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20th Anniversary of the Oviedo Convention. Conclusion and suggested actions. Report prepared by the Rapporteur Group appointed by the Committee of Bioethics of the Council of Europe [*]

Background to the Report

Under the auspices of the Czech Presidency of the Committee of Ministers of the Council of Europe, a conference to celebrate the 20th anniversary of the Oviedo Convention was held in Strasbourg on October 24th-25th 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.

The conference addressed the following subjects. The Session I dealt with *International case-law in Bioethics: insight and foresight.* The Session II was related to the *evolution of practices in the biomedical field*: *autonomy – consent and privacy* as well as *equity of access to health care*. And the Session III was concerning the *New scientific and technological*

[*] This report was prepared by the Rapporteur Group appointed by the Committee of Bioethics of the Council of Europe and composed of the following Members: Siobhán O'SULLIVAN (Chair), Isabelle ERNY, Anne FORUS, Tina GARANI-PAPADATOS, Constantinos PHELLAS and Stefano SEMPLICI. Rapporteur Report, 24-25th October 2017, Strasbourg. Available at: https://rm.coe.int/oviedo-conference-rapporteur-report-e/168078295c

developments, that is to say*, genetics– genomics, brain technologies and information technologies/NBIC and big data*.

We include, below, some conclusions that were reached in the aforementioned conference.

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"[1]. 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"[2].

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[3]. 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 reconnect 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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[1] Explanatory Memorandum to the Convention §7

[2] ANDORNO R., *J Int Biotech Law,* No. 1, Vol. 2, 2005, pp. 133-143, p.143

[3] 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*, No. 81, Vol. 31, 2015, pp. 5-16.

Use of genomic data collected in the clinical context is increasingly being utilised for research purposes. Likewise, emerging technologies and NBIC[4] convergence enables the application of biomedical technologies beyond the medical sphere. One clear illustration of this point is the increasing use of biodata for nonmedical 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[5]. 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'[6]. The drafters of the 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

[4] NBIC convergence refers to the convergence of nanotechnology, biotechnology, information technology and cognitive technology

[5] Experiments in Democracy. Human Embryo Research and the Politics of Bioethics. J. Benjamin Hurlbut. Columbia University Press, 2017, p.142

[6] 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.

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[7] 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[8] 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 Bioethics in their report on emerging technologies[9] 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

[7] Recommendation 2115 (2017) The Use of New Genetic Technologies in Human Beings, available at: http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTMLEN.asp?fileid=24228&lang=en

[8] In combination with 'soft law' such as Recommendations of the Council of Ministers to the Member States

[9] Nuffield Council of Bioethics. Emerging biotechnologies: technology, choice and the public good (2012) available at: http://nuffieldbioethics.org/wpcontent/uploads/2014/07/Emerging_biotechnologies_full_report_web_0.pdf

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[10]. 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 Liefaard et al, it would be important 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)[11] 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[12] on the rights of inter-sex children which called for the deferral of "sex-normalising"

[10] 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. LIEFAARD,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

[11] Available at: https://rm.coe.int/168066cff8

[12] Resolution 2191 (2017). Promoting the human rights of and eliminating discrimination against intersex people. Available at: http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTMLen.asp?fileid=24232&lang=en

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 which published a report[13] on the situation of refuges, 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

[13] Report of the IBC on the Bioethical Response to the Situation of Refugees. Available at: http://unesdoc.unesco.org/images/0024/002487/248721e.pdf