
1367th meeting, 12 February 2020

4 Human rights

4.2 Committee on Bioethics (DH-BIO)

Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025)

Item to be considered by the GR-H at its meeting on 4 February 2020

Note from the Secretariat

The Committee on Bioethics (DH-BIO) has been instructed by the Committee of Ministers to finalise a Strategic Action Plan on human rights and technologies, on the basis of the results of the international conference organised on the occasion of the 20th anniversary of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention) (24-25 October 2017).²

At its 16th plenary meeting (Strasbourg, 19-21 November 2019), the DH-BIO adopted this Strategic Action Plan on Human rights and technologies in biomedicine (2020-2025), which aims to address priority human rights issues raised by technological developments (such as those in the field of genetics and genomics; brain technologies and artificial intelligence), as well as by changing practices in the field of health care (such as those concerning vulnerable older persons, children and people with mental health problems). It also agreed to organise a conference to launch the Strategic Action Plan on 2 June 2020 at its 17th plenary meeting (2-5 June 2020). The report of the DH-BIO meeting is available on the Committee's website: <https://www.coe.int/en/web/bioethics/abridged-reports>

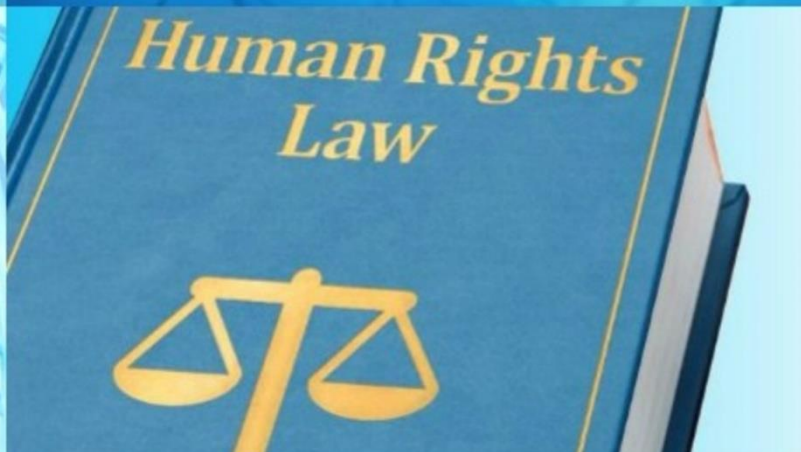
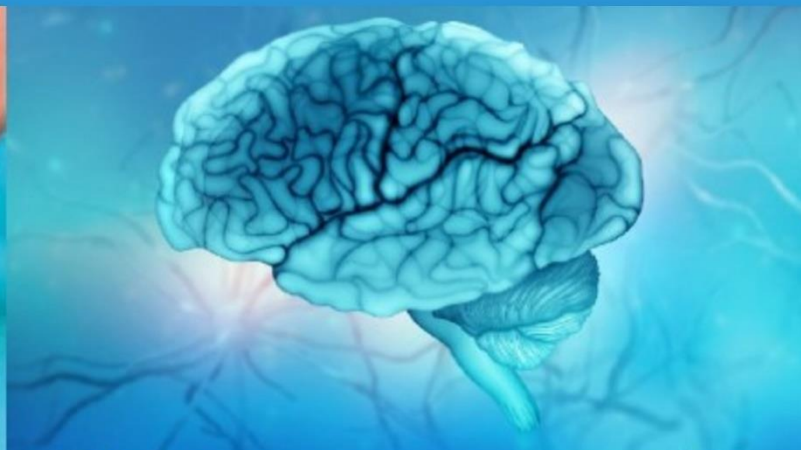
The Strategic Action Plan was presented to the Steering Committee for Human Rights (CDDH) at its 92nd plenary meeting (Strasbourg, 26-29 November 2019). The CDDH took note of it and welcomed the work carried out by the DH-BIO. It expressed its support for the Strategic Action Plan on Human Rights and Biomedicine Technologies (2020-2025) and the actions planned within this framework.

The Committee of Ministers is invited to welcome the adoption of the Strategic Action Plan and to invite the DH-BIO to inform it of the progress with its implementation.

¹ This document has been classified restricted until examination by the Committee of Ministers.

² DH-BIO terms of reference 2018-2019, specific task (ii).

Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025)



Adopted by the Committee on Bioethics (DH-BIO)
at its 16th meeting (19-21 November 2019)

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

TABLE OF CONTENTS

INTRODUCTION.....	3
Vision and approach of the Strategic Action Plan.....	4
GOVERNANCE OF TECHNOLOGIES.....	6
Embedding human rights in the development of technologies which have an application in the field of biomedicine.....	6
Fostering public dialogue to promote democratic governance and transparency in the field of biomedicine.....	7
EQUITY IN HEALTHCARE	9
Promoting equitable and timely access to appropriate innovative treatments and technologies in healthcare.....	9
Combating health disparities created by social and demographic changes in Council of Europe member States.	10
PHYSICAL AND MENTAL INTEGRITY	11
Strengthening children’s participation in the decision-making process on matters regarding their health.....	11
Safeguarding children’s rights in relation to medical practices which have future or long-term implications for them.	12
Safeguarding the rights of persons with mental health difficulties.....	12
CO-OPERATION AND COMMUNICATION	14
Developing long-term strategic co-operation with Council of Europe committees and other intergovernmental bodies working in the field of bioethics.....	14
Ensuring the communication and dissemination of the outputs of the Committee on Bioethics to internal and external stakeholders in order to maximise their uptake and utility.....	15
IMPLEMENTATION.....	17
LIST OF SOURCES.....	19

INTRODUCTION

1. We are now at a turning point in human rights in biomedicine. This became evident during the International Conference that was held in Strasbourg on 24-25 October 2017 on the occasion of the 20th anniversary of the Convention on Human Rights and Biomedicine (Oviedo Convention), the only international legally binding instrument exclusively concerned with human rights in biomedicine. The Conference concluded that the principles enshrined in the Oviedo Convention remain of crucial relevance and that, in the 20 years since the Convention came into force, important new human rights challenges have emerged that need to be addressed.

2. Bioethics is often construed as a “culture of limits”. However, its role should be to accompany progress in science and to reflect on and to protect and promote human 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 the broader society. Human rights challenges are posed by scientific and technological developments as well as by the evolution of established practices in the biomedical field.

3. New technologies are emerging, for instance in the field of genetics, and some technologies, such as those involving artificial intelligence and big data, are being combined to produce new applications. 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 they offer significant opportunities within and beyond the field of biomedicine, they also raise new ethical challenges related to inter alia identity, autonomy, privacy, and non-discrimination. The Committee on Bioethics has been discussing these emerging and converging technologies for some time and has developed considerable expertise in addressing the human rights challenges posed by them.

4. Important human rights challenges are also emerging through established practices in the field of biomedicine. Changes in the perception of the decision-making capacity in children, persons with mental health difficulties, and vulnerable older persons, are prompting 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, are resulting in new or increasing barriers to accessing healthcare services. At the same time, there is unprecedented scientific progress, which results in innovative therapies that are not always available or affordable to disadvantaged individuals and groups. This development indicates that, in addition to the traditional focus on patient’s rights, there is a need to guarantee equitable access to healthcare.

5. The Council of Europe is uniquely placed to address these developments through its Committee on Bioethics with regard to the Oviedo Convention, and has an important role in being a forum for continuous reflection and discussion to root the answers to new ethical challenges in human rights and shared European values.

Vision and approach of the Strategic Action Plan

The vision and approach of the Strategic Action Plan are to protect human dignity and the human rights and fundamental freedoms of the individual with regard to the application of biology and medicine. The Strategic Action Plan puts particular emphasis on addressing the challenges posed by new technological developments and by the evolution of established practices in the field of biomedicine.

6. In January 2018, a drafting group was established to elaborate the Strategic Action Plan. A number of drafting group meetings were held, the fruits of which were presented and discussed during plenary meetings of the Committee on Bioethics, notably in June and November 2018 and in June 2019. The feedback received from member States' delegations was incorporated in the Strategic Action Plan. To ensure synergy with others, information was provided to, and exchanges held with, a number of Council of Europe committees. There were also exchanges with a number of intergovernmental bodies as a means of developing long-term strategic co-operation. The Strategic Action Plan was adopted by the Committee on Bioethics at its 16th meeting in Strasbourg on 19-21 November 2019.

7. The Strategic Action Plan was developed by the Committee on Bioethics based on a number of preparatory studies, replies to questionnaires, and the findings of international conferences. The Strategic Action Plan also considers the work that has been done or that is currently under way in other Council of Europe committees and other intergovernmental organisations.

8. The Strategic Action Plan 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 of technologies; equity in healthcare; and physical and mental integrity. The fourth pillar is transversal and concerns co-operation and communication. These pillars contain strategic objectives and actions.

9. Priority actions for the 2020-2025 reference period 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 opportunities to pool resources and increase impact through co-operation with the other committees of the Council of Europe and/or with other intergovernmental organisations. The range of activities has also been balanced to ensure that due attention is given to building on previous work by the Committee on Bioethics and to the implementation of previously elaborated tools.

10. The proposed actions take into account complementarity and co-operation with internal and external key partners. Several issues identified as posing important human rights challenges in the field of biomedicine, such as migrant health, have not been included because they are already being comprehensively addressed by other bodies. Further, it should be noted that various actions should be considered as building blocks for future work to be extended beyond the lifetime of the current Plan.

11. The timeline introduced at the end of the Strategic Action Plan outlines the expected year of delivery of the outcomes of the actions. In realising a specific action, the Committee on Bioethics intends to initiate work well in advance of the expected

year of delivery and a number of modalities will be determined, including the establishment of drafting groups, the commissioning of expert reports, and the organisation of seminars.

Structure and specific objectives of the Strategic Action Plan



GOVERNANCE OF TECHNOLOGIES

12. Research and innovation are particularly difficult to govern because they create novelty and surprise. Rolling out technology into society is a complex and unpredictable process. The full extent of the risks and unintended consequences of a given innovation can only be fully appreciated with experience, and by that time, control and change can be difficult, if not impossible, as the technology becomes embedded in social infrastructures or human culture. The ways in which technology is steered and controlled have significantly changed. Whereas before technology was governed mainly by national governments that adopted regulations to protect the rights and freedoms of citizens, new technologies are now governed in more heterogeneous and flexible ways by a variety of stakeholders, arguably with less focus on the protection of human rights.

13. Governance frameworks are necessary to optimise the chances of stimulating innovation that contributes to human flourishing, whilst minimising applications that have negative consequences for individuals and society. Therefore, the first pillar of the Strategic Action Plan addresses the governance of technologies, emphasising that it is necessary to change the way in which technologies with an application in biomedicine are governed. Governance models are required to guarantee that the protection of human rights is a guiding consideration throughout the entire process of research, development, and application. In addition, ongoing dialogue between the public, scientists, and policy makers should be ensured so that technological developments are robustly deliberated, democratic, and legitimate.

Embedding human rights in the development of technologies which have an application in the field of biomedicine.

14. Technological innovation often creates its own dynamic. Major technological breakthroughs in fields such as artificial intelligence, genome editing, and neurotechnology have the potential to advance biomedicine and healthcare. However, uncertainty exists about the impact and direction of these developments. For example, artificial intelligence is increasingly proficient in diagnostics but depends on massive amounts of patient data which may impact on transparency and patient trust, thereby necessitating the provision of guidance for healthcare professionals. Genome editing techniques which introduce inheritable changes in the human genome raise serious concerns about the possibilities of irreversible harm to future persons. Developments in neurotechnologies, such as deep brain stimulation, brain-computer interfaces, and artificial neural networks, raise the prospect of increased understanding, monitoring, but also of control of the human brain, raising issues of privacy, personhood, and discrimination.

15. The role of governance in biomedicine is often restricted to facilitating the applications of technology and to containing the risks that come to light. In this way, 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. To overcome this problem, there is a pressing need to embed human rights in technologies which have an application in the field of biomedicine. This implies that technological developments are from the outset oriented

towards protecting human rights. For that reason, governance arrangements need to be considered, which seek to steer the innovation process in a way which connects innovation and technologies with social goals and values.

Actions

► Examining Article 13 of the Oviedo Convention in the light of developments in gene editing technologies.

In its statement of December 2015 on gene editing technologies, the Committee on Bioethics made a commitment to examining the ethical and legal challenges raised by genome editing technologies in the light of the principles laid down in the Oviedo Convention. To this end, this action necessitates an examination of the practical and legal implications of Article 13 of the Oviedo Convention as it relates to the use of gene editing technologies in the context of research, and of clinical applications of gene editing in somatic cells and the germline. The examination may indicate a need to clarify or amend Article 13.

► Assessing the relevance and sufficiency of the existing human rights framework to address the issues raised by the applications of neurotechnologies.

Applications in the field of neurotechnology raise issues of privacy, personhood, and discrimination. It therefore needs to be assessed whether these issues can be sufficiently addressed by the existing human rights framework or whether new human rights pertaining to cognitive liberty, mental privacy, and mental integrity and psychological continuity, need to be entertained in order to govern neurotechnologies. Alternatively, other flexible forms of good governance may be better suited for regulating neurotechnologies.

► Developing a report on the application of AI in healthcare, in particular regarding its impact on the doctor-patient relationship.

Artificial Intelligence (AI) has the potential to improve diagnostic and therapeutic outcomes for patients. Although deep learning algorithms in a variety of tasks in radiology and in medicine generally have demonstrated significant promise, it is likely to be several years before AI is mainstreamed into the healthcare domain. The predictive capability of AI raises concerns about privacy and discrimination. Moreover, as AI evolves, it will create new complexities for the doctor-patient relationship. In the light of these challenges, the Committee on Bioethics intends to prepare a report highlighting the role of healthcare professionals in respecting the autonomy, and right to information, of the patient, and in maintaining transparency and patient trust as critical components of the therapeutic relationship.

Fostering public dialogue to promote democratic governance and transparency in the field of biomedicine.

16. In order to guarantee that the directions of innovation and the ethical challenges raised by technological developments are robustly deliberated, governance should go hand in hand with broad and informed public dialogue. Fostering a dialogue between the public, scientists, and policy makers should promote democratic governance and

transparency in the field of biomedicine. This can assist policy makers in public consultations and, therefore, in ascertaining the most appropriate governance models needed for biomedical technologies and their applications. This is in line with Article 28 of the Oviedo Convention, which provides 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 relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation”.

Actions

► Translating the Guide to public debate on human rights and biomedicine in non-official languages and disseminating it in Council of Europe member States.

The Guide to public debate, presented at the high-level seminar held in Strasbourg on 4 June 2019, is a tool for policy makers to help them engage with the public. It aims at raising public awareness, 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. Translating the Guide to public debate into non-official languages and disseminating it will foster public debate initiatives in Council of Europe member States, including in countries and regions where public debate is less developed.

► Promoting dialogue amongst the public, practitioners, and policy makers to ensure that patient and public interest is a key priority in the development and regulation of genomic medicine.

The future success of personalised medicine depends upon access to and sharing of exceptionally large amounts of genomic and other health data from patients and healthy individuals. The concept of solidarity recognises our common vulnerability to illness, and that we will all need healthcare at some point in our lives. Solidarity emphasises the willingness to accept certain potential costs (e.g. sharing our genetic data) in order to realise the common good, in this case better healthcare. Altruism and solidarity are intertwined with the principle of reciprocity. In agreeing to share genetic information, this gives rise to certain obligations on the part of researchers, healthcare professionals, and the state. These include providing information to data donors, including in relation to incidental findings, robust governance mechanisms, and equitable access to the treatments developed. In the interests of patients and the general public, the Committee on Bioethics intends to promote a dialogue between the public, practitioners, and policy makers on how to incorporate the principle of reciprocity in the governance of genomic medicine.

EQUITY IN HEALTHCARE

17. Since the adoption of the Oviedo Convention, developments in biomedicine and in society have taken place that result in increasing disparities in access to healthcare. For instance, an increasing number of innovative treatments and healthcare technologies have entered the market yet, because of their price, may not be accessible to everyone. In a parallel development, broader social and demographic changes (e.g. ageing populations and migration) are causing some groups in society to systematically face more difficulties in accessing healthcare. These difficulties are compounded by budget cuts which are putting pressure on healthcare systems and are increasing the risk of inequities in healthcare. These inequities are especially harmful for individuals and groups who are already disadvantaged.

18. The second pillar of the Strategic Action Plan addresses the increasing risk of health disparities by promoting equity, in accordance with the right to equitable access to healthcare pursuant to Article 3 of the Oviedo Convention. This obliges States party to the Convention, to adopt the necessary measures to prevent discrimination, thereby implying the identification, reduction, and ultimately elimination of disparities in access to existing and new treatments and technologies. This necessitates special efforts to improve access for disadvantaged individuals and groups, and to ensure that new developments do not create or exacerbate existing disadvantage.

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

19. New developments in healthcare hold the promise of greatly improved health but can entail, at the same time, risks of deepening inequalities and new forms of discrimination and marginalisation. For instance, innovative treatments, such as for cancer, multiple sclerosis or very rare medical conditions, are often expensive and may only be affordable to a small portion of the population. Similarly, new healthcare technologies, such as health apps, telemedicine, and healthcare assistive robots, may only be available to those who possess the knowledge, skills, and financial means to use them. Consequently, it is necessary to encourage member States to ensure that new treatments and healthcare technologies are made available in an equitable and timely manner.

Action

► **Elaborating a draft Recommendation on equitable and timely access to innovative treatments and technologies in healthcare systems.**

It is essential that innovative treatments and new healthcare technologies are made available in an equitable and timely manner. However, in view of the competing demands on healthcare services, it may be a challenge to know how best to achieve this goal. To assist member States, the Committee on Bioethics intends to prepare a Recommendation laying down principles to ensure that patients may benefit from timely and affordable access to safe and effective medicines, and that fairness and consistency in decision-making, regarding equitable access to the products of innovation, are promoted.

The Recommendation, while allowing flexibility at member State level, would ensure that decisions regarding access to innovative treatments and interventions would take account of fundamental principles such as justice and beneficence. Moreover, a harmonised framework across member States would help to combat inequities between them and to empower them. This is especially relevant considering that many citizens travel between states to access innovative treatments and technologies, which is a challenge for all member States.

Combating health disparities created by social and demographic changes in Council of Europe member States.

20. There is concern that existing healthcare resources are less accessible to certain patient populations because of their particular social circumstances. More specifically, the issue of equitable access to healthcare for older persons is an enduring challenge for member States. For instance, older persons frequently experience difficulties when accessing basic healthcare as a result of age-based rationing, priority-setting, and poorly founded concerns regarding their capacity to make healthcare decisions. In addition, access to clinical trials and innovative treatments and healthcare technologies often depends on information found on the internet and social media which may be more difficult for older persons to glean. Combating such health disparities is therefore important, for instance by making healthcare services and resources more accessible to older persons and by training healthcare professionals to ascertain their level of health literacy and capacity to participate in decision-making. Such efforts are consistent with, and build on, Recommendation [CM/Rec\(2014\)2](#) of the Committee of Ministers to member States on the promotion of human rights of older persons.

Action

- ▶ **Developing a Guide to health literacy for older persons in order to empower them to access health care of appropriate quality on an equitable basis with other groups in society.**

It has been well documented that older persons experience difficulties in exercising their right to access health care services. This has become even more challenging as a result of the emergence of innovative treatments and new healthcare technologies that are very expensive and may require specific knowledge and skills to obtain. At the same time, established practices in healthcare have become more patient-centred and attentive to human rights, in a way that increasingly recognises the rights and decision-making capacity of older persons. To this end, it is essential that they understand health information and know what healthcare services are available and how best to access them. In response to this need, the Committee on Bioethics intends to prepare a Guide to health literacy for older persons in order to empower them to be more effective advocates in accessing healthcare services and in making appropriate decisions regarding their health.

PHYSICAL AND MENTAL INTEGRITY

21. Technological developments in the field of biomedicine create new possibilities for intervention in individual behaviour. For instance, certain technologies raise the prospect of increased understanding, monitoring, and control of the human brain, while other developments allow for the permanent health monitoring of individuals. These developments raise novel questions relating to autonomy, privacy, and even freedom of thought. Moreover, the evolution of existing practices, such as the collection and sharing of genomic and health data, may give rise to similar concerns. There should also be consideration of other important social trends (e.g. pressure of social media on young people) and changing societal perceptions in how to balance the protection and respect for autonomy of children, persons with mental health difficulties, and vulnerable older persons, with increased recognition of their decision-making capacities.

22. In the light of these developments, the third pillar of the Strategic Action Plan addresses concerns for physical and mental integrity. Guaranteeing respect for a person's integrity in the sphere of biomedicine is one of the central tenets of the Oviedo Convention. This is understood as the ability of individuals to exercise control over what happens to them with regard to, inter alia, their body, their mental state, and the related personal data.

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

23. There are changes in the general perception of the autonomy and protection of children regarding their capacity to participate in decision-making. This is confirmed and endorsed by human rights instruments, notably the UN Convention on the Rights of the Child, which recognises that children are rights-holders with a progressively evolving ability to make their own decisions. However, on matters concerning their health and general well-being, there is uncertainty as to how the increased recognition of their decision-making capacity should be addressed. Finding the right balance between autonomy and protection is a challenge when considering that children's rights are situated within a larger set of parental rights and responsibilities which also focus on their best interests.

Action

► **Developing a Guide to good practice concerning the participation of children in the decision-making process on matters regarding their health.**

Acknowledging the need to recognise the evolving nature of the decision-making capacity of children also in matters regarding their own health, the Committee on Bioethics intends to prepare a Guide, containing principles and good practices, to involving children in medical decision making. This will include consideration of the rights of the child, the rights and responsibilities of the child's legal representatives, and the child's interests interconnected with those of their family members. The Guide should primarily target healthcare professionals but should also be accessible to the children's parents and/or legal representatives.

Safeguarding children's rights in relation to medical practices which have future or long-term implications for them.

24. Every child is a rights holder in his or her own capacity as recognised in Article 14 of the UN Convention on the Rights of the Child. The child's autonomy can be conceptualised as "the child's right to an open future", meaning a right to have one's future options kept open until one can make one's own decisions. The content of the right to an open future therefore includes restrictions on what parents (and others) can do for children, and, on some interpretations, indicates what parents (and others) ought to provide children with. There are challenges regarding the most appropriate interventions which parents and others should be allowed to authorise in order to safeguard the health of the child.

Action

► **Organising a seminar on relevant legislation and good practices with regard to early intervention on intersex children.**

Resolution [2191\(2017\)](#) of the Parliamentary Assembly of the Council of Europe on promoting the human rights of, and eliminating discrimination against, intersex people, 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. It recommended to carry out further research into the long-term impact of these treatments and to ensure that, unless there is an immediate risk to the life of a child, altering the sex characteristics of children is postponed until the child can participate in the decision. In response, the Committee on Bioethics intends to organise a seminar focusing on how the Resolution can be upheld in practice, by identifying good practices in dealing with interventions on intersex children.

Safeguarding the rights of persons with mental health difficulties.

25. The issue of mental health is expected to be one of the biggest challenges facing healthcare systems in the future. Mental healthcare should be treated no differently to physical healthcare in that a human rights-based approach should be adopted in both. It is vital that the rights and self-determination of all patients, including persons with mental health difficulties, be promoted and that they may actively participate to the greatest possible extent in all decisions regarding their treatment and care. In this context, the development and use of voluntary measures and practices in mental healthcare should be promoted.

Actions

- ▶ **Elaborating a legal instrument to protect the human rights and dignity of persons with mental disorders with regard to involuntary placement and/or involuntary treatment.**

The deprivation of liberty involved in involuntary placement and treatment impacts on a person's right to freedom from cruel, inhuman or degrading treatment (Article 3), right to liberty (Article 5), and the right to respect for private life (Article 8) as enshrined in the European Convention on Human Rights. In this connection, Article 5 of the Oviedo Convention refers to the principle of free and informed consent for any medical treatment. Article 7 of the Oviedo Convention constitutes an exception to the general rule of consent for the protection of persons who have a mental disorder. To this end, three conditions must be satisfied: the person must have a serious mental health problem; the treatment must aim to alleviate the mental health problem; and without treatment of the mental health problem, serious harm to their health is likely to result. More recently, Recommendation [Rec\(2004\)10](#) of the Committee of Ministers has detailed the conditions under which a person may be subjected to compulsory medical treatment (Article 18) and the conditions for involuntary treatment (Article 19). The Committee on Bioethics seeks to build on its previous work in this area to ensure that involuntary detention of persons is a last resort and, in this case, when strictly necessary, that the human rights and dignity of patients are consistently and effectively upheld.

- ▶ **Developing a Compendium of good practices to promote voluntary measures in the field of mental healthcare.**

In mental healthcare for persons with psychosocial disabilities the focus is shifting towards avoiding recourse to involuntary measures. To assist member States in this shift, the Committee on Bioethics intends to develop a Compendium of good practices to promote voluntary measures in mental healthcare, both at a preventive level and in situations of crisis, by focusing on examples in member States.

CO-OPERATION AND COMMUNICATION

26. Many of the challenges raised by new developments in biomedicine necessitate effective and efficient co-operation with other organisations and bodies. This is an opportunity to share knowledge, experience, and skills. It also allows for the pursuit of mutual interests and the realisation of common goals in innovative ways, with synergy and without duplication of resources. The importance and relevance of such co-operation is reflected in the objective of the UN Interagency Committee on Bioethics to which the Council of Europe is an associate member. Co-operation concerns both normative and methodological aspects, i.e. how and on what issues the Committee on Bioethics should co-operate with other actors in the field. All actions should be visible, and achievements strategically communicated to raise awareness and to inform public policy. Consequently, the fourth pillar of the Strategic Action Plan is focused on transversal co-operation and communication as a prerequisite for achieving the strategic objectives in the Strategic Action Plan.

Developing long-term strategic co-operation with Council of Europe committees and other intergovernmental bodies working in the field of bioethics.

27. The resources of the Committee on Bioethics should be deployed to maximise its efficiency and to ensure that it makes a unique contribution to the challenges presented to it. It is therefore essential for the Committee to develop long-term strategic co-operation with other actors in the field of bioethics, both within and outside of the Council of Europe.

Actions

- ▶ **Reviewing the working methods of the Committee on Bioethics in order to elaborate a Framework for effective co-operation with Council of Europe committees and other intergovernmental organisations working in the field of bioethics.**

In view of the need to ensure effective co-operation, the Committee on Bioethics considers it important to review its working methods and to elaborate a standardised mechanism for co-operation with other bodies. A framework should set out ways to prioritise requests to comment on initiatives from other bodies and to strengthen collaboration with the Parliamentary Assembly of the Council of Europe, other Council of Europe committees, other intergovernmental organisations working in the field of bioethics, and policy makers at member State level, in order to best achieve shared objectives.

- ▶ **Establishing links and co-operation with National Training Institutions to help disseminate the HELP course on bioethics in Council of Europe member States.**

The European Programme for Human Rights Education for Legal Professionals (HELP), together with the Bioethics Unit of the Council of Europe, have developed an online training course on bioethics. The course addresses ethical and legal issues raised by developments in the field of biomedicine and brings attention to

the principles enshrined in legal instruments developed by the Committee on Bioethics and other committees and bodies of the Council of Europe, and adopted by the Committee of Ministers, as well as to relevant case law of the European Court of Human Rights. To raise awareness of key human rights principles in the biomedical field and to encourage interdisciplinary interaction and learning, the Committee on Bioethics intends to disseminate its HELP course on bioethics not only to legal professionals but also to health professionals and other categories of users. This includes its roll-out in cooperation with the National Training Institutions for legal and health professionals.

Ensuring the communication and dissemination of the outputs of the Committee on Bioethics to internal and external stakeholders in order to maximise their uptake and utility.

28. To raise awareness of human rights principles and the challenges raised by developments in the field of biomedicine, it is important for the work of the Committee on Bioethics to be widely communicated and rendered more visible to all stakeholders. This will facilitate an increased understanding of the contribution of the Committee on Bioethics, and of the Council of Europe more generally, to protecting human rights in the field of biomedicine. It is therefore essential for the Committee on Bioethics to develop effective dissemination strategies for its outputs, which are accessible to a wide range of different relevant stakeholders. This helps to inform public policy. This will require considering the most effective ways to communicate outputs to target audiences and to engage stakeholders throughout the process. In this regard, it is important to recognise that young people should be a key focal point for bioethical deliberations, considering that they will experience the impacts of emerging and converging technologies and that they will be shaping the future of society.

Actions

- ▶ **Developing an annual online newsletter covering the work of the Committee on Bioethics, bioethical developments in Council of Europe member States, and the case law of the European Court of Human Rights.**

To ensure communication and dissemination of bioethical developments in the Council of Europe, an annual online newsletter oriented towards lay audiences should be developed. The newsletter should provide information on the work of the Committee on Bioethics and its impact on Council of Europe member States, the work of committees and other bodies of the Council of Europe in the field of biomedicine, relevant case law of the European Court of Human Rights, and bioethical developments in Council of Europe member States. It intends to serve as a platform for information to be shared between member States, making connections between States with similar interests. It should also serve as a useful means of communicating and promoting the work of the Committee on Bioethics and the Council of Europe to relevant third parties.

- ▶ **Hosting a Youth Forum for Bioethics to provide young people with an opportunity to share their views on bioethical topics and to inform the work of the Committee on Bioethics.**

As a way to bring the voice of European youth into bioethics discussions at the Council of Europe, the Committee on Bioethics intends to host a (one-off) Youth Forum. The Forum should provide a space for younger people to interact with the Committee on Bioethics and to provide input on bioethical issues, thereby empowering them to represent and advocate their needs and interests. Moreover, it will provide the Committee on Bioethics with valuable insights from younger people to inform its own work. The Youth Forum should, where appropriate, act as a model that could be used in the future.

IMPLEMENTATION

Timeframe: The Strategic Action Plan is intended to be implemented within a timeframe of six years (2020-2025).

Methodology: The proposed actions will be carried out in the light of the principles set out in the Oviedo Convention and its Additional Protocols, in the relevant Recommendations of the Committee of Ministers, as well as in reports, guides, and position statements issued by the Committee on Bioethics. The findings of the International Conference on the 20th Anniversary of the Oviedo Convention, the International Conference on Emerging Technologies and Human Rights, and the High-Level Seminar on International Case-Law in Bioethics will also be used as a basis. The proposed actions take into account complementarity and co-operation with other Council of Europe bodies and other relevant intergovernmental organisations.

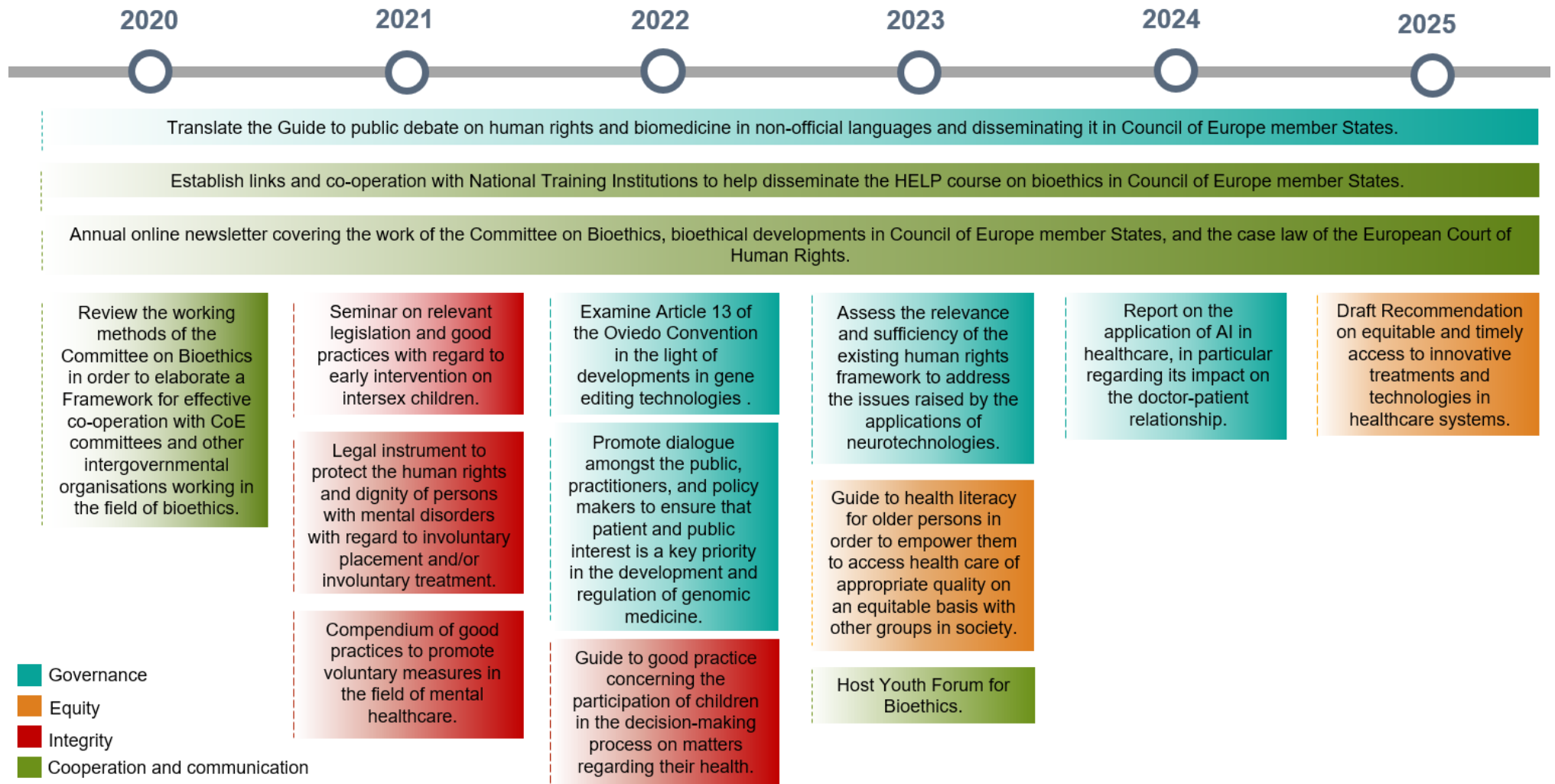
Gender equality and diversity: Throughout the implementation of the Strategic Action Plan, gender equality and respect for diversity will be ensured, in particular in partnership with the Gender Equality Rapporteur designated by the Committee on Bioethics. Gender balance and respect for diversity will be promoted in the composition of working groups and panels and in the appointment of rapporteurs, chairs, and external experts. An approach that is sensitive to gender equality and diversity has been integrated in the process of identifying priorities for the Strategic Action Plan and gender equality and diversity-specific challenges that may arise during the implementation of its actions will be monitored, evaluated, and addressed.

Leadership: The actions proposed under the Strategic Action Plan are intended to be carried out under the responsibility of the Committee on Bioethics and, where appropriate, in co-ordination with other Council of Europe bodies or intergovernmental organisations.

Funding: The implementation of actions will be covered by existing budgetary allocations provided from the Council of Europe's Ordinary Budget. For some actions, such as translating and disseminating the Guide to public debate on human rights and biomedicine, the roll-out of the HELP course on bioethics, and the DH-BIO Youth Forum, the implementation depends on voluntary contributions.

Reporting: The Committee on Bioethics will prepare mid-term and final reports to be communicated to the Steering Committee on Human Rights and to the Committee of Ministers. The mid-term report will contain a review of progress in respect of the objectives and actions in the Strategic Action Plan, and an assessment of their ongoing relevance.

SAP Year Action Delivered



The timeline indicates the year in which it is estimated that the action will be delivered; work will be initiated in advance of the year indicated as there may be a number of sub-actions required to realise the final outcome.

LIST OF SOURCES

- Proceedings of the International Conference on the 20th Anniversary of the Oviedo Convention: Relevance and Challenges, 24-25 October 2017, Strasbourg, available at <https://rm.coe.int/english-proceedings-20-anni/168089e570>
- Rapporteur Report on the International Conference on the 20th Anniversary of the Oviedo Convention: Relevance and Challenges, 24-25 October 2017, Strasbourg, available at <https://rm.coe.int/oviedo-conference-rapporteur-report-e/168078295c>
- The Rights of Children in Biomedicine: Challenges Posed by Scientific Advances and Uncertainties. Report prepared by Zillén, Kavot; Garland, Jameson and Slokenberga, Santa. Uppsala University, 2017, available at <https://rm.coe.int/16806d8e2f>
- From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine. Report prepared by Liefwaard, Ton; Hendriks, Aart and Zlotnik, Daniella. Universiteit Leiden, 2017, available at <https://rm.coe.int/leiden-university-report-biomedicine-final/168072fb46>
- Proceedings of the High Level Seminar on International Case-Law in Bioethics: Insight and Foresight, 5 December 2016, Strasbourg, available at <https://rm.coe.int/proceedings-caselaw-/1680736452>
- Proceedings of the International Conference on Emerging Technologies and Human Rights, 4-5 May 2015, Strasbourg, available at <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680495b44>
- Report on Ethical Issues Raised by Emerging Sciences and Technologies. Report prepared by Strand, Roger and Kaiser, Matthias. Bergen University, 2015, available at <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168030751d>
- From Bio to NBIC Convergence – From Medical Practice to Daily Life. Report prepared by van Est, Rinie; Stemerding, Dirk; Rerimassie, Virgil; Schuijff, Mirjam; Timmer, Jelte and Brom, Frans. The Hague, Rathenau Instituut, 2014, available at <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307575>