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*This report does not represent the conclusions of the Conference but is a report prepared by the Conference's rapporteurs to the Committee on bioethics, as a basis for its further work on this topic.

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SESSION 1: INTRODUCTION

In 2014 the committee DH-BIO of the Council of Europe agreed to organise a symposium on *Emerging Technologies and Human Rights*, the aim of which was to identify human rights challenges that arose in connection with emerging and converging technologies such as nanotechnology, biotechnology, and information and cognitive technologies (NBICs). The conclusions of the conference are intended to inform further consideration by DH-BIO of the possible need for a response in the context of the Oviedo convention, including a possible white paper.

The symposium was held on 4-5 May 2015, and was informed by two reports commissioned by DH-BIO, and published in advance of the symposium. These were *From bio to NBIC convergence – from medical practice to daily life*, prepared by the Rathenau Institute (Van Est et al, 2014), and the *Report on ethical issues raised by emerging sciences and technologies*, prepared by the University of Bergen (Strand and Kaiser, 2015).

The Rathenau report identified a number of areas where new and converging NBIC technologies might present challenges in a human rights framework, including areas such as privacy, safety and autonomy, but also set out a number of other more complex areas of potential concern, such as questions relating to enhancement, ownership and control of biological data, and the use of biomedical technologies outside of the medical domain. It raised the question as to whether current instruments and regulatory mechanisms are adequate to respond to such challenges.

The Bergen report looked more specifically at the way these challenges would present themselves in the context of human rights instruments such as the Oviedo convention. It identified a number of ways in which implications for (in particular) human dignity, identity and integrity might engage various articles of the Convention. It found that consideration needed to be given to the ways in which the mandates of Council of Europe extended to emerging technologies, and recommended that continuous reflection was needed, together with new forms of governance that should include wide participation and engagement.

This theme was also taken up in the introduction to the Symposium, presented by Professor Andrew Stirling, who highlighted that the challenges of emerging technologies are only partly about the balance of risk and benefit in any particular application, but are rather about recognising the social contexts in which they emerge, and the need for wider debate to support a more democratic shaping of the choices entailed.

He presented the notion that the so-called ‘race’ to innovate is not a single trajectory, but consists of a wide range of choices. However, market forces and dominant political, commercial and technological powers tend to narrow down these choices, creating the risk of lock-in and path dependency, meaning that society often has limited choices, leaving a

democratic deficit in the range of social and technological possibilities and pathways that are available. This means that human and social choices and innovations can become marginalised, with ethical considerations applied only to the single trajectory on offer. Ethics, in this sense, should become a process of choosing not the single good, but about opening the discussion to multiple choices. In turn, this demands a democratic and participative engagement at every level, one where discourse is a civil activity, rather than an academic, corporate or political one. An ethical discourse is one that engages all stakeholders - from business, Government, civil society, etc – so that a wide range of innovation remains available, and progress becomes democratised.

It is in this spirit that a wide range of delegates convened in Strasbourg and, having received the Rathenau and Bergen reports, heard from a range of experts from different fields and from around Europe and beyond, joined in a wide-ranging discussion structured around the themes of *intervention and Control; Data collecting and processing; Equity of access; and Governance*.

This report from the rapporteurs at the symposium is not intended to provide a full account of everything that was said and discussed at the meeting (the sessions are all available online <http://www.coe.int/fr/web/bioethics/conference-videos>), but it tries instead to provide a digest of the meaning and implication of what was raised and discussed in each of the sessions. As such it is not so much a summary of the symposium, but rather an aid to further consideration by DH-BIO of potential future actions.

SESSION 2: TECHNOLOGY, INTERVENTION AND CONTROL OF INDIVIDUALS

(Rapporteur: PD Dr Michael Fuchs, Germany)

Background and Introduction

The term *technology* can be understood as referring to an object or an artefact, as an activity or a complex of activities, or – following etymological analysis – as knowledge or as an epistemic system. Examples of technology referred to in Session 2 included synthetic biology, tissue engineering, nanomedicine, deep sequencing, blood doping, gene doping, implanted camera eye and deep brain stimulation. Most of these represent an activity or a complex of activities. The implanted camera eye is an artefact or an object. Synthetic biology may be another exception here: As a part of biology it is an epistemic undertaking. Nevertheless, synthetic biology makes use of engineering techniques and is, in this respect, a complex of activities. Some of these activities are defined according to their goal (e.g. doping), others are defined according to the procedure or method that is used.

Conceptual Framework

Speakers in Session 2 proposed different approaches to describe new developments in technology. The notion of *emergence* of technologies was used to refer to the appearance of technical tools in the bordering area between therapy and enhancement. What is new was especially seen in the shift from *prosthetic* technical tools to *implants* of artificial tools. Besides the allusion to the emergence of technologies the concept of *convergence* was also introduced. Referring to the thesis of and the publications cited in the Rathenau report it was argued that the convergence of different technologies creates more complexity, and technology assessment becomes more difficult, though it was left unresolved whether convergence means the appearance of an overlapping zone or a complete coincidence of formerly distinct technologies. Moreover it was not specified if this overlap or coincidence refers to a set of objects, a cluster of activities or a group of epistemic approaches.

Another concept that is prominent in the publications of the Rathenau Instituut was introduced in Session 2, and is called “intimate technology”. With intimate technology the authors of the Rathenau study from 2014 do not only refer to technology in us, but also technology between human beings, about human beings and “just like us”. It is used as a set phrase for the thesis that the distance between technology and people is rapidly decreasing. This formula was especially utilised to refer to implants of artificial tools in the

human body. It was balanced or confronted, though, with the concept of “extimate technology”. Speaking of the same tools as both “intimate” and “extimate” technology at the same time sounds paradoxical, to say the least. Instead, this effect of paradoxical appearance was intentionally used to stress that the tendency of technological development in society is double-faced, somehow obscure, and, as it was expressed, “uncanny”. The notion of extimate technology is taken from psychoanalytical discourse and is prominent in some parts of post-structural literature. “Extimité” was proposed by Jacques Lacan in 1969 during his Seminar XVI at the Hôpital Sainte-Anne in Paris. It was meant to describe, from a psychiatric perspective, the desire to make some aspects of the self visible that had otherwise been considered as belonging to the intimacy of an individual person.

In the context of technology assessment, such desires are not just individual pathologies. They are indicators that the realm of the private and the public are not fixed for all time. They are defined by a given society and specific communities. This was illustrated by the example of a prominent geneticist who voluntarily was closely monitored over the course of 14 months, measuring everything¹. The resulting integrative personal ‘omics’ profile was made publicly accessible.

Evaluative Approach

New technologies are associated with opportunities, but also with dangers and risks. This holds for NBIC technologies as well. As an activity or social practice, the development of any particular technology can be an intervention in a social context or social setting or an intervention in the individual person. The presentations and debates in Session 2 chose a perspective that focused more on the impact on individuals than on the impact on social institutions and groups. With regard to this focal point, opportunities connected to emerging technologies express themselves, for example, in the vision that individuals can become the proactive managers of their own condition. This can be described by positive evaluating terms like autonomy or empowerment. All instruments and micro machines that are worn in and on the body broaden the spectrum of courses of action of the affected individual, and can serve him/her as instruments of life planning.

The self-control aimed at here can also be described negatively. In this sense, assistive systems and computers appear as quasi-actors: “The computers tell the individuals to change their lives.” The quantified self needs reference data (“molecularized super-ego”). Thus, autonomy suddenly turns into heteronomy. Heteronomy, in a classical sense, could

¹ Chen R. et al (41 authors) (2012) Personal omics profiling reveals dynamic molecular and medical phenotypes. *Cell* 148, 1293–1307, March 16, 2012.

also arise if freely collected data are available to third parties and are incorporated for goals that do not serve the self-determination and well-being of the affected individual.

The human individual that likes to take her health into her own hands (self - empowerment) can therefore become the target of the interests of other individuals and groups and institutions. Also if the individual uses personal data on himself as currency, i.e. to pay for health care, though, individual protection claims seem to be at stake. Problems may also arise if self-control becomes a requisite to offer certain health services. The self-measurement of health data could be required by health insurers as a prerequisite for insurance (compliance of the patient /client).

There are several scenarios and reasons that can explain individuals becoming objects of external control and interests instead of proactive managers of their own condition.

External control, though, exists by virtue of various legal systems and codes of conduct as well. Doping in competitive sports served an example for this given its usually critical public response. Doping can also be used as an example of a technological *transgression* – where medical technologies are introduced for non-medical purposes. Precisely the attempt to avoid such a transgression through the establishment and employment of testing methods can be understood as a freedom-threatening intervention if athletes are monitored, limited in their private spheres, or maybe even criminalised. Thus, it was suggested that controlled release of technological developments may be a preferable alternative to the existing anti-doping systems.

Normative Approach

The complexity and uncertainty of technological developments, and their anthropological and social impact, make it difficult to find out what the normative requirements are in our situation and in the future even if the normative principles are agreed. One possible way to cope with the complexity would be to differentiate among a plurality of sub-systems. It was proposed that the normative discourse should not be organised around the different *technologies*, but should rather focus on *practices* (medical /non-medical, sports performance, research, etc.) or on specific *goals* (health, care, prevention, et al.) or on different *social contexts*. For all practices, goal-specific activities and social contexts, principles such as autonomy, integrity, identity, dignity, privacy, equity of access, consent, non-discrimination, justice and solidarity have to be taken into account. But what are the most relevant principles in each specific sub-system and how should these principles be balanced and specified? Following the presentations of the speakers in Session 2,

autonomy, integrity, dignity and consent are the most prominent principles. These normative principles can also be articulated in the language of human rights.

Governance and Legal Approach

Human rights issues in the use of NBICs may be at stake both if the procedure is invasive (e.g. Deep Brain Stimulation) and non-invasive (e.g. Diabeo Project²). Generally speaking the physical integrity of the person has to be respected. The approach in Session 2 was shaped by the question of whether current regulatory instruments suffice to adequately regulate the new technologies. If one refrained from the hint that the strategy of the Council of Europe concerning doping in competitive sports should be regarded as a freedom-threatening strategy and as harmful in its results, the question was left mainly characterised by the report of the Rathenau Instituut. This report carries out an examination in which it enquires which areas have already been discussed by the Committee on Bioethics of the Council of Europe, and which new technologies and areas of application have so far been underdetermined. From Session 2, it emerged that, with respect to future activities of the Council of Europe, not only the documents prepared by the CDBI and the Committee on Bioethics are relevant. Other relevant instruments and articles have already been listed in the Bergen report, and Article 4 of the Oviedo Convention was specifically mentioned in the session: “Any intervention in the health field including research must be carried out in accordance with relevant professional obligations and standards.”

In the realm of international jurisdiction, it is not only the ECHR and the Oviedo Convention with their additional protocols that might be relevant for the judgement of new courses of action in the light of human rights, but also other conventions of the Council of Europe as well as documents of the European Union, such as its Charter of Fundamental Rights. But in looking at the variety of legal instruments in an international and European framework, it can be difficult to see in some cases how instruments can be extended to these new fields. What activities are susceptible to the provisions of Art. 4 of the Oviedo Convention? Can we build on such standards in fields of practice that go beyond the medical field? And with regard to which professions or standards could that be possible? Is it generally speaking appropriate and justified to refer to any kind of professional ethos in a human rights context?

² <http://rslnmag.fr/post/2014/06/14/Sante-quand-le-numerique-repond-aux-nouveaux-enjeux-de-la-prevention.aspx>

The application and updating of the international law documents needs to be further investigated and checked regarding its necessity, its enforceability, its possible negative consequences and its alternatives in the realm of governance.

(Rapporteur: Hugh Whittall, UK)

In this session the speakers addressed the question of whether and how specific data gathering and processing features of new technologies (and in particular NBICs) might bear upon questions of human rights, and how existing norms and frameworks (legal or ethical) could respond to them.

It was generally acknowledged that with increasing digitisation and technical capacity in data collection and processing there were important opportunities through NBIC technologies for developing research that could be of great societal benefit, but also that these developments put pressure on certain existing human rights protections, notably that in relation to privacy.

Introduction

The continuing development of NBIC technologies, especially as they converge through the application of digital technologies whose capacity and power are also expanding rapidly, and combined with the opportunities for data mining, present a technical challenge to the current human rights framework in several ways.

The preliminary reports presented to the Symposium by the teams at Bergen and the Rathenau Institute show how there are potential implications for human dignity and integrity, as well as potential questions about justice and access. But in the dimension of the new technologies that relates to the collection and processing of data, the central concern is about risks to the privacy of individuals, in terms of the protection of personal data.

Various neuro- and bio-technologies, including those that are wearable or implantable in the body, have the ability to collect a wide range of genomic and biometric data, and to transfer this rapidly and in large volumes to data repositories. Using advanced analytical tools, researchers can use this data, often in combination with data from other sources, to support research that may have the potential to deliver significantly improved diagnostics and therapeutics. The sources of this data can be medical and health-related environments, but equally huge amounts of personal data can be gathered through social media applications and commercial and administrative services. Whilst the services or apps might themselves offer convenience to their users, those users are not always fully

aware of the possible future commercial and research uses of their personal data. The risk to those users is the potential loss of privacy, if not through the immediate use of their personal data, but perhaps with its future use if shared or combined with other databases. This risk is exacerbated by the fact that the anonymisation, or de-identification, of data can no longer be relied on to permanently de-identify data. It is increasingly possible (although technically challenging) to re-identify data, often by merging data from different sources – whether from health-related or social or commercial environments.

Which Human Rights?

Whilst the data collection and processing aspects of NBICs most obviously put pressure on the privacy elements of the human rights framework (and specifically in this context Article 8 of the ECHR), it should be recognised that privacy is not an absolute right, but a qualified right, in that it can be balanced or aligned with other rights, and with the interests of the community as a whole. Moreover, whilst society has an interest in the protection of the privacy of individuals, individuals also have an interest in the broader societal benefits that derive from collective data use. Thus it could be suggested that multiple rights and interests are at stake in considering the use of personal data for research purposes, including the rights under other instruments to, for example, ‘share in scientific advancement and its benefits’ (UN Declaration on Human rights - UDHR), or of ‘equitable access to healthcare of appropriate quality’ (Oviedo Convention, Art 3). In this way, human rights could be seen as providing for the need to protect the privacy of individuals and their personal data, but also (which might be in tension with strict application of privacy rights) to support the need to facilitate scientific enterprise where it can be for the benefit of society.

Privacy and Data Protection

One of the main ways (but certainly not the only way) in which privacy is currently protected is through the application of Data Protection legislation. Data Protection (DP) generally identifies certain roles: the data subject, the data processor, the data controller, and the data recipient. These roles are relevant in the contexts of the various phases of data analysis: the collection of individuals’ data (whether through service provision, web tracking, smart devices, etc); the collection and aggregation of the data into large data repositories; the analysis of the data (whether through data mining, use of algorithms, profiling, etc); and the usage of the data (for research, commercial prediction, personal profiling, etc).

Data Protection is founded on a number of principles that are aimed at protecting the privacy interests of individuals. The principles include the requirement (with some exceptions relating to national security, etc) for fair and lawful processing; for only the minimum necessary amount of data to be collected and stored, and only for the intended purpose; for the data subject to be informed of the intended processing; and for the data subject to have the right to correct and to delete the personal data.

Amongst the difficulties with DP in relation to NBICs in the age of Big Data, are that on the one hand DP laws do not comfortably accommodate the needs of data-intensive research, and on the other hand it becomes very difficult, despite all good intentions, to maintain DP principles. At the same time, care must be taken not to look only to 'hard' instruments of law, whether Human Rights or Data Protection, as responses to this issue, as the problems, being contextualised in cultural environments, will also demand a broader societal and ethical response.

Big Data and the Internet of Things

What makes the advent of NBICs particularly difficult to manage is a combination of the complexity of the technologies themselves, especially when developed in converging technical applications, and the complex social context into which they emerge, but also the increasingly important trends in Big Data and the Internet of Things. What characterises Big Data is the volume, velocity, variety and (potentially) veracity of data that is being generated and captured through global digital systems. This makes the data environment extremely complex, and once data is shared across sectorial and jurisdictional boundaries, it becomes increasingly difficult to control the use of data, including the possibility of re-identification of personal data. To this extent it becomes difficult to maintain the central data protection principles.

At the same time, rapid developments in the 'Internet of Things' - devices, sensors and objects that have online connectivity and that are capable of collecting and transmitting large volumes of personal data (using NBIC technologies) - creates opportunities for the construction of large data repositories which can be shared, mined and monetised. Indeed, data in general, and personal data in particular, has become a valuable asset not only for health research, but also for commercial and marketing purposes. It has been estimated that the market value of the combined Internet of Things is as much as \$14 trillion³, and whilst this value does not all reside in the data itself, the market is driven by data.

³ http://internetofeverything.cisco.com/sites/default/files/docs/en/ioe-value-index_Whitepaper.pdf

In the health field, the application and use of NBIC technologies in the context of Big Data applications and analytical methods mean that researchers can gain access to huge datasets, from which they may be able to discover new knowledge, and develop new diagnostics and therapeutic applications that are better tailored to individual needs. But the force and potential of this research is maintained only if the data can be accumulated in very large numbers, indeed on a global scale. The research and clinical value of datasets is enhanced if can be shared through collaborative approaches, so that they can be combined, compared and cover large populations. At present progress in this area is limited by a lack of integration and compatibility amongst data collection and management approaches; an unwillingness to share datasets; and a lack of harmonisation in technical standards and governance arrangements. Progress in these areas should be possible, but they challenge existing expectations as to consent; there is a risk that they will be hijacked by vested (the more powerful) interests; and there is an awareness that this will need to be accompanied by appropriate mechanisms to promote and protect privacy.

Challenges

A number of particular challenges arise from the use of NBICs in the context of data collection, storage and use, especially once Big Data approaches are applied to them.

Repurposing. As the sources of data are many and varied, and arise in different contexts, whether through smart devices, health-related investigations or social media applications, there are numerous opportunities for data collected in one context to be used for a totally different purpose. In principle, the individual data subject should be informed of the further use, but on the one hand the illegitimate use of data in this way becomes increasingly difficult to monitor, and at the same time, the data subject may not find the information about future uses easy or convenient to access. So the volume and rapidity at which data are collected, and transmitted and the ubiquity of the data collection points, make the usual principles of data protection difficult to maintain.

Transfer to third countries. As the value of large datasets increases, especially the collection of large volume datasets for both health-related and commercial purposes, the transfer of data across national and jurisdictional boundaries becomes more likely. The data subject should be informed of the data transfer, and be assured that equivalent protections will be in place. But, again, such activity will be difficult to monitor both on an individual and an institutional/commercial level.

Consent and the consumer/participant. Linked to the repurposing and transfer questions is the issue of the extent to which the individual, as a data subject, has the realistic opportunity to manage the control of their personal data. Whilst data processors should inform data subjects of the purpose, potential future use and transfer of their data, it becomes increasingly unrealistic that data subjects will, in reality, be aware of the data storage, processing and use. With online services, applications and products that offer convenient leisure, health and professional activities, and devices that are wearable, implantable and connected, data subjects will often be unaware of the extent of data collection and use, even where they have been given the opportunity to be informed. There is often poor security, poor awareness, and asymmetric data flow systems.

Realising the benefits. Whilst researchers and other service providers make claims about the importance and potential of NBICs and the related data collection and use to deliver important social and economic benefits, many of these benefits have yet to be realised. The benefits are therefore as yet unproven, and are certainly unlikely to accrue to the individuals whose data is collected and used, data which is often personal data by virtue of the fact that it could become re-identified. If people are to have confidence in data collection and processing systems, and broadly agree to the use of their data, it will be important that widely-shared benefits can be clearly demonstrated.

Conclusion, Solutions, Recommendations?

In summary, the risks and challenges identified in relation to NBICs in the data context include:

- the possible increase in fraud or unauthorised use;
- the loss of data 'sovereignty' for individuals;
- uncertainty about ownership and control of data;
- the loss of trust in the collection and handling of personal data;
- the need to rely less on the law as an instrument of governance; and
- the need to develop better and more effective self-governance.

It was generally acknowledged that responding to the challenges presented by NBICs for data collection/use and the protection of privacy will not lie simply in refining or modifying existing data protection laws and systems. Rather, a more comprehensive approach will be needed that recognises the reality of data gathering in the digital age through NBIC and other technologies; that supports the opportunities that data access and sharing present for socially valuable research in genomics, healthcare and other areas; and that employ

social norms, soft law and cooperation by various 'market' players as well as the underlying data protection and human rights protections of privacy.

One approach to the fundamental problem of how to facilitate data-intensive research whilst respecting the privacy interests of individuals is that developed by the Global Alliance for Genomics and Health (GA4GH), a non-profit organisation concerned with in genomics health research. The approach acknowledges the importance of privacy as a human right, but seeks to balance or align this with other rights, such as the right to benefit from the fruits of science. It identifies four 'foundational' principles as the basis for data sharing: respect for individuals, families and communities; to advance research and scientific knowledge; to promote health and wellbeing and the fair distribution of benefit; and to foster trust, integrity and reciprocity. Privacy is recognised as a further elaboration of these principles, in particular of the principle of respect for individuals, albeit not as an absolute right. This approach acknowledges that inadequate privacy and security arrangements can compromise the interests of both participants and the research itself, but recommends a proportionate approach to privacy, given the realities of the internet age, and the difficulty in ensuring a zero privacy risk. The intention is to recognise that the interest of those allowing their data to be used includes the interest in it being used effectively. Guidance for researchers therefore advises on the responsible use of data, and that privacy risk assessments should be conducted that focus on 'reasonably likely harms' rather than on unsustainable assurances of absolute privacy, and on the subsequent just distribution of the benefits of research.⁴

In any event, the future protection of privacy in the age of Big Data will involve a range of responses, presenting society and policymakers with some difficult challenges. These will include elements such as:

- Revised Data Protection laws that are more responsive to a dynamic environment and the different contexts in which data might be collected, stored and used;
- A constructive approach to 'soft law' in which moral norms can be identified and supported through guidance, industry standards, etc
- Effective cooperation amongst those involved in the various phases of data collection, storage, analysis and use, whether in health, research, commercial or industrial sectors; and
- Increased education and participation in discourse around data management by the public, civil society and NGOs, as a way of securing trust and legitimisation of future approaches.

⁴ Knoppers, Bartha M. (2014b). International ethics harmonization and the global alliance for genomics and health. *Genome Medicine*, 6(13), 1-3.

Specifically, there are a number of types of initiative that could be helpful in fostering this more nuanced approach to privacy protection on the new NBIC/Big Data environment, such as:

- Privacy by Design as a default approach, in which those who are developing data initiatives should build in the technical and procedural processes needed for securing data privacy. This would apply to state and to market players, and should engage civil society actors in the design so as to help secure transparency, trust and support.
- Privacy Impact Assessments as an element of data-gathering initiatives, to demonstrate that risks and vulnerabilities have been addressed in a reasonable, appropriate and proportionate fashion.
- A top-down programme of public discussion to help facilitate the engagement of civil society actors in the design and implementation of data initiatives, and to help develop realistic expectations about what risks and benefits data collection and use might entail.

SESSION 4: EQUITY OF ACCESS

(Rapporteur: Prof. Laura Palazzani, Italy)

1. Justice and equality at stake in the 'emerging technologies divide'

Emerging technologies are generally presented in the context of their potential to promote development as advancement in techno-science and improvement of human beings, as individuals and in the sense of society as a whole. The technologies are seen to go beyond therapy and healthcare, blurring boundaries between medical/non medical applications, and between health/illness. The scenarios outlined are generally complex, uncertain and likely to reach an unpredictable (for some aspects imaginable, for others unimaginable) benefit/risk balance with regard to individuals and society, present and future generations. That's why the question of safety (physical and mental integrity) individual privacy, social acceptability, is generally at the centre of discussion, but there is another ethical challenge at stake: the challenge of justice.

This emerging field of scientific and technological development brings on the one hand expectations of great benefits/improvement, and on the other, big challenges, among which also the challenge of inequality. The risk of deepening inequalities and creating new forms of discrimination, stigmatization and marginalization, arises as a result of the high level of human and material resources involved. Justice would require us to seek equity/fairness/equality and avoid increasing divisions. An 'emerging technological divide' would mean unequal and unfair access to emerging technology, leading to (possible) new forms of technological discrimination.

Emerging technologies are challenging and require a re-framing in the elaboration and application of the criteria of justice, equality, equity. In this sense the appeal to equality is an appeal to the UNESCO Declaration on Bioethics and Human Rights (art. 15) and to the Council of Europe Convention of Human Rights and Biomedicine (art. 3 contains an explicit reference to healthcare): the interpretation of both international documents may need to be specifically adapted to new issues arising from emerging technologies, at both the European regional level and the global level.

2. Equity of access: ethical and juridical considerations

2.1. Access and affordability of emerging technologies

The rapid, dynamic and complex development of emerging/converging technologies occurs primarily in scientifically and technologically developed Countries, in wealthy Countries where there is financial support of research, trust in the advancement of techno-science and individual and social willingness to use it in everyday practice. Given the fact that the common-convergent goal of emerging technologies is improving human life of individuals and society, in the present and in the future, ensuring equity of affordability and access becomes a necessary condition of their ethical acceptability, as a guarantee of equality, justice and fairness worldwide.

Whilst the advancement of technologies deserves financial and social support, the cost of technologies remains high, specifically of emerging technologies which require high-level competence, and highly sophisticated tools. Ensuring equitable access to all may be difficult, but the principle and value of justice is relevant insofar as the macro and micro level distribution of new technologies should be accessible to all, or at least widely accessible.

The risk concerns discrimination and stigmatization of those having no access to technologies, and who live under disadvantaged conditions. This right of access is therefore fundamental for the dignity of the human being (not to be discriminated in access) and for freedom of choice (access to technologies is a necessary condition of the possibility to use it). As always occurs with breakthrough innovations, even if the initial development may be very expensive, the further development of technology is likely to dramatically cut down the costs. Return on investment is essential, at least in the case of private investment, in order to make resources available for further research and progress. So the intellectual property regime has a valuable function, but needs to be balanced with other principles and fundamental human rights (see The Doha Declaration on the TRIPS agreement and public health of 2001). A shared responsibility would be needed to avoid the unacceptable prioritization of profit for some Countries or people, over benefit for all.

2.2. The need for scientific education and to critical knowledge/awareness of technologies

Once access to technologies is established, there is also a need to be informed/educated, to acquire 'scientific and technological literacy', to facilitate awareness and use of technologies, a use that is respectful of the dignity of the human person, that includes safety and privacy. In this sense, equity of access to emerging technologies requires a duty of adequate information and education and transparent communication of scientific novelties. Such understanding and awareness would also support a right not to be exploited, for example through lack of awareness of being unwittingly monitored, checked, measured and quantified.

The condition for using emerging technologies in an appropriate way includes the need to be adequately informed on risks/benefits: information is necessary in order to protect the right to safety (physical, mental, emotional integrity) and to privacy (confidentiality). This right is necessary, but may be fulfilled in many ways, according to different technologies. Specific attention would need to be given to minors, the elderly, disabled.

Emerging technologies require, because of their complexity, uncertainty and unpredictability, a specific critical awareness and rational cautiousness, and the skill to balance opportunities/risks can help promote effectively informed and fair engagement as active participation of the public. This in turn facilitates the ability of each to make choices with regard to their own life, but also entailing consequences for society as a whole, both present and future. In this sense, it is necessary to develop transparency, as a requirement of public trust, as a requirement of an authentic democratic debate.

2.3. The 'right' not to use emerging technologies

Having 'in principle' access to technologies and critical information on their use is also relevant for recognising the right not to use technologies when safety and privacy are at stake, or whenever personal identity or interpersonal relationships are at stake.

This refusal to use technologies may be expressed in different ways: a right not to enhance; a right not to take risks upon oneself due to social external pressure; a right not to be controlled through digital technologies in a panoptical society; a right to perform everyday life without being monitored; a right to be forgotten and to delete data; a right to be assisted, treated and taken care of without innovative technologies.

These 'rights' reflect an emerging need: the need to protect vulnerable individuals who, whilst adequately informed, might nevertheless feel an undue pressure to use them, as a hidden form of exploitation, reducing freedom of choice and autonomy. And whilst the 'right not to enhance' should be recognised, it should also be acknowledged that improvement is always possible and intrinsic to all human beings: every function, physical, mental, emotional, can be improved in other ways through instruction, education and continuous training, a rich social life and interpersonal relationships. Whilst this may demand more time than technological enhancement, it is perhaps more respectful of the opportunities for growth and development of personal and relational identity as well as of self-esteem and the feeling of self-fulfilment.

3. 'Enhancement divide': fair or unfair?

In the context of emerging technologies, with reference to the possibility to enhance individuals, there are specific challenges to justice and fairness.

3.1. Access to enhancement: from self-determination to hidden coercion

According to a libertarian perspective, prohibiting access to technology on the grounds that it is not available to all, is not justified. Libertarian theory recognises the right to self-determination and the right to reach technologically the best health condition possible (bearing one's own expenses), even through the technological (invasive, intrusive) control of one's own body, if informed and aware of taking risks upon oneself. A requisite for enhancement must be, as for any other medical practice, informed consent which expresses the conscious choice of the patient who, after being fully informed by the doctor, assumes the responsibility of deciding to intervene on his or her body, even in the case of a non-therapeutic intervention. In this sense, there would be no duty of fair distribution in a competitive society based on maximal market.

Utilitarians, conversely, grounded on the principle of utility stemming from cost/benefit analysis on a collective level, call for the right to enhanced opportunities that render possible the best quality of life for the highest number of individuals. According to collective utilitarianism, justice coincides with the guarantee of a certain quality of life or wellbeing: the distribution aims at giving the greatest number possible of individuals the satisfaction of their interests, to guarantee productivity, efficiency and efficacy, or the prevailing of benefits over costs in an overall sense. Every social obligation is justified in view of achieving the collective advantage, reducing disadvantages. Inequalities exist in nature and in society: enhancement is considered a right (and even a duty of enhancement

or of 'beneficence', both on individual and social levels, with responsibilities in case of omission) as it improves individuals and indirectly society as a whole, in a sort of 'enhancing evolution'.

3.2. The unfairness of the search for perfection

A recognition of the right to enhancement or of a duty to enhance can lead to 'perfectionism' or search for perfection, carried out at the individual and social levels. The perfectionist desire widens the gap between disability-ability-superability, which may become unbridgeable. The search for betterment and improvement at all technological costs threatens fairness and social justice insofar as it produces social hierarchies and inequality among those enjoying perfect health and those staying in natural imperfect or (ontologically) limited conditions.

New forms of discrimination might appear, fostering a mentality of non acceptance and marginalisation of imperfections. Equality is at stake in a society where the distribution of these technologies is regulated by the free market, especially where only wealthy people could afford access to these technologies, resulting in further worsening of the already existing natural and social inequalities. In a global perspective the gap would become more evident, leading to growing inequality in an inter-national, and intra-national perspective.

4. Benefit sharing in emerging technologies

With the rapid pace of the advancement of emerging technologies, which builds on huge investments and the availability of highly specialized skills, low-income countries will not have the ability to catch up with such development. Emerging technologies are a powerful driver, which could exacerbate the divide between rich and poor countries, rather than reverse it. There is an ethical need therefore to plan appropriate interventions in order to avoid the widening gap and lay the foundations for international cooperation.

Equity of access and a sustainable ethics of benefit sharing at a global level, can be delivered by:

- i. identifying the basic general needs of the population of poor and low-income countries and the possibility of new technologies that can address these needs;
- ii. developing national research policies in the richer part of the world that include sustainable plans for how the benefits stemming from these research programs of emerging technologies can be shared, in an equitable way, with poor and low-income countries;

- iii. overcoming the barriers to equitable access to new emerging technologies and elaborating models of just distribution of benefits with specific reference to emerging technologies ;
- iv. recognising specific duties of wealthy countries towards poor and low-income countries in the normative framework of human rights;
- v. developing a global medical science policy and research strategy that takes into account specific research for health needs of poor and low-income countries, including them in the co-evolution of a fair and sustainable global policy on research priorities, scientific literacy and benefit-sharing; giving priority to national research programs that aim at forms of benefit directly transferable to poor and low-income countries; and encouraging bi- and multilateral projects.

The goal should be the one of overcoming all forms of discrimination or exploitation of poor and low-income Countries in techno-scientific research and (possible) benefits of research. The goal is not only the transfer of knowledge to comply with principles of beneficence, justice, equity and fairness, but also to enable access as active participation.

5. The participatory right to governance of emerging technologies

The complexity of techno-scientific knowledge demands an informed, inclusive and active democratic participation of citizens: this will be made possible by fostering public debate as part of the regulatory process. This constitutes an innovative 'governance' model for technologies under conditions of uncertainty and unpredictability of progress: a horizon guided by a triangulation of science, ethics and society, capable of grounding the law on updated scientific consultation, balanced ethical evaluation and social needs.

Regulations should, in this context, be based on reliable empirical data, and the imaginary anticipation of possible scenarios, weighing pros and cons, as well as considering alternative options, at the scientific, ethical and social levels, while analysing the decision in the context of a transparent, wise and precautionary approach.

Regulations should be focused on adjusting the instruments needed to protect human health to the specificity of different technologies, in order to safeguard personal freedom and justice, in a spectrum ranging from restrictive to permissive regulatory forms.

Regulatory issues arise at National and International levels, and efforts are needed to harmonize rules across different countries. A transnational and intercultural biojuridical

dialogue is underway, seeking to develop an effective and global answer, especially in a number of particularly timely bioethical areas.

6. Proposals

Given the new ethical challenges arising from the development of emerging technologies, States, scientists and citizens need to work towards an articulated strategy of inclusion, protection and promotion of awareness, and participation. Three areas for specific consideration emerge:

- i. the possibility of extending the principle of “equitable access” enshrined in international instruments such as the Oviedo convention and the UNESCO declaration to include converging technologies, which are likely to produce a major impact on the quality of life and the protection of health;
- ii. the adoption of a strategy for education aiming at reducing the gaps with regard to scientific knowledge among and within countries, including legislators and policymakers; promoting “open” and equitable access to knowledge and offering specific fora and opportunities to disseminate sound and reliable information;
- iii. to make knowledge sharing a priority, through new frameworks of research cooperation, networking of people and institutions, and other initiatives oriented to enable as many countries as possible to become producers and not only beneficiaries of emerging technologies.

SESSION 5: GOVERNANCE

(Rapporteur: Dr. André Gzásó, Austria)

Emergence and convergence

One of the earliest attempts to employ the concept of convergence can be found in a 2002 report by Roco and Bainbridge (National Science Foundation, 2002) on linking the highly separated research areas of nanotechnology, biotechnology, information technology, and the cognitive sciences (NBIC) for “improving human performance”. In the 2003 report of the NSF the NBIC vision is stated as “[T]he convergence of nanotechnology, biotechnology, information technology, and cognitive science can greatly improve human performance over the next ten to twenty years. The chief areas of application include: expanding human cognition and communication, improving human health and physical capabilities, enhancing group and societal outcomes, strengthening national security, and unifying science and education.”

Depending on the context the term “convergence” can refer to different meanings and fulfil different purposes. First, the NSF report suggested that science and engineering disciplines were converging toward the same principles and *tools*, the central supposition being the possibility of measuring and manipulating matter on the nanoscale, and to build up functional systems bottom-up at atomic and molecular levels. It seems that the specific meaning of the term “convergence” here referred to some kind of envisioned future where the manipulation of matter would be enabled by applying an engineering approach to all involved research fields, even the life sciences.

A second argument emphasizes the necessity of bring different *research disciplines* closer together. The convergence is therefore a convergence of the involved research areas and researchers and includes the need to reorganise research policies, especially in national funding schemes; the organisation and structure of the research system; and the communication practices between disciplines. The term *convergence* therefore encompasses also the (implicit) desire to make traditional research policy more permeable and to foster the exchange of approaches from different disciplines which are currently unnecessarily separated.

A third way to apply the term “convergence” is to use it to stress the supposition that something which exists as a scientific possibility can (and should) been done on a technical

level. In this case basic research and technological development are converging, and the term expresses some kind of necessity to strive for the development of certain *applications*.

The term *convergence* is therefore amenable to several different meanings and it is necessary to clarify from the onset in which way and to what purpose this term is used.

Governance – legal frameworks

One of the areas or instruments of governance considered in this session was the specific use of human rights law, which is inevitably challenged by developments in technology and their societal impact. Various human rights are potentially engaged, most of which (the right to life being the main exception) are not absolute. Moreover, new claims tend to be made as to rights to, for example, participate in new technology, or to abstain, or to be forgotten.

International human rights law is generally *soft law*, with variable understanding of its meaning and effect in practice in this area. The Oviedo Convention is the closest to an attempt to put bioethics on a clear legal footing, but its implementation is patchy, and bioethics, by its nature, is difficult to make subject to binding law in any event. In addition to specific conventions, lower order Recommendations might be made, adding to the tools of soft law that might be available.

At the same time, jurisprudence offers the possibility of a more flexible and dynamic approach to the application of human rights laws and principles in the context of emerging technologies, and examples were given of how European Court of Human Rights has used its discretion to apply the ECHR in ways that are responsive to prevailing norms.

In this way, the use of the incremental interpretation of general laws, supplemented if needed by other *soft law* instruments, probably provides a better (pragmatic, but not perfect) legal governance mechanism than seeking to establish new Treaties or amend existing Treaties in ways that may become obsolete as technology and societal norms evolve.

Governance – the governable subject

A different approach considered in the session was to look at *governance* in terms of not so much the legal instruments, but of the discourse which informs the issues of risk

evaluation and the steering of technology development.

As the 2002 NSF report identified, NBICs tend to be geared towards aspects of enhancement - of human physical and cognitive capabilities, of human communication, but also of groups, of societal performance or even national functions such as national security. Two main paradigms to achieve these goals can be identified those of risk, and of human rights. The risk paradigm focuses on possible harms and refers to safety targets such as human health or environmental integrity. Risk analysis and risk evaluation methods are usually expert driven and centred on cognitive discourse. Risk management is likewise a rather technocentric approach and leads to rather mechanistic interventions in decision processes (regulation, control, prohibition, etc.). On the other hand, the legal approach does not have its origin in technological adoptions of systems but in human needs and wants, often focused on freedoms and claims which can be accepted, rejected, and/or shaped according to societal norms. Rights are dependent on enforcing institutions rather than on expert judgement and the discourse is dealing with values and not so much with scientific knowledge.

A traditional risk assessment approach would insist that risk analysis should be clearly separated from risk management (including the option assessment and risk communication). On the other hand risk research has shown that risk assessment occurs within particular frames which reflect social and political values and differ across cultures. Therefore, evaluative decisions already influence already the analytical elements of the risk regulation system which means that there can be no clear separation between risk analysis/assessment and risk management. Finally, the traditional view of risk assessment assumes that there exists a clear boundary between science and politics, but especially the debates on new technologies like GMOs or nanotechnologies, show that the boundary between science and policy is far from clear. In the case of new technologies classic risk assessment methods are further limited by uncertainty and ignorance.

The development and application of new technologies therefore pose several challenges to governmental decisions and regulatory interventions. Many of the convergent technologies are in reality umbrella terms for quite diverse scientific methods and interdisciplinary approaches lacking a general definition. And whilst research on possible negative effects usually lags behind technological research and the development of possible applications, regulatory authorities are at the same time under pressure to act, by public safety concerns, yet without the possibility of basing their regulatory measures on scientifically sound findings. Meanwhile, the communication failures of public debates on certain technologies in the past two decades (e.g., genetically modified crops) have

decreased the credibility of research and development in general. All recent debates are more or less overshadowed by the negative experiences made in the GMO-debate and are increasing the resistance to new technologies. Additionally, a highly competitive environment originated in new approaches in science policy (“knowledge society”, “excellence”) and a policy dominating economy and an enlarging global market reduce the capacity of regulatory authorities to take an active role. Finally, the increasing willingness of at least some parts of the public to engage with technology rather than be the receiving end of political decisions on the application of technologies apply additional pressure on governance systems.

Five major modes of public governance (or steering) of new science and technology can be identified, each associated with a certain model of democratisation:

- i. In *research policy* the aspect of scientific merit is the main driving force.
- ii. *Markets* are mainly influenced by consumer preference and choice.
- iii. *Regulatory decisions* with the possibility and degree of public participation can be an instrument of democratic control.
- iv. *Ethical debates* try to incorporate values into political decision processes on technological choice.
- v. *Public engagement* seeks to assure the representation of individual needs in shaping the development of science and technology. Public engagement is particularly able to integrate the user perspective in the specific design of technological applications.

However, each of these mechanisms of governance has limitations. In case of research policy the main obstacle might be a rather vague understanding of the research field, or indeed a poor appreciation of the state of readiness of the science. In many cases – especially regarding the NBIC complex – the main hindrance exists in form of unclear interdisciplinary approaches or the lack of a clear differentiation between basic and applied science. Pure market mechanisms are not able to ensure good governance because of their one-dimensional focus on products, their limited set of values, and their failure to learn. Regulatory systems are insufficient alone to exercise good governance because of their tendency towards a rigid, bureaucratic and managerial approach, and their inability to operate in a global environment. Ethics privatizes questions of value and privileges individualist values (e.g., bodily integrity) over collective values (e.g., inequality). Moreover ethical debates tend to incorporate presumptions in favour of research and development. Finally, the limitations of public engagement can be connected to problems of representation and political linkage. Attempts of public engagement lack in many cases a

proper representation of the general public. They are often undertaken without clear definition of purpose or links to policy and are not well adapted to changes in technology or society. Going forward it will be important to be aware of, to be self-conscious about, the limitations of each of these approaches.

Risk governance and risk management

David Collingridge's characterisation of novelty as a double dilemma is relevant to many of the aspects encountered in emerging technologies. To begin with, new technological developments are associated with a kind of informational problem, because the impacts of its specific applications cannot be easily described or predicted until the technology is extensively developed. At the same time we are able to change the development paths of a certain technology only at its earliest stages. As soon as it becomes entrenched by economic, bureaucratic and procedural boundary conditions, control and change become more and more difficult, if not impossible. This is especially important for risk and safety features of these technologies because it takes some time to properly describe and evaluate the behaviour of new materials with regard to possible safety targets such as human health and environmental integrity.

In this session it was therefore observed that risk assessment is not well suited to evaluate the positive and/or negative consequences of the implementation of new and emerging technologies. Likewise the available standard risk management processes might not be sufficient to handle problems deriving from as yet unknown applications. This is because classical risk assessment concentrates on some basic criteria which are quantified, or at least expressed in a semi-quantitative manner. These criteria consist of the main aspects of *hazard* (of a certain source or activity) and *probability* of occurrence (of an adverse effect) which are complemented by other criteria depending on the area of application (e.g. detection or expansion of a toxic substance). These assessments, and also the evaluation process deriving from the collected data, are normally expert driven processes, and the discourse type is essentially cognitive. As mentioned above, in the case of new and emerging technologies and materials there are insufficient data available to assess these criteria in the same way because there will have been no suitable long-term studies, or the results available will at least be ambiguous.

In this case, risk assessment has to be organised in a different way and the related risk management process has to be based on other discourse types, and in some cases a public discourse on fundamental values (e.g. human rights) will be necessary. It is of utmost importance to discuss the specific usage of new technologies and the intended ends in an

open and transparent manner in public, especially in early phases of technology development where even the factual situation and the quality of the available data on a specific technology is unclear. However, classical top-down decision structures normally applied to technology choice debates should be given up in favour of a more horizontal structure, engaging as many concerned parties as possible as early as possible during technology development, enabling public discourse to bear upon research policy, market management, regulation and the identification and application of ethical values, so that a democratic public discourse can help inform questions about what we want in the world, who makes the necessary decisions, and through what fora and institutions.

Conclusions

Referring to the governance of emerging technologies in general there might be several considerations that are of particular interest:

- Legal instruments can be important tools of governance, especially when supplemented by 'soft law' accompaniments of case law and secondary-level recommendations. Legal instruments alone, however, are unlikely to provide adequate governance systems;
- conventional risk assessment approaches are likely to be unsuited to emerging technologies as they either demand specific risk measurement, or embody value-laden assumptions about risk factors;
- to assess and evaluate the available safety data and possible hazards to material and non-material values it is essential to include as many concerned parties as possible, and at an early stage. This includes not only scientists and developers, but also people from regulatory bodies, the industry and non-governmental organisation. It will also be necessary to set up participatory processes including the general public and certain user groups, but ensuring continuous, rather than episodal, engagement;
- suitable risk communication formats need to be developed to engage all involved parties (including the interested public) in an open and transparent communication process;
- democratic discourse as governance should not be merely about tolerance of risk, but of what kind of world is wanted; what solutions are to be sought; and how decisions are made, and by what means.

SESSION 6: CONCLUSIONS

It is not easy – indeed not possible – to discern a single, simple set of conclusions or recommendations from the symposium. It is part of the nature of emerging and converging technologies that they are complex; that they arrive in socially and culturally defined circumstances; and that they embody uncertainties and ambiguities that make any specific or universal responses inappropriate.

There are undoubtedly significant potential benefits for individuals and society, which might be medical, personal, social or economic or, most likely, a combination of all of these. But of course they bring challenges of various kinds, and are not without risk. Though sometimes it is too easy to focus on the potential, but largely unknown, risks, so that the opportunity to optimally harness benefits could itself be put at risk.

The novelty of some new technologies, and in particular the way that they come together through convergent technologies and applications, make it particularly difficult to find ways of addressing the challenges as they breach some of the usual boundaries by which discourse is so often framed. Converging technologies might not sit comfortably in a medical model, or in a biological context, or even in a human (as opposed to animal or environmental) context.

One thing that became clear from the discussions was the need to focus not simply on the technologies themselves, but rather on the practices, the goals, and the contexts in which they emerge. It is only in this way that we can elucidate the implications that they have for the kind of concerns that we might have in a human rights context – for autonomy, integrity, dignity, privacy, equity, non-discrimination, justice, etc.

In the course of the sessions, speakers and delegates identified a number of areas that are particularly challenging. In particular:

- the threat to individual identity, agency and privacy that comes with the potential for surveillance, control and personal data use;
- that the protection of privacy will not lie simply in refining or modifying existing data protection laws and systems. Rather, a more comprehensive governance approach will be needed that recognises the reality of data gathering in the digital age through NBIC and other technologies, based on responsive ‘soft law’ approaches and on engaging civil society as a way of securing trust and legitimisation;
- the risk of increasingly unequal sharing of risks and burdens as well as benefits in the context of novel and expensive technologies, given existing and potential future inequalities both within societies and across different states;
- whether the principle of equitable access enshrined in international instruments such as the Oviedo convention and UNESCO declaration can be interpreted or extended to include converging technologies, which are likely to produce a major

- impact on the quality of life and the protection of health;
- the difficulty in finding adequate risk measurement, management and communication approaches where technologies are still little understood in terms of their stage of development and likely applications;
 - the difficulty in applying specific legal instruments in the context of uncertain and ambiguous scientific and technological development;
 - the limitations of other governance mechanisms, whether through policy, regulatory, market-based, ethical discourse or public engagement approaches;
 - the need for new and flexible governance approaches that are capable of responding to a wider variety of applications and contexts than conventional sector-specific governance mechanisms;
 - promoting wider public education and adequate scientific knowledge among and within countries, promoting open access to knowledge and offering opportunities to disseminate sound and reliable information;
 - the need to develop participatory mechanisms, to engage a wider public in the discussion around the research policies, practices and governance that emerging and converging technologies necessarily involve.

Put briefly, the underlying question is how on a societal level it is possible to generate a continuous, democratic public discourse that addresses questions about how essential rights can be protected, what we want in the world, who makes the necessary decisions, through what fora and institutions, and with what governance and accountability mechanisms.

Each of the Session reports sets out in more detail some of the opportunities, questions, challenges – and some potential, if only partial, solutions – that were identified in the contexts of intervention and control, data collection and processing, equity of access, and governance. But this is not an exhaustive account of all the issues that might be at stake, whether in a human rights context, or in a wider societal context. Equally, the fact that the discussion focussed on NBIC technologies does not mean that these considerations apply only in those cases – they are illustrative of the types of technology that need to be considered, but precisely one of the points of the discussion is that we can no longer contain discussions to discreet categories, whether technological developments or social practices. Further close examination will be needed to consider how the Convention might be applied in these contexts, what the limits of that approach might be, how participative processes can be engaged, and what alternative or complementary governance mechanisms might be needed.