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COMMITTEE ON BIOETHICS
(DH-BIO)

Guide to Public Debate on Human Rights and Biomedicine

Adopted by the Committee on Bioethics (DH-BIO)
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Essential elements

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I. INTRODUCTION

1. Developments in the field of biomedicine promise significant benefits for individuals, for society and for future generations. The pursuit of these benefits, however, often involves significant ethical and social challenges. It may rest on decisions made in the context of scientific uncertainty and conflicting values, but which may have far-reaching implications. Many biomedical developments have the potential to produce profound changes in the social and economic environment. They can challenge and potentially reconfigure the norms by which life is ordinarily lived. This is why the directions taken by biomedical developments, and the way the risks and potential benefits are distributed, are of profound public interest.

2. The Council of Europe Committee on Bioethics (DH-BIO) has produced this guide to assist member States in promoting public debate in this field. It aims to give guidance to those who take on the responsibility of initiating or supporting public debate and to those who respond to it through public policy. These include decision makers within member States, government officials and public authorities, national ethics committees, educational and academic institutions and other relevant organisations.

3. Promoting public debate in the light of Article 28 of the Oviedo Convention has the aims:

   ➔ to raise public awareness, in particular by encouraging the circulation of information, views and opinions,

   ➔ to promote discussion in the public sphere between different actors, groups and individuals, including those who may be in vulnerable or disadvantaged situations,

   ➔ to consult the public including target groups and thereby to consider their interests and understandings, with a view to making informed policy decisions.

II. THE NEED FOR PUBLIC DEBATE

4. Developments in biomedicine potentially affect everyone, and their effects can be profound, implicitly engaging questions of public interest. Public debate can be an important source of information and views when setting appropriate standards and a point of reference for the development of governance. Public debate can usefully broaden the basis for the appraisal of new developments, the consequences of which are uncertain.

   ➔ Public debate is important for public trust in governance and policy making.

   ➔ Public debate increases legitimacy and support for ethically difficult decision-making.

The need for public debate in relation to health and biomedicine

5. The characteristics of biomedical developments, and the ways in which they have an impact on people’s lives and the broader societal context, set them apart from many other kinds of technical or organisational change. They have particular implications for

human rights because they often raise concerns about integrity, dignity, autonomy, privacy, justice, equity and non-discrimination among human beings.

➔ Public debate contributes to the responsible introduction of biomedical developments and technologies in the health sector.

➔ The long-term implications for individuals and for the future of society require democratically mandated decisions that are informed by shared values and demonstrate respect for human rights.

Why public debate is especially important now

6. The structure of social relations and the way people share information, form collective opinions and influence public decisions has undergone significant change in the twenty-first century, not least owing to new information technologies, which have led to new modes of social interaction.

7. In some cases, regulatory frameworks addressing the risk, effect and societal implications do not exist or have not kept pace with technical developments. Many technologies are under continuing development leading to applications that may not have been foreseen. They may be difficult to define and may, therefore, fall outside existing regulatory frameworks.

➔ Technical developments can occur rapidly in the field of biomedicine and may pose challenges to legislators and health professionals.

➔ New platforms for social interaction can create polarised debate within segregated communities around issues that may deserve broader and more inclusive reflection.

➔ Without efforts to promote public debate the voices of marginalised and vulnerable groups may be drowned out or overlooked.

Aspects that deserve special attention

8. Some developments in biomedicine have human rights implications that give rise to specific ethical concerns and make them particularly challenging.

Speed of developments

➔ Public debate can be an important resource for defining appropriate standards and provide a reference for the development of governance.

Opportunities for data mining

➔ The large volume and variety of data, and opportunities for data mining with many biomedical technologies, call for appropriate protection of information privacy, the need to inform the public, and the need for public debate on the risks and possibilities that modern technologies offer in this context.

New conditions for access to healthcare

- ➔ The implications of introducing new technology in medicine may create new conditions for healthcare. This warrants a wide public debate to set fair and appropriate standards.

Ambiguity of regulation

- ➔ When new technologies find new areas of application, public debate can help to raise awareness about the uncertainties raised and to find appropriate frameworks for use.

Uncertainty about the risks of innovations

- ➔ Public debate can help to bring to the surface different impacts and unforeseen consequences and can reveal differences in the ways they are valued by different people.

Impact on social norms and the question of equity

- ➔ There is good reason to involve the public in debate about biomedical developments that may lead to changes in social norms and where there are risks of increasing inequalities and marginalisation of certain groups.

- ➔ Public debate can help to find appropriate and acceptable mechanisms to protect minorities and ensure equality of access to developments in biomedicine.

III. PREPARING FOR PUBLIC DEBATE

9. Reflecting on a number of questions before initiating a public debate activity can help to identify the approach that will best meet the interests of all participants. Understanding which approaches are likely to be the most appropriate and effective in any particular case is perhaps the most fundamental challenge for policy makers and others who want to initiate public debate.

10. This section identifies four key considerations to help those preparing for public debate to think about what actions and approaches are most appropriate to their circumstances. Often, it will be valuable to use a mixture of methods and to carry out more than one kind of activity. The most appropriate approach does not necessarily serve the objectives of one set of parties; different participants will have different reasons for engaging in debate and may hope for different outcomes.

Reasons for initiating public debate

11. Perhaps the first question for those considering initiating a public debate activity concerns their reasons for doing so. Both organisers and participants benefit if the reasons behind the process are clearly stated.

Ethical reasons

- Consideration should be given to whether a development has implications for people’s human rights.

Making better informed decisions

- It is useful to open up questions in ways that can challenge professional assumptions in a constructive way. The framing of questions to be addressed can reveal or embed underlying values.
- Consulting the public can help to ‘crowd source’ expert input or identify considerations that may not be present in the mainstream.

Seeking legitimacy

- Consideration should be given to the need to inform the public about the proposed introduction of new biomedical developments and what level of public awareness and acceptance would provide assurance that implementation decisions enjoy broad societal support.

What are the objectives?

12. Having clarified the reasons for initiating a public debate, a second set of questions concerns the specific objectives of the public debate activity: what are the anticipated outcomes and what benefits are they expected to deliver, and to whom? Again, there may be more than one objective and different benefits may flow to different parties involved in the activity.

Informing the public

- Consideration should be given to the information needs of the public and the roles of different actors as information providers, in particular attention should be given to the increasing role played by social media in people’s awareness and perception of biomedical developments.
- The involvement of both researchers and media can help to foster a culture of trust in science and technology.
- Consideration should be given to how researchers and policy makers might work with the media to encourage and support the unbiased presentation of factual information and the sober critique of evidence and opinion from different sources.

Identifying issues of concern

- Handling issues of concern at an early stage can give policy makers and researchers confidence in the broader acceptability of their aims.
- Identifying issues of concern can improve the chances of implementing new developments successfully.

Gathering evidence of public views

- ➔ Interaction with the public provides an opportunity to collect evidence of public views in order to confirm or to contest claims about the range, content and (possibly) balance of views on a particular subject.
- ➔ Certain forms of interaction with the public can help to reveal the bases on which public views are founded and explore the facts and beliefs by which they are informed.

Increasing participation

- ➔ Consideration should be given to building opportunities for public participation or involvement in decision making processes (e.g. at the stage of mapping the possible policy options) and to building capacity and promoting opportunities for participation in governance (e.g. patients' panels).

Who should be involved?

13. Who counts as a member of 'the public' may be anyone who is not primarily acting as an agent of political authority or of a relevant profession. In this sense, who makes up the public will depend on the issue at hand and the kind of interest and relationships they have to it. One person may have both a personal and social interest as a member of the public, and possibly also an interest through their work experience or sphere of professional interest.

- ➔ Relevant publics will emerge around a particular issue; some will assert their interests while others may need to be sought out and efforts made to involve them.

Stakeholders

- ➔ Everyone is potentially a stakeholder in biomedical developments. Consideration should be given to identifying or mapping the range of different interests and differential effects.
- ➔ It is important to avoid unjustly privileging the views of certain stakeholders and to recognise both those who are indirectly affected as well as those who are directly affected.
- ➔ Overrepresentation of disadvantaged groups may be desirable to ensure that their voices are heard in public spaces.
- ➔ It is important not to assume that, for example, civil society groups or patient interest groups speak for all of civil society or for all patients.
- ➔ It is equally important to keep in mind that those who are most assertive on public and social media may not represent the views of the majority of the public.

Representative groups

- ➔ Careful consideration should be given to the relevant parameters for defining a representative sample of the population.

- ➔ National referenda may be informative but are not a substitute for public debate; they can be counterproductive in the absence of effective public debate.

- ➔ Involving a representative sample of the population may help to alert policy makers to possible distortions of the public interest created by intense lobbying or campaigns by interest groups.

Including diverse voices

- ➔ Young people's participation might be safely enabled through school or youth groups.

- ➔ To encourage the participation of older persons, it might be necessary to adapt the means of communication to their needs.

- ➔ Trusted mediators can facilitate the participation of people in positions of vulnerability in ways that allow their voices to be heard and protect their privacy.

When is the appropriate time to initiate a public debate?

14. Public debate should be a continuous process rather than an event, although different kinds of public debate activities may be appropriate in different contexts and at key junctures. Public debate should be seen within the broader context of democratic governance.

15. Public debate activities usually have a specified purpose and a predefined frame. But public debate does not have to culminate in the production of a single decision at a particular point in time.

- ➔ Continual public debate fosters a culture of active public participation which helps to create awareness and competence in matters that concern all citizens.

Early 'upstream' public debate

- ➔ The early involvement of the public around values, hopes and fears can help researchers and policy makers orient innovations and developments in a direction that is acceptable to the public.

Public debate in connection with policy making

- ➔ There may be a need to avoid politically sensitive timing so that the outcome responds to issues rather than being influenced by political affiliation.

IV. EFFECTIVE PUBLIC DEBATE

16. For public debate to be effective, it should be meaningful and valuable for, as well as respectful of, all those involved. Participants should recognise that they have had a fair opportunity to be heard and that their contribution has been considered even if they do not agree with any conclusion that may have been reached as a result of the process.

17. Public debate is a two-way process of communication. The nature of the exchange – what is communicated, by whom, to whom – may differ, and any public debate activity will very likely involve multiple kinds of exchange.

    ➔ The effectiveness of public debate activities can be increased by attention to principles of design and conduct.

    ➔ Effective public debate activities foster empowerment, and trust among citizens and between citizens and government or public authorities.

Effectiveness through design

18. A key design principle for effective public debate activities is to enable participation. The most important features concern how the process design expresses or manages the power relations among those involved, including the various participants and those initiating the initiative. This can be improved by creating an environment and process that are adequately resourced, inclusive and enabling.

Commitment of resources

➔ Resisting pressures to reach hasty conclusions and allowing time for public debate may be more effective in the long run, especially when the issues to be debated are complex.

➔ Thinking of public debate as part of a policy process from the beginning, rather than an optional ‘add-on’ exercise helps to ensure that the debate serves the purpose of informing the policy-making process.

➔ Openness to uninvited public debate initiatives can help identify matters of public importance and provide a focus for further activities.

➔ Having decided on an appropriate public debate activity, it is important to ensure that sufficient resources can be committed.

➔ Opportunities for participation in public debate can be provided relatively easily, for example by facilitating online petitions.

➔ Public debate activities that serve the interests of all participants can also justify sharing cost burdens.

➔ Where possible making use of existing organisational infrastructures can be cost efficient, although possible embedded power structures and barriers to inclusion must be taken into account.

Meaningful participation and co-design

➔ Participants’ interests in a public debate may be respected by involving them in the design of the process or the framing of the issues it addresses (co-design).

➔ Empowering participants in public debate to determine what information they consider to be relevant may help to motivate them to participate, for example, by having the ability to select experts or obtain evidence to inform their views.

- ➔ Involving independent, impartial and professional facilitators and intermediaries can help to empower individual participants and marginalised subgroups.

Accessibility and inclusion

- ➔ Public debate needs to be inclusive and welcoming. Consideration should be given to what measures may be required to enable all participants to take part in a public debate activity on an equal footing with others. There may be a need to take specific steps to counteract insidious forms of social exclusion.
- ➔ Attention should be paid to providing venues for debate that are accessible to all. Existing public institutions and venues, such as museums and exhibition spaces, and occasions on which people come together, such as science festivals and public events, can provide suitable venues for debate and also help to invigorate those sites as places for social interaction.
- ➔ During a public debate, different forms and means of expression could be used to encourage participation, for example, using drawing and acting instead of spoken dialogue.
- ➔ Initiators may need to take special steps to engage socially marginalised groups, for example through using peers, intermediaries or representatives.

Oversight mechanisms

- ➔ Some form of oversight, independent from the initiating organisation or commissioner, could be desirable as a part of the design of public debate activities. This might take the form of an independent oversight group or a person with independent authority.

Effectiveness through conduct

19. A key principle of public debate is that it should respect the interests and freedoms of participants, a principle which also lies at the foundation of human rights. The effectiveness of public debate activities cannot be assured by design alone but requires them to be conducted in accordance with principles of procedural justice.

- ➔ Identifying or setting out principles of conduct to be observed in a public debate activity can help to increase transparency and support accountability.

Fairness

- ➔ Moderation or independent, impartial and skilled facilitation can help to ensure that all participants have a fair opportunity for their views to be heard, regardless of social, political, educational and economic differences.

Privacy

- ➔ It is necessary to consider the potential for conflict between the importance of transparency and the need to protect the privacy of individuals participating in a public debate.

- ➔ It might be appropriate to engage different publics separately where, for structural or contingent reasons, certain subgroups cannot participate on an equal footing with others.
- ➔ A rule like the 'Chatham House Rule' (that information received may be subsequently disclosed so long as neither the identity of the information provider nor of any other participant is revealed) may allow people engaging in public debate to express opinions without fear of negative consequences for doing so. If this is to apply it should be agreed at the outset and credibly enforced.

Transparency of interests

- ➔ Initiators, experts, sponsors and participants should disclose any relevant interests they have in the initiative or its outcome. This might be done when introducing themselves to others for the first time or, in the case of experts by a written declaration of interest.

Candour

- ➔ It is important to ensure that relevant evidence is given due attention and that the balance of expert opinion is fairly represented.
- ➔ Experts should be asked to be transparent about known risks and consequences, and the limits of knowledge and prediction.
- ➔ Sometimes expert cross-examination or the participation of experts with contrary views can help to achieve balance where impartiality is unlikely.

V. PUBLIC DEBATE THAT COUNTS

20. For public debate to make a difference there needs to be a functional connection between public debate and the governance of health care and biomedicine, so that the public are empowered to influence the conditions of their collective future in a way that is appropriate in a democratic society.

Commitment

- ➔ Commitment may be demonstrated by the initiator of public debate activities by setting out explicitly what is open for debate (and what is not open for debate, and why) and what influence public debate is expected to have.
- ➔ Understanding and mutual trust between participants and initiators, for example between publics and public authorities, may be improved by face-to-face encounters.

Accountability

- ➔ Accountability may be demonstrated by publishing information about the ways in which public debate has informed decisions or practices.

- ➔ Reporting back to the participants of a public debate can help to encourage future participation and to break down barriers between publics and public authorities.
- ➔ Publishing and disseminating information about a public debate activity, for example in the form of a description of the proceedings and a summary of the outcome, can help to secure wider impact and consolidate a foundation for further debate.

Evaluation

- ➔ Setting criteria, measures and a framework for evaluation at the outset and, so far as possible, agreeing these with participants at an early stage promotes confidence in the integrity of the public debate process.
- ➔ Evaluation of the public debate process can be supported by feedback from participants (collected, for example, by a questionnaire at public events or by the inclusion of suitable questions as part of the process).
- ➔ Depending on the nature of the process, evaluators might seek to inform their conclusions by undertaking qualitative interviews with participants.

Continuing public debate

- ➔ Public debate in a specific context may give rise to further opportunities for continuing the involvement of participants.
- ➔ Aside from the legacy of connection among people and between publics, relevant experts and professionals, and public authorities, public debate may also generate tangible social resources in the form of records of events and reference documents on which future debate can build.

Embedding public debate on bioethics

- ➔ Adequately resourced and politically supported national ethics committees or similar bodies can have an important role in fostering public debate, in carrying out public debate activities when needed, and in securing the impact of public debate.

VI. CONCLUSIONS

21. Article 28 of the Oviedo Convention (on ‘public debate’) was drafted with the conviction that the pursuit and implementation of developments in biomedicine are not only questions for experts or authorities but for a society as a whole.

22. Showing respect for the interests and views of the public is a cornerstone of democratic societies. Questions relating to developments in biomedicine are often complex and can challenge the way that social life is organised around ethical values, standards and principles. The response to these questions can profoundly shape the societies of the future.

23. In the contemporary world in which knowledge, people and technologies pass freely across national borders, such developments have an impact not only on the societies of

individual member States but on all states. On questions that have an impact on the global direction of biomedicine, states therefore need to engage with each other to find a common strategy. In doing so, they will need to be informed by the views of their citizens represented to them through open debate in the public sphere.

24. It is important to recognise that public debate is as much about informing and developing views as it is about identifying and clarifying them. No single public debate activity, nor any mixture of public debate processes, can provide a complete solution to the ethical governance of biomedicine and biotechnology. Public debate is a valuable part of the process, but neither sufficient nor an end in itself.

APPENDIX

COMMITTEE ON BIOETHICS
(DH-BIO)

<u>Examples of public debate with regard to the Guide on public debate in the biomedical field</u>

BELARUS – THE RIGHTS AND RESPONSIBILITIES OF DOCTORS AND PATIENTS IN MODERN HEALTHCARE SYSTEMS (LEGAL AND ETHICS ISSUES) (2018)

Background, initiator and participants

A debate about the rights and responsibilities of a doctor and a patient in a modern healthcare system (legal and ethical issues) was initiated in September 2018 by the Ministry of Health and Bioethics Committee of the Republic of Belarus, with participation of the Republican Bioethics Center.

The main aims of the debate were to discuss the issues of improving medical practice, exchange experiences between various hospitals and medical centers, and also to make changes and additions to new laws including the Law on Healthcare, Transplantation of Organs and Tissues, and Assisted Reproductive Technologies.

The need for debate was described as follows: In Belarus, there is a new situation where patients want more care and expect that doctors acknowledge their autonomy, where patients don't know their rights and need skilled professional communication. There is also a new generation of doctors, whose professional skills are much more technical than communicative and ethical; these doctors need to know the laws, the elements of ethical practice, and to how to treat their patients as persons, requiring a holistic view of their health needs. For these reasons the debate needed to include all of society.

The debate was also developed to feed into later amendments to the Law of Healthcare.

Objective

To improve medical practice in healthcare, in relation to transplantations of organs and tissues and the use of assisted reproductive technologies, and to improve the understanding and collaboration in society for solving these important questions.

The question

The debate addressed the following topics:

- the meaning of informed consent in medical practice,
- the extent of patient knowledge about their rights to choose a doctor,
- how to protect medical confidentiality in e-health systems,
- the extent of the doctor's duty to tell the truth about severe diagnosis for all kind of patients,
- how to arrange for family members to exercise their right to participate in the care of their relatives when the patient is in an intensive care unit

Method

Different methods were used during the organisation of the public debate, including:

- Discussion on selected topics in mass-media,
- a survey of medical professionals and medical lawyers understanding of the main topics of the conference debate,
- practical conference,
- open lecture with free discussions,
- the role of hospital ethical committees as an instrument for solving ethical problems of the treatment process.

A discussion about the rights and responsibilities of doctors and patients in the legal and ethical sphere was introduced in the mass media. The participants of the debate were medical doctors, lawyers, healthcare managers, bioethicists, scientists as well as members of patient organisations. The discussion was presented in different articles, and in roundtables, in mass media, and in scientific journals.

The Republican Bioethics Committee, The Republican Center of Bioethics and employees of the Legal Firm “JURSPECTR” started preparing the Practical Conference "Ethical and legal issues of ensuring the rights of patients and medical professionals in modern healthcare". Prior to the conference, there was a survey among medical lawyers and doctors to identify the main questions for discussion during the conference. The conference was held in March 2019, hosted by the Belarusian Ministry of Healthcare, Belarusian Medical Academy of Postgraduate Education and “JURSPECTR”. During the Conference, different speakers from the medical and legal professions participated in public discussions concerning the above-mentioned issues. Participants also included patient organisations.

The “Doctor's ethical duty” was the theme of the Orthodox Church programme for members of the society, which included:

- A lecture in ethics by a Russian Academician of the Academy of Sciences, which took place in July 2019 at the Church Seminary with free public entrance,
- a press conference entitled “The Feat of the New Martyrs in the Prism of the Ethical Duty of a Doctor".

Impact or notable features

The main ideas, the questions debated and solutions arising were taken into account by working groups during the development of new versions of Republican Laws (Laws of the Healthcare, Transplantation of Organs and Tissues, Additional Reproductive Technologies). These Laws were supplemented with articles that were discussed by the Parliament and adopted by the National Assembly of the Republic of Belarus in Summer 2019.

Basic ethical issues:

- To specify the basic concepts (informed consent, etc)
- how to satisfy the patient’s refusal to enter their data into electronic databases (according to the requirements of Healthcare system),
- to determine one of the goals of National Bioethics Committee to coordinate activity of local commissions on medical ethics,
- the proper conduct of a doctor in an emergency regarding the informed consent of the patient and their relatives, etc.

Notable features and lessons learned

The working process was founded on the main definitions of the Council of Europe's "Draft Guide on Public Debate". Also, our slogan was "We may say that public debate is therefore debate that is in public, with the public and for the public."

Organisers of various public discussions were inspired by the draft Guide's idea and based their activities on the guidance given.

CYPRUS – AWARENESS WEEK (2018)

Background, initiator and participants

An Awareness Week is organised in Cyprus on an annual basis. In 2018, the theme was the Bioethical Dimensions of Ageing, the launch of which was accompanied by a press conference, under the auspices of the President of the Republic of Cyprus, the Cyprus Minister of Health, and the Cyprus Minister of Labour and Social Welfare.

Objective

The objective of the Awareness week is twofold: (i) to inform the public about bioethical developments and (ii) to inform policymakers of the challenges and the need for governance arrangements raised by public debate.

Method

The Awareness week in 2018 comprised a wide range of events, including the following:

- Photo exhibition on old age,
- a round table discussion with the President of the House of Representatives and Members of the Parliamentary Committees on: i) Human Rights, ii) Health Affairs, and iii) Legal Affairs,
- a round table discussion with the Commissioner for Personal Data Protection and the Commissioner for Administration and Human Rights (Ombudsman),
- a seminar on the topic of Social Inclusion and Vulnerability,
- a round table discussion on death and bereavement,
- a workshop on “Making Decisions in Ethical Dilemma Situations - End of Life”,
- a workshop on the “Ethics and Medical Ethics in everyday Medical Practice to elderly people”,
- a Code of Journalistic Ethics – A Code of Conduct for Journalists and the Mass Media regarding elderly people,
- a workshop on “Ethics and Ethical Issues in Dental Practice for elderly people”,
- a seminar on “Ethics and Deontology in Pharmacy regarding elderly people",
- a seminar on “Therapeutic options for coping with dependence in Cyprus”,
- lectures targeting medical students on: Ethical Obligations in Medicine - Learning from the Past and Preparing for the Future; What is changing in the Ethics of Resuscitation? The bioethics of new surgical techniques,
- a workshop entitled “Deontology and Ethics in Educational Research: The Case of Student Participants”,
- debates between medical students on: (i) The moral, political and social implications of end of life issues, (ii) The medico-legal aspects of elderly sexual abuse,
- a conference on “Intergenerational Programs: Keeping Seniors Young, Making Youth Wiser”.

A public round table discussion on Raising Awareness on Ageing & Elderly People was organised by The Cyprus National Bioethics Committee (CNBC). The participants were experts, policymakers and relevant stakeholders who included the Cyprus Elders Parliament and the Cyprus Elderly People Observatory (NGO). The audience was the general public. There were two overarching questions: (i) What is the level of care in nursing homes and the quality of the checks carried out by the Social Welfare Department (Cyprus Ministry of Labour, Welfare & Social Insurance)? (ii) What are the living conditions in nursing homes in Cyprus (both public and private)? The debate, which involved the public audience, revealed the following problems in nursing homes for elderly people:

- No regular checks were carried out at night by the staff, often due to staff shortages.
- shortage of certified carers in the nursing homes,
- need for more effective and adequate protection of the elderly from any form of abuse and maltreatment,
- inspections ought to be carried out by competent authorities,
- need for better handling of complaints from residents.

The round table concluded that a change of policy was necessary. Instructions were immediately given to amend existing legislation regarding the quality of nursing care in Cyprus (both public and private nursing homes for the elderly).

Notable features and lessons learned

Public debate can be very valuable as a tool for informing the public of policy-making challenges and decisions to be taken. The variation of methods served to involve as many subjects as possible in the process. The activities targeted a wide range of beneficiaries (the public at large, high school students, senior citizens, medical university students, research community, health professionals) which were very well received and garnered broad coverage on TV, print and electronic media.

A key factor was the openness of the debate which allowed for views to be shared freely by individuals who were well informed about the challenges at hand whilst having representatives of the policy-makers present. The conclusions prompted the government to review the legislation concerning elderly people. In particular, the debate on elderly care had a direct impact on governance. A Ministerial mandate was given to the CNBC to undertake an investigation into state and private nursing home establishments with a view to reviewing existing legislation, for example in order to ensure appropriate staffing around the clock. This legislation is being amended and will be presented to the House of Parliament for ratification.

An obvious downside of a large-scale public debate is that it limits the topic to one per year. On the other hand, it creates an opportunity for a deeper understanding of the challenges at hand.

DENMARK – PUBLIC DEBATE IN DENMARK ON THE FUTURE OF THE HEALTHCARE SYSTEM (2008)

Background, initiator and participants

The Danish health care system was under political and public pressure to implement more, better and faster treatments but was lacking the required financing.

In 2008, the Health Committee of the Association of the Danish Regions established a project on “The Future Health Care System”, which consisted of two elements:

- Simultaneous Citizen Summits in four of the Danish Regions comprising 800 citizens, on 1 November 2008,
- a Policy Summit based on the outcomes of the Citizen Summits, with politicians, stakeholders, experts and health care system officials, on 14-15 January 2009.

The Danish Board of Technology (“Teknologirådet”) and the secretariat of the Health Committee formed a common secretariat to execute the project.

Objective of Citizen Summits

Under the heading “values and challenges”, the Danish Regions sought the informed and considered judgements of citizens as to how, for example, technologies could be used to increase productivity, notably whether the prioritisation of the treatment of disease was acceptable at the cost of other procedures, for example certain plastic surgery procedures, whether private insurances could be used for financing certain treatments, and whether patient compliance with treatment could be demanded etc.

Objective of Policy Summit

To make consensus decisions on new developments and prioritisation in healthcare between actors in the Danish health care system, based on the assessments of citizens.

Outcome

Some notable results of the initiative:

- At the time, it was possible to get tax refunds for private health insurance, which was expensive for the health care system, but there was uncertainty about the public reaction if it were to be abolished thereby resulting in a lack of courage among politicians to abolish it. However, at the Citizen Summits some 80 % of participants expressed their support for a fully public health care system or private insurances without tax refunding. This resulted in a political shift of attitude. Shortly after the Policy Summit tax refunding was abolished.

- There was citizen support for requiring patients to adopt lifestyles that did not compromise their treatment. This was discussed intensively at the Policy Summit and received much more focus in health care policy afterwards.

- Capacity building for healthcare personnel was supported by 71%, in order to qualify personnel across disciplines. Decisions were made to reduce the barriers between disciplines (e.g. so that specialised nurses can perform certain tasks previously only conducted by doctors).

Method

Citizen Summit: 4 full-day meetings with approximately 200 citizens in each, selected to reflect the composition of the Danish population. Information materials were sent to participants 1 week before the summits; the program and questions were exactly the same in all meetings. The 6-hour programme was separated into 5 thematic sessions, each beginning with an introductory video, and prompt questions, which citizens discussed in groups sitting at tables with 8 citizens and a chairperson.

The sessions were about:

- The most important challenges (each table identified two challenges, which were voted on by all at the end of the meeting),
- how to give health the right conditions,
- personal contribution (from the patient),
- resources available for health care,
- what should the health care system be able to deliver in the future?
- principles for prioritisation,
- the extent to which treatment should be seen as a common responsibility or a commercial good.

Each session ended with citizens voting on 3-5 questions using ‘clickers’. For example, in session 2a, the questions were:

- Who should take responsibility for our health?
- how should we deal with unhealthy impacts from working conditions and environment?
- how should we deal with unhealthy lifestyles?
- should the treatment be adapted to the patient’s lifestyle or the other way around?
- should citizens contribute to the health of others by becoming donors?

For each question, there was a set of alternative answer options.

The Policy Summit lasted 24 hours – from 12 to 12. During the first day, policy actions were brainstormed and discussed, which could follow-up on citizens’ judgements. The second day involved workshops in order to explore the actions in more depth and to share the responsibility for actions concerning them.

Notable features and lessons learned

The exercise showed how public debate can make a significant contribution to a policy-making process. A key to creating impact is to consider the decision-making processes as a whole, in which citizen participation methods are one step. A very important next step is to provide a process for political follow-up, and from the beginning to commit policy-makers to that.

The cost/benefit ratio of public debate should be reviewed across many debate activities. Public engagement may seem like a costly affair and not every activity offers the same rewards in economic terms. However, over time some single projects release decision-making power/courage that has very high impact on productivity, quality of decisions, and on the economy. This is particularly true in the case of abolishing tax refunds on private health insurances. To quote the organiser: “The abolishment of the tax refund would probably not have happened without the clear statement from citizens – and it has saved the public budget by an amount that manifold exceeds the total accumulated cost of public engagement activities in Denmark.”

Public debate promotes deep reflection, which gives different results than polls/surveys. An important difference between polls and public participation methods is that the latter often bring unexpected results in terms of willingness to break with what is assumed to be “public opinion” as stated by e.g. media, polls or lobbyists. The opinions are informed, reflected upon and debated rather than remaining personal views of an or the official line of one party. An example is the answer to the compliance problem, which introduced a new approach, namely that patients should have co-responsibility for their treatments. This was not supported by patient organisations, lobbyists or polls, which normally reflected that everyone had an unconditional right to the same treatment. However, the majority of the participants supported the approach.

FINLAND – CITIZENS' INITIATIVE TO THE PARLIAMENT (2012)

Background, initiator and participants

From March 2012, the Constitution of Finland made it possible to allow for a citizen action to be submitted to the Parliament of Finland subject to the support of a minimum of 50,000 signatures. Formal conditions and processes can be found in the Citizens' Initiative Act (12/2012). The Ministry of Justice launched a web service (see www.kansalaisaloite.fi) to facilitate the creation of citizens' initiatives which can be supported by the general public.

Citizens' initiatives have been very well received in Finland. In the last six years, more than 1000 initiatives have been processed, with 37 initiatives successfully reaching the minimum number of 50,000 signatures. One initiative led to direct changes in legislation (concerning equal marital rights) while others had an indirect influence on legislation.

Of those initiatives having successfully reached the minimum of 50,000 signatures, at least six related to bioethical issues. Several initiatives on bioethical issues did not reach the required number of signatures. Overall, it can be said that bioethical issues are well reflected in the initiatives by Finnish citizens.

The most well-known initiative concerned euthanasia and assisted suicide (over 63,000 supporters). Parliament repealed the law on euthanasia but required the Government to nominate a working group investigating these issues and possibly making a proposal for new legislation.

An initiative to ensure equal marital rights (with over 166,000 supporters) led to new legislation allowing the same rights for those in same-sex marriages as formerly given to married heterosexual couples. This initiative (with over 55,000 supporters) resulted in a new Maternity Act (which allows both parties in a lesbian couple equal rights of legal parenthood according to a defined process. Also, the definition of motherhood now allows transsexual men to be recognised as mothers and to access social support connected to the birth of a child.

Method

Proposal to enact or draft legislation - A citizens' initiative can propose the enactment or drafting of new legislation. It can also concern the amendment or repeal of existing legislation. An initiative in the form of a bill must contain the proposed legal text. An initiative must confine itself to a particular matter and must present justifications.

Fixed period for gathering signatures - An initiative must be signed by the required number of people within a period of six months. Signatures can be collected on paper or online (e.g. kansalaisaloite.fi). When enough signatures have been collected, the initiative is sent to the Population Register Centre, which checks names and confirms the number of approved signatures.

Consideration in Parliament - After the Population Register Centre has checked names and confirmed that at least 50,000 approved signatures have been collected, a spokesperson for the initiative can submit it to Parliament for consideration. If an initiative is not submitted to Parliament within six months of the date on which the Population Register Centre has made its decision, it is allowed to lapse.

Parliament has an obligation to consider a citizens' initiative, but it is up to Parliament whether it wishes to approve an initiative, with or without changes. If an initiative is rejected by Parliament, a new initiative concerning the same matter can be set in motion.

Notable features and lessons learned

The citizens' initiative is today the most important democratic innovation at the national level in Finland. According to a report from 2016 on Democratic Innovations (in English on page 4), about one third of those eligible to vote have signed at least one initiative. The citizens' initiative seems to engage some of those socio-demographic groups which tend to be otherwise politically passive, especially younger citizens.

The citizens' initiative is an effective way to promote and support free civic activity and public debate and thus strengthen civil society. The websites have provided an active platform for the citizens to reach out to a broader audience while, at the same time, providing an opportunity to feed ideas into the political arena. They allow for greater visibility of the public's views.

There are several initiatives on bioethical issues on the website. The most well known was the citizen initiative on euthanasia, which led to an inquiry. This will most certainly lead to a better understanding of the options and possibly eventually to a proposal on legislative changes on end-of-life care, assisted suicide and/or euthanasia. This example shows how providing a forum for citizens to voice their views can create an opportunity for the government to explore new directions.

A website allowing for the public to participate in initiating new legislation can have great impact for marginalized groups or in relation to a specific issue. The transparency of the website allows for citizens to be involved in the legislation process and makes the process easy to follow. This includes citizens in a whole new way and brings them closer to the legislators.

The limitation, in comparison with other ways to involve the public, is that the website only provides information given by the initiator and does not provide a forum of further debate, which must be organised separately.

FRANCE – PUBLIC DEBATE ON THE LAW ON BIOETHICS (2018)

Background, initiator and participants

France has had specific legislation on bioethics issues since 1988, and since 2009 it has involved the public in public debates. Since 2011, the French law on bioethics stipulates that the National Consultative Ethics Committee (CCNE) organises public debates and consultations within the scope of bioethical questions on medical and/or research practices affecting the human body and the embryo. The first National Consultation (les États Généraux) – as provided for in the 2011 Bioethics Law – was held from 18 January to 30 April 2018.

The question

The CCNE defined nine themes for debate, 7 scientific and 2 societal questions, namely:

- Research on human embryos and human embryonic stem cells,
- genetic testing and genomic medicine,
- organ donation and transplantation;
- neurosciences,
- health data,
- artificial intelligence and robotization,
- health and the environment,
- assisted reproduction,
- end-of-life care.

topics were chosen because they are at the core of the Bioethics Law and are important in the light of recent developments in the field of bioethics. Although the two last themes did not follow from the Law, the CCNE decided to promote debate on these topics because of their relevance in society and to benefit from the opportunity provided by the National Consultation to hear the public's views.

Method

In March 2018, an "Introduction to the themes of the National Consultation" was organised for around 60 journalists. Both the national and regional media were engaged throughout the National Consultation to report on the events and debates held across the nation. In some cases, on sensitive subjects, the press were deliberately left unaware of the timing as not to have a negative impact on the openness of the participants in the debate.

The CCNE created a Citizen Committee to consider the process of the debate and to choose two themes for consideration in greater depth: end-of-life and pre-conception genetic testing. The exercise resulted in three "Opinions" that were published in the CCNE synthesis report.

Besides the Citizen Committee, the CCNE organised the following as part of the public debate:

- 271 regional gatherings organised by The Regional Forums for Ethical Reflection (Espaces de réflexion éthique régionaux - ERER); 21,000 people participated in these meetings;

- a website was created where individuals could provide contributions online. Between February and April 2018, a total of 183,498 single visitors logged on to the website with 29,032 people providing 64,985 contributions to the consultation. The themes that attracted the most attention were "Procreation and Society" and "End-of-life Management", representing 69% of total contributions.

- 154 hearings between February and May 2018 involving 400 associations and scientific institutions, as well as organisations representing philosophical or religious interests.

Notable features and lessons learned

In this example, it is evident that political commitment helped to support the realisation of a very broad engagement of the public in debates on bioethical issues.

The example also shows how different methods can be combined to advance the informed debate on different and difficult topics.

A particular feature was keeping secret the venues and dates of the Citizen Committees meetings in order to avoid pressure and influence by the media and others. At the same time, the media had received special training in order to stimulate their interest in the project and the topics to be debated. This proved very successful in promoting the visibility in national media.

Another impact of this nation-wide initiative was a clear increase in public awareness on the topics that were the subject of debate.

The impact of the consultation on the revision of the Law on Bioethics is yet to be assessed, as the law has not yet been passed by Parliament. But it already seems that the public debate has contributed to the elaboration of the new draft law.

Despite a diversity of tools and a large plurality of views expressed it would be wrong to conclude that it provided a true representation of public opinion. The major part of regional discussions took place in a climate of tolerance and serenity, but this was not always the case. During debates on so-called "societal" issues, certain exchanges sometimes left little latitude for doubt, query or nuance, and thus for listening to other points of view.

Modes of online expression of opinion were also the subject to some criticism, such as: (i) the difficulty in accessing the website; (ii) the imprecision of formulation of the "findings and challenges"; (iii) the moderation, which some people considered insufficient; (iv) the definition of certain expressions that was not considered sufficiently acceptable to all parties.

Such encounters revealed that standpoints may vary with age and gender. Finally, hearings, that were numerous and diverse in nature, served not so much as fields of debate, but rather as a time for clarification and elucidation by the organisations who had accepted the invitation.

At this point, several findings should be emphasised:

- The significant role played by the younger generations in regional debates, varying with the themes under discussion, thanks to efforts on the part of regional forums (ERER),
- the difficulty of including the less informed and the more vulnerable members of the population in the consultations,
- the scant discussion on several major subjects during the consultation, for reasons which will need to be examined,
- the essential need for information that is of concern not only to citizens, but also to healthcare professionals,
- the importance of respect for differences and personal values, in particular as regards homosexual and intersex people.
- finally, the CCNE found that its operations were modified, but also enriched, by reflection during this process and the CCNE was also convinced that such participation henceforth would be necessary to consolidate sustainable national and regional debate on bioethical issues.

GERMANY – PUBLIC DISCOURSE ON GENOME EDITING (2019)

Background, initiator and participants

The project *Genomchirurgie im gesellschaftlichen Diskurs* (genome editing in societal discourse) aimed to stimulate public discussion regarding the ethical, legal and social aspects of new methods in genetic technology. The project is a cooperation between *Wissenschaft im Dialog* (WiD) and the German National Academy of Sciences – Leopoldina. It was funded by the German Federal Ministry of Education and Research as part of the research-funding program ELSA (ethical, legal and social aspects) in the life sciences.

The question

Conventional genetic technologies have been a subject of debate for many years and now the field is being revolutionised by new genome editing technologies, the most famous of which is the CRISPR-Cas9 system. The project focused on the medical applications of genome editing. Its target audiences included interested members of the public, school students, teachers, university students and apprentices, as well as stakeholders from politics, science and the media. These groups took part in various interactive activities that informed them about the new technology, and the opportunities and risks associated with it, with the goal of motivating them to develop their own opinions. 16 events took place from Autumn 2017 to Spring 2019 on topics about cancer treatment using somatic gene therapy, the use of gene drive against malaria vectors, and the opportunities and risks of genome editing.

Method

Wissenschaft im Dialog was responsible for 13 events across Germany designed for interested members of the public and school students. Some of the public events were examined from a social science point of view by external students and scientists.

As part of the project, a simulation game for school students was developed. It focused on gene drive technology, which might be used to control malaria by genetically modifying anopheles mosquitoes. After a testing phase involving four visits to schools of different types, the game was published as a toolkit. The toolkit includes presentations, a video, playing cards and work sheets, which allowed teachers to run the game independently with their students.

Five “lower house debates” targeting the "general public" were arranged to provide an opportunity to discuss genome editing. Two experts, one for the natural scientific part, one for the ethical or legal part, introduced the topic, then joined the audience for a debate focused on specific questions. The participants showed their opinion on each question by changing seats.

Three further public events took the form of a simulation game about cancer treatment using somatic gene therapy. During the game, participants engaged intensively with a hypothetical situation about a cancer patient who is unsure whether a new gene therapy using CRISPR-Cas9 is the right choice for her. The audience received expert input and support from moderators.

Leopoldina was in charge of three events for journalists and researchers, and political and scientific stakeholders in Halle/Saale and Berlin. In two training seminars organised by Leopoldina Journalist Collegium, journalists and editors joined scientists from the fields of biology, medicine, ethics and the law to elaborate in-depth insights into the specialist field of genome editing from multiple perspectives. The goal was to raise awareness of this complex topic among journalists and to encourage qualified media coverage. Within the framework of the workshop, a lower house debate was organised and attended by Leopoldina members and experts from hospitals, health care administration, medical societies, and patient associations.

The final workshop for stakeholders from all the target groups aimed to present and discuss the findings of previous events and to enable the participants to gain new perspectives through group discussions. In advance, masters' students in the social sciences had the opportunity to study the events to determine how the participants reacted to the interactive event formats. Their findings were discussed at the workshop. The summarising documentation was made available at the end of the project.

Project website (German): www.genomchirurgie.de

Notable features and lessons learned

The different event formats tested in the project had different strengths and weaknesses making them suitable for different audiences and purposes. The corresponding advertising measures should be well planned and widely spread.

“Lower house debates” are suitable for large audiences (up to 100 people) and for audiences with little or no prior knowledge of the topic. In comparison to a podium discussion, lower house debates are much more interactive and allow more people to speak. An experienced moderator is required, and the experts should be well briefed.

Simulation games are suitable for smaller groups (max. 50 people) and usually attract participants with a pre-existing interest in the topic. They run for longer and enable a deeper and more detailed discussion of the issues. Developing a new game or adapting one to a new topic requires an investment of time and resources.

The key benefits of the seminars for journalists were to link science and media, to communicate scientific findings, and to facilitate joint discussions on opportunities and benefits of research. Also, the participants were able to make personal contacts and these relationships often support future reporting rather than immediate stories about the event itself.

It is not easy to encourage a representative sample of the population to discuss such complex issues together. For the most part, such formats reach committed and interested people. This series of events succeeded in attracting sufficient participation. The participants greatly appreciated the offer of an evening event on the topic of genome editing; the appetite for information and discussion was high.

Impact of the project

All participants of the stakeholder workshop stressed the importance of such participatory events and expressed their desire for additional thematically complementary debates (e.g. embryo research, germ line therapy, green genetic engineering, genetic engineering and farm animals). Care should be taken to ensure that complexity of debates remains manageable for the public. Overall, further and more diverse participants could also be included in the events.

The accompanying socio-scientific research examined the participation formats from different angles. The formats and insights gleaned can be used for future communication projects.

IRELAND – PUBLIC DEBATE CONCERNING ABORTION AND THE REPEAL OF THE EIGHTH AMENDMENT TO THE CONSTITUTION (2016)

Background, initiator and participants

In May 2016, the Programme for a Partnership Government committed the Irish Government to the establishment of a Citizens' Assembly with a mandate to look at a limited number of key issues over an extended time period. One of these issues was to consider whether to repeal or replace the Eighth Amendment to the Constitution which prohibited abortion.

A number of tragic cases that ended up in court had put increasing pressure on the Irish government to address this controversial issue. In 2013, the death of a woman from sepsis after being refused assistance to abort a pregnancy following partial miscarriage triggered campaigners calling for the repeal of the amendment.

The chairperson of the Citizens' Assembly was appointed by the Government and a representative group of 99 citizen members were chosen at random to broadly represent the views of the people of Ireland.

Objective

To give advisory recommendations for consideration in a parliamentary committee, which in turn would make a recommendation to government.

Method

The Citizens' Assembly held five weekend-long meetings between October 2016 and April 2017 during which time legal and medical expert witnesses were invited to give evidence and be questioned. A final report and recommendations were prepared and then considered by a committee of parliamentarians from both Houses which, in December 2017, recommended a citizens' referendum on the removal of the Eighth Amendment to the Constitution. A referendum is required to amend the Constitution, which the Irish government proposed. This referendum took place on 25 May 2018 and passed by a clear majority of 66.4 per cent to 33.6 per cent in favour of removing the Eighth Amendment.

Notable features and lessons learned

The Citizens' Assembly was composed of private citizens; politicians did not participate in its deliberations. The government defined its parameters, and the Parliament responded to its report.

The consensus-building techniques facilitated greater engagement and mutual respect. The tone of the proceedings in the Citizens' Assembly was non-aggressive and the information presented to it was intelligible for the lay person.

The parliamentary committee largely mirrored the tone and approach of the Citizens' Assembly and was thereby inquisitive rather than adversarial.

The 'Yes' and' No' campaigns for the referendum were largely built outside traditional political party structures.

Although politicians were prominent in both campaigns, the main parties allowed their members to support either side.

Decision making was deliberately slow to allow debate in the public and within the parties.

POLAND – CONSTITUTIONAL WEEK TO INFORM AND DIALOGUE WITH CITIZENS (2018)

Background, initiator and participants

The initiator of the Constitutional Week, the Association Pro Memoriam Zbigniew Hołda, was founded by a group of legal specialists aiming to commemorate the scientific and social activity of professor Hołda through, among other things, delivering legal education in an open and creative way.

Objective

The Association aims to build common ground for consensus and cooperation among representatives of different legal professions. The objective of this public debate is to inform or educate people and encourage them to be proactive in public. This equips society with the tools to help make informed choices, while increasing the active participation of citizens in public life and contribute to the strengthening of civil society.

The Constitutional Week is a nationwide project that the Association has been organising since 2015.

At first, the project was addressed only to students of junior high schools and high schools, but since the 4th edition other institutions such as municipal offices, houses of culture as well as cafes, cinemas, depots and religious communities are invited to participate.

To date, 2,300 lawyers have conducted lessons on constitutional law in about 1,700 schools. It is estimated that approximately 170,000 students have attended the classes.

The question

Practical cases of the influence of basic law are the subject of interactive lessons conducted by advocates, judges, prosecutors, academics and legal trainees.

In a wider perspective, the initiative can be seen as a way to communicate in society that the Constitution is not a collection of general rules that concerns only a narrow and hermetic group of those who apply the law, but obeying the law, obeying the Constitution, remains a matter of common interest.

Method

Information about the Constitutional Week and the online registration form is published on the official website of the Association and disseminated using social media, primarily Facebook. Schools and other institutions can register via an online form indicating inter alia their location, number of students that will attend the constitutional lesson, and preferences for the timing of lessons. Lawyers can register in the same way and they are required to advise where, when and how many lessons they can conduct. Then the Association links the institution with the lawyer so that they may discuss the organisation of the lesson.

The lawyers who agreed to participate in the project are handed case studies prepared not only by the members of the Association, but also by the members of the Association of Young Journalists, which is an organisation aiming at engaging young people in activism and promoting human rights, and also by the students' Scientific Association of Constitutional Law of the Warsaw University. The lecturers are instructed to speak in a simple language, adapted to the age of students. At the end of the lesson, students are asked to give a feedback to the lecturers.

The substantive supervision of the project is provided by eminent jurists. All the lawyers who agreed to participate in the project conduct lessons pro bono, and they do not receive reimbursement of travel expenses. A wide range of legal professionals are involved in conducting lessons during the Constitutional Week, including the deans of the District Chambers of Advocates, the Commissioner for Human Rights and other well-known lawyers or academics.

Notable features and lessons learned

The Constitutional Week demonstrates that public debate, which aims to inform and educate people and to encourage them to be proactive in public life, can be achieved with relatively modest financial resources.

The project demonstrates the power of social media, which, when used appropriately and targeted at the right group, may attract significant attention. The Association owes the success of the Constitutional Week to the fact that they have created a very positive atmosphere around the project using social media among other things.

The project, as any other, is not a perfect one. Despite opening it beyond educational institutions, schools remain the main participants. Moreover, the lawyers conducting lessons and schools are not required to send feedback to the Association which evaluates the project.

Impact

Despite of the differences of political opinions in society, the Constitutional Week proves that communication about fundamental values that are shared in a democratic society is possible, especially when we discuss these values in specific, clear cases that people can relate to.

Challenges

One of the challenges facing the project's organisers is to separate the political narrative from legal problems in order to refute allegations regarding the political nature of the event.

Website: http://stowarzyszenieholda.pl/

PORTUGAL – PUBLIC DEBATE ON THE END OF LIFE (2017)

Background, initiator and participants

The National Council of Ethics for the Life Sciences (CNECV) launched a national debate on end of life issues which included, in addition to euthanasia, several ethical questions related to end of life care.

The initiative started in Lisbon in May 2017, followed by a series of public debates. There were 14 debates, attended by large numbers of members of the public, that were held in 12 different cities all over the country.

Objective

To raise public awareness and encourage the promotion of free and informed debate among all citizens to allow a responsible participation in democratic decisions.

The question

Several questions were raised during the debate, mainly:

- The respect for individual autonomy,
- the limitations of autonomy when requesting euthanasia and assisted suicide,
- how to care at the end of life and the availability and adequacy of end of life care,
- arguments for and against the legalisation of euthanasia and assisted suicide.

Method

All the debates were open to citizens.

Experts were invited to present their views on the dilemmas corresponding to their professional roles (i.e. medical doctors, religion, philosophy, law) but also their personal points of view (e.g. as young people, patient representatives, opinion makers).

In the last conference (the international conference), two approaches were sought regarding the importance of the role of civil society and the deliberation process, and regarding the experts from different countries it was asked not to express their points of view but rather to provide information on the legal and factual situation in their own countries. The “main actors” were the citizens who attended all the conferences and were free to intervene, to ask questions and to exchange experiences.

Society had the chance to discuss relevant issues on the end of life (e.g. palliative care, informed consent) apart from the specific euthanasia issue.

The project ended in December 2017. In the beginning of 2018, the Parliament voted against the proposal to amend the law.

The debates were recorded and largely disseminated by the media. A media partner covered the debates on a regular basis (interviews, photos, announcements and post-debate reporting).

A book called “Deciding on the end of life – cycle of debates” was published with a collection of excerpts from the conferences as well as interventions from the public (with an overview of all the views expressed), which included the texts of the conferences presented at the international seminar. It also included a glossary, a conclusion with the main questions and arguments presented in the debate as well as a short study on comparative legislation.

Notable features and lessons learned

The work was applauded by all the sectors of society that recognized the importance of helping citizens to build their own opinions though open and pluralistic debate.

The involvement of all the main actors in discussions helped citizens understand their views, hopes and fears.

A publication containing the highlights of the debates, the main conclusions, a glossary and a summary of a comparative legal framework was launched on 1 Feb 2019 in a ceremony attended by the President of the Republic. The documentation remains relevant despite the Parliament’s decision against the proposals. It manifests the conclusions of the debates for future reference.

Impact

The debates had considerable impact in local communities as evaluated by the number of media news and opinion articles issued via national and regional broadcasts and press. They acknowledged the format for the audit process and the free and open discussion on the topic, which had never been done before.

Interestingly, several institutions challenged the CNECV to extend the period of public discussions offering to organise initiatives in places that were not included in the original roadmap of debates.

A special volume of the summary of debates was edited containing the most relevant positions of the discussants (speakers and general audience), together with the main consensus conclusions and the key issues generating controversial and opposed opinions.

This volume was disseminated throughout a wide network of bookshops all over the country and sold out in a short period of time. The President of the Republic was present at the launching event having stressed the relevance of the initiative, which made greater the media impact of the book’s content.

RUSSIAN FEDERATION – PUBLIC DEBATE AND ITS IMPACT ON THE LAW ON TRANSPLANTATION OF HUMAN ORGANS AND TISSUES (2016)

Background

The Russian Federation has a long-standing practice of consultations on draft laws at the level of state authorities as well as public discussions. Public discussions takes place at various venues and with interested representatives of professional communities and public organizations, including patient communities.

The Resolution of the Government of the Russian Federation "on measures to improve the legislative activities" (2009) provides that a Bill that has been approved by Governmental bodies and Executive authorities is placed on a special website for public discussion. Comments and suggestions provided by citizens are posted on or submitted through the same website. Replies to the suggestions are also posted on the website. These replies are prepared by the Ministry of Health, employees of the Department of Medical Care and the Legal Department, with the involvement of expert groups.

In addition, public discussions on draft laws are held with various target audiences: the professional community, including academics, representatives of faiths, patient organizations, representatives of the public chamber, where the diversity of civil society is represented.

Bills are amended based on the views gathered. If adoption of the draft law is considered to violate or restrict human rights, such bills may be re-directed for public comment.

The question

The law of the Russian Federation of 1992 "on transplantation of human organs and tissues" permits organs to be removed from the body of an adult person after his death, if there is no record of this being against the persons wish. In other words, a presumed consent based on an opt-out system. The legislation focuses on organ transplantation and has significant gaps in issues related to human rights in organ donation

There has been a discussion about whether relatives should participate in the decision on organ donation from a deceased person, including whether they have a right to refuse organ donation when the person has not registered their wish.

Another discussion relates to organ donation from children. The law of 1992 prohibits live donations from children under the age of 18, and requires informed consent of one of the parents (explicit consent, “opting –in”) in order to remove an organ from a deceased child.

New legislation, proposed in 2016, aimed to improve legislation in the field of organ donation in order to fill in legal gaps related to the rights of organ donors; to balance the rights of donors, recipients, their relatives, and specialists of medical organizations; and improve the legal and ethical aspects of donation.

Another aim was to inform the population about the importance of organ donation and the current legislation, including its development and improvement.

Method

The proposed amendments were subject to public consultation and debate, as required by the Bill from 2009.

Discussions took place in different forms. Online debate was mainly attended by ordinary citizens, mainly over the age of 40 years old, who discussed the proposed bill and expressed their views regarding organ donation. Their attitudes to organ donation were mainly negative or neutral.

Discussion on organ donation, amongst the younger generation, took place in social media.

Detailed debate of the draft law took place in the professional community, in meetings with experts. Expert opinions were analyzed in accordance with the rules for preparing a draft law for submission to the Government. The analyses were responded to by the Ministry that prepared the draft law.

Outcome

The outcome of the debates allowed the Ministry to improve the provisions of the draft law and to improve programs for informing citizens about organ donation.

The part of the law that allows for donation from deceased children is constantly criticized. The debate showed that Russian society is not ready for organ donation from deceased children, although this is already regulated by law, and there are no obstacles to the implementation of this provision.

The proposed amendments to the law received a lot of criticism, and the new law was stopped before it reached Parliament (Duma).

Notable features and lessons learned

Organ donation is a very sensitive issue for Russian society because of the importance placed on the integrity of the body of deceased persons. It was possible to reach consensus among experts on many issues, but there are still difficulties in regulating the rights of relatives of donors.

One of the most important lessons learned is that the debate will only be effective if people have a full understanding of the subject, especially when the subject raises human rights issues. The debate should be preceded by a broad information campaign, with detailed explanations of all the provisions discussed in the current and new legislation.

The discussion of the draft new law continues, and the most difficult is to overcome the negative attitudes to organ donation among citizens over the age of 50-60 years, who are very actively involved in public discussions on this issue.

Public debate should be adapted to the cultural context. Perhaps this issue has its own historical and cultural roots, since the Russian Federation is a multi-ethnic and multi-confessional country where it has always been important to preserve the integrity of the body of a deceased person before burial.

UNITED KINGDOM – PUBLIC ENGAGEMENT ON BRAIN SCIENCE, ADDICTION AND DRUGS (2007)

Background, initiator and participants

In 2006, the Academy of Medical Sciences (AMS) launched an independent inquiry into the societal, health, safety and environmental issues that had been identified in an earlier report, *DrugsFutures 2025?*, published in 2005.

The drugsfutures public engagement activities ran from January to April 2007 and engaged specific groups that included parents of children with ADHD, students, teachers, drug users and ex-drug users, older people, young people, and people with mental health problems.

Objective

To explore the hopes and concerns of a broad cross-section of the public on current and future issues relating to brain science, addiction and drugs.

The question

The public engagement programme was intended to focus on the areas where addiction, brain science and drugs overlap, covering the three types of drugs identified in the original Foresight report: illegal and legal ‘recreational’ drugs, medicines for mental health and a new category of substances termed ‘cognition enhancers’ that might enhance the performance of the brain in specific ways, such as enhancing short term memory or speed of thought.

Specific questions were asked based on the following scenarios: drugs and young people, drugs for a smarter brain, and drugs and the law.

Method

A working group was set-up by the AMS to support its independent review of the societal, health, safety and environmental issues raised by scientific advances in brain science, addiction and drugs (BSAD). The membership of the Working Group was intended to reflect the diversity of the issues to be explored and included experts in epidemiology, medicine, neuroscience, psychiatry, psychology, pharmacology, philosophy and law.

The Working Group consulted with relevant stakeholder organisations (for example, scientists, research funders, health professionals, charities and patient groups) on issues that may arise from current and future scientific developments.

There was a wide range of types of events, with a public launch in London (113 participants), 19 short (2 hour) outreach workshops (146 participants) around the UK, 5 regional workshops around the UK (180 participants) each focusing on a different topic (e.g. the law, mental health), and a Brainbox - two 2-day sessions six weeks apart for more in depth discussions covering all 5 topics from the regional workshops (25 participants). The outreach events, some of which involved presentations by drug users and ex-drug users themselves, included stakeholder consultation and expert examination simultaneously.

Notable features and lessons learned

The project was thoroughly evaluated. Some notable features on the value for the public participants are cited below (for more information, see the full evaluation of the project):

- The process worked well for public participants. Overall, the respondents were very satisfied with the process and the way it was run. The process engaged people effectively,
- the participants felt the process was very enjoyable, informative and worthwhile. The quality of discussion, and the interest and enthusiasm of the participants, was high,
- participants learned something new. Many also said that being involved had clarified their thinking and affected their views about drugs and mental health issues,
- there was increased enthusiasm for future involvement. As a result of being involved in this process, almost all respondents were more willing to get involved in discussions on policy issues in future. Almost all respondents also felt it was important to involve the public in discussing these sorts of issues, and many expressed the wish for more events of these sorts in the future,
- many participants valued having a say and being listened to by the AMS and felt they could make a contribution to public policy and influence future decisions.

Impact

- One of the public priorities, on the need for research into addiction as a disease, was picked up by the AMS and new funding of £8 million was made available from the Medical Research Council to do that research,
- in July 2009, the Advisory Council on the Misuse of Drugs (Home Office) launched a detailed review of the safety and regulation of cognition enhancers, which was raised as a research priority by public participants in its project,
- the dialogue increased available intelligence on why some legal interventions on drug use do not work,
- the dialogue directly influenced and improved the final AMS Brain Science, Addiction and Drugs (BSAD) report to Government. Public participants could trace their contribution in the final report.