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COMMITTEE ON BIOETHICS
(DH-BIO)

Draft Strategic Action Plan 2020-2025

Prepared by the Drafting Group

INTRODUCTION

1. 2017 marked the 20th anniversary of the Convention on Human Rights and Biomedicine (Oviedo Convention). On this occasion an International Conference was held on 24-25 October 2017.[1] The purpose 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 as well as the evolution of established practices in the biomedical field in the 20 years since the Convention came into force.

2. A number of important human rights challenges were identified, reflecting the findings of preparatory studies commissioned by the Committee on Bioethics (DH-BIO),[2] the replies of its delegations to a questionnaire exploring new challenges to the Oviedo Convention, and the conclusions of the International Conference on Emerging Technologies and Human Rights, organised by the DH-BIO on 4-5 May 2015, and of the High Level Seminar on International Case-Law in Bioethics, organised by the DH-BIO on 5 December 2016.[3]

3. Bioethics is often construed as a "culture of limits". However, its role should be to accompany progress in science and to reflect on and promote fundamental rights. Bioethics serves to safeguard human rights principles and goes to the heart of how we want to shape both the lives of individuals and broader society. The Strategic Action Plan is considered both timely and necessary in light of the major human rights challenges that have been identified during the conference and in previous work of the DH-BIO. It has now become clear that we are at a turning point in human rights in biomedicine, as a result of two major developments.

4. First, human rights challenges are posed by emerging and converging technologies that have an application in human biology and medicine and have the potential to bring about radical changes in medical [and non-medical] practice. Emerging technologies are technologies that are radically novel in their methods or applications. They are for instance found in the field of genetics and genomics and their applications include genomic sequencing, genetic tests, and gene editing. Converging technologies involve technologies that were developed separately but have been brought together to increase efficiency or to create new applications. Converging technologies include nanotechnology, biotechnology, information technology, and cognitive science, and their applications are for instance the use of [nanomedicines, tissue engineering, artificial intelligence,] big data or brain technologies in healthcare. Importantly, the application of emerging and converging technologies in biomedicine results in a blurring of boundaries, between the physical and the biological sciences, between treatment and research, and between medical and non-medical purposes. Although emerging and converging technologies offer significant opportunities within and beyond the field of biomedicine, they also raise new ethical challenges related to identity, autonomy, privacy, and non-discrimination.

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[1] International Conference on the 20th Anniversary of the Oviedo Convention: Relevance and Challenges.

[2] From Bio to NBIC convergence – From Medical Practice to Daily Life; Report on Ethical Issues Raised by Emerging Sciences and Technologies; The Rights of Children in Biomedicine: Challenges Posed by Scientific Advances and Uncertainties; From Law to Practice. Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine.

[3] International Conference on Emerging Technologies and Human Rights; High Level Seminar on International Case-Law in Bioethics: Insight and Foresight.

5. Second, important human rights challenges are also raised by established practices in the field of biomedicine that are evolving and taking on different dimensions. The blurring of boundaries between treatment and research, and the linkage of different types of health-related data, including genetic data, are putting under pressure existing protections of autonomy and privacy. Similarly, changes in the perception of the decision-making capacity in children, persons with mental health difficulties, and vulnerable older persons are prompting a reconsideration of the balance between protection and respect for autonomy. In addition, important demographic changes, such as migration and ageing populations, coupled with budgetary restrictions in healthcare, result in new or increasing barriers in accessing healthcare services. At the same time, we are witnessing unprecedented scientific progress and the development of innovative and often very expensive therapies, which may not be available to already disadvantaged individuals and groups. This development indicates a need to complement the traditional focus on patient's rights with a focus on guaranteeing the human right to healthcare itself.

6. It has become clear that recent developments in the field of biomedicine, while holding the promise of revolutionising healthcare, also raise fundamental and new challenges for human rights. [These challenges are particularly important and urgent because of the scale of the changes that these developments are bringing about, their irreversible and unpredictable nature, and the fact that they affect all of society.] Through its role, expertise, and geographical scope, the Council of Europe is uniquely placed to address these challenges. The Council of Europe has adopted a variety of binding and non-binding legal instruments laying down human rights standards that are of crucial relevance to address these challenges. It counts several expert committees with the required knowledge and expertise to examine and address these challenges from all relevant perspectives, and is closely collaborating with other international organisations in the field. More generally, the Council of Europe has an important role in being a forum for continuous reflection and discussion needed to root the answers to new ethical challenges in human rights and shared European values.

7. Within the role of the Council of Europe to address the human rights challenges raised by new developments in the field of biomedicine, the DH-BIO occupies a central place. The Oviedo Convention, adopted by the DH-BIO in 1997, is the first and only binding international legal instrument in the field of biomedicine. The Convention provides a common framework for the protection of human dignity and human rights with regard to both longstanding and new applications of biology and medicine. The Convention harmonises human rights protections in the field of biomedicine in Council of Europe Member States, and acts as a reference document internationally. The DH-BIO has the task to conduct regular re-examinations of the Convention and to assess the ethical and legal challenges raised by new developments in the biomedical field. Consideration will be required as to whether existing human rights provisions, including those contained in the Convention, are still fit for purpose or whether there is a need to re-examine, clarify or elaborate them in the service of protecting human dignity and human rights.

VISION FOR THE STRATEGIC ACTION PLAN

8. The vision of the Strategic Action Plan (SAP) is to **protect human dignity and the human rights and freedoms of the individual with regard to the application of biology and medicine**, with a particular emphasis on addressing key human rights challenges raised by new developments.

APPROACH OF THE STRATEGIC ACTION PLAN

9. The SAP is developed in the light of the human rights challenges identified in preparatory studies commissioned by the DH-BIO, in the replies of its delegations, and in recent international conferences organised by the DH-BIO. The SAP also takes into account the work that has been done or that is currently under way in other Council of Europe Committees, as well as other intergovernmental organisations.

10. In January 2018, a drafting group[4] was established to elaborate the SAP. A number of drafting group meetings were held,[5] and the plan was discussed by delegations in plenary session of the DH-BIO in June and November 2018. Feedback received from delegations both at, and following, the plenary meetings was incorporated into the draft plan. To ensure a complementary approach to the work of other Council of Europe committees, there was an engagement with a number of internal bodies/committees.[6] Moreover, exchanges regarding the SAP were had with a number of intergovernmental bodies[7] in the interests of developing long-term strategic cooperation for mutual benefit. [This section will be amended/added to as the process proceeds].

11. The SAP is built on four thematic pillars. Three of these pillars correspond to three critical human rights aspects that are affected by the new developments: **Governance**, **Equity**, and **Integrity**. Within each of these pillars strategic objectives have been identified that it would be essential for the DH-BIO to consider. In turn, within these strategic objectives specific action points have been developed. The fourth pillar is transversal and concerns **Co-operation and Communication**.

12. The action points that are proposed do not cover all the issues that have been identified. Among the wide range of possible action points, those action points that have been suggested for the SAP are considered priorities. Priorities were determined on the basis of several criteria, including the demonstrated need, the feasibility in light of available resources, expertise, and time, the impact on Council of Europe Member States and their populations, the potential to elicit changes in policy or practice over the longer-term, and the opportunities to pool resources and increase impact through cooperation with other relevant partners.

13. Consequently, the SAP focusses on action points where the DH-BIO, when appropriate in cooperation with the other committees of the Council of Europe and/or with other intergovernmental organisations, can achieve the most important, effective, and efficient contribution within the foreseen timeframe. There has also been an effort to balance the range of activities to ensure that due attention is given to building on previous work by the DH-BIO and to the implementation of previously

[4] Appendix I: list the members of drafting group- meetings and consultations
[5] ibid
[6] ibid
[7] ibid

elaborated tools. It should be noted that various actions included in the SAP are considered as building blocks for future work which may extend beyond the lifetime of the current SAP.

Pillar I: GOVERNANCE

14. Taking into account the complexity, the speed of development, and the major impact of emerging and converging technologies, the question of how technology can be used ethically in biomedicine is acquiring a new dimension. For instance, medicines and diagnostic devices based on nanotechnology create possibilities for permanent health monitoring, but also raise the prospect of unprecedented interference with the autonomy and personal sphere of individuals. In another development, genomic data collected in the clinical context are increasingly being used for research purposes, and future combinations with growing volumes of biological and lifestyle data that are publicly shared, are expected to escalate current concerns about control and re-identification of our personal data.

15. These developments indicate that human rights may no longer be adequately protected if we keep relying only on existing protective mechanisms, such as consent and data protection. On a more general level, these developments also suggest that the protection of human rights may be inadequate if we apply existing models of governance to emerging and converging technologies. These models of governance, such as legislation, ethical guidelines, monitoring by an ethics committee, or self-regulation, are typically developed when technology is already implemented, and they disproportionally focus on risk assessment and management. They are likely to offer insufficient protection since they fail to assess whether the direction of technological innovation is in itself in accordance with human rights, and since the risks of emerging and converging technologies are still little understood and cannot always be anticipated.

16. The studies commissioned by the Committee of Bioethics and the conferences that it organised, concluded that, in order to guarantee respect for human dignity and human rights in the light of new developments in biomedicine, it may be necessary to change the way in which technologies with an application in biomedicine are governed. For that reason, the first pillar concerns **Governance**. Governance refers to the ways in which technology is steered and controlled. It involves the establishment of policies that guide the research, development, and application of technology, and the adoption of oversight mechanisms to monitor the implementation of these policies.

17. The studies and conferences of the DH-BIO emphasised that adequate governance models may need to be developed to (re)connect technological progress in biomedicine with human dignity and human rights. More specifically, it was suggested that in these governance models the protection of human rights should be a guiding consideration throughout the entire process of research, development, and application, and that an on-going dialogue between scientists, policy makers, and the public should be ensured. In this pillar, two strategic objectives have been identified:

1. Embed ethical values and human rights in emerging and converging technologies which have an application in the field of biomedicine.

18. Previous work[8] of the DH-BIO indicates that, in order to provide appropriate human rights protection, models of governance for emerging and converging technologies should overcome the "law-lag narrative". This narrative promotes the notion that it is the task of policy makers and legislators to react to technological developments and to adjust the law to accommodate them. This narrative is problematic since it sees technology as self-governing and the role of governance as facilitating possible applications of technology. It was indicated that, in this way, technological innovation creates its own dynamic and human rights considerations will only come into play at the end of the process, when the technological applications are already established and the technological pathways often have become irreversible.

19. To overcome this problem, governance models need to be established that focus on built-in human rights reflection and monitoring. These governance models should ensure that human rights considerations are taken into account from the earliest stages of innovation, so as to guarantee that technological developments are from the outset beneficial and oriented towards protecting ethical values and human rights. Such a model of governance would allow anticipating possible human rights challenges, and adapting the regulatory response whenever evolving applications would need to be brought into conformity with human rights. Such a need has also been underlined by the Parliamentary Assembly, which in Recommendation 2102 (2017) [on Technological Convergence, Artificial Intelligence and Human Rights] "notes with concern that it is increasingly difficult for lawmakers to adapt to the speed at which science and technologies evolve and to draw up the required regulations and standards" and emphasises that it "strongly believes that safeguarding human dignity in the 21st century implies developing new forms of governance".

20. Thus, it is considered vital that models of governance that facilitate on-going human rights reflection and monitoring of emerging and converging technologies be determined and promoted.

Proposed actions

1. Develop guidance on the application of AI in healthcare for health care professionals, with a specific focus on the impact of AI on the doctor-patient relationship.

RATIONALE: As AI systems become more autonomous and have greater applications in the field of healthcare, there is a critical need to establish the role of healthcare professionals in maintaining quality, safety, transparency, and patient trust.

PROPOSED METHOD:

- Establishment of a drafting group comprised of DH-BIO delegates, invited AI experts (from academia and industry), and medical professional bodies, such as WMA and WHO.
- Consultation in relation to a draft guide with national medical representative bodies.
- Publication and dissemination of the guide.

[8] Bergen Report, International Conference on Emerging Technologies and Human Rights, International Conference on the 20th Anniversary of the Oviedo Convention.

2. Examine the practical application of Recommendation CM/Rec(2016)6 of the Committee of Ministers to Member States on research on biological materials of human origin, amongst Council of Europe Member States.

RATIONALE: Biobanks are a critical piece of infrastructure for clinical research. This was recognised in the updated Recommendation CM/Rec(2016)6. Given that the Recommendation is three years old, it could be anticipated that the principles contained therein have now been adopted by those involved in biobanking. Article 24 of the Recommendation provides for a regular re-examination of its provisions.

PROPOSED METHOD:

- Organisation of a workshop with the biobanking community to establish the uptake and relevance of the Recommendation. This could be done in conjunction with T-PD, in light of their guidance on big data.
- Report from workshop to be used as the basis for a decision on if/when the Recommendation should be re-examined.

3. Develop a Common Assessment Framework – a standard approach to assessing the compliance of emerging and/or converging technologies with human rights standards in the field of biomedicine.

RATIONALE: The purpose of such an assessment tool is to ensure that human rights considerations guide the entire process of research, development, and implementation of emerging and/or converging technologies.

PROPOSED METHOD:

- Examination of principles and best practices that are currently used to govern various emerging and converging technologies, and an analysis of common concerns and possible solutions. To be completed by external consultants.
- Establishment of a drafting group to elaborate the framework with extensive external consultation informing the process, this may take various formats e.g. conference.

4. Re-examine Article 13 of the Oviedo Convention in light of developments in gene editing technologies.

RATIONALE: In the DH-BIO statement of December 2015 on gene editing technologies, the Committee committed to examine the ethical and legal challenges raised by genome editing technologies, in the light of the principles laid down in the Oviedo Convention (the only international legally binding instrument governing gene editing). It should be clarified that the proposed action does not pre-suppose a change in Article 13 of the Convention, but rather to re-examine its provisions in the light of current scientific understanding.

PROPOSED METHOD:

- Commission scientific and legal studies to establish the state of the art in the fields of somatic and germline gene editing.
- Further specific actions to be discussed with special rapporteur (Dr. Ingo Haertel).

5. Examine the desirability/feasibility of new human rights in response to advances in the field of neurotechnology, likely to be deployed in the field of biomedicine.

RATIONALE: In the face of developments in the field of neurotechnology, there have been proposals for the development of new human rights, namely cognitive liberty, right to mental privacy, or right to mental integrity and psychological continuity. There is a question of whether the existing human rights framework is sufficient to govern neurotechnologies and if and how it might be developed to address the issues of privacy, personhood, and discrimination.

PROPOSED METHOD:

- Commission a study on: (1) the applicability of the existing human rights standards; (2) the feasibility of developing new human rights to govern the use of neurotechnologies in the field of biomedicine; (3) the usefulness of more flexible forms of good governance in this context. This study will guide future actions.

2. Foster scientific, political, and public discourse to promote democratic governance and transparency in the field of biomedicine.

21. Another overarching theme of the Bergen and the Rathenau Reports and of the International Conference on Emerging Technologies and Human Rights and the International Conference on the 20th Anniversary of the Oviedo Convention was the necessity of public dialogue in the governance of technological developments in the field of biomedicine. In this regard, it was emphasised that, in order to guarantee that the directions of innovation and the ethical challenges raised by technological developments are robustly deliberated, democratic, and legitimate, governance should go hand in hand with a process of societal deliberation, involving expert, political, and public opinions.

22. This proposal reflects Article 28 of the Oviedo Convention, which requires "that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of rele application is made the subject of appropriate consultation." In the same way, the Parliamentary Assembly has in Recommendation 2017 (2013), Recommendation 2115 (2017), and Recommendation 2102 (2017) underlined the need to foster a broad and informed public debate on the medical potential and possible ethical and human rights consequences of the use of new technologies in biomedicine.

23. Many speakers at the International Conference on the 20th Anniversary of the Oviedo Convention called upon the Council of Europe to play a leading role in this respect, by providing for the development of tools for democratic governance, including the promotion of public debate on the ethical issues arising in the biomedical field.

Proposed actions

1. Translate and disseminate the short version of the Guide on Public Debate in non-official languages.

RATIONALE: This Guide is a tool for policy makers to help them engage with the public and aims in particular at raising public awareness, at promoting discussion between different actors, groups, and individuals, including those who are marginalised and disadvantaged, and at facilitating consultation of the public by authorities with a view to making policy decisions. The draft Guide on Public Debate was presented at a seminar on public debate held in June 2019. Translating the Guide in non-official languages and disseminating the Guide will foster initiatives of public debate in Council of Europe Member States, including in countries and regions where public debate currently is less developed.

PROPOSED METHOD:

- Translation and dissemination of the short version of the Guide on Public Engagement in non-official languages.

2. Organise a European public debate on neurotechnologies using citizens panels.

RATIONALE: In recent years there have been a number of developments in the field of neurotechnology which will imminently find their way into clinical practice. It seems timely to organise a public debate on which technologies will be acceptable and how they should be governed. This presents an opportunity for the Guide to be implemented across Council of Europe Member States, in the service of an open and transparent public engagement.

PROPOSED METHOD:

- Organisation of a European-wide debate on neurotechnologies, making use of citizen panels.
- Collaboration with a number of National Ethics Councils and Committees that have extensive experience in promoting public dialogue on bioethics. Additional collaborating partners could be the Organisation for Economic Co-operation and Development and the Nuffield Council on Bioethics, which have recently published reports on neurotechnology and have advocated a public discourse approach to policy making and governance of such technologies.

3. Organise a European debate on the acceptability of gene editing (both somatic and germline).

RATIONALE: In the last three years there have been a plethora of statements/reports on gene editing emanating from various bodies and actors and which have different addressees. However, the need for a wide ranging and inclusive societal debate is common to all documents. The rationale for such dialogue and what forms it should take is less well developed.

PROPOSED METHOD:

- "Trialling" the diverse methodologies discussed in the Guide for Public Engagement, to ensure that the public has an opportunity to steer human rights compliant innovation in this field.

4. Host a workshop for politicians and policy makers on the ethical acceptability and models of governance for gene editing technologies.

RATIONALE: It is critical for politicians and policy makers to understand how and why gene-editing research is being conducted, in order to inform what form of governance gene-editing technologies and their applications should be subject to. There have been calls for a global moratorium on human germline gene editing, the establishment of a global coordinating body, and flexible regulatory frameworks which could adapt to rapid scientific developments in the field. It is not clear which form of governance will work best, or indeed if different forms of governance will be required for somatic and germline gene editing and how to distinguish between therapeutic and enhancement applications of genome editing for the purposes of regulation.

PROPOSED METHOD:

- Organisation of a workshop facilitating an exchange of ideas regarding the most suitable models of governance. This workshop could be organised in conjunction with the WHO, who have recently established a global multi-disciplinary expert panel to investigate the ethical and legal challenges associated with human gene editing.

5. Organise a dialogue on a "social contract" between citizens and governments/private enterprise on genomic data sharing.

RATIONALE: There is widespread recognition that genomic data can lead to important improvements in our understanding of health and in the diagnosis and treatment of disease. Sharing of genetic information is considered critical to advancing that goal. In recognition of the value that individual genomes have in the research endeavour, there have been calls for

reciprocity. The concept of a social contract between patient, public, clinicians, and academics in relation to genomic medicine has gained prominence in this regard.

PROPOSED METHOD:

- Organisation of a number of citizens' dialogues together with clinicians, academics, and industry to discuss in depth the science and issues of genomic medicine in a range of Council of Europe Member States.

Pillar II: EQUITY

24. Since the adoption of the Oviedo Convention, a number of developments in biomedicine and in society have taken place that result in increasing disparities in access to healthcare. For instance, a rapidly increasing number of innovative treatments and healthcare technologies has come onto the market, but because of their price, these are accessible to some, but unavailable to others. This evolution may create or exacerbate divisions in society and the discrimination of already disadvantaged individuals and groups when it comes to healthcare. In a parallel development, broader social and demographic changes are also causing some groups in society to systematically have more difficulties in accessing healthcare. For example, the rapid ageing of populations and increasing migration may result in ever larger segments of the population experiencing discrimination in access to healthcare. This evolution is reinforced by budget cuts in many countries, which, forced by austerity policies that are prompted by the economic crisis, are putting pressure on healthcare systems.

25. During the International Conference on the 20th Anniversary of the Oviedo Convention it was emphasised that, in the light of these technological, social, and demographic changes, the principle of equitable access to healthcare has recently acquired special significance. Confronted with the increasing risk of inequities in access, both to existing healthcare resources and to innovative treatments and new healthcare technologies, the second pillar aims at promoting **Equity**. The right to equitable access to healthcare is enshrined in Article 3 of the Oviedo Convention. The term equitable is used to denote that no unjustified discrimination in healthcare is permitted. More specifically, those with equal healthcare needs should have equal access to healthcare. This requires disadvantaged individuals and groups to be assisted so as to enable equal opportunities to access healthcare. Further, the Explanatory Report to the Convention states that "care must be of a fitting standard in the light of scientific progress and be subject to a continuous quality assessment". Moreover, it is clarified that the purpose of Article 3 is to encourage States to adopt the necessary measures as part of its social policy to ensure equitable access to health care.

26. One of the main conclusions of the Conference was that the principle of equity of access to healthcare needs to be integrated systematically into all health policies and programmes, and that the question of equity of access needs to be part of the discussion around healthcare priorities. More specifically, it was emphasised that measures should be taken to identify, reduce, and ultimately eliminate disparities in access to existing and new treatments and technologies. Within an overall strategy to ensure that healthcare of appropriate quality is accessible for its entire population,

special efforts should be made to improving access of individuals and groups that are disadvantaged and to avoiding that new developments create or aggravate disadvantages. Within this pillar, two strategic objectives have been identified as requiring priority action of the DH-BIO:

1. Promote equitable and timely access to appropriate innovative treatments and technologies in healthcare.

27. Innovative treatments, such as for cancer, multiple sclerosis or very rare medical conditions, are often very expensive and may only be affordable for a small part of the population. Similarly, the advent of new healthcare technologies such as mHealth, telemedicine, and healthcare assistive robots, suggest that the benefits of certain evolutions in healthcare will only be available to those who are well-informed and proficient in the use of modern technology.

28. Technological developments, while holding the prospect of greatly improving health, entail at the same time the risk of deepening inequalities and creating new forms of discrimination and marginalisation. More specifically, technological developments may create healthcare infrastructures that exclude those who do not possess the knowledge, skills, and financial means to use the technology.

29. Council of Europe Member States should be encouraged and supported to adopt and implement measures of inclusion, guaranteeing that new treatments and healthcare technologies are made available in an equitable and timely manner.

Proposed action

1. Develop an ethical framework to ensure just allocation of innovative medicines/interventions.

RATIONALE: An ethical framework, while allowing flexibility at Member State level, would ensure that decisions regarding access to innovative treatments/interventions would take account of fundamental principles such as justice and beneficence and non-maleficence. Moreover, a harmonised framework across Member States would combat inequities between Council of Europe countries.

PROPOSED METHOD:

- Organisation of a survey of Council of Europe Member States to establish how decisions are made regarding how and to whom innovative treatments are made available.
- Organisation of a conference to discuss findings, invite WHO and EU (which both have documents on access to innovative medicines) as well as patient groups, Ministries of Health and private industry to participate.
- Each Member State could commit funds to carry out a public survey in their country to assess the public's attitude to how decisions regarding access to innovative treatments should be made and which principles should form part of the deliberation.
- Establishment of a drafting group to draft the ethical framework.

2. Combat health disparities created by social and demographic changes in Council of Europe Member States.

30. During the International Conference on the 20th Anniversary of the Oviedo Convention the question of equity in access to healthcare by disadvantaged groups was identified as a significant problem. More specifically, the issue of equitable access to healthcare for older persons and especially for migrants was considered an enduring challenge for Council of Europe Member States. In this regard, it was noted that older persons generally receive less screening and

preventative care, are excluded from many clinical trials that could be relevant for their age group, and frequently receive poorer treatment as a result of age-based rationing and priority-setting in healthcare. Similarly, since the ability of individuals to access healthcare may depend on their visa or residence status, some migrants may find it very difficult or even impossible to receive the healthcare they need.

31. Consequently, several participants in the Conference expressed real concern that existing healthcare resources are becoming less accessible to some patient populations because of their particular social circumstances. The scope and urgency of this issue is also illustrated in Resolution 1946 (2013), where the Parliamentary Assembly recalled that the right to health is a fundamental right and observed that inequalities in access to health care are growing in the Council of Europe Member States, particularly affecting vulnerable groups, including older persons, migrants, and refugees. In this regard, the Parliamentary Assembly pointed out the importance of continuing to protect the right to health enshrined in Article 11 of the European Social Charter.

32. Considering that many Council of Europe Member States are looking into reforming their healthcare systems as a result of austerity and demographic changes, one of the main goals identified during the Conference was to ensure that human rights and the principle of equitable access are incorporated in programs of health reform, with particular attention to the protection of migrants and older persons.

Proposed actions

1. Commission a study if/how equitable access to healthcare is being embedded in health reform programmes/policies in Council of Europe Member States

RATIONALE: Many Council of Europe Member States are currently undergoing health reform. The specific focus of many of these reforms is to curb cost expenditure and re-orient services to be cost-effective. This is a legitimate aim and may well ensure a more just allocation of health services. It is important, however, that States do not lose sight of their obligations under international law to adopt a human rights-based approach to health.

PROPOSED METHOD:

- Commission a study to examine if and how human rights concerns are being considered as part of a country's health reform process.
- Preparation of a report detailing best practices on how human rights are being embedded in Health reform programmes
- Organisation of a series of workshops involving policy makers/politicians to share best practice. WHO could be considered as a potential partner in this action.

2. Draft a Recommendation on access of migrants to healthcare.

RATIONALE: The question of migrants and access to healthcare has been widely discussed by a number of bodies both within and outside the Council of Europe. DH-BIO should not duplicate actions already undertaken by other bodies. Thus, it is proposed to harness the rich set of resources already available in order to draft a Recommendation which will have the effect of setting minimum standards to be achieved in all Council of Europe Member States.

PROPOSED METHOD:

- Establishment of a drafting group to elaborate the Recommendation.
- In elaborating such a Recommendation, DH-BIO would collaborate closely with CDDH and UNESCO given their current programme of work dedicated to protection of migrant's human rights.

3. Develop a Guide detailing strategies to improve participation of older persons in clinical trials, with a special focus on the issue of consent.

RATIONALE: It has been documented that older persons are systematically excluded from participation in clinical trials. This is problematic as the drugs that are being used in older persons have not been properly evaluated, and they are less likely to access innovative treatments. There are a number of factors that tended to mitigate against inclusion of older persons in clinical trials, with concerns about the consent procedure being foremost amongst them. Inclusion of older persons in clinical trials should be promoted and their discrimination prevented.

PROPOSED METHOD:

- Establishment of a drafting group to draft a guide on models of consent/consent procedures for older persons participating in clinical trials. This work could be done in collaboration with WHO and the European Medicines Agency, both of whom have done work in this area.

4. Commission a study to provide an overview of the impact of digital technologies on meeting the health needs of older persons.

RATIONALE: Digital technologies hold great potential to improve and advance home-based integrated care for older persons living with multiple chronic health issues. There is a fine line between technology that promotes independence and technology that threatens individual freedom. It is vital that technologies serve the health needs of older persons, as defined by that group and that technologies will be made available to this cohort of the population. There is a need for debate and research to ensure that human rights such as autonomy, informed consent, privacy, and data protection are protected.

PROPOSED METHOD:

- Commission an overview of advanced digital technologies in health and an analysis of their impact on older persons. This overview can inform future actions.

Pillar III: INTEGRITY

33. Since the adoption of the Oviedo Convention, several technological developments have taken place that are predicted to raise unprecedented challenges for the physical and the mental integrity of the individual. For instance, developments in neurotechnologies, such as deep brain stimulation, brain-computer interfaces, and artificial neural networks, raise the prospect of increased understanding, monitoring, and control of the human mind. Similarly, developments in nanotechnology offer new options for intervention in the body based on nano-scale medicines and diagnostic devices, opening new possibilities for permanent health monitoring. As indicated in the Bergen and Rathenau Reports, these developments are part of a broader engineering approach aimed at permanently improving the human body and mind. This approach results in the introduction of more and new types of technologies within our bodies and brains. During the International Conference on Emerging Technologies and Human Rights and the International Conference on the 20th Anniversary of the Oviedo Convention it was emphasised that these developments would involve new possibilities for intervention in individual behaviour, raising novel questions relating to autonomy, privacy, and even freedom of thought.

34. The Bergen and Rathenau Reports also indicate that, as a result of emerging and converging technologies, the engineering approach is equally extending to biological processes. Examples of this evolution are biopharmaceuticals and bio-engineered stem cells, tissues, and organs, which may hold considerable promise for the treatment of various diseases. In this respect, the most significant ethical issues in the field of bio-engineering are raised by developments in genetics and genomics.

35. Issues with regard to the physical and the mental integrity of the individual also result from the evolution of existing practices. For instance, samples, genomic data, and associated health-related data from persons participating in biomedical research are increasingly being stored and shared. However, genomic data may be stored and used indefinitely, may change in relevance over time, may reveal information about family members, and do not allow complete and permanent de-identification. That this development may give rise to important ethical concerns, particularly with regard to the autonomy and the privacy of the persons concerned, was emphasised in the Bergen and the Rathenau Reports and at the International Conference on Emerging Technologies and Human Rights and the International Conference on the 20th Anniversary of the Oviedo Convention.

36. Another important evolution of existing practices involves changing perceptions of how protection and respect for autonomy should be balanced when it comes to children, persons with mental health difficulties, and vulnerable older persons. For instance, the United Nations (UN) Convention on the Rights of Persons with Disabilities (CRPD) represents a paradigm shift from a biomedical model of disability to a human rights-based model. The CRPD can be seen in recent years to have affected the development of mental health law, as evidenced by new vocabularies and principles being advanced in specific mental health legislative reform, and in debates about repealing mental health law and the abolition of involuntary detention measures for those with psychosocial disabilities. Similarly, the UN Convention on the Rights of the Child guarantees the right of children to participate effectively in decision-making affecting them. As highlighted in [the Uppsala and the Leiden Study,] two studies on the rights of children in biomedicine commissioned by the DH-BIO, current legal standards in the field of biomedicine do not always fully recognise the right of children to be effectively involved in decision-making about interventions affecting them. More generally, it was indicated during the 20th Anniversary of the Oviedo Convention, that as a result of changing perceptions, more emphasis would need to be put on the functional capacities of children, persons with mental health difficulties, and vulnerable older persons, instead of on their legal status, when decisions are made about interventions affecting them.

37. In the light of these developments, the third pillar concerns **Integrity**. Guaranteeing respect for everyone's integrity in the sphere of biomedicine is defined in Article 1 of the Oviedo Convention as one of the Convention's central aims. In the biomedical field, integrity is understood as the ability of individuals to control what happens to them, including with regard to their body, their mental states, and their physical and mental data. Therefore, it will be essential to identify and address challenges for the physical and the mental integrity of the individual, raised by emerging and converging technologies, and by the evolution of existing practices. Within this pillar, three strategic objectives have been identified:

1. Strengthen children's participation in the decision-making process on matters regarding their health.

38. Changes in the public and policy perception of the autonomy and the protection of children indicate a need to recognise the evolving nature of their capacity to participate in decision-making that involves them. This evolution was confirmed and endorsed by human rights instruments such as the UN Convention on the Rights of the Child. However, considerable uncertainty still exists as to how this change of emphasis needs to be reflected when it comes to interventions in the biomedical sphere. Finding the right balance between autonomy and protection is especially challenging since the rights of children are situated within a larger set of parental rights and responsibilities which also need to be taken into account.

39. The need to define an appropriate way to guarantee respect for the physical and mental integrity of children is also identified with regard to particular children, including inter-sex children and children diagnosed with serious physiological and psychological health needs.

Proposed actions

1. Develop a guide for healthcare professionals on children's participation in the decision-making process in the biomedical field

RATIONALE: Healthcare professionals are often concerned with securing the consent of the legal guardian of the child prior to any clinical/research intervention. It should be clear that this Guide will not focus on matters of legal representation, but instead will focus on modalities of ensuring the child's voice in heard in decisions relating to their healthcare. The target audience for the Guide would be healthcare professionals, but it should be drafted in a way to be accessible to parents/guardians.

PROPOSED METHOD:

- Establishment of a drafting group in cooperation with CAHENF, which could include experts designated by other intergovernmental organisation (e.g. UN Committee on the Rights of the Child).

2. Map relevant national legislation and practices in Council of Europe Member States regarding the decision-making process concerning children in the biomedical field.

RATIONALE: In the report commissioned by the DH-BIO on children's rights and biomedicine and authored by Prof Liefaard and others, an informational gap was identified and a recommendation made to map the current practices regarding the modalities for children's inclusion in their medical decision making.

PROPOSED METHOD:

- Development and circulation of a questionnaire to all Council of Europe Member States in order to map current practices regarding decision making of children in the healthcare context. This questionnaire could be supplemented with an academic legal review of current practices amongst Member States. This is considered an important building block in order to inform future actions (which may extend beyond the five-year strategic plan)

3. Organise a seminar on children's participation in the decision-making process in the biomedical field.

RATIONALE: A seminar could facilitate information exchange on children's participation in decisions affecting their healthcare and could also serve as a platform for exchange of best practice and provide useful indications for future work for DH-BIO in this area.

PROPOSED METHOD:

- Organisation of a seminar on children's participation in the decision-making process in the biomedical field. This could be a standalone item or could be envisaged as a support action in achieving actions 1 and 2. This seminar could be organised in collaboration with CAHENF.

4. Develop an information leaflet for family members, legal representatives, and carers on ways to support children faced with decisions concerning their health.

RATIONALE: The development of information leaflets is directed towards raising awareness and providing strategies for family members, to ensure that the child's voice is heard in decisions regarding their healthcare.

PROPOSED METHOD:

- Development of information leaflets. This could be a standalone item or could be envisaged as a complementary activity to action 1. For example, following the completion of a Guide, information leaflets could be developed.

2. Safeguard children's rights in relation to medical practices which have future/long term implications for the child(ren).

40. Every individual child is a rights holder in his or her own capacity as recognised in Article 14 of the Convention on the Rights of the Child. The child's autonomy can be conceptualised as, what Feinberg coined, "the child's right to an open future," meaning a right to have one's future options kept open until one is capable of making one's own decisions. The content of the right to an open future therefore includes restrictions on what parents (and others) are allowed to do to children, and, on some interpretations, tells us with what parents (and others) ought to provide children. Recent developments in reproductive and genetic technologies, ranging from pre-natal testing, genetic testing of minors, and treatment interventions for intersex children all challenge the future autonomy of children. These developments raise questions of what parents and others should be permitted to know in terms of health information which could directly impact on the future of the child. Moreover, in light of such developments there are challenges regarding the most appropriate interventions which parents/others should be allowed to take in order to safeguard the health of the child.

Proposed actions

1. Commission a study on the relevance of the Oviedo Convention and its Additional Protocols for the protection of children's rights, in view of developments in genetic testing.

RATIONALE: One of the conclusions drawn from the 20th anniversary conference was that rather than elaborating new legal instruments, future work of the DH-BIO should be focussed on the application of already existing instruments to new fields of study. This may require that provisions in the Convention itself and/or in the Additional Protocols are clarified in explanatory texts to demonstrate their relevance to new developments, such as those in genetic testing.

PROPOSED METHOD:

- The special rapporteur for genetics and genomics, in conjunction with the Secretariat and Bureau, defines the scope of the study and prepares a tender document.
- Commission the study with a particular emphasis on a child's right to autonomy, bodily integrity, and privacy. This work would provide a basis to identify further actions.

2. Organise a seminar on relevant legislation and good practices with regard to early intervention on intersex children.

RATIONALE: In 2017, PACE adopted a specific Resolution on the human rights of intersex people. The resolution calls for "medically unnecessary, sex-normalising surgery" on intersex babies to be prohibited, along with other treatments practiced on intersex children and young people without their informed consent. The seminar would focus on how the Resolution can be upheld in practice, by identifying good practices in this area.

PROPOSED METHOD:

- Establishment of an organising committee which could include representatives of CAHENF, HR Commissioner, and SOGI Unit.
- Publication of a report based on the learnings from the conference to be disseminated widely

3. Develop a Recommendation for the protection of the rights of intersex children with regard to early physical intervention.

RATIONALE: Drafting a Recommendation would build on previous extensive work completed by the Council of Europe in the area of inter-sex children. The Recommendation would be a legal instrument with specific reference to clinical interventions in inter-sex children.

PROPOSED METHOD:

- Establishment of a drafting group, with representation from CAHENF and SOGI Unit. It is envisaged that the seminar (action 2) would support the development of a Recommendation.

3. Safeguard the mental integrity of the individual in light of the evolution in our understanding of mental health and with regard to developments in neurotechnology.

41. This strategic objective aims at safeguarding the mental integrity of the individual with regard to new developments in biomedicine. Neurotechnology is increasingly finding applications with the field of biomedicine. There are currently a multitude of neural prostheses available or in development. In most cases they are intended to cure or improve the condition of patients affected by some cerebral deficiency. In other cases, their goal is to provide new means to maintain or improve an individual's normal performance. In both cases, a risk exists of violating the mental integrity of the individual.

42. With issues relating to mental health expected to be among the biggest challenges facing our health systems in the future, it is essential to ensure that better mental health can be promoted and that discrimination of persons with mental health difficulties can be prevented. DH-BIO has undertaken work on the protection of the human rights and dignity of persons with regard to involuntary measures, in the context of a draft additional protocol to the Convention on Biomedicine. It is recognised that involuntary measures are exceptional and used as a last resort in the absence of alternatives. Mindful of the comments of the Commissioner for Human Rights in his comments on the draft additional protocol, there is a need for information exchange and sharing of best practices on alternative measures to involuntary detention.

Proposed actions

1. Commission a study examining the availability of effective systems of community-based care which diminish the need for involuntary placement of persons experiencing mental health difficulties

RATIONALE: In response to submissions received from INGO's, other Council of Europe Committees, PACE, and the Commissioner for Human Rights, it was agreed at the November plenary meeting of the DH-BIO to commission a study to look at the existence and the effectiveness of community-based alternatives to involuntary detention.

PROPOSED METHOD:

- Commission a study examining the availability of effective systems of community-based care. The scope of study is to be defined in cooperation with INGOs, HR Commissioner, FRA, European Commission. This study would inform the work of DH-BIO in relation to the relevant provisions of the draft Additional Protocol concerning the protection of human rights and dignity of persons with mental disorder with regard to involuntary placement and involuntary treatment.
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2. Identify the ethical issues raised by the applications of neurotechnologies in the biomedical field.

RATIONALE: While much has been written about the ethics of neurotechnologies, their specific application in the field of biomedicine and the ethical issues arising has been less well explored,

PROPOSED METHOD:
Commission a study to prepare an "inventory" of recent advances in the field of neurotechnology such as neurostimulation, with a particular focus on how such technologies impact on human rights and the ethical principle of autonomy. This work could inform a decision regarding the necessity for a Recommendation or Additional Protocol concerning neurotechnologies.

Transversal pillar IV: CO-OPERATION AND COMMUNICATION

43. Since many of the challenges raised by new biomedical developments extend beyond national borders and beyond bioethics, effective and efficient co-operation of the DH-BIO with other bodies is a critical aspect of the SAP. At a time of fiscal challenge such as the present, it is useful to think more strategically about collaboration. Collaboration provides an opportunity to share knowledge, experience, and skills, and allows for the pursuit of mutual interests and the realisation of common goals in cost effective and innovative ways, while ensuring there is no duplication of effort. Co-operation concerns both normative and methodological aspects, i.e. how and on what the DH-BIO will cooperate with other actors in the field.

44. In addition, it is important that these actions are widely communicated to stakeholders and gain public visibility. It is essential that the DH-BIO develops effective dissemination strategies to ensure that its outputs are accessible to a wide range of different relevant stakeholders and to inform/influence public policy. Effective dissemination of the Committee's work will not only contribute to greater accountability for the Committee, but also facilitate an increased understanding of the contribution of the Committee to protecting human rights in the field of biomedicine.

45. Within this pillar, two strategic objectives have been identified. Effective collaboration and communication are inherently valuable, but is also a prerequisite to achieving the strategic objectives in the three other pillars of the SAP. Thus, it is conceived of as a transversal pillar of the SAP.

1. Develop long-term strategic cooperation with Council of Europe Committees and other intergovernmental bodies working in the field of bioethics.

Proposed actions

1. Develop a strategy setting out how the DH-BIO can most effectively co-operate with, and provide requested feedback to, interlocutors both within and outside of the Council of Europe.

RATIONALE: It is vital that the limited resources of the DH-BIO (both in terms of personnel and budget) be deployed to maximise efficiency and to ensure that the Committee is making a unique contribution to the challenge it is presented with. The Committee receives a number of requests to comment on initiatives from other bodies and there should be a way to prioritise such requests. Moreover, there needs to be a consideration of how to achieve objectives shared by other actors in the field of bioethics.

PROPOSED METHOD:

- Establishment of a drafting group to draft a strategy for cooperation that sets out several ways in which the DH-BIO can strengthen its collaboration with other relevant actors both in and outside the field of bioethics.
- Elaboration of this strategy in close collaboration with these interlocutors. The appointment of an external expert consultant with experience in strategic cooperation should be considered.

2. Co-operation with national training institutions to roll out the HELP course on bioethics to healthcare professionals.

RATIONALE: The European Programme for Human Rights Education for Legal Professionals (HELP) supports the Council of Europe Member States in implementing the European Convention on Human Rights at the national level. Courses are directed at enhancing the capacity of judges, lawyers, and prosecutors in all 47 Member States to apply the European Convention on Human Rights in their daily work. The HELP course on Bioethics offers the ideal opportunity to extend high-quality training to healthcare professionals.

PROPOSED METHOD:

- Issue an invitation to all Member States (via legal and medical training bodies/institutions) to organise the roll out of the HELP course on Bioethics to a restricted number of tests sites.
- Organisation of a training of the trainer session.
- Roll out HELP course on Bioethics to a small number of test sites for a multi-disciplinary audience of lawyers and healthcare professionals.

2. Ensure the communication and dissemination of the outputs of the DH-BIO to internal and external stakeholders to maximise their uptake and utility.

Proposed actions

1. Survey Council of Europe Member States to establish the reasons/rationale for non-ratification of the Oviedo Convention and its Additional Protocols.

RATIONALE: One of the conclusions of the 20th Anniversary Conference was rather than elaborating new instruments, the focus should be on consolidating and applying existing legal instruments in the field of biomedicine. In recent years the DH-BIO has expended significant efforts in drafting a series of Additional Protocols to the Oviedo Convention and yet the number of ratifications of some Protocols remains rather low. Moreover, ratification of the Convention itself seems to have plateaued. In order to ensure that the Convention and its Additional Protocols remain relevant it is important to understand the reasons for non-ratification.

PROPOSED METHOD:

- Appointment of a special rapporteur to draft a survey to be circulated to Governments of Member States to establish reasons/obstacles for ratification of the Convention/Additional Protocols. In parallel the survey should also be circulated to reference persons/academics in each State to get their view on the reasons for non-ratification of their countries.
- Drafting of a report by the special rapporteur in conjunction with the Secretariat, providing an analysis of survey responses and recommendations for further actions if appropriate.

2. Establishment of a DH-BIO Youth Forum.

RATIONALE: A Youth Forum is being suggested as a way to bring the voice of European youth into bioethics discussions at the Council of Europe. This should serve to empower young people to participate actively in society by representing and advocating their needs and interest and those of other young people. Moreover, it will provide the DH-BIO with valuable insights from younger persons to inform its work.

PROPOSED METHOD:

- Ask Member States to identify and fund (through an agreed mechanism, e.g. competition) two delegates (third level students from a variety of relevant disciplines to ensure a multidisciplinary perspective) to attend a plenary session where delegates will sit in plenary in parallel to DH-BIO and will discuss an issue under consideration by the Committee. It is proposed that there would be one day of expert presentations to delegates, while a second day would involve guided deliberations by delegates. On the third (half day), the Youth Forum would prepare and present a statement to be submitted to DH-BIO for consideration. Each Council of Europe Member State would be asked to fund travel expenses of delegates (plus some central support).

3. Online publication of a bi-annual newsletter reporting the latest bioethical developments in Council of Europe Member States.

RATIONALE: The purpose of such a digital newsletter is two-fold. Firstly, it would serve as a valuable platform for information to be shared between Member States and could prompt valuable connections to be made between States with similar interests. Secondly, it would serve as a valuable means of communicating and promoting the work of the DH-BIO to relevant third parties.

PROPOSED METHOD:

- Submission of current developments in the field of bioethics by Member States on a bi-annual basis.
- Review of media, official reports to be completed by the Secretariat on a rolling basis; newsletter compiled by the Secretariat.
- Dissemination of the newsletter to Member States, permanent representatives, the PACE, other interested parties as well as posting it on the website of the DH-BIO, which may encourage increasing traffic to the site.

Appendix I

Members of the Drafting Group – Meetings and consultations

Composition of the Drafting Group:

- Chair
  - Dr Siobhan O'Sullivan, 20th anniversary Conference general rapporteur
- Conference rapporteurs
  - Ms Isabelle Erny (France)
  - Ms Anne Forus (Norway)
  - Ms Tina Garanis-Papadatos (Greece)
  - Prof. Stefano Semplici (Italy)
  - Prof. Constantinos Phellas (Cyprus)
- Chair of the Conference preparatory Group:
  - Prof. Zvonko Magic (Serbia),
- Bureau member :
  - Prof. Givi Javashvili (Georgia) – Step down at the end of 2018 when his terms in the Bureau ended
- Mr Mark Bale (United Kingdom), starting in 2019

- Prof. Kristof Van Assche (Belgium), consultant for the Secretariat

Meetings of the Drafting Group

First meeting of the DG: Joint session at the DH-BIO Bureau meeting 16 March 2018
Second meeting of the DG: 29 – 30 January 2019
Third meeting of the DG: 7-8 March 2019

Consultations

Other COE bodies participating in the work of the DH-BIO:
Conference of INGOs, Human Rights Commissioner, PACE

Other CoE committees (informal exchanges at the level of the Secretariat)

- Ad Hoc Committee on the Rights of the Child (CAHENF)
- Consultative committee of the Convention for the protection of individuals with regard to the automatic processing of personal data (T-PD)

Other CoE Secretariat (**informal exchanges)**

- Sexual Orientation and Gender Identity Unit
- Secretariat of the PACE Committee
  - on culture science, education and media
  - on social affairs, health and sustainable development

Other intergovernmental organisations with which exchanges have taken place at the level of the Secretariat

- UNESCO, WHO, European Commission (EGE), OECD and other members of the UN interagency Committee on Bioethics (18th meeting – 21-22 February 2019, Strasbourg)

Appendix II – Summary of the actions proposed

Pillar I: GOVERNANCE	Pillar II: EQUITY	Pillar III: INTEGRITY
1. Embed ethical values and human rights in emerging and converging technologies which have an application in the field of biomedicine 1. Develop guidance on the application of Artificial Intelligence (AI) in healthcare for health care professionals, with a specific focus on the impact of AI on the doctor-patient relationship. 2. Examine the practical application of Recommendation CM/Rec (2016)6 of the Committee of Ministers to member States on research on biological materials of human origin, amongst Council of Europe member States. 3. Develop a Common Assessment Framework – a standard approach to assessing the compliance of emerging and/or converging technologies with human rights standards in the field of biomedicine. 4. Re-examine Article 13 of the Convention on Human Rights and Biomedicine in light of developments in gene editing technologies. 5. Examine the desirability/feasibility of new human rights in response to advances in the field of neurotechnology, likely to be deployed in the field of biomedicine.	**1. Promote equitable and timely access to appropriate innovative treatments and technologies in healthcare** 1. Develop an ethical framework to ensure just allocation of innovative medicines/interventions **2. Combat health disparities created by social and demographic changes in Council of Europe member States** 1. Commission a study to examine if/how equitable access to healthcare is being embedded in health reform programmes/policies in Council of Europe member States. 2. Draft a Recommendation on access of migrants to healthcare. 3. Develop a Guide detailing strategies to improve participation of older people in clinical trials, with a special focus on the issue of consent. 4. Commission a study to provide an overview of the impact of digital technologies on meeting the health needs of older persons.	**1. Strengthen children's participation in the decision-making process on matters regarding their health**. 1. Develop a guide for healthcare professionals on children's participation in the decision-making process in the biomedical field. 2. Map relevant national legislation and practices in Council of Europe member States regarding the decision-making process concerning children in the biomedical field. 3. Organise a seminar on children's participation in the decision-making process in the biomedical field, in cooperation with CAHENF 4. Develop an information leaflet for family members, legal representatives, and carers on ways to support children faced with decisions concerning their health. **2. Safeguard children's rights in relation to medical practices which have future/long term implications for the child(ren).** 1. Study on the relevance of the Convention on Human Rights and Biomedicine and its Additional Protocols for the protection of children's rights, in view of developments in genetic testing 2. Organise a seminar on relevant legislation and good practices with regard to early intervention on intersex children.

2. Foster scientific, political, and public discourse to promote democratic governance and transparency in the field of biomedicine. 1. Translate and disseminate the short version of the Guide on Public Engagement in non-official languages. 2. Organise a European public debate on neurotechnologies using citizens panels. 3. Organise a European debate on the acceptability of gene editing (both somatic and germline). 4. Host a workshop for politicians and policy makers on the ethical acceptability and models of governance for gene editing technologies. 5. Organise a dialogue on a "social contract" between citizens and governments/private enterprise on genomic data sharing.		3. Develop a Recommendation for the protection of the rights of intersex children with regard to early physical intervention. **3. Safeguard the mental integrity of the individual in light of the evolution in our understanding of mental health and with regard to developments in neurotechnology.** 1. Commission a study examining the availability of effective systems of community-based care which diminish the need for involuntary detention of persons experiencing mental health difficulties. 2. Identify ethical issues raised by the applications of neurotechnologies in the biomedical field.

Transversal pillar IV: CO-OPERATION AND COMMUNICATION

1. Develop long-term strategic cooperation with Council of Europe Committees and other intergovernmental bodies working in the field of bioethics.

1. Establish a drafting group to develop a strategy setting out how the Committee on Bioethics can most effectively co-operate with and provide requested feedback to interlocutors both within and outside of the Council of Europe

2. Co-operation with national training institutions to roll out the HELP course on bioethics to healthcare professionals.

2. Ensure the communication and dissemination of the outputs of the Committee on Bioethics to internal and external stakeholders to maximise their uptake and utility

1. Survey Council of Europe member States to establish the reasons/rationale for non-ratification of the Convention on Human Rights and Biomedicine and its Additional Protocols

3. Translation of and adaptation to the national legal order of the HELP course focusing on human rights in biomedicine in an expanded number of Council of Europe member State

4. Establishment of a DH-BIO Youth Forum.

5. Online publication of a bi-annual newsletter reporting the latest bioethical developments in Council of Europe member States.