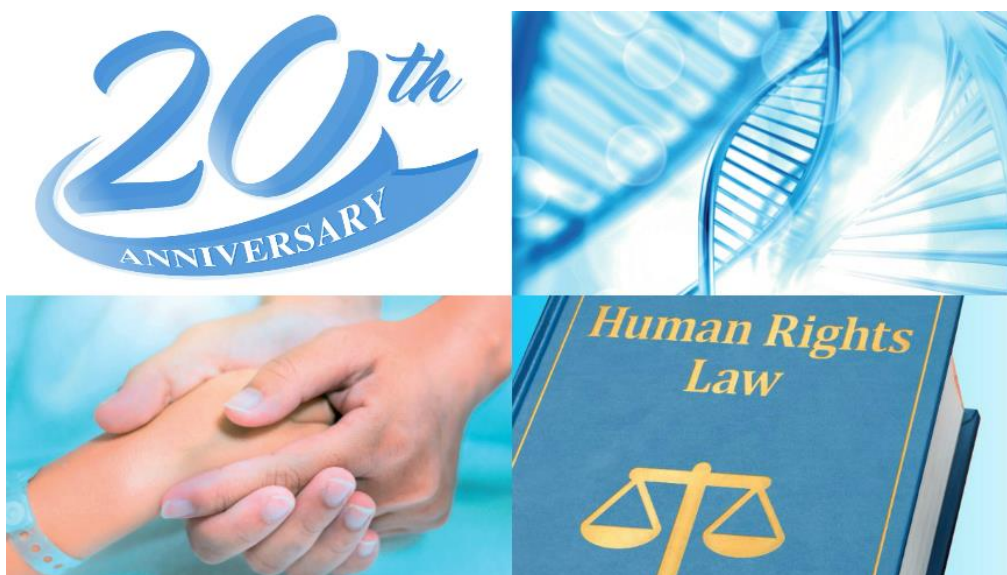


## 20TH ANNIVERSARY OF THE OVIEDO CONVENTION



24-25<sup>th</sup> October 2017, Strasbourg  
Rapporteur Report

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## INTRODUCTION

The Convention on Human Rights and Biomedicine (ETS No.164, full title, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine), is a general framework for the protection of fundamental rights and freedoms with regards to the applications of biology and medicine. The Convention was opened for signature in Oviedo, Spain, on April 4<sup>th</sup> 1997 and came into force in December 1999. To date 29 States have ratified the Convention<sup>1</sup>.

The Oviedo Convention contains 38 articles organised into 14 chapters. The general principles are contained in chapter I (articles 1-4), while chapter II (articles 5-9) sets out the requirement for informed consent prior to biomedical intervention. Chapter III (article 10) enshrines the right to privacy of health information, including the right to know and the right not to know about a medical condition. Chapter IV (articles 11-14) prohibits genetic discrimination, germline-intervention and sex selection other than in cases of serious sex-related disease. Chapter V (article 15 to 18) pertains to the rules governing the conduct of biomedical research and includes a prohibition of creation of human embryos specifically for the purpose of research. Chapter VI (articles 19-20) concern living organ donation, while Chapter VII (articles 21-22) prohibit any financial gain from the human body and its parts. Chapters VIII-XIV deal with procedural elements.

The Convention itself contains broad, general principles, however in the intervening years, these have been supplemented with four Additional Protocols which deal with the specific issues; *Prohibition of Cloning Human Beings* (ETS No. 168; 1998), *Transplantation of Organs and Tissues of Human Origin* (ETS No. 186; 2002), *Biomedical Research* (CETS No. 195; 2005), *Genetic Testing for Health Purposes* (CETS No. 203, 2008).

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<sup>1</sup> A full list of signatories and ratifications is available at [https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p\\_auth=TLyLVfpB](https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=TLyLVfpB), accessed on 4<sup>th</sup> December 2017

## OBJECTIVE OF THE CONFERENCE

Under the auspices of the Czech Presidency of the Committee of Ministers of the Council of Europe, a conference to celebrate the 20<sup>th</sup> anniversary of the Oviedo Convention was held in Strasbourg on October 24<sup>th</sup>-25<sup>th</sup> 2017. As outlined by Prof. Zvonko Magic, Chair of the Preparatory Group for the Conference, in his opening remarks, the objective of the conference was to reflect upon the relevance of the principles articulated in the Convention and the possible challenges posed to those principles in light of the scientific and technological developments and the evolution of established practices in the biomedical field in the 20 years since the inception of the Convention.

## SESSION I – OPENING- TUESDAY 24 OCTOBER 2017

**Chair:** Dr Beatrice Ioan (Romania), Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe

The Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe, **Dr Beatrice Ioan** opened the conference and welcomed speakers and participants. She invited Dr Radek Policar, Deputy Minister for Legislation and Legal Affairs of the Czech Republic to make some opening remarks.

**Dr. Policar** observed that the willingness of states to sign and ratify the Convention was testament to the fact that states were willing to adhere to universal standards in the field of biomedicine. Nonetheless, it was important to understand the reasons why some countries felt unable to sign/ratify the Convention and its additional protocols. He made the point that while human dignity may be an obtuse concept, it is the key principle protected by many countries constitutions. Legislators have a responsibility to explain and clarify what this concept means and patients and medical professionals alike should be aware of the rights enshrined in the Oviedo Convention. He articulated his view that justice and solidarity, along with human dignity were key principles which needed to be upheld while delivering healthcare.

*Note: The Czech Republic could signed the Additional protocol concerning genetic testing for health purposes during the conference. This fifth signature and subsequent ratification are the last steps needed for the Additional protocol to enter into force.*

**Ms Gabriella Battaini-Dragoni**, Deputy Secretary General Council of Europe remarked that it is the notion of human dignity which lies at the heart of the entire human rights edifice and this concept is prevalent in and connects the disciplines of law and ethics. The Oviedo Convention is a concrete manifestation of this link between law and ethics in the field of biomedicine. While advances in science and medicine are a source of hope, they also elicit concern. The Oviedo Convention as a framework convention, serves to counter potential misuse of scientific developments and protects the fundamental principles of autonomy, dignity and justice. Ms. Battaini-Dragoni observed that bioethics is often seen as an obstacle to scientific development, however, she made the point that principles are open to scientific progress through a process of serene and constructive disagreement. The need for constant vigilance in relation to any development that could pose a threat to fundamental human rights was stressed. Ms. Battaini-Dragoni also emphasised the importance of public debate as foreseen by article 28 of the Convention and the critical role that national ethics councils and research ethics committees can have in this process.

**Ms Nada Al-Nashif**, Assistant Director-General for Social and Human Sciences at UNESCO made the point that human rights are at the core of sustainable development. The United Nations 2030 Agenda for Sustainable Development, with its 17 Sustainable Development Goals, has human rights and dignity at its core. Thus, advances in science and technology should promote human rights and values. She argued for stronger links between science and ethics which could forestall increasing anti-science sentiment. She also mentioned the importance of dovetailing the European position with the global perspective. She observed that the principles articulated in the Oviedo Convention while not directly dealing with developments in gene editing and artificial intelligence, will be important in regulating these areas. She informed the conference that UNESCO is considering an ethical declaration on climate change; if realised, this would be the first of its kind.

## SESSION I – KEYNOTE SPEECHES

**Dr Octavi Quintana**, Director of the Partnership on Research and Innovation in the Mediterranean Area (PRIMA), gave some background on the drafting of the Oviedo Convention, explaining that the AdHoc Committee of Experts on Bioethics (CAHBI), later called the Steering Committee on Bioethics (CDBI) set up a working group in 1992 to prepare a draft Convention. He explained that from the outset the Convention was envisaged as a “framework instrument” containing general principles. Basic norms governing biomedical activities on which there was a European consensus were identified. This rather minimalist approach was adopted for pragmatic reasons as in some areas e.g. human embryo, it was only possible to reach minimal agreement. As Dr. Quintana pointed out, Article 27 of the Convention prohibits states from adopting a lower standard of protection than that provided for in the Convention, while allowing states the flexibility to establish stricter regulations.

This pragmatic approach facilitated the drafting of the first multilateral binding instrument exclusively concerned with biomedicine. The Convention gave rise to a structured landscape for research ethics and was instrumental in harmonizing research ethics across Europe. The Convention remains a reference for frontier science but to be effective requires the existence of democratic and law-abiding institutions.

While bioethics can be viewed as a “culture of limits” its role should be to accompany progress in science and to reflect on and promote fundamental rights. This is recognized by Article 32 of the Convention which provides for a periodic review of the provisions of the Convention, as according to Dr. Quintana prohibitions in certain areas are time limited. Bioethics serves to safeguard human rights principles and should not be seen as simply a bureaucratic question. Rather it goes to the heart of how we want to live as individuals and as a society. Thus, there is a need to engage the public in bioethics debate so they can shape the future. There is a need for an informed public dialogue on developments such as gene editing where reflection is required as is a weighing of the various principles at stake.

**Prof. Dr. Dr. h.c. Ludger Honnefelder**, Professor emeritus of Philosophy, Friedrich-Wilhelms University, pointed to the fact that science is by its nature a transnational activity thus, national regulation is not a tenable approach to governing scientific and technological developments. Human rights are the crucial starting point of the Oviedo Convention but they diverge somewhat from those articulated in the European Convention on Human Rights (ECHR). Prof. Honnefelder argued that in the ECHR the concept of human dignity is presupposed as the basic value, but is defined only by prescribing requirements against its violation. For drafting a more detailed convention and additional protocols it was therefore necessary to go back to those ethical convictions which are underlying the legally defined norms of the ECHR and the fundamental rights that are part of the various national constitutions and some other international documents. Article 4 of the Convention reflects professional standards and endorses normative principles such as truth telling and informed consent, closely related to human rights norms.

While there may be a tension between balancing different human rights, it should be possible to combine normative human rights with scientific progress. The inclusion of Article 32 in the Convention was a recognition that scientific developments would be forthcoming and Article 28 provided for public debate on these developments. Genomics has blurred the boundaries between medicine and research and challenges self-determination, while the development of brain technologies threatens individual autonomy.

Prof. Honnefelder maintained that the Oviedo Convention is best understood as a learning process that is still not complete. New regulations are necessary; however, these should not reduce the protection of human rights. Human dignity and human rights, ethical and legal claims can all serve to protect trust in science.

**Prof. Sheila Jasanoff (USA)**, Pforzheimer Professor of Science and Technology Studies, Harvard Kennedy School, Harvard University discussed the fragmentations, reductions, and recombinations of the human associated with today's technological developments and the role of transnational bioethical agreements, such as the Oviedo Convention, in safeguarding concepts such as dignity and integrity. The term human dignity is almost a black box since what

constitutes dignity or indeed the human is far from clear. This poses challenges for how human dignity can be protected in the field of biomedicine when the boundaries of the human appear blurred and distributed as never before. One example proffered in this regard was germline editing which is prohibited by Article 13 of the Convention.

Prof. Jasanoff pointed to a fraying of the social contract between scientists and the public with a loss of trust by the latter in the former. The question of who has the power to re-write the Convention when it comes to matters of scientific developments such as gene editing was raised. The “law-lag” narrative presumes that normative standards come from science and are then enshrined by law at a later time point. Prof. Jasanoff challenged this narrative and advised that we should rather be thinking of reconnecting technologies with norms. The language we use when discussing technological advances can often be influential in framing the nature of the debate on these issues. Talk of editing humanity, engineering the human, and precision medicine conjure up an age of miracles. There is also a tendency towards “thin” and “thick” narratives, which either seek to minimise or maximise the importance of the issue at stake.

The question of ownership of life was raised. There is a school of thought reflected in the story of King Canute<sup>2</sup> which argues that everything should be the subject of intellectual property law, as we cannot stop the tide of technological development. Prof. Jasanoff pointed to the fact that jurisdictions adopt varying approaches in how technology is governed. In the United States of America science and politics are strictly separated; in the UK a common-sense approach prevails around how knowledge and norms are aligned while in Germany, regulation of technology is by law which in turn is the product of expert opinion. According to Prof. Jasanoff harmonisation is an essential instrument of international risk governance and requires technical and political co-operation. Standards should be co-produced in response to technical and political uncertainty. She described three models of subsidiarity which are useful in this regard. The first is *co-existence* where interstate contradictions need not be resolved but rather respected, this however raises challenges in managing science across borders. The second is *cosmopolitanism*; where there is a degree of mutual

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<sup>2</sup> See [https://en.wikipedia.org/wiki/King\\_Canute\\_and\\_the\\_tide](https://en.wikipedia.org/wiki/King_Canute_and_the_tide)



recognition. The difficulty here is recognising cultural divergences and risk of misunderstanding. Finally, *constitutionalism* which imposes certain duties and obligations across jurisdictions. The Oviedo Convention is in many respects an example of this form of subsidiarity.

Prof. Jasanoff concluded her presentation by remarking that science is not a spectator sport and we must strive for constitutional order. She emphasised the importance of the principles of diversity, inclusiveness, deliberation and recursiveness in this endeavour and the need for scientific, political and public discourse.

## SESSION I – INTERNATIONAL CASE-LAW IN BIOETHICS: INSIGHT AND FORESIGHT

**Mr Hans-Jörg Behrens**, Vice-Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe presented an overview of a seminar which took place on 5 December 2016 in Strasbourg aimed at analysing the qualitative and quantitative evolution of the bioethics case-law of the European Court of Human Rights (ECtHR) and its impact at national level. Questions regarding the beginning and end of life feature prominently in the ECtHR case law. While the right to life is guaranteed under Article 2 of the ECHR, the Court has not made any determination on when life begins as it would be neither possible or indeed desirable to do so. The ECtHR while recognising individual autonomy gives a considerable margin of appreciation to states when it comes to end of life decisions. This is characteristic of the Court where issues raise moral or ethical considerations. Mr. Behrens maintained that the philosophical questions raised by the beginning and end of life were quite different. The nature of the conflict at the end of life was that between personal autonomy and the state's duty to protect life. In the case of beginning of life, the issues are less well defined so the Court relies heavily on the facts of the specific case in reaching its judgment.

Article 8 of the ECHR nominally protects private life, family life, the home and correspondence, yet over time and through interpretation of the right by the Court, it has come to protect

numerous specific interests, such as self-determination and by extension informed consent, protection of genetic and other clinical data, the right to know one's genetic identity and gender identity.

Recently the ECtHR has adjudicated on a number of surrogacy related cases. The substantive issue of surrogacy has not been addressed by the Court but rather it is the parental rights of children born as a result of transnational surrogacy agreements which has been at question. The Court in each of these cases has stressed that it is the child's best interests which is of paramount importance. Couples/individuals who have the financial means to pay for such arrangements can circumvent legal prohibitions in their own jurisdictions and this raises questions of equity and justice.

Mr. Behrens raised the question of who should decide (patient, family, doctor, courts) on matters of biomedicine and what needs to be taken into consideration when making these decisions e.g. cultural/social background, history, human dignity - which may have different meanings in different societies. The question of how much should be regulated was also raised; the margin of appreciation has to be balanced with core values, for which international oversight is necessary.

## SESSION II - EVOLUTION OF PRACTICES IN THE BIOMEDICAL FIELD

### AUTONOMY – CONSENT AND PRIVACY

**Chair:** Ms Ina Verzivolli (Albania), Chair of the Ad hoc Committee for the Rights of the Child (CAHENF) of the Council of Europe

Along with beneficence/non-maleficence and justice, autonomy is one of the four major internationally-recognised principles of medical ethics. Respect for autonomy is therefore an essential yardstick by which the degree of recognition of people's fundamental rights can be gauged. The main components of the principle of autonomy are the principle of consent and the protection of privacy. In the reflections surrounding the 20th anniversary of the Convention, it seemed appropriate to assess the

extent to which these fundamental rights are recognised and applied in the case of children and older persons.

A study on children's rights in medicine commissioned by DH-BIO was carried out by Dr Kavot Zillen and Dr Jameson Garland from the University of Uppsala. Dr. Zillen's presentation to the conference, based on the findings of this report, was given by **Dr Santa Slokenberga**, on her behalf. Although the rights of children, as people, are recognised both at international level and in national legal systems, beyond the statement of principle, the way they are put into effect in different areas of medicine, and in relation to new medical practices in particular, is often inadequate or not clear-cut.

Children's rights, including the principle of respect for dignity, integrity, autonomy, non-discrimination and access to justice, are enshrined in the UN Convention on the Rights of the Child, but these rights do not relate specifically to health and medical interventions. The principle of autonomy and expression of consent, in particular, is restricted by the legal protections that prevent a child from participating fully in the decision-making process.

The Oviedo Convention, which establishes the principle of free and informed consent prior to all interventions (Article 5), contains a special provision for minors (Article 6). However, Article 6 assigns this prerogative to parents insofar as the minor does not have capacity to consent to an intervention. It is stated that "*The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.*" Therefore, although children do not have the right to consent, they "*must be listened to*". This raises the question of how far parental authority should extend. In cases such as living tissue donation, end of life decisions and subjecting children to unproven innovative therapies, the question arises of whose interests, rights and will are being served by parental decisions.

The point was made that intersex children are submitted to invasive surgery and hormonal treatments to be "placed" into traditional gender categories. To respect the child's rights of autonomy, it was suggested that such procedures should be delayed. This view is reflected in the Council of Europe Resolution on Children's Right to Physical Integrity 1952 (2013). Article 10 of the Oviedo Convention which enshrines the right to know and not to know about your genetic information is challenging in the context of

children, since it is parents who often make the decision for their children, yet it is the children who will live with the consequences of those decisions.

**Prof. Dr Ton Liefwaard**, Professor of Children's Rights/UNICEF Chair in Children's Rights, Law School, Leiden University opened his presentation by pointing out that there is a disconnect between children's' rights and biomedicine. Based on the mapping exercise proposed by the Uppsala University study and the analysis of the provisions of the Oviedo Convention and its additional protocols, he concluded that the existing international biomedicine regulatory frameworks focus on child protection, and as such, they even exclude them from some measures, such as organ donation and participation in research, or limit their access to them. This focus on protection is important and justifiable but is somewhat at odds with seeing children as rights holders in and of themselves. Human rights are children's rights. The Convention on the Rights of the Child also provides specific rights to children including the right to participation, the right to privacy and their own identity and recognises their evolving capacity to vindicate these rights.

The failure to take children's rights into account is especially noticeable in certain specific areas of biomedicine which are heavily impacted by new practices and innovations. The issues surrounding these interventions are important for children themselves and respect for their integrity, identity and right to private life. This is true of not only treatment, but also participation in research.

Prof. Liefwaard focused on two areas of human rights which are especially called into question in relation to children: the right to privacy and confidentiality and the principle of consent and, more generally, participation in the decision-making process. He drew attention to the consequences of certain decisions which have a direct impact on children and concern their future, such as genetic tests and the storage of personal data. As for free and informed consent, it was essential not to forget its corollary, which is the right to information laid down by Article 10 of the Oviedo Convention.

Prof. Liefwaard made the point that children's rights must be seen in relation to the rights of others. The starting point should be to respect the relationship between parents and their children but also to recognise that there can be a conflict of rights and the balancing

in these situations is complex and the child's view must be taken into account in line with their evolving capacity to participate in the decision to be made. In this regard age limits for assessing capacity may be practical and allow for clear limits to be set, but decisions regarding treatment and research are often context dependent. The point was made that there are in any case situations where it is impossible to obtain a child's consent. This is true where the intervention is made before the child is born: assisted reproductive technologies, antenatal diagnosis or even, in future, modification of the germline genome. The very meaning of the principle of autonomy as applied to children is called into question here by interventions which are perinatal or carried out on a child who has not yet been born.

**Chair:** Mr Miroslav Mikolášik, Member of the European Parliament and Chairman of the EPP Working Group on Bioethics and Human Dignity

The presentation of **Prof. Ana Sofia Carvalho**, Director of the Bioethics Institute, Universidade Católica Portuguesa, focussed on the need for a functional model of decision making capacity assessment in older populations which is case, task and time specific. There are different categories of vulnerabilities found in older persons including cognitive, situational, allocational, differential, clinical and social and strategies for maximizing decision making in the clinical and research contexts should be developed to take account of these different vulnerabilities. This will require a careful assessment of the risk factors for impairments in decision making capacity. The Decision-Making Capacity Model needs to be understood in terms of respect for those who can and protection to those who cannot give informed consent. There needs to be appropriate protection of older persons from improper consent but this should not lead to over-protection, which may preclude them from clinical and research opportunities.

Prof. Carvalho made the point that in healthcare there are systematic prejudices and discrimination based on age. Older persons may be less likely to receive potentially beneficial treatment or interventions than younger people due to a range of factors. Despite the fact that older persons are the most significant group of consumers of drugs, they are often underrepresented and even excluded from clinical trials.

Evidence based medicine has in many ways created a tension between a curative model of care (which privileges scientific objectivity) and the person-centered model (which values the patient's subjective experience). Rather than treating death as the enemy it needs to be viewed as an inherent part of life which requires us to provide humane, ethical and clinically appropriate end of life care for older persons. Invasive treatments that will prolong the quantity of days without prolonging the quality of the days and that would not foster the dignity of the patient may be considered unacceptable. Prof. Carvalho argues that age cannot be a criterion *per se*, for how resources are allocated but other factors related with age could, sometimes, constitute legitimate and ethical robust criteria of choice. Thus, equity rather than equality is key in addressing the underlying causes of health disparities and giving each person what he/she really needs in order to foster their dignity.

**Prof. Antonio Cherubini**, Director, Geriatrics and Geriatric Emergency Care, IRCCS-INRCA, Ancona, echoed many of the sentiments expressed by Prof. Carvalho. He argued that ageing has traditionally been treated through the quantitative lens but it now needs to be understood through the qualitative lens. The equation of old age with illness has encouraged society to think about aging as pathological or abnormal, as a set of medical 'problems' which affect older people and to which medicine holds the solutions. Among the most significant implications of this way of understanding old age has been its impact upon public opinion – it is now taken for granted that ageing is a negative, irreversible process of decline and decay. Discrimination based on age is pervasive in healthcare. Research has shown that older people receive less screening, less preventive care and poorer management. He argued for harmonising anti-discrimination legislation in an effort to combat ageism. He pointed to poor care provided to older persons in state run facilities that lack adequate staff and/or resources to ensure their dignity. This raises the question of how health care budgets allocated to elder care are being spent as it seems the healthcare system is not attuned to the needs, wishes and preferences of older persons.

Prof. Cherubini made the point that securing informed consent from individuals, has become an ever-increasingly complex exercise. While there has been significant work done on optimal methodologies for assessing capacity and gaining informed consent

from older populations, physicians are not trained in these techniques and they are rarely deployed in the clinic. Thus, he argued there needs to be cross-national respectful, effective and efficient standards developed to ascertain the capacity of older persons to consent and procedures in place to facilitate their decision making.

Prof. Cherubini questioned whether evidence based medicine extended to the care of older persons given that many of the treatments they receive have not been tested in their demographic group. He contrasted this situation with the paediatric arena in which European legislation<sup>3</sup> had been introduced to ensure that medicines prescribed to children should be the subject of clinical trials in children. He advocated considering a similar approach in the geriatric field. Moreover, he argued that action needs to be taken in relation to barriers to digital inclusion especially in those over 75 years to ensure equitable access to the benefits of e-health.

## EQUITY OF ACCESS TO HEALTH CARE

**Chair/Moderator:** Ms Brigitte Konz (Luxembourg), Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe

Article 3 of the Oviedo Convention, which establishes the principle of equitable access to health care, concerns all situations and not just the start and end of a person's life, which are key focal areas for bioethics. This is a fundamental right with general scope.

This provision has a very special significance in the light of the challenges currently facing our societies: demographic issues, budgetary restrictions and, at the same time, unprecedented scientific progress and the development of innovative therapies.

In this context, groups or individuals are especially vulnerable, and this situation necessitates measures to enable the principle to be applied.

The presentation given by **Ms. Marit Frogner**, member of the European Committee of Social Rights (ECSR), firstly pointed out

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<sup>3</sup> [Regulation \(EC\) No 1901/2006](#) of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use;

that equitable access to health care implies that the cost of health care should be borne by everyone. Any additional amounts that people have to pay, should be based on their resources and should not be discriminatory. The right to equitable access to health care also depends on the effectiveness of other rights: the right to social security, social, economic and legal rights, and policies that combat exclusion. Particular attention should therefore be paid to the situation of disadvantaged or vulnerable groups, observation of which serves as a meaningful indicator.

The ECSR takes decisions on complaints made by the social partners or associations and ensures that the European Social Charter is complied with. Based on an analysis of these decisions, Ms. Frogner highlighted the failings of health systems in terms of the application of rights which are enshrined in both Article 3 of the Oviedo Convention and in the Social Charter in relation to certain disadvantaged persons or certain particularly vulnerable groups: Roma and travellers, migrants and especially children, pregnant women, transgender persons, the elderly, and prisoners.

As was illustrated in the presentations concerning older persons, the question of equity in access to care is indeed a significant problem and a social challenge for all European countries which are affected by the ageing of their populations. The decisions of the ECSR reveal an increasing number of aggravating factors, such as the fact of being a child or a woman in addition to belonging to one of the aforementioned vulnerable groups.

Over and above this observation with regard to membership of certain groups, analysis of the decisions of the ECSR shows that there are inequalities in access to care not only between “rich” European countries and “disadvantaged” countries, but also within a single country depending on the region considered. Ms. Frogner concluded that the principle of equity of access to care needs to be integrated systematically into all health policies and programmes. This needs to happen regardless of the available resources of the country concerned. The policies pursued and measures implemented by policymakers and legislators must seek to strike a balance in the allocation of resources between support for the development of expensive innovations and efforts to ensure equitable access to health services.

## ROUND TABLE DISCUSSION



**Participants:** Dr Rogelio Altisent, Director of academic projects on the Clinical Ethics and Professionalism Chair, University of Zaragoza; Ms Liliane Maury Pasquier, Chair of the Committee on Rules of Procedure of the Parliamentary Assembly of the Council of Europe; Ambassador Santiago Oñate Laborde, Permanent Observer to the Council of Europe, Mission of Mexico to the Council of Europe; Dr Ucha Vakhania, Executive Director of the “Coalition Homecare in Georgia”

**Dr. Altisent** made the point that three of out of every four patients require basic palliative care and that equity of access to such services should be a priority for healthcare systems given the magnitude, impact and suffering experienced not alone by patients but also their families. He argued that palliative care is possible in all kinds of health care environments, both at home in palliative care units and in the hospital setting. He presented data showing the diversity amongst individual countries in the provision of palliative care, indeed there are also differences in service provision within individual countries. He emphasised the importance of providing basic training in palliative care to healthcare professionals through the undergraduate curriculum.

**Ms. Pasquier**, pointed to the Parliamentary Assembly report from 2015 which demonstrates that unequal access to health care is growing in all Council of Europe countries, partly because of social differences. Vulnerable groups such as transsexuals, pregnant women, Roma, refugees and migrants are disproportionately affected. In the case of Roma there is an absence of prenatal screening and long-term quality care. Migrants face linguistic barriers to accessing healthcare while undocumented migrants are reluctant to seek health care. Prisoners may not have access to palliative care and children living in precarious situations have great difficulty in accessing healthcare.

**Ambassador Laborde** pointed to the fact that while the issues of beginning and end of life tended to dominate discussion of the Oviedo Convention, the Convention is also concerned about what happens between those two seminal points. He considered the primacy of human dignity and the principle of equitable access to health care as two key principles of the Convention. The issue of equitable access to healthcare has assumed greater relevance in an

age of demographic pressure, the existence of fiscal constraints and the availability of innovative therapies. He maintained that there are already enough rules establishing the necessary principles but that rights are futile if they are not enforceable.

**Dr. Vakhania** pointed to the specific challenges faced by Eastern Partnership Countries in equity of access to healthcare, most especially for older persons. She maintained that a biomedical rather than holistic approach dominates healthcare provision and there is a lack of integrated care and healthcare professionals as well as poor infrastructure. Older persons face specific challenges; there is a lack of preventative strategies (resulting in increasing incidence of dementia), a lack of diagnostics and treatment due to poverty and a dearth of geriatric institutions. Rehabilitation and long-term care services are also deficient.

A discussion followed regarding what exactly constitutes a satisfactory standard of care. Who should decide what is the highest attainable standard of care? If health is a fundamental human right, what does this right imply and how can this right be vindicated in the absence of a firm consensus on the content of the right? Without such a consensus on minimal standards there can be no concrete enjoyment of the right to health. It was also pointed out that even in countries which have significant healthcare budgets, inequities in access to healthcare still exists and this is an issue which requires attention. The question of equity of access to healthcare needs to be part of the discussion around healthcare priorities.

## SESSION III - NEW SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS WEDNESDAY 25 OCTOBER 2017

Genetics – Genomics

**Chair:** Prof. Milan Macek (Czech Republic), Head of Department of Biology and Medical Genetics, Charles University, Prague

**Prof. Anne Cambon Thomsen**, Emeritus Research Director, Paul Sabatier University, Toulouse addressed the human rights

challenges posed by developments in the field of genetics and genomics. Genomics is an example of a technology that changes the scale and blurs several limits: Instead of trying to solve specific clinical issues by focusing on certain genes we move up in scale to full genome exploration. Such analyses give rise to data that will be useful for clinical purposes, but also data that are only useful for research. There is no clear border between clinical care and research.

Research was previously performed in a framework of a research protocol. Genomics opens the possibility of looking into databases without having a research protocol. The information in these databases can be health information, but also information that is not related to health. Thus, genomics creates a continuum instead of discrete categories. Genomic sequencing give rise to incidental findings; we discover things we were not looking for. The capacity to interpret and understand the data also evolves over time. This challenges our current understanding of the right to know and not to know, which is particularly relevant to genetics. Prof Cambon Thomsen raised the question of whether this right should be addressed in the same way for all parts of the genome.

Genomics transforms established concepts and creates a world of “documented uncertainty”. Instead of remaining ignorant we are in a situation where uncertainty is more or less documented. How can we communicate the results when the interpretation is uncertain? Should patients be informed about incidental findings that predict serious disease that can be prevented? What about diseases that cannot be prevented? The question of whether targeted tests and genome wide screening should be subject to the same type of regulation was raised. Likewise, the issue of consent was questioned: does sequencing require another level of consent than other genetic tests? And what do we mean by consent when data is being reused, re-analysed and stored?

In Prof Cambon Thomsen’s view these questions relating to incidental findings, informed consent, storage of data and re-contact of patients, database participation and access are all in need of urgent attention. Whole genome sequencing is already in use, but there is little experience to date with how this technology should be governed. In response to questions from the floor and concerns expressed about the lack of involvement of ethicists in the planning

of genomic research, she argued that there is a need for concrete recommendations in this area (as current biomedical ethical and legal frameworks may not be fit for purposes, given the scale of information offered by whole genome sequencing) and this has to be addressed through collaborative efforts involving geneticists, ethicists, health economists, patients and decisions makers. She also concluded that there is a need for empirical studies embedded in pilot projects that takes into consideration the views of stakeholders.

**Prof. Bartha Knoppers**, Director of the Centre of Genomics and Policy, Faculty of Medicine, McGill University, Montreal opened her presentation by reviewing the recent Council of Europe Recommendation (2016)<sup>8</sup> on processing of personal health related data for insurance purposes; including data resulting from genetic tests. The recommendation relates to private contracts of private life insurance, disability etc., not the social security. Prof. Knoppers pointed out that private insurance is a basic contract in modern society; in the absence of such insurance, most citizens cannot buy a house or get a loan. Principle 4 in the recommendation says that insurers should not require genetic tests for insurance purposes. However, processing of insurance data can be authorised by law. Principle 5 says that insurers should take account of new scientific knowledge. Although insurers are not supposed to discriminate based on predictive information, they have a duty to take account of new scientific knowledge. If actuarial calculations are not based on updated knowledge, this could be regarded as professional malpractice.

There are several studies on the approaches adopted for preventing genetic discrimination<sup>4</sup>: human rights, genetic exceptionalism of law, as in the US, sectoral prohibition, moratorium as in the UK where no questions are asked except for diseases recognised by a special commission, ethical guidelines, self-regulatory principles by the sector, a hybrid between two or more; and status quo - do nothing – wait and see. Mapping of the typology of approaches around the world show that the human rights approach is more common. There are also systematic reviews on genetic discrimination in insurance<sup>5</sup>. The available data document

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<sup>4</sup> Joly Y *et al* Trends Genet 2017;33(5):299-302

<sup>5</sup> Joly Y.,Feze, I. N. and Simard, J. BMC Medicine 2013;11(1): 25-40

individual cases of genetic discrimination, but the methodology in most studies is not sufficiently robust to establish either the prevalence or the impact of discriminatory practises. Thus, there is no conclusive data demonstrating a systemic discriminatory practise based on genetic data. Prof. Knoppers argued that genetic data should be destigmatised and not discriminated from other sensitive medical data.

By singling out genetic information, we may be fostering genetic exceptionalism and stigmatization of certain types of genetic profiles considered to be at risk. Legislation can help to prevent it, but there is a need to engage stakeholders and revisit regulations on the limits and potential of genetic analysis and integrate genetics into everyday life. Modern society has heterogeneous populations; profiles from only some groups are not representative of the diversity and needs of modern citizens. Prof Knoppers argued for the need to link data, through electronic patient records and databases, in order to see patterns and allocate resources where needed to better serve the health of the citizens. Universal health systems she warned, will not be sustainable in the absence of linked data. In this regard she referenced the OECD 2017 recommendations on Health Data Governance which support trans-border cooperation in the processing of health data for health system management, research, statistics and other health-related purposes that serve public interests; subject to certain privacy safeguards. The question of whether intellectual property rights stifles data sharing was raised from the floor and Prof. Knoppers made the point that increasing consortiums realise the need for pre-competitive collaboration and sharing of basic data. The question of whether trans-border flows of genetic information were premature in advance of national efforts to link genetic data with other big data was also raised from the floor. Prof. Knoppers suggested that most countries were already quite well advanced in that endeavour and that sharing of data from national biobanks or longitudinal studies could be a first step in trans-border glow of genetic information.

Data sharing does raise concerns, but according to Prof. Knoppers bioethics should facilitate a more positive model of personal health promotion. Article 27 of the Universal Declaration of Human Rights enshrines a right to share in the benefits of scientific advances and Prof. Knoppers suggested this “sleeping right” should be used to

frame a human rights approach to data sharing. We should have a virtuous circle where research leads to the clinic and back to research in a learning health-care system. We need to have core medical data available and we need to use residual samples for approved research. This will be facilitated if a basic level of insurance coverage is available on a no question asked basis.

**Chair:** Dr Petra de Sutter, member of the Council of Europe Parliamentary Assembly

**Prof. Jonathan Montgomery**, Professor of Health Care Law, University College, London, commenced his presentation by reflecting on the genesis of Human Rights Conventions as bringing together the messy world of politics and the reflective activities of academia with the aim to co-create a new normative order. In their operation they can play a conservative role, using the textual formulations of the past to judge the present and limit imagined futures. They may also operate as living documents, supported by institutional activity and nurturing a methodology for scrutiny and deliberation in the face of new challenges. Such an approach aims to preserve the spirit of the value tradition against those who would dilute it, while avoiding its fossilisation into the letter of past formulations in ways that undermine social justice by blocking the application of science and philosophy for the common good.

Prof Montgomery used human genome modification as an example of how Article 13 of the Oviedo Convention should be understood, taking into account the Preamble and Articles 15 and 28 of the Convention. He referred to the Oviedo Convention as a crucial example of a process which creates stability by holding together competing values. Thus, the Convention should be viewed as a living document, with a specific history, involving experts, politicians and the public. The question of whether it hopes to enshrine a universal vision of humanity or if it is better understood as the expression of distinctive European values needs to be asked. Intertwined with this question is whether the Convention belongs primarily to the family of bioethics documents, the older sister of the UNESCO Declaration, or is related more closely to the wider human rights movement and especially its European expression.

Professor Montgomery offered an example of how a strict ban on prohibition of germ line modification in the UK context could lead to

possible human rights challenges with regard to the rights of equitable access (Article 3), non-discrimination (Article 11) and private life (ECHR Art 8). Moreover, such a prohibition would in his view, contravene Article 12 of the UNESCO's Universal Declaration on the Human Genome and Human Rights of 1997, according to which the benefits of advances must be available to all and the sentiments expressed in the Preamble of the Oviedo Convention that *progress should be available to 'future generations' and 'all humanity'*. Further, a prohibition of germline editing could constitute the interests of society prevailing over the individual; a breach of Article 2 of Oviedo.

Professor Montgomery then proceeded to a genealogical appraisal of Article 13. An examination of the *travaux préparatoires* of the Oviedo Convention reveals that there were discussions over the use of genetics for exceptional cases (in the absence of conceivable alternatives) in order to correct recognised abnormalities only for the purpose of alleviating severe human suffering. Although it was proposed that such interventions would take place with regulatory oversight from "an independent body, preferably a national ethics committee", the proposition was rejected unanimously as was a subsequent attempt to add the sentence "given the current state of scientific knowledge". At the time, many things were considered as temporary and the need for periodic review of Article 13 was emphasized. The uncertainty was also reflected in the unstable character of language, e.g. 'genome' instead of 'germ cell line', 'intervention' and 'modification' instead of 'interference'.

Prof Montgomery recommended that engaged and legitimate competing interests must be balanced fairly, in a non-arbitrary way and that the interplay between individual rights to therapies and public health morals in the light of current scientific understanding, be clarified. Also, further approaches should be consistent with the expectations of those who produced the Oviedo Convention and in particular with Articles 28, 31 and possibly 32. He also referred to Rec 934(1982) on Genetic Engineering, and "the right to a genetic inheritance which has not been artificially interfered with, except in accordance with certain principles which are recognised as being fully compatible with respect for human rights (as, for example, in the field of therapeutic applications)". Professor Montgomery proposed that actions be taken and ways found to integrate political, expert and public opinions into a mature deliberation. Thus, the

principle behind Article 13 should be revisited, a view shared by some interveners from the floor. However, other comments made from the floor suggested that a reliance on the preamble of the Convention to invalidate the prohibition laid down in Article 13 of the Convention was not tenable. Concerns were also raised from the floor about the impact of germline editing on human dignity and diversity, both of which are protected by the Oviedo Convention.

**Prof. Ewa Bartnik** (Poland), Professor of Genetics, Faculty of Biology, University of Warsaw Prof Bartnik emphasized in her presentation, the need for regulation with regard to genome modification. She pointed to the diversity of regulatory frameworks concerning research with human embryos and assisted procreative technologies across Europe. Thus, in countries which allow in vitro fertilization and whose legislation allows for the use of supernumerary embryos for research purposes CRISPR-Cas9 could be used in experiments but only if the embryos are not subsequently implanted. She referenced the letter by Baltimore *et al*<sup>5</sup> published in Science in the spring of 2015 which called for reflection and discussion on the possibility of using CRISPR-Cas9 to modify human embryos, and strongly discouraged any attempts at germ line modification for clinical application in humans while societal, environmental, and ethical implications of such activity are still being discussed among scientific and governmental organisations. Reference was made to a number of regulative attempts for establishing an oversight system for germ line editing such as the Principles specified by the Committee on Human Genome Editing (promoting well-being, transparency, due care, responsible science, respect for persons, fairness and transnational cooperation). She also referred to the importance assigned by the European Academies Science Advisory Council Report on public engagement and enhancing global justice. The National Academy of Sciences, Engineering and Medicine has recommended that human germline editing would only be acceptable in the absence of reasonable alternatives; restriction to editing genes that have been convincingly demonstrated to cause or strongly predispose to a serious disease or condition; credible pre-clinical and/or clinical data on risks and potential health benefits; ongoing, rigorous oversight during clinical trials; comprehensive plans for long-term multigenerational follow-

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<sup>5</sup> Baltimore D *et al.* Science. 2015;348(6230):36-8



up; and continued reassessment of both health and societal benefits and risks, with wide-ranging, ongoing input from the public.

Prof Bartnik went on to clearly demonstrate the difficulty of achieving regulatory consensus on this issue, given the complexity of the regulatory situation in Europe and the fact that according to the Deutscher Ethikrat, the emphasis has shifted from "do not allow till the risks are better understood" to "allow when the risk can be better evaluated". It was noted that the European Group on Ethics in Science and New Technologies has called for an inclusive debate on "acceptability and desirability" extending to civil society, not limited to safety issues, potential health risks and health benefits, but also taking into consideration fundamental ideas such as dignity, justice, equity, proportionality and autonomy. Reference was also made to Rec 2115(2017) of the CoE which sets out five steps that should be undertaken by member countries with regard to human germline modification regulation, namely that 1) Member States should be urged to ratify the Oviedo Convention or at least implement ban on pregnancy with a modified embryo 2) a broad and informed public debate should be fostered 3) the Council of Europe Committee on Bioethics should assess the ethical and legal challenges 4) a common regulatory and legal framework should be developed 5) Member States should develop a clear national position on use of new genetic technologies.

Prof Bartnik pointed out that concerns around genetic enhancement through gene editing should not be overstated as most traits that we may wish to improve are not monogenic, so enhancement is unlikely. She concluded that two actions are of fundamental importance: First, the creation of transnational agreements in order to avoid a situation similar to that of mitochondrial replacement', in which, although legal mechanisms were implemented in the UK, babies were born in Mexico and the Ukraine without appropriate oversight. Second, at the national level, countries that allow modification of the human genome in embryos must have appropriate regulatory mechanisms in place with competent bodies responsible for oversight.

## BRAIN TECHNOLOGIES

**Chair:** Mr Jean-Yves Le Déaut (France), former member of the Council of Europe Parliamentary Assembly

**Prof. Nikola Biller-Andorno** Director of the Institute of Biomedical Ethics and history of medicine, Center for Medical Humanities, University of Zürich commenced her presentation by emphasising the growing importance of brain science and its applications and mentioned some of the most important projects in the field, such as the Human Brain Project, a flagship project of the European Commission, and the Brain Initiative, sponsored by the US Department of Health and Human Services and other partners. While the brain is not specifically mentioned in the Oviedo Convention, the principles of dignity, non-discrimination, privacy and personal integrity contained therein are relevant to neuroscience.

Prof. Biller-Andorno highlighted the unprecedented possibilities opened up by brain technologies, including the ability to read, simulate, alter and stimulate the brain as well as control devices such as neuroprostheses. The ability to detect or monitor brain activity is of clinical relevance in the case of patients in a minimally conscious state but can also be used to gain insights about consumers, their preferences and behaviours. Brain activity data can also be saved on an external device which makes uploading our minds a theoretical possibility. It can also serve to identify us from others. Artificial neural networks can simulate brain activity allowing computers to perform a variety of tasks, including computer vision and speech recognition.

However, brain technologies also pose ethical challenges. A feature of brain technologies is their potential for dual use, both for civil and military applications and for clinical and enhancement purposes. The point was also made that when decisions are taken automatically (such as in self-driving cars) in closed loop systems, questions of accountability arise – who is responsible in the case of damage, the user, the company, the individual or group who developed the algorithms? Prof. Biller-Andorno argued that when considering the ethical issues pertaining to brain technologies, it is as important to distinguish their purpose, the area of application and their methodologies (e.g. invasive/non-invasive; closed loop/open loop). Nonetheless, there are principles and issues which are cross-cutting brain technologies including respect for persons,

risk of harm, justice, benefits which are in part hypothetical and social values, particularly solidarity and liberalism.

There are those who are claiming that these challenges should be addressed by establishing/recognising a new set of human rights such as the right to cognitive liberty; right to mental privacy; right to mental integrity; right to psychological continuity. It can be debated, however, whether the goal could also be achieved by specifying and concretising existing human rights enshrined in the Oviedo Convention and the European Convention on Human Rights, such as the right to liberty, the right to respect for private life and freedom of thought. Prof. Biller-Andorno concludes that it may be time for the Council of Europe to consider an Additional Protocol to the Oviedo Convention on Brain Technologies.

**Prof. David Winickoff** (OECD), Senior Policy Analyst OECD focused on the question of whether new human rights are necessary to address issues raised by neurotechnologies. He argued that the prudent approach would be to *develop* the existing framework of human rights rather than *invent* new rights. In his view the human rights discourse should be considered as one of many mutually reinforcing pathways of governance. Moreover, we should be thinking in terms of *process* rather than substance, for example the fostering of broad societal conversations among stakeholders and relevant actors, including business, consumers, governments and clinicians. At a time when legal agreements may be difficult to reach, more flexible forms of “good governance” might be useful. The development of standards will be necessary, but they may not be sufficient.

Prof. Winickoff made the point that there is a lot of interest and money going into the area of brain technologies and we need to be aware that it is sometimes difficult to disentangle hype from reality when it comes to developments in this field. Thus, there is a need for careful and judicious assessment of such developments before any rush to action. Reflecting on the ethical challenges (and recalling Nikola Biller-Andorno’s presentation), Prof. Winickoff went on to underline the affinities between the issues raised by genetics and neurotechnology (e.g. the potential slippage towards biological determinism) and the therapy versus enhancement questions that are common in the field of bioethics, as well as potential “dual use”. Addressing the proposal for the development of two new human rights, namely cognitive liberty and psychological

continuity, he raised the question of whether the existing human rights landscape may be adequate to protect these rights. Prof. Winickoff questioned the feasibility of creating sets of rights for each new emerging technological field and pointed to the “cost” of rights inflation, which could potentially spread skepticism about fundamental rights. He pointed to the real challenge of regulating particular technologies, which have potential applications in a number of different fields. He suggested that the proposal for a Convention on emerging technologies made in the Bergen study<sup>7</sup> commissioned by the Council of Europe could help avoid the problems stemming from multiple applications in diverse areas by identifying common issues for humanity in technology.

The “law lag narrative” was also mentioned, that is the idea that “law needs to catch up with the science and technology”. If you are a formalist/structuralist, you may want to “legislate” *a priori*. If you think rights can evolve, you can be less specific and favour broad rights that can and should speak to new situations as they arise.

If not more human rights now, wherein lies the path to good governance? One answer lies in tracing the shape of global governance today. It is complex, it is multi-scalar, and it is cross-sectoral. Prof. Winickoff closed his presentation by proposing 5 recommendations under the heading *Good governance of emerging technology: disparate streams, mutually deepening*.

- Human rights bodies and legal/ethics scholars should continue to develop their reflection on unique aspects of neurotechnology, with particular work on the concepts of privacy, personhood, and discrimination.
- Bioethics experts and stakeholders should continue to develop principles for clinicians and researchers working with human participants.
- Both public and private funders of brain science and neurotechnology should support social science scholarship *parallel to* and *integrated with* neurosciences examining the co-constitution of new knowledge and new kinds of rights.

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<sup>7</sup> Report on Ethical Issues Raised by Emerging Sciences and Technologies Report written for the Council of Europe, Committee on Bioethics by Roger Strand & Matthias Kaiser Centre for the Study of the Sciences and the Humanities, University of Bergen, Norway. 23 January 2015

- Open science and transparency should be promoted by scientists, engineers, and funders both to enable discovery and to support good governance.
- Stakeholder and publics should promote processes to help develop codes of responsible innovation (science, government, industry, publics) to steer the innovation process.

## INFORMATION TECHNOLOGIES/NBIC AND BIG DATA

**Chair:** Ms Tesi Aschan, Vice-Chair of the Committee on Bioethics (DH-BIO) of the Council of Europe

**Speaker:** **Dr. Antoinette Rouvroy**, of the Research Centre in Information, Law and Society (CRIDS), Namur University, argued that we experience the emergence of Big Data in health, as an enlarged health data ecosystem involving new data and new actors. This represents a radical shift from causation to correlation; a shift from civilisation of signs and text to signals and algorithms. What does this impose in terms of disruptions in the way we are creating, producing or discovering knowledge? This shift has ethical, legal, societal and political ramifications and raises new issues of discrimination and data protection. Where is agency or subjects defined in the Big Data universe? Subjects do not exist for data algorithms. Dr. Rouvroy argued that it has become necessary “to tame correlations”.

Big health data is characterised by its: **Volume:** Each person creates more than one million gigabytes of health data over their lifetime. Health related data are not only produced by doctors but also by the persons themselves as connected health – such as wearable sensors. Trivial data may reveal health information through pattern recognition and machine learning techniques. **Velocity:** Data circulates at high speed allowing for real-time collection, processing, prediction and evaluation by scoring, ranking, and matching of data. Data are rapidly included in new datasets, and are transferable across contexts. **Variety:** Data come from a variety of sources, actors and formats. Data a priori unrelated to health may become health data. Challenges arise because data scientists may not be trained in ethical handling of health data. Big health data can create a false illusion that correlations are enough to provide

reliable data. According to Dr. Rouvroy, this could shift attention from patient to profile; the patient may disappear behind the profile. Profiling based on recognition of small patterns in new methodology of epidemiology and precision medicine may be used for risk stratification, but the patients feeling of belonging to a group may disappear because they cannot recognise themselves. *Veracity or validity*: Big health data gives rise to new epistemic ambitions: The ambition of science has been to understand the world, pathways and causes of phenomena. Big data leads to a shifting towards other ambitions, where predictions dispense our understanding. Reliability is enough; we do not need “truth” about causation.

In Dr. Rouvroy’s view a critical question is whether causation is still required or is correlation now enough? Using pure correlation, it will be difficult to identify what causes what. Hazardous correlations meaning nothing appear more frequently in Big Data; and this can result in adverse outcomes in the context of health. Therefore, causation cannot be abandoned; hypothesis is necessary to frame the dataset.

A concern expressed by Dr. Rouvroy is the potential for discrimination when using big data in healthcare. Even the most trivial aspects of everyday life are potential indicators of a person’s current health status. Differences in the way people are treated can take increasingly subtle forms, and be based also on features of their lifestyles. She raised the question of how we should deal with discrimination arising from big data and which framework is best suited for preventing discrimination and protecting privacy in the healthcare arena.

Big Data also raises issues of privacy and data protection. Utility of data is a function of quantity of available data much more than quality of information. Privacy is often seen as the possibility for individuals to develop their personality. Group profiling can negatively impact on privacy. Dr. Rouvroy concluded her presentation by warning that making a decision is not the same as obeying the result of a calculation. Correlations are not enough. Data needs to be framed by hypotheses.

**Ms Alessandra Pierucci**, Chair of the Council of Europe Consultative Committee of the Convention for the Protection of

Individuals with regard to Automatic Processing of Personal Data (T-PD) pointed to the fact that ‘dignity’, ‘identity’, ‘non-discrimination’, and ‘integrity’ of the individual, are recurring terms in both the text of the Oviedo Convention and the Council of Europe Convention 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data. Convention 108 also stresses the ‘free’, ‘informed’, and ‘withdrawable’ nature of consent and draws attention to the importance of the information to be given to the patient/data subject. It was observed that Convention serves as the legal basis for a large number of domestic laws. The main novelties of the modernised Convention were then presented with a focus on Big data as a new paradigm in the way in which information is collected, combined and analysed. It is recognised as a source of significant value and innovation for society, including the health sector, and as a tool for enhancing productivity, public sector performance, and social participation. Nevertheless, the Consultative Committee of the Convention while acknowledging the potential benefits of Big Data, also addressed the risks deriving from an unregulated use of such data and developed Guidelines focusing on the need for:

- adopting a broader idea of control, evolving a more complex process of multiple-impact assessment of the risks related to the use of data.
- adapting traditional principles of data protection to the new technological scenario, (transparency and fairness of processing),
- promoting an ethical and socially aware use of data, to safeguard fundamental rights,
- providing for preventive policies and assessment of the specific risks for the protection of personal data including with regard to equal treatment and non-discrimination,
- ensuring by-design solutions at the different stages of the processing in order to minimise the presence of redundant or marginal data, avoid spurious correlations, potential hidden data biases and risk of discrimination or negative impact on the rights and fundamental freedoms of data subjects, in both the collection and analysis stages,
- using anonymisation where possible, being aware that a relevant part of controllers' accountability is also to assess the risk of re-identification,
- stressing the role of the human intervention in Big data-supported decisions, by providing the possibility to the data subject to request a human decision-maker to provide her or

him with the reasoning underlying the processing and the consequences.

The Revision of the Recommendation on the protection of medical data (1997) and its modernisation was the next theme presented. Albeit still in process, Dr Pierucci explained that the revision provides for an expanded notion of ‘health-related data’ (no longer limited to medical data). It includes privacy by design, by default and accountability obligations for data controllers; specific safeguards for genetic data, consistent with Recommendation CM/Rec(2016)8 on the processing of personal health-related data for insurance purposes; it explicitly extends to mobile health applications of relevant data protection principles; it ensures that interoperability, a condition for data portability, is carried out in due respect for strong security measures.

Artificial Intelligence was also addressed as it is raising unprecedented challenges for human rights and data protection. The PACE Recommendation 2102(2017) on Technological Convergence and Artificial Intelligence, the EU Parliament Resolution of 16 February 2017 on Civil Law rules on Robotics, the Paper of the European Data Protection Supervisor on Artificial Intelligence, Robotics and Data Protection of 2016 were mentioned as relevant examples of the increasing attention devoted to artificial intelligence.

Dr Pierucci concluded by stating that privacy and data protection should not be seen as an obstacle but rather as a necessary requirement to ensure a fair and transparent processing of data and to guarantee to all individuals the control of their personal information and self-determination, in particular when health and ethical choices are at stake. In her view, the Council of Europe is an ideal forum to explore such new frontiers and their impact on fundamental rights.

## SESSION IV – PAVING THE WAY FOR A STRATEGIC ACTION PLAN



**Moderator:** Prof. Dr. med. Christiane Woopen (Germany), Professor of Ethics and Theory of Medicine, University of Cologne

**Participants:** Prof. Nikola Biller-Andorno on behalf of WHO, Prof. Jean-François Delfraissy, President of the French National Ethics Committee; Dr Lyalya Gabbasova, Adviser to the Russian Health Minister; Ms Paula Kokkonen, former emeritus Chairperson of the Finnish National Advisory Board on Health Care Ethics, Ms Brigitte Konz, Chair of the Steering Committee for Human Rights (CDDH) of the Council of Europe; Dr Petra de Sutter, member of the Council of Europe Parliamentary Assembly

**Prof. Biller-Andorno** introduced the WHO workplan in the area of ethics. The first topic under consideration by WHO is the use of big data in healthcare. A multidisciplinary working group has been established in order to define governance models for the use of big data and to find solutions to the unequal diffusion of data technologies across countries. WHO is also concerned with vector borne disease and is working towards producing global guidance on the specific ethical questions raised by vector borne disease. A third area of work which will be undertaken in 2018-2019 is to produce an ethical framework to respond to the challenges posed by ageing, which will inform and guide policy makers. WHO also intends to engage with national research ethics committees to explore how the system of research ethics review can be made less burdensome and complex. Finally, the WHO will continue to support the global summit of national ethics committees. WHO welcomes collaboration with other likeminded bodies in the realisation of their workplan

**Prof. Delfraissy's** primary message was the importance of dialogue between researchers, civil society and patient organisations when it comes to making policy decisions about the ethical acceptability of various scientific developments. He identified four priority issues which require attention. The first are new genomic technologies and their application in germ cells. Research should be permitted in this area however clinical trials should not be undertaken at this juncture. The use of big data in the healthcare arena means that new actors such as industry will join doctors and patients in delivering healthcare. A pressing issue which requires examination is what the concept of informed consent means in the era of big data. Prof. Delfraissy pointed out that the issue of migrant health was likely to be an enduring challenge for states and that heretofore

there had been a number of diverse approaches adopted in response to the issue. The issue of access to innovative therapies was also identified as a priority issue. It was suggested that such drugs over time should become the property of society rather than remain the exclusive property of pharmaceutical companies.

**Dr Gabbasova** in her contribution choose to highlight the issue of organ transplantation. The Russian Federation operates a system of presumed consent in regard to organ donation and this approach raises specific challenges with respect to the participation of the family of the donors in the decision-making process regarding organ donation. It was suggested that the role of the family in the organ donation consent process should be addressed in a consensus document, guidance or technical recommendation. It was recommended that definitions in international instruments regarding organ transplantation be harmonised e.g. between Council of Europe and WHO documents. The point was made that transplantation and in particular combatting organ trafficking requires a multi-sectoral and multi-stakeholder approach.

**Ms. Kokkonen** questioned what we mean by health, is it an ability to function? What is normal, that is a rather subjective concept. There is a trend towards medicalisation and layification where people receive more and more information about their health status. Access to health information from the internet and from predictive medicine has lead increasingly to a form of reactive healthcare. At the same time there is an increasing trend towards self-care supported by technology. It has to be remembered however that the doctor/patient relationship is a social experience and that it is important to appreciate that medicine is art as well as science. Ms. Kokkonen reiterated concerns about migrant health but raised the question of undocumented migrants and the difficulties they face in accessing healthcare. She also raised the challenge of maintaining privacy in the cybersphere. She called for continuous dialogue and a common European thematic day for schools as a platform for such dialogue.

**Ms. Konz** situated her comments in the context of increasing globalisation, political and financial uncertainty and the rise of nationalism and global terrorism. Against this backdrop she identified a number of challenges for human rights in the field of biomedicine; equality in access to treatment, exploitation of vulnerable groups, illicit trafficking of human organs and cells and

safety of pharmaceutical products and by extension the availability of counterfeit drugs. Ms. Konz outlined the priorities of the CDDH which include equal access to medical care and scientific progress, as well as to new and safe medicines; protection of the environment; protection of the human body, in particular organs, tissues and cells, from commercialisation. The CDDH is planning two thematic conferences regarding the rights of older persons and combating discrimination on the grounds of sexual orientation and gender identity. The committee will also seek to foster cooperation in Member States and heighten public awareness on efforts to combat female genital mutilation and forced marriages. Efforts are required to promote effective implementation of regional and international instruments, if human rights are to be upheld. There was a recognition of the difficulty involved in drafting new binding instruments but it is crucial to continue to give thought to promoting and disseminating ethical values.

**Dr. de Sutter**, presented the work of the Committee on Social Affairs, Health and Sustainable Development which was established in 2012. The committee has published a number of documents, opinions, recommendations and resolutions in the intervening years concerning organ trafficking, children's right to physical integrity, coerced sterilisation, nanotechnology and the relationship between the pharmaceutical industry and public health. The most recent work undertaken by the committee has been in the field of surrogacy; a draft recommendation on this topic was rejected by PACE in October 2016 due to the difficulty of achieving consensus on this ethically sensitive and complex topic. In May 2017 the committee published a report on "The use of new genetic technologies in human beings"<sup>8</sup>. Work is ongoing in the area of organ transplant tourism and in a related vein, work has already started on combatting trafficking in tissue and cells, including gametes and embryos. Dr. de Sutter proceeded to raise four issues of ethical concern which require examination and reflection; commercialisation of egg donation; anonymity of gamete donors; uterus transplantation and stem cells. Induced pluripotent stem cells can be used to generate gametes and gene editing techniques could be used to modify the gametes and by extension the resulting embryo. This type of research while futuristic in nature needs to be

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<sup>8</sup> Available at: <http://website-pace.net/documents/19855/3313570/20170426-recours-nouvelles-technologies-g%C3%A9n%C3%A9tiques-EN.pdf/75b25d58-a122-4896-91ae-295d49d42549>

done hand in hand with ethicists so that responsible decisions can be made about the future of procreation.

The presentations were followed by a discussion which included several contributions from the floor. Updates were provided with respect to the work of the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) which has recently published a global ethical framework for artificial intelligence and robotics<sup>9</sup> and is currently working on the internet of things. The International Bioethics Committee of UNESCO (IBC) published a report on Big Data in Healthcare<sup>10</sup> in September 2017 and future work includes individual responsibility and modern parenthood. The Chair Prof. Woopen informed the meeting that the European Group on Ethics in Science and New Technology were currently addressing the future of work and the meaningful human control in so called autonomous system. It was noted that there was a confluence of interests amongst international bodies and this presented opportunities for collaboration.

The point was made that increasingly pluralistic societies may interpret conventions and recommendations from the Council of Europe and other international bodies in diverse ways. The challenge is to develop methodologies for the effective adoption and implementation of bioethics instruments to promote basis values. Moreover, it was suggested that rather than elaborating new legal instruments that are subject specific, a more pragmatic approach would be to synthesise and harmonise the principles of existing instruments across disciplines. There is also a need to bridge the often-disconnected discourse between different bodies working on similar issues. Attention was drawn to the danger of revising existing instruments in that it could open a “pandora’s box” and serve to undermine hard won consensus on ethical principles.

The view was expressed that in deciding the future strategy for the Oviedo Convention, two guiding principles should be adopted; the first is to ask whose human rights are most under threat in the field of biomedicine, in this respect it was suggested that refugees are of prime concern, and secondly what are the existing medical taboos in

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<sup>9</sup> Available at: <http://unesdoc.unesco.org/images/0025/002539/253952e.pdf>

<sup>10</sup> Available at: <http://unesdoc.unesco.org/images/0024/002487/248724E.pdf>

Member States as the issues underpinning such taboos likely require ethical attention.

Several contributors emphasised the need for public dialogue on scientific developments. Doubt was expressed about whether citizens had a good understanding of the principles enshrined in the Oviedo Convention and in human rights instruments more generally. It was suggested that concrete examples of the applicability of the principles in the Convention be given to the public so that a two-way dialogue could be initiated. This work should begin at the national level.

## CONCLUSION AND SUGGESTED ACTIONS

The Convention on Human Rights and Biomedicine is the first and only internationally binding legal instrument in the field of biomedicine. The Convention provides a “common framework for the protection of human rights and human dignity in both longstanding and developing areas concerning the application of biology and medicine”<sup>11</sup>. While Europe shares many common values including human dignity, which is ascribed a fundamental role in the Convention, there still exists a diversity of views regarding bioethical issues. Thus the “adoption of a binding instrument in this sensitive field represents a remarkable accomplishment of the Council of Europe”<sup>12</sup>.

The Convention acts as a reference document internationally and has had significant influence on legislation and practices at the national level, even in those Council of Europe Member States who have not signed and/or ratified the Convention. Indeed, the Convention is a beacon for the protection of human rights in the biomedical field outside the European context; Mexico is currently considering accession to the Oviedo Convention. Another interesting development highlighted in this conference is the increasing frequency with which the ECtHR refers to the Convention in its judgments<sup>13</sup>. Thus, the Convention remains influential and relevant and the Committee on Bioethics may wish to consider surveying Member States who have not ratified and/or signed the Convention to ascertain the perceived obstacles to their accession to the Convention.

A number of over-arching themes emerged during the course of the conference, including the increasing blurring of the boundary between medicine, research and the private sphere; the need to re-connect technologies to values and the necessity of public dialogue and deliberation in the regulation of scientific advances in the field of biomedicine.

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<sup>11</sup> Explanatory Memorandum to the Convention §7

<sup>12</sup> Andorno R. *J Int Biotech Law* 2005;2(1):133-143, p.143

<sup>13</sup> For a discussion of The Experience of the European Court of Human Rights with the European Convention on Human Rights and Biomedicine see Seatzu, F. & Fanni, S. *Utrecht Journal of International and European Law* 2015; 31(81):5-16

Use of genomic data collected in the clinical context is increasingly being utilised for research purposes. Likewise, emerging technologies and NBIC<sup>14</sup> convergence enables the application of biomedical technologies beyond the medical sphere. One clear illustration of this point is the increasing use of biodata for non-medical purposes for example, marketing. A key characteristic of the NBIC convergence is the gradual dissolution of the borders between the physical and the biological sciences. This raises the question of how to balance technological progress with human values and whether existing governance frameworks including the Convention on Biomedicine can deal with the ethical issues raised by the blurring of boundaries. While the question of the ethical use of technology and the protection against the misuse of technology is not a new one, the speed of development and the complexity of NCIB convergence means it acquires a new dimension. The law-lag narrative promotes the notion that the task of policy makers and legislators is to react to technological developments and adjust the law to accommodate them. This narrative is problematic as science is seen as self-governing demanding deference from the law<sup>15</sup>. Safeguarding human rights principles is not a bureaucratic question but goes to the heart of how we want to shape our lives and societies. Thus, access to the benefits of scientific/technological advances needs to be grounded in the overarching principle found in the Convention, of the primacy of the human being and the protection of human dignity. While a pluralism of values and subsidiarity needs to be recognised, not all values are relative and as the elaboration of the Convention on Biomedicine has demonstrated, an overlapping of consensus can be achieved.

Advances in science and technology can promote human rights and values. We need be to mindful of what our values commit us to but also to guard against ossification. The Convention on Biomedicine is a 'living instrument' that should be interpreted and applied in 'light of present-day circumstances' to ensure that the protection of human rights remains 'practical and effective'<sup>16</sup>. The drafters of the

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<sup>14</sup> NBIC convergence refers to the convergence of nanotechnology, biotechnology, information technology and cognitive technology

<sup>15</sup> Experiments in Democracy. Human Embryo Research and the Politics of Bioethics. J. Benjamin Hurlbut. Columbia University Press (2017) p.142

<sup>16</sup> The doctrine of the living instrument developed by the ECtHR can first be found in *Tyrer v. CASE OF TYRER v. THE UNITED KINGDOM*, no. 5856/72, 25 April 1978. The Court of Justice of the European Union, while not referring to the 'living instrument' doctrine, is also follows a principle of 'evolutive interpretation' of rights.

Convention recognised this with the inclusion of Article 32 which acknowledges the requirement for review of the provisions of the Convention in light of scientific developments. One such development discussed at the conference are genome editing technologies. Article 13 of the Convention states “An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modifications in the genome of any descendants.” In October 2017 the Parliamentary Assembly of the Council of Europe adopted a Recommendation<sup>17</sup> urging Member States to institute a national ban on establishing a pregnancy (as distinct from performing research on embryos and germlines) with germ-line cells or human embryos having undergone intentional genome editing. The Recommendation also called for a broad and informed public debate in order to facilitate the development of Member State policies on the practical use of new genetic technologies. This debate should be informed by input from DH-BIO which can offer a platform that enables Member States to reflect on policy and practice in this area. The European Group on Ethics in Science and New Technologies have also called for a public debate on germline gene editing and there may be opportunities for synergistic activities between the two groups.

In coming to any conclusion about whether the Convention on Biomedicine<sup>18</sup> can adequately protect human rights in light of advances in science and converging technologies, or whether new rights or instruments are required, political, expert and public opinions need to be integrated into a mature deliberation in order to ensure that governance of the biomedical field is democratic, legitimate and effective. The importance of the public debate was specifically reiterated throughout the conference. Combining the normative framework of human rights with scientific progress requires informed public dialogue; normative deliberations cannot remain limited to the expert level. The Nuffield Council on

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<sup>17</sup> Recommendation 2115 (2017) The Use of New Genetic Technologies in Human Beings, available at: <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-EN.asp?fileid=24228&lang=en>

<sup>18</sup> In combination with ‘soft law’ such as Recommendations of the Council of Ministers to the Member States,



Bioethics in their report on emerging technologies<sup>19</sup> advocated a ‘public discourse ethics’ approach to policy making and governance of such technologies. The Council suggested a number of procedural virtues to foster this discourse including openness and inclusion, accountability, public reasoning, candour, enablement and caution. A working group has been established by DH-BIO with the intention of elaborating a guide on how to foster a pluralistic and informed debate on bioethical issues in the public sphere. Ultimately it is from this kind of debate that common ground can be identified and solutions can emerge. A number of National Ethics Councils/Committees have extensive experience in promoting public dialogue on bioethics and DH-BIO might wish to consider harnessing this expertise in preparing the guide.

In addition to the aforementioned over-arching themes, a number of specific recommendations were made by invited speakers and conference participants, which have been captured in the main body of the report. These recommendations will inform the development of a strategic action plan by the Committee on Bioethics (DH-BIO) to address the human rights challenges raised by developments in the fields of biology and medicine. In that context it is perhaps worth raising some specific areas where action by DH-BIO might be considered.

The Committee on Bioethics has previously commissioned two studies on the rights of children in the biomedical sphere<sup>20</sup>. The findings of both studies were presented at the conference and recommendations made with respect to future actions. While various international human rights instruments including the Convention on Biomedicine do offer some protection of the rights of children in the area of biomedicine, these rights tend to be rather general in nature and are focussed on the vulnerability of the child rather than recognising the evolving nature of their autonomy. As was suggested in the report by Liefwaard *et al*, it would be important

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<sup>19</sup> Nuffield Council of Bioethics. Emerging biotechnologies: technology, choice and the public good (2012) available at: [http://nuffieldbioethics.org/wp-content/uploads/2014/07/Emerging\\_biotechnologies\\_full\\_report\\_web\\_0.pdf](http://nuffieldbioethics.org/wp-content/uploads/2014/07/Emerging_biotechnologies_full_report_web_0.pdf)

<sup>20</sup> Zillén, K., Garland, J., & Slokenberga, S. The Rights of Children in Biomedicine: Challenges posed by scientific advances and uncertainties (Jan 2017) available at: <https://rm.coe.int/16806d8e2f>

Liefwaard, T., Hendriks, A. & Zlotnik, D. From law to practice:

Towards a Roadmap to Strengthen Children’s

Rights in the Era of Biomedicine (June 2017) available at:

<https://rm.coe.int/leiden-university-report-biomedicine-final/168072fb46>

to have a comprehensive view of the national legal frameworks operating within the Council of Europe Member States with regard to the rights of children as they pertain to biomedicine and research. This would form the basis of any future action. In keeping with the Council of Europe's Strategy for the Rights of the Child (2016-2021)<sup>21</sup> resources should be concentrated on the implementation of existing standards. Thus, DH-BIO may wish to consider the elaboration of a guide specifically dealing with rights of children in the area of biomedicine by building on existing standards. The Committee might also wish to develop practical tools for both health professionals and parents to assist them in recognising children's evolving capacities and to facilitate children's involvement in decision-making affecting them. Zillén *et al* in their report identified the particular vulnerability of inter-sex children. In October 2017, the Parliamentary Assembly adopted a resolution<sup>22</sup> on the rights of inter-sex children which called for the deferral of "sex-normalising" surgery until the child themselves could participate in the decision. The Committee on Bioethics may wish to consider how it might assist Member States to give effect to the recommendations made in the Resolution.

The question of equitable access to healthcare enshrined in Article 3 of the Convention on Biomedicine was discussed in particular with reference to older persons and migrants, the latter group being considered particularly vulnerable. The Committee on Bioethics could consider establishing a working group to assemble specific policies and best practice aimed at reducing inequalities in access and health outcomes for migrants. Consideration could be given by DH-BIO to collaborating with other Council of Europe bodies in this endeavour, such as the European Committee of Social Rights since Article 11 of the European Social Charter guarantees "Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable". Another potential collaborating partners could be the World Health Organisation, which has a number of on-going initiatives in the field of migrant health, and the International Bioethics Committee of UNESCO

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<sup>21</sup> Available at: <https://rm.coe.int/168066cff8>

<sup>22</sup> Resolution 2191 (2017). Promoting the human rights of and eliminating discrimination against intersex people. Available at: <http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=24232&lang=en>

which published a report<sup>23</sup> on the situation of refugees, including their access to healthcare, in September 2017.

Due to the plurality of opinions which exists on bioethical issues within Europe, reaching consensus on internationally binding legal instruments in this field is challenging. Thus, the strategic action plan should privilege the interpretation and application of existing human rights instruments, over the modification of the Convention on Biomedicine or the elaboration of additional protocols to the Convention. That is not to say that the door should be closed to such possibilities but rather to underscore the importance of improving the implementation of existing instruments. The strategic action plan should be developed in cooperation with other Council of Europe as well as international bodies, and should provide for the development of tools for participatory democracy, including the promotion of public debate on the ethical issues arising in the biomedical field.

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<sup>23</sup> Report of the IBC on the Bioethical Response to the Situation of Refugees. Available at: <http://unesdoc.unesco.org/images/0024/002487/248721e.pdf>