instituut is named after Professor G.W. Rathenau (1911-1989), who was successively professor of experimental physics at the University of Amsterdam, director of the Philips Physics Laboratory in Eindhoven, and a member of the Scientific Advisory Council on Government Policy. He achieved national fame as chairman of the commission formed in 1978 to investigate the societal implications of micro-electronics. One of the commission's recommendations was that there should be ongoing and systematic monitoring of the societal significance of all technological advances. Rathenau's activities led to the foundation of the Netherlands Organization for Technology Assessment (NOTA) in 1986. On 2 June 1994, this organization was renamed 'the Rathenau Instituut'.

The Rathenau Instituut promotes the formation of political and public opinion on science and technology. To this end, the institute studies the organization and development of science systems, publishes about social impact of new technologies, and organizes debates on issues and dilemmas in science and technology.

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