

GUIDE TO PUBLIC DEBATE ON HUMAN RIGHTS AND BIOMEDICINE



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COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

**GUIDE
TO PUBLIC DEBATE
ON HUMAN RIGHTS
AND BIOMEDICINE**

Council of Europe

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I. INTRODUCTION

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. 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. Besides promoting a culture of public debate, the guide describes why public debate is important in the governance of biomedicine and helps to identify appropriate and effective approaches according to the topic and circumstances. It does this mainly by encouraging a deeper reflection on the reasons, aims, participants and forms of public debate, and by offering some suggestions and examples. It is not intended to be a manual for public debate but a guide to approaching public debate in a way that can benefit all those involved, and ultimately, the public as a whole.

In this guide, the overarching concept of “public debate” is used to describe discursive interactions in the public sphere through which individuals and groups may identify, explore and resolve their different interests in matters that potentially affect them all. “Debate” is understood as an open-ended process; it does not imply any expectation that it will lead to an outcome with which everyone agrees.

A number of different tools and approaches exist, many of which have developed in the light of social science research, or in the course of practical policy making. Each of these has advantages and limitations, which are discussed in a large and growing academic literature. Many of these are illustrated by the examples presented in this guide and are further elaborated in the selected resources provided at the end of the document.

The Council of Europe Convention on Human Rights and Biomedicine (ETS No. 164 “Oviedo Convention”) aims to promote human rights, democracy and the rule of law in relation to biomedical science and the practice of medicine. Article 28 of the convention creates an obligation on member states to offer members of the public the opportunity to make their opinions count in the field of biomedicine. It says:

“Parties to this Convention shall see to it 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.”

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

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.

The norms and common principles that emerge from such involvement are also the source of public morality. Well-grounded norms are more apt to increase the public's trust in governance. A key function of public debate is to bring forward a more robust basis for decision making while helping to identify issues of concern that may warrant a public policy response.

Public debate can strengthen the role of citizens in the governance of their society. We may say that public debate is therefore debate that is in public, with the public and for the public.

- ▶ 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

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.

Biomedical developments often require long-term strategic commitments that raise questions of collective values, aims and visions of the “good life”, including questions about how benefits should be distributed within society. Governance that is guided only by political ideology, or that considers only limited technical questions such as the potential benefit and harms of treatments, or that responds only to existing preferences, may fail to address adequately these broader and longer-ranging questions. Given the potential effect on the lives of individuals, it is important that members of the public are informed about biomedical developments and can formulate, communicate and interrogate their views. This is important because it enables the public to take part in shaping policies and strategies for their society, and for building the competence of individuals to make informed decisions about their own health and welfare. It is equally important for policy makers to be aware of different opinions and diverse values among the public in order to respond to them.

- ▶ 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

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.

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.

Developments in biomedicine, especially new technologies, are often complex; they arrive in socially and culturally defined circumstances, and they embody not only possibilities but also uncertainties and ambiguities. Very often the benefits are initially more apparent than risks and side effects, which cannot always be anticipated. These risks and side effects often come to light only through practical experience. By the time the consequences become more apparent it may be too late to change the course of developments.

Responsible approaches to biomedical innovation recognise a duty to anticipate and inform the public about developments that could have a profound impact on their lives and the societies they live in and involve them in guiding decisions towards an acceptable outcome, for instance how and under which circumstances to use a new technology. Public debate can help to explore the values and principles that underlie different responses to biomedical developments so that, when unanticipated implications emerge, policy makers can be better prepared to address them.

Despite its obvious benefits, the era of mass access to digital information technologies has, unfortunately, fuelled division in society. It has enabled the spread of misinformation, divided society and incubated self-reinforcing discussions among homogenous groups, encouraged intolerance of criticism, and excused the rejection of evidence in favour of opinion. The promotion of public debate, where contrary opinions can challenge each other, combined with tools of evidence, is an important counterbalance to such developments.

It is particularly important that interests should not be appraised only through aggregated opinion in environments that offer little opportunity for challenge or accountability, such as social media. Without inclusive debate there is a real risk that the voices of those in positions of vulnerability may be overlooked, even to the extent of them being unable to claim the protection offered by their human rights.

- ▶ 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.



Germany, 2019: The rapidly evolving gene editing technology CRISPR-Cas9 has been identified as a bioethical concern which is highly amenable to being addressed through public debate, both for purposes of awareness raising and for mapping risks and benefits. Germany is one of the countries that has organised a broad public debate on the issue; see the German example – the “Genomchirurgie im gesellschaftlichen Diskurs” initiative in 2019 – in the Appendix.

ASPECTS THAT DESERVE SPECIAL ATTENTION

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

Public debate can be particularly important around biomedical developments that have a profound impact on society and individuals, developments that may fall outside existing regulatory frameworks, and developments that may entail unknown risks or have an unpredictable effect on society, or disproportionately affect certain groups.

Speed of developments

The speed of development may cause legal gaps. These can arise from the difficulties legislators face in assessing the implications of and making provision for novel applications in fast-moving areas of technology. This can create uncertainty for everyone concerned.

In introducing new developments where there is no long-term experience and little certainty about outcome or impact, broad ethical consideration is needed to set a long-term strategy to control their use within socially acceptable limits.

- ▶ 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 application of digital technologies creates opportunities for data mining. When combined with new biomedical technologies, this may present a challenge to the protection of the privacy and autonomy of individuals in several ways. For an individual, it may become difficult to understand the complex flows of data about them, to make informed decisions about how all the information is used or spread, and thus, to exercise autonomy.

Biomedical innovations increasingly rely on access to large and detailed data sets, often from a variety of sources. Combining large amounts of data from different kinds of sources may make the re-identification of the person concerned possible.

- ▶ 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

Whereas biomedical innovations can reduce the risk of disease or alleviate symptoms they may also require people to accept new conditions in order to receive healthcare. For instance, genetic testing may in the future involve the generation of standardised or complete genomic data sets, and access to certain services may imply that all data are stored. Storage of a person's genome data implies storage of knowledge that, with increasing scientific understanding, could provide information about predisposition to disease or even to certain behaviours. Withholding or not allowing for the generation of such data may entail opting out of services in a way that could leave an individual without access to the best available standard of care.

- ▶ 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

Biomedical developments have the capacity to blur and challenge normative boundaries. They can translate rapidly from one field of application to another, where different regulations may apply. They can also create ambiguities in the application of regulatory measures, for example, over whether a particular use is medical or non-medical, or whether a given use is a therapy or a non-therapeutic enhancement.

For instance, when devices are brought to the market for non-medical purposes, they are not seen as medical devices and thus may fall outside the scope of existing

medical device regulation. An example of a technology that produces findings which have an ambiguous status is direct-to-consumer genetic testing, where information about genetic predispositions with health relevance is provided outside the healthcare context and without proper counselling.

- ▶ 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

Biomedical innovations can entail risks that may be foreseen or unforeseen. In some developments in biomedicine, there may be substantial areas of uncertainty where the nature of the risks cannot be identified reliably or where there is no clear understanding of how to describe or evaluate them. In such situations, an appropriate response may be to broaden the appraisal of emerging biomedical technologies. This could include taking account of different perspectives, evaluation of alternatives, and consideration of aspects such as irreversibility.

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

Impact on social norms and the question of equity

The uptake of biomedical developments can lead to profound changes in social norms. Such effects may not have been anticipated when implementing technologies in healthcare settings. These developments may also have further implications for access to healthcare for different groups.

For example, the establishment of prenatal diagnosis as a routine examination, in combination with simplified abortion methods, has led to significant reductions in the birth of people with Down's syndrome in some societies. The increased access to the technology can have a potentially significant effect on the expectations of pregnant women and heighten the risk of marginalisation of those affected by Down's syndrome. Inequities in access to the benefits of innovation can also compound and exacerbate underlying social and global inequalities and have an insidious effect both on individuals and societies.

- ▶ 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

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.

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

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.

Inevitably, there will be more than one reason for any given initiative. Reflecting on the nature and balance of reasons can help to identify what approaches may be appropriate. Public debate activities should never be undertaken without careful prior reflection, as just a “box-ticking” exercise, since this is unlikely to serve the interests of anyone involved and could even lead to public distrust.

Ethical reasons

One reason for initiating a public debate activity might be a principled commitment to involve those potentially affected by biomedical developments in the governance of those developments, recognising that all voices are entitled to be heard. In the case of developments in biomedicine, the scope of those potentially affected extends to the whole of society.

A development that concerns people's human rights or challenges implicit social norms is likely to be one where public debate is not only desirable but morally and, in some domains, legally required.

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



Germany, 2019: The public debate “Genomchirurgie im gesellschaftlichen Diskurs” (about genome editing) is a good example of a range of actions being undertaken for ethical reasons.

Making better-informed decisions

Good decision making requires consideration of broad questions of vision and value that technical experts are not always well placed to answer. Professional advice is often limited in scope and questions about the application of new developments are not necessarily technical questions so much as moral and political questions.

Technical questions could be whether it is safe, useful or economical to implement a new technology, whereas the initiator may further want to explore whether any risk is considered socially or morally acceptable, and who should be empowered to decide this.

- ▶ 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

Another reason policy makers may wish to initiate public debate is to seek legitimacy for decisions about the implementation of a development that raises novel or unusual issues that have not been discussed previously. This might occur further “downstream” where a technology has emerged rapidly or where there is pressure to transfer a new technology from other national settings.

In circumstances in which policy makers propose to introduce a controversial new development, initiating public debate activities can help to inform the public, assess the development's acceptability and, where appropriate, prepare the way for implementation.

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



France, 2018: There is a provision in law that requires public debate periodically when amending legislation on bioethics, and in any case every five years. This was last undertaken through a large-scale public debate called “États généraux” in 2018.



Russian Federation, 2016: The Russian Federation has a long-standing practice of discussion on draft laws at the level of state authorities and through public discussion at various venues. Views from the public are also collected via an internet portal. A debate on the amendments to the law “on transplantation of human organs and tissues” took place in 2016. The discussion is still ongoing.

WHAT ARE THE OBJECTIVES?

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

The objective of engaging the public might be to inform people about new developments in biomedicine, to stimulate debate or to lay the foundation for further consultation or participation, and to open up a dialogue that could inform policy making in return. This might also have the effect of encouraging public engagement more generally.

Public debate should not only be about educating the public about biomedicine but also about exploring the interaction between biomedical developments and social understandings and values. Bringing the debate into these terms helps to redress imbalances of knowledge and power that can occur when publics interact with experts or officials.

In most states, the media play an important role in consolidating knowledge and spreading information. This is also the case when reporting advances in biomedical research, treatment methods, biomedical technologies and applications, making this knowledge explicit in relation to current events and issues, as well as curating new information and expertise.

A free press plays an important role in society (as the “Fourth Estate”), as a way to expose the manipulation of information, challenge orthodoxies and evaluate new knowledge. Public media reach a large number of people but are often seen as reporting from a particular “angle” and as trying to mobilise emotional responses. They can be responsible for “hyping” new developments or distorting the level of technical uncertainty. Nevertheless, their role should not be underestimated as an important channel of information, which is essential for involving the public.

Social media can support and extend the function of public media but, insofar as they produce self-referential “information bubbles” or “echo chambers”, they can just as easily reinforce prejudice and misinformation, and even spread disinformation. Another limitation is that not all have access to the same information, as discussion groups in social media tend to be for members only.

Biomedical researchers can have an important role to play in communicating with the public about developments in biomedicine. Exchanges between researchers and the public help to foster public trust in science and help scientists pursue their research with regard to the interests and values of society. Experts, however, often require specific training in how to communicate their work to non-specialists. Communicating with the public (for example, speaking to the mainstream press) may be seen as part of the obligations of researchers, particularly if their work is publicly funded, and might be made a condition of grants. Early and continuous information about research can be achieved by, among other things, funding and promoting seminars, developing webpages and producing educational material for schools.

- ▶ 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.



Belarus, 2018: In the public debate on “The rights and responsibilities of doctors and patients in modern healthcare systems (legal and ethics issues) (2018–2019)”, the main purpose was to inform patients about their rights and to remind doctors about their responsibilities, including knowledge about new legislation and ethical practices.



France, 2018: In the French “États généraux” project, the media were recognised as a key actor and training for media professionals was organised ahead of public debate activities to promote balanced reporting on the selected topics and their ethical implications.



Cyprus, 2018: During the Cypriot Awareness Week on nursing homes for the elderly, a Code of Conduct for Journalists and the Mass Media was prepared as a result of the public debates held in order to provide guidance for journalists when reporting on aspects regarding the care of elderly people.



Germany, 2019: In the debate “Genomchirurgie im gesellschaftlichen Diskurs” in 2019, two training seminars were organised where journalists and editors convened with scientists from the fields of biology, medicine, ethics and the law to understand genome editing from multiple perspectives. The goal was to foster informed media coverage on the topic.

Identifying issues of concern

One important aspect of engaging the public is to identify issues of concern. These might be concerns that experts and policy makers anticipate will arise and want to explore in more detail or they might be unexpected concerns that emerge when people begin to consider biomedical developments.

Early debate around such developments can help to anticipate concerns before they become entrenched and difficult to address. It can allow for concerns to be met in more time- and cost-effective ways, for example, through adaptation in the design of technologies and the ways in which they are brought into practice.

- ▶ 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.



Finland, 2012: An official website was introduced in 2012 where the public may raise issues of concern, bring them to the attention of legislators and automatically have them debated by parliament if more than 50 000 citizens sign an online petition.

Gathering evidence of public views

An important objective of public debate activities is to gather evidence of the range and content of public views to inform decision making.

It is important to know to what extent the evidence of public views will represent informed conclusions and to what extent it is the expression of underlying beliefs or values. It may also be important to know what informs these views (for example, technical knowledge or religious faith), how entrenched they are, and in what ways and for what reasons they might alter over time.

Consideration should be given to the kind of evidence that will be relevant to understanding public views (e.g. quantitative or qualitative) and how the use that is made of the evidence will be justified. For example, observational research, such as social media analysis, can be cost effective but has limitations in terms of how informative it can be, owing to the lack of control over information and the social dynamics in play.

- ▶ 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

The objective of public debate might be to involve the public in decision making, for example, to shape the development of policy options, or to involve them in the governance of new technologies, through monitoring or reviewing activities.

Public participation has a number of benefits, including increased legitimacy through representation and ensuring conformity with social values. However, it is important to understand the relationship between the members of the public involved and the broader public whose interests are at stake (see next section, “Who should be involved?”).

- ▶ 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).



France, 2018: The French National Consultation (“États généraux”) aimed to involve as large a public as possible in public debate on bioethical themes feeding into the legislative process. Broad coverage in the media, a website that allowed the public to participate and the use of regional forums for public debate activities created good opportunities for participation and helped to build capacity for further debate.

WHO SHOULD BE INVOLVED?

A person 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, the question of who makes up the public will depend on the issue at hand and the kind of interest in and relationships to the issue they have. 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.

There is no single, comprehensive, homogeneous and invariant “public”. Who is actually involved in public debates is important, particularly if some who might wish to participate are unable to do so. When thinking about public debate, it is important to consider who should be involved, what interests they would represent and whether there are barriers to participation for certain groups.

To speak of “the public” can often imply homogeneity whereas, in reality, all societies embrace diverse social interests and perspectives. Not all issues affect the interests of everyone to the same extent, but everyone is entitled to a voice in public debate.

Some publics, such as participants in open consultations and uninvited public debates, may be self-selecting. In many invited public debate activities, particularly those that have the purpose of eliciting public views, the participants may be carefully constructed samples based on demographic information and following established social science methodologies.

- ▶ 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

The intended public may be those with a direct interest, often referred to as stakeholders. The views of those with direct interests will be relevant in public debate on biomedical developments but many others may also be indirectly affected. To the extent that developments in biomedicine potentially transform opportunities for all, everyone will have an interest and is therefore a “stakeholder”.

Consideration should be given to how to represent the interests of those potentially affected with low impact but possibly high frequency as well as those affected with high impact but at low frequency. Those people might be remote in space and time from the initial implementation of a development.

- ▶ 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 and 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

In developments that potentially concern the interests of everyone, it is usually neither practical nor necessary to involve a whole population in public debate. A sample of a population can give a helpful indication of the range of public views present in society.

The criteria by which a sample is defined and the size of the sample, however, need to be decided and thus depend on judgements. It is important to try to avoid these judgements embedding biased assumptions about what interests are relevant.

- ▶ 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.



Ireland, 2016: A Citizens' Assembly comprising a representative group of 99 citizens and a chairperson appointed by the government was formed to advise a parliamentary committee on repealing the Eighth Amendment to the Constitution, which prohibited abortion.

Including diverse voices

When initiating a public debate activity, it may be necessary to take special steps to incorporate the voices of those who have non-obvious or indirect interests, or who may encounter barriers to participation. In many societies, for example, minority ethnic communities have not enjoyed equal access to the public sphere. Some relevant sections of a population might not be offered or able to find opportunities to participate in public debate. Some may even be unable – due to language, physical or psychological barriers, or for cultural and religious reasons – to take part in an invited event. In some cases, this lack of opportunity can relate to their human rights, or compound existing forms of social and political exclusion.

Children and young people have particular interests in the long-term consequences of adopting technological pathways. They may offer novel perspectives and distinctive views, but different approaches may be required to enable their safe participation in public debates, especially when the subject matter is sensitive. Older people comprise an equally significant part of the general population and are often disproportionately affected by alterations to health services.

Minority voices can easily become lost in quantitative or aggregative approaches when the participants are selected at random or as a representative sample of the general population.

Existing relevant networks and interest groups can provide a route to involving those with a particular interest in the issue or who may be otherwise hard to reach as well as people in positions of vulnerability. There may also be a need to take specific steps to include socially marginalised groups, who may be less likely to participate, for example, by working with recruiters or trusted mediators.

Issues of policy that affect a whole jurisdiction may affect the interests of people in different geographical areas differently. This might mean differences between metropolitan and rural, north and south, industrial and service centres, mainland and offshore, etc.

- ▶ 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.



Germany, 2019: The project “Genomchirurgie im gesellschaftlichen Diskurs” engaged different groups, including school children. The students took part in a simulation game about a gene drive technology with their teachers using a specially developed toolkit.



United Kingdom, 2007: The United Kingdom example of public debate “Public Engagement on Brain Science, Addiction and Drugs” demonstrated the value of taking innovative steps to involve hard-to-reach groups who may find it difficult to participate openly in invited public debate activities.

WHEN IS THE APPROPRIATE TIME TO INITIATE A PUBLIC DEBATE?

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.

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.

Participants should not feel like the decision has already been made and that they can have little real influence. This applies both when decisions have been made on a political level but are facing criticism, and when the views of the public are sought before making the decision.

- ▶ 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

“Upstream” public debate activities take place at an early stage before research and scientific developments are translated into applications. They have been advocated as a way to increase social influence over the aims and directions of research and innovation, with the purpose of making science more socially responsible. The involvement of the public at an early stage can contribute to steering developments in a direction that is acceptable for society.

- ▶ 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.



Denmark, 2008: The Danish Board of Technology organised a public debate to help inform policy makers about the public’s view on, among other things, priorities within healthcare, before deciding on the policy direction to be taken.

Public debate in connection with policy making

Public debate helps to identify a shared public interest among citizens. Connecting this public interest with public policy is one way of making public debate count.

Quite often public debate is initiated in connection with a public policy-making process with the intention of providing proposals for amendments to law or public policy.

When the initiative is politically controversial, there is a greater need to consider timing carefully and to avoid the likelihood that participants will debate only their different political positions. Under such circumstances it is important to allow sufficient time for a reflective consideration of the issues so that a variety of opinions and values are brought into the debate.

Conversely, where complex issues are caught up in conventional political oppositions, public debate processes can provide a space to explain and discuss these issues with a view to finding common ground.

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



Denmark, 2008: The public debate on the future of the healthcare system concerned a politically sensitive question about changing the provisions for public versus private funding of certain treatments, and thus it was important to avoid a politically sensitive timing. It also took a politically sensitive subject out of the political context and turned it into a public debate. Policy making was eventually guided by its outcome.



Ireland, 2016: The question of repealing the Eighth Amendment of the Constitution of Ireland concerning the prohibition of abortion was a politically very sensitive issue, making it important to distance the Citizens' Assembly from political influences. This was achieved by getting public agreement of key parties not to prejudice the debate.



IV. EFFECTIVE PUBLIC DEBATE

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.

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.

This section is about how to secure and improve the quality of public debate activities. The quality is related to, but distinct from, any judgement about whether the process is appropriate to the purpose or situation (see Section III, “Preparing for public debate”) or how well the outcome meets the expectations of its initiators or participants (see Section V, “Public debate that counts”).

Effective public debate provides individuals and groups with access to public life in a way that can stimulate interest and create opportunities for empowerment. It can help to foster trust among citizens, and between citizens and government or public authorities. Ineffective public debate activities may not merely fail to produce these effects but risk giving rise to their opposites: lack of interest, mutual suspicion and, ultimately, a sense of alienation from public life.

- ▶ 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

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 launching the initiative. This can be improved by creating an environment and process that are adequately resourced, inclusive and enabling.

Allowing sufficient time for public debate may often be at odds with the need to make a policy decision on a pressing matter. Over-hasty decision making, however, runs the risk of simply deferring or displacing debate that may become more divisive or disruptive later.

Often the reasons for time pressure are contingent, for example, on securing reputational or economic advantage, and may be mitigated by foresight and anticipation. Any urgency may, however, need to be resisted where the quality of public decision making, rather than the outcome, is particularly important. This is likely to be the case where significant uncertainties persist, for example, where risks and consequences are poorly defined and where there is significant ambiguity about meanings and values that people attach to the issue.

Commitment of resources

In order to enable participants to contribute meaningfully, public debate needs to be adequately resourced. Depending on the methodology and scale, public debate activities can be expensive. At the very least, the resourcing needs to be adequate for the approach taken.

Adequate resourcing demonstrates the commitment of initiators of public debate and may include not just meeting financial costs but also devoting time to supporting the process from conception to follow-up. Inadequate resourcing or “cutting corners” can undermine public debate and lead to outcomes that can be counterproductive.

Where resources are limited, approaches can be framed to meet more limited objectives. Over-reaching and over-claiming, by not respecting the methodological limitations of the process, could be counterproductive. Alternatively, resources might be expanded by working in partnership with professional or civil society organisations, although diligence will need to be exercised to ensure that such arrangements do not compromise the integrity of the partners or the process.

As well as adequate financial support, it is important that sufficient time is available to allow citizens to participate fully in public debate activities. Time may be required for adequate planning, to communicate with the intended audience, to allow participants to plan their involvement in the light of their other commitments, and to prepare themselves to participate. This is often at odds with the demands of responsive policy making. In most cases, it is important that time is allowed for participants to consider evidence and arguments, to discuss these with others (if appropriate), and to formulate their views.

- ▶ 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.



Ireland, 2016: A public debate activity was initiated concerning the repeal of the Eighth Amendment of the Constitution, which prohibited abortion. The process involved the establishment of a Citizens' Assembly, which met five times during 2016 and 2017. Its conclusions in 2017 laid the groundwork for a decisive national referendum in May 2018. The commitment of sufficient time was an important factor in the effectiveness of the process.

- ▶ 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.



Finland, 2012: Public debates can be costly, but there are also more affordable ways to create spaces for public influence. An example is the Finnish initiative to build an easily accessible website for the public to raise support for an issue that they wish to be addressed by parliament. In its first six years, this initiative resulted in 37 petitions being debated.

- ▶ 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.



France, 2018: The French "États généraux" initiative made use of existing regional forums in an efficient way, reaching out to the public across the country and in overseas territories, and making it possible for the wider public to engage in national debate via a local infrastructure.



Poland, 2015: The Polish Constitutional Week makes use of the existing organisational infrastructure of schools and other institutions to involve students with legal professionals by offering lectures in constitutional law as part of a public debate activity that has taken place annually across the country since 2015. It is a capacity-building exercise offered on a voluntary basis by legal scholars, free of charge.

Meaningful participation and co-design

Respecting the interests of participants is a requirement for meaningful public debate. Participants' interests may be respected by rewarding them financially for participation, even if it is only a nominal value. The rewards of participating in public debate, however, more often lie in the opportunity to influence public decision making (see Section V, "Public debate that counts") and to contribute in the shaping of society. For effective public debate, it is necessary for participants to understand that they have a stake in the outcome and to realise that participation offers them a genuine influence over that outcome.

Framing questions for debate in an unbiased way, or even enabling participants to frame the questions in a way that is most meaningful to them and that is agreed between them (co-design), can help to maintain trust in the impartiality of the exercise. Those initiating public debate activities may need to conditionally relinquish some power to the participants in exchange for their commitment. Likewise, the participants may feel they have a need for more information or a better understanding of different viewpoints before they can have a meaningful exchange over an issue. They should be given the opportunity to express such a need at an early stage of the planning so that relevant experts can be identified and involved in the process.

The initiator should also be aware of possible imbalances between participants, e.g. differences in education and social status, which may call for a facilitator or intermediary to articulate relevant questions to the experts, making all voices and possible concerns heard.

Linking the public debate activity to a tangible outcome can give participants a clear stake in the process and encourage them to be more committed to it.



Denmark, 2008: The participants in the public debate on the future of the Danish healthcare system discussed and later voted on very tangible questions, among other things setting principles for healthcare resource allocation and guidance for the policy makers.

- ▶ 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 allowing them to select experts or obtain evidence to inform their views.



Ireland, 2016: The Irish Citizens' Assembly was empowered to invite the experts it wanted to hear from and to question them in order to establish a solid basis for its deliberations.



United Kingdom, 2007: In a wide-ranging series of public debate activities around the theme “Public Engagement on Brain Science, Addiction and Drugs”, the participants were able to interact with a wide range of experts to inform their debate.

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

Accessibility and inclusion

To speak of “public debate” can also imply a public space where participants can express their interests freely. In reality, spaces of discourse are almost always structured by imbalances of power and knowledge, and their accessibility to all citizens is not necessarily equal or guaranteed. This applies just as much to the design of a questionnaire as to the physical accessibility of a venue.

Public debate takes place through the medium of language. Those for whom the local language is not their first language, for example recent immigrants, may require interpreters. Some who lack native language skills or basic education may be less adept with written communication. Literacy remains an issue in all member states. This can be compounded by the use of technical terms, which are particularly common in biomedicine. Differences in language capability can be particularly significant where there is less mediation, for example, in online platforms, certain public media and social media. For these reasons, considering alternative ways of communicating, by drawing and acting or showing videos and voting with “clickers” may stimulate the discussion. Information might be conveyed using multiple media (e.g. video, artworks) to stimulate discussion.

Certain interfaces may also present a problem: older people or those with less familiarity with technology, for example, may be less comfortable than others with online platforms and social media, so alternative or complementary means of involvement might need to be considered. Some people find certain media or environments unwelcoming.

The setting and mode for participation is equally important. For example, those with low social status or educational attainment may be less likely to take part in a seminar at a university building and to challenge others in face-to-face discussions. Venues may need to be chosen to facilitate the participation of those with different access requirements, for example, wheelchair users and those with baby carriages. Furthermore, the absence of facilities, such as restrooms, prayer rooms or nursing rooms, or lack of free parking or accessibility by public transport, can prevent some from participating in an activity. The absence of a hearing loop or the presence of acoustic interference such as traffic noise or ambient noise may make a venue unsuitable for a discussion with many participants.

The inclusion of everyone can also mean avoiding days on which some people are required to undertake religious observances and accommodating or compensating those with work commitments or childcare responsibilities.

- ▶ 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.



United Kingdom, 2007: As part of the “Public Engagement on Brain Science, Addiction and Drugs” public debate initiative steps were taken to ensure the active participation of recreational drug users and ex-drug users, not only those coming forward through patient organisations. These groups were enabled to develop their own preferred mode of participation, which they did by debating among themselves in a secure environment and designating intermediaries with whom they had built up trusting relationships to represent their views in the debate.

Oversight mechanisms

Mechanisms may be needed to ensure that public debate activities respect the interests of all concerned, and, if necessary, are adapted in order to do so. This function should be separated both from the practical management and delivery of public debate initiatives, and from the commissioners, sponsors or addressees of such initiatives.

- ▶ Some form of oversight, independent of 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

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. Procedural measures can help to counteract imbalances or inequalities among those involved, including those participating in and those initiating or sponsoring public debate activities.

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

Fairness

Respect for all participants may involve paying special attention to or taking special steps to encourage and enable the participation of certain groups, and to ensure that all voices are given a fair hearing, including those expressing contrary or unorthodox views. It is important that the focus in a public debate should be the issue to be debated and not on the person debating it.

In particular, respect for ethnic, cultural, religious and sociodemographic differences, and the equal entitlement of all participants to have their views taken into account, should be ensured. Demonstrating respect and fairness encourages trust in the initiative.

- ▶ 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

The personal, lived experiences of individuals can offer important insights alongside data and factual evidence. Individuals may find their personal experiences relevant to public debate and may wish to share them with others. It is important that debate offers a “safe space” in which to do so. Respecting privacy by protecting the anonymity of participants might be important, for example, to protect participants from media intrusion. This may, in any case, be a legal requirement of data protection law.

The participation of some individuals may expose them to vulnerability, stigmatisation, discrimination or even direct harm. This can be particularly important to consider where an activity involves the participation of children and young people. Many biomedical developments raise issues that impact disproportionately across differences of gender, age and health status or disability, which entails a risk of compounding structural inequalities if disadvantaged groups cannot participate fairly in debating them.

Where the participation of particular groups or individuals affected by a proposed measure is important, and direct involvement poses a threat to their privacy, alternative means of enabling participation should be considered. For example, this can be done by video link, through trusted intermediaries or by written submissions. If participation from particularly affected individuals requires anonymity, the legitimacy of the process could be maintained for example through independent assurance.

- ▶ 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

Transparency is an important aspect of fairness. Initiators and participants alike should be transparent about their aims and interests in sponsoring or participating in public debate, and about the sources of any funding. Because of their interests, it is often appropriate for sponsors of initiatives to separate themselves or to involve independent professionals to conduct public debate activities on their behalf.

Relevant interests are not limited to public interests. Personal interests should also be taken into account and declared, as hidden personal interests of participants, experts or stakeholders can undermine trust and the credibility of the outcome of the public debate. Having an interest in the issue at hand should not, however, prevent involvement. On the contrary, it is a reason for involvement. However, on matters of public interest, it should not entail privileged influence.

- ▶ 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 that people participate candidly and in good faith, rather than manipulating public debates for private interest. This is particularly important where questions of scientific fact and evidence are relied on in public debate and when expert testimony is involved. The use of clear, non-technical and unambiguous language is desirable to avoid misunderstanding. Those offering expert evidence should explain any uncertainties and limits of technical knowledge. Honesty about sources is important. Experts should be reminded to avoid evaluative language and to reserve their personal opinions.

- ▶ 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

For public debate to make a difference there needs to be a functional connection between public debate and the governance of healthcare 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.

Section IV concerned the quality of the public debate activity itself; this section concerns its further impacts and how to optimise them. These further impacts are of two sorts: i) direct effects (for example, giving rise to new policies) and ii) increasing the integrity of the public as a social body and, therefore, the capacity of the public to participate in governance through democratic processes.

COMMITMENT

For public debate to be effective, it is important that both participants and those initiating public debate activities are committed to the process. On the part of the initiator, this stake is demonstrated by support for the process of public debate and by taking account of the outcome. From the outset, there should be transparency about how an initiative is expected to relate to the matters under consideration, what other measures may be possible (or not possible) and what account participants and the wider public can expect to receive of this. In turn, the participants are likely to be more committed to the process when they know that their engagement counts. Initiators of public debate may benefit from face-to-face encounters with other participants in a public debate. Participants could, for instance, be invited to present the outcome of discussions to initiators and to discuss how the initiators propose to take forward the issues discussed.

- ▶ 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

There is an implicit obligation on any democratic state to take the interests of its public into account and to demonstrate how it has done this by accounting for its decisions. Those responsible for initiating public debate activities should provide feedback on what conclusions they have drawn from the public debate and how the views of publics were taken into consideration, for example, in subsequent policy making and/or other related decisions or processes. This information can be conveyed for example via websites and public media.

- ▶ 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.



Portugal, 2017: The public debate on end of life resulted in the publication of the book *Deciding on the end of life – Cycle of debates*, which contained a collection of excerpts from conferences including contributions from the public. It also included a glossary and a conclusion, the main questions and arguments presented in the debate, and a short study on comparative legislation.



France, 2018: The “États généraux” was carefully analysed afterwards by the National Consultative Ethics Committee (CCNE), which, in June 2018, published a summary report that included in the outcome of the initiative the opinions formulated by the Citizens’ Committee.

EVALUATION

The process and the outcome of public debate activities should be evaluated. Confidence in the good faith of the initiators of public debate activities can be assured by engaging an independent and skilled evaluator who has access to the whole process. The evaluator should ideally be appointed during the planning/

commissioning stage. At the very least, those initiating the debate could publish their reflections on the activities so that others are able to review and discuss it.

Evaluation should address the effectiveness of the activity (see Section IV, “Effective public debate”) as well as how well the activity met the aims and expectations of participants and initiators, including a reflection on the added value of the public contribution.

The outcome of the evaluation should be made public in accordance with the principle of transparency, so that all interested parties, not only the participants, can be informed about the activity and to encourage further public debate and provide a reference point for further activities.

- ▶ 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 should ideally contribute to socially constructive discourse that is reflected in the decisions and policy making of governments and public authorities. An experience of effective debate can also help to foster political engagement on the part of the public and positive social interaction more generally.

Furthermore, through the process of engagement, participants may find that they develop considerable expertise in relation to certain issues. For example, networks and connections developed through participation in public debate activities might lead to involvement in further initiatives.

Continuing public debate is valuable in monitoring and evaluating the implications of policy decisions, invigorating the public sphere and building capacity and confidence that can carry through into future engagements.

- ▶ 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.



Portugal, 2017: The debate on end of life did not lead to changes in Portuguese legislation, but the documentation in the form of a book serves as a record and reference point for future debates on the topic.



France, 2018: The French National Consultative Ethics Committee (CCNE) recommended in its Opinion 129, issued in September 2018, that the French law on bioethics be supported by ongoing public debate on bioethical issues so that debate is not carried out as a “one-time” event. The aim is to foster a culture of debate on these issues. In this context, the report by the CCNE will most likely serve as an important reference point for the future.



Russian Federation, 2016: The public discussion on the suggested amendments to the law “on transplantation of human organs and tissues” confirmed that organ donation is a very sensitive issue in Russian society. The suggested amendments were met by substantial criticism from the public. 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.

EMBEDDING PUBLIC DEBATE ON BIOETHICS

A society in which the habits of democratic participation are established through education and opportunities for public participation will be better prepared to engage the public on questions of the governance of biological and biomedical developments. Assigning specific responsibilities to institutions to support public debate, such as national ethics committees, independent organisations, public authorities, regulators or advisory committees, can help to promote public debate, maintain a continual level of public involvement with developments in biomedicine and provide institutional mechanisms to support public debate in practice.

This continuing process can help to bridge the gap between social norms, which are rarely examined, and the need to address urgent policy questions arising in relation to new biological and biomedical developments.

Institutions such as those mentioned above can help to promote a culture of public debate and public participation by being alert to pockets of relevant discourse within society, being open to engaging with these, and facilitating the connection of these debates with each other and with relevant stakeholders and policy makers. In a culture of public debate, these institutions could welcome and benefit from uninvited and “bottom-up” contributions as well as planned public debate activities.

- ▶ 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.



France, 2018: In the “États généraux”, key to the successful involvement of the public was the mandate given to the National Consultative Ethics Committee (CCNE) to foster public debate and organise the activities it considered appropriate. The CCNE was given this broader mandate in 2011, and funding was secured for the revision of the law on bioethics in 2018.



Denmark, 2008: The Danish Board of Technology was previously funded by the Danish government but is now an independent institution which is no longer publicly funded. It was considered important to detach it from the government; however, it does not have a mandate stipulated by law and thus works on a commission basis.



Cyprus, 2018: The Cyprus National Bioethics Committee is mandated to foster public debate by, each year, organising a public debate on a chosen topic.



VI. CONCLUSIONS

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. 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.

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.

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

EXAMPLES OF PUBLIC DEBATE



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 doctors and patients 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 the participation of the Republican Bioethics Center.

The main aims of the debate were to discuss the issues of improving medical practice, to exchange experiences between various hospitals and medical centres, and to make changes and additions to new laws including the laws 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 do not 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 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 on Healthcare.

➔ Objective

The objective was to improve medical practice in healthcare and in relation to transplantation of organs and tissues and the use of assisted reproductive technologies, as well as to improve 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;
- ▶ a practical conference;
- ▶ an open lecture with free discussion;
- ▶ the role of hospital ethical committees as an instrument for solving ethical problems arising from 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. Participants in the debate were medical doctors, lawyers, healthcare managers, bioethicists and scientists as well as members of patient organisations. The discussion was presented in different articles, and in round-tables, mass media and scientific journals.

The Republican Bioethics Committee, the Republican Bioethics Center and employees of the legal firm JurSpectr LLC started preparing the practical conference "Ethical and legal issues of ensuring the rights of patients and medical professionals in modern health care". 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 abovementioned issues. Participants also included patient organisations.

The "Doctor's ethical duty" was the theme of the Orthodox Church programme, and 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 entry;
- ▶ 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, questions debated and solutions arising were taken into account by working groups during the development of new versions of Republican laws (laws on healthcare, transplantation of organs and tissues, and assisted reproductive technologies). These laws were supplemented with new sections which 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 the healthcare system);
- ▶ to determine one of the goals of the 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 ideas and based their activities on the guidance given.



➔ 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 Minister of Health and the 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 “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, including the Cyprus Elders Parliament and the Cyprus Elderly People Observatory (a non-governmental organisation (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 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 or 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 variety 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, the research community, health professionals) and were very well received and garnered broad coverage on TV and in 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 in the presence of representatives of the policy makers. 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 ON THE FUTURE OF THE HEALTHCARE SYSTEM (2008)

➔ Background, initiator and participants

The Danish healthcare system was under political and public pressure to implement more, better and faster treatments but lacked 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 healthcare 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

The objective of the Policy Summit was to make consensus decisions on new developments and prioritisation in healthcare between actors in the Danish healthcare 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 healthcare system, but there was uncertainty about the public reaction if it were to be abolished, 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 healthcare system or private insurance 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 healthcare policy afterwards.

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

Method

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

The sessions concerned:

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

Each session ended with citizens voting on three to five 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 arising from working conditions and environments?
- ▶ 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 which could follow up on citizens’ judgements were brainstormed and discussed. The second day involved workshops in order to explore the actions in more depth and to share out responsibility for actions.

Notable features and lessons learned

The exercise showed how public debate can make a significant contribution to a policy-making process. Key to creating impact is to consider decision-making processes as a whole in which citizen participation is 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 the economy. This is particularly true in the case of abolishing tax refunds on private health insurance. 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 to polls or 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, for example, media, polls or lobbyists. The opinions are informed, reflected upon and debated rather than remaining personal views 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 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 1 000 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 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 to investigate these issues and possibly to make 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 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 six months. Signatures can be collected on paper or online (e.g. at www.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 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 sociodemographic 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 website has provided an active platform for 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 citizens' initiative on euthanasia, which led to an inquiry. This will most certainly lead to a better understanding of the options and possibly 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 marginalised groups or in relation to a specific issue. The transparency of the website allows citizens to be involved in the legislative process and makes the process easy to follow. This includes citizens in a whole new way and brings them closer to legislators.

The limitation, in comparison with other ways to involve the public, is that the website provides only information from the initiator and does not provide a forum for 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) organise 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, seven scientific and two 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 robotisation;
- ▶ health and the environment;
- ▶ assisted reproduction;
- ▶ end-of-life care.

These 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 so as to avoid 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”, which were published in the CCNE synthesis report.

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

- ▶ A total of 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 individual 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.
- ▶ A total of 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 very broad engagement of the public in debates on bioethical issues.

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

A particular feature was keeping secret the venues and dates of the Citizen Committee 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 visibility in national media.

Another impact of this nationwide 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. However, it already seems that the public debate has contributed to the development of the new draft law.

Despite a diversity of tools and the large plurality of views expressed it would be wrong to conclude that the consultation process provided a true representation of public opinion. The major part of regional discussions took place in a climate of tolerance and calm, but this was not always the case. During debates on so-called “societal” issues, certain exchanges 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 of some criticism, such as: (i) 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, which was not considered acceptable by all parties.

Such encounters revealed that standpoints may vary with age and gender. Finally, hearings, which 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 younger generations in regional debates, varying with the themes under discussion, thanks to efforts by regional forums (ERER).
- ▶ The difficulty of including the less informed and 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 it 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 co-operation 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 programme 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. Sixteen events took place from Autumn 2017 to Spring 2019 on topics including 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, and enabled 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 develop deep 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 informed media coverage. Within the framework of the workshop, a lower house debate was organised and attended by Leopoldina members and experts from hospitals, healthcare 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, master's degree 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 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, a greater number 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

The objective was 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, and this was proposed by the Irish Government. The referendum took place on 25 May 2018 and passed by a clear majority of 66.4% to 33.6% 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 co-operation among representatives of different legal professions. The objective of this public debate is to inform and 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 contributing 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 fourth event, other institutions such as municipal offices and houses of culture as well as cafes, cinemas, depots and religious communities were 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 within 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 that 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 can discuss the organisation of the lesson.

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

Substantive supervision of the project is provided by eminent jurists. All lawyers who agree 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, like any other, is not perfect. Despite opening it beyond educational institutions, schools remain the main participants. Moreover, neither the lawyers conducting lessons nor the schools are required to send feedback to the Association for evaluation.

Impact

Despite the differences of political opinion 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/>



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 was launched in Lisbon in May 2017, and a series of public debates followed. There were 14 debates, attended by large numbers of members of the public, which were held in 12 cities all over the country.

Objective

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

The question

Several questions were raised during the debate, mainly:

- ▶ 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 debates were open to citizens.

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

At the last conference (the international conference), two approaches were examined. One related to the importance of the role of civil society and the deliberation process, while the second involved experts from different countries, who were asked not to express their own points of view but rather to provide information on the legal and factual situation in their countries. The “main actors” were the citizens who attended all the conferences and who were free to speak, 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. At 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, containing a collection of excerpts from the debates as well as contributions from the public (and an overview of all the views expressed). It included the texts of the debates 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 sectors of society, which recognised the importance of helping citizens to build their own opinions through 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 February 2019 in a ceremony attended by the President of the Republic. The documentation remains relevant despite the parliament's decision against the proposals. It expresses 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 of the consultation 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 views of the participants (speakers and general audience), together with the main consensus conclusions and the key issues generating controversial and opposing opinions.

The volume was distributed through a wide network of bookshops all over the country and sold out in a short time. The President of the Republic was present at the launch, having stressed the relevance of the initiative, which increased the impact of the book on the media.



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 take place at various venues with interested representatives of professional communities and public organisations, 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 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, 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 organisations; and representatives of the public chamber, resulting in the diversity of civil society being 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 death, if there is no record of this being against the person’s wish. In other words, the approach is 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, “opt-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 legal gaps related to the rights of organ donors; to balance the rights of donors, recipients, relatives and medical specialists; and to 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 2009 Bill.

Discussions took place in different forms. Online debate was attended primarily by ordinary citizens, mainly over the age of 40, 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 among the younger generation took place on social media.

Detailed debate on the draft law took place in the professional community, in meetings with experts. Expert opinions were analysed 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 programmes for informing citizens about organ donation.

The part of the law that allows for donation from deceased children is constantly criticised. 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.

Discussion of the draft new law continues, and the most difficult issue is to overcome negative attitudes to organ donation among citizens over 50 or 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?” (Foresight report), published in 2005.

The Drugsfutures public engagement activities ran from January to April 2007 and engaged specific groups including parents of children with attention deficit hyperactivity disorder (ADHD), students, teachers, drug users and ex-drug users, older people, young people and people with mental health problems.

➔ Objective

The objective was 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 events, with a public launch in London (113 participants), 19 short (two-hour) outreach workshops (146 participants) around the UK, five regional workshops around the UK (180 participants) each focusing on a different topic (e.g. the law, mental health), and a Brainbox – two two-day sessions six weeks apart for

more in-depth discussions covering all five 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 like these 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 report to government. Public participants could trace their contribution in the final report.

TERMS USED IN THIS GUIDE

As it has emerged as an area of professional practice, public debate has developed distinctive concepts and terminology, many of which are contested or reflect different preferences and commitments. The following is not intended to be a definitive explanation of the meaning of terms but merely to clarify how certain, potentially confusing, terms are used in this guide.

Citizen – a natural person subject to the laws and policies of a state and enjoying legal rights protected by that state. In compound terms such as “citizens’ assembly”, for example, the meaning of “citizen” is broader than just those having nationality or entitled to vote in that state.

Co-design – the design and shaping of a process by participants either among themselves, with facilitation or by negotiation with the initiator of the public debate.

Consultation – elicitation of qualitative information with a view to modifying or confirming a proposed measure that is within the areas of responsibility of the initiator. Typically, the aim is to seek input from a wide range of perspectives. Consultation may be open to the public (especially on matters of public policy that may indirectly affect everyone) or target groups or individuals with specific interests, knowledge or expertise. Respondents are self-selecting.

Debate – any discourse in which several individuals or groups interact to identify, explore and resolve their different viewpoints and interests, through the presentation of evidence, arguments and values. In this document, this more general concept of “debate” is to be distinguished from that of a formal debate between two opposing sides on a motion proposed by one of them. (See also “public debate”.)

Deliberative methods – sustained discursive encounters in which participants address an issue of common interest by sharing information, examining evidence and engaging in mutually respectful argument.

Dialogue – “public dialogue” is a form of deliberative engagement between professionals, policy makers and non-specialists, in which participants attend to and respond to each other, and which takes place on terms designed to neutralise asymmetries of power and knowledge.

Governance – in this guide “governance” means the accountable use of power or authority to set, monitor and enforce standards and behaviours within systems or organisations. It can mean both steering people’s behaviour and ensuring that they are held to account. Governance can be given effect through compulsory and non-compulsory measures (legal provision, licensing systems, professional norms, codes of conduct, recommendations, etc.). Governance can be a function of both public and private actors.

Initiator – the person who takes the initiative in a public debate activity (see “invited/uninvited public debate”). The initiator will usually provide or co-ordinate the resources for the activity and may commission specialists to facilitate or deliver the activity on their behalf.

Invited/uninvited public debate – in invited public debate a responsible authority invites members of the public to participate in an activity for a purpose that they have defined; in uninvited public debate, members of public and civil society organisations make representations to a responsible authority in order to effect change.

Participant – public authorities, experts and citizens all may be regarded as participants in a public engagement activity or debate.

Public/publics – many social scientists and public engagement practitioners prefer the plural term “publics” to the singular “public” to avoid implying the existence of a single homogeneous group or that “the public” has objective existence independently of the issues in question.

Public debate – in this document and in Article 28 of the Oviedo Convention the overarching concept of “public debate” is used to describe discursive interactions in the public sphere (that is, not in a professional context) through which individuals and groups may identify, explore and resolve their different interests in matters that affect (or potentially affect) them all. (See also “debate”.)

Public debate activity – an organised activity, delimited in scope, intended to stimulate and to attend to public debate on a specific theme in the expectation that it will inform or influence policy development or governance.

Public sphere – the space of public debate; a notional communicative environment in which private individuals can formulate and discuss societal challenges that affect them in common and influence policy. In practice, it may be supported by institutions, such as social and political institutions, and the media.

Qualitative/quantitative methods – quantitative methods collect information which is output as numerical values (for example, the number or proportion of people who give a particular answer to a question); qualitative methods provide discursive information and usually enable exploration of phenomena of interest in depth through interrogation and reflection.

Representativeness – invited engagement may be set up in such a way as to be representative of the general population or of a particular subset of the population according to certain criteria, for example, sociodemographic criteria. The appropriate size of a sample, the criteria for representativeness and the meaning that can be attributed to “representative” findings all require careful critical reflection.

SELECTED RESOURCES

delib – a for-profit social venture providing a range of tools for citizen involvement (in English, www.delib.net/)

Dicopart (Dictionnaire critique et interdisciplinaire de la participation) – lexicon of terms and concepts concerning engagement (in French, www.dicopart.fr/)

Les États généraux de la bioéthique (Bioethics Forum) is a form of citizen consultation provided for by law (hearings, events in the regions, consultation on the internet, citizen committees) to gather the opinion of citizens before the re-examination and possible modification of existing French bioethics law (in French, <https://etatsgenerauxdelabioethique.fr/>)

Fonden Teknologirådet (Board of Technology Foundation) – Danish organisation supporting technology assessment and foresight, public engagement, Responsible Research and Innovation (RRI), and new forms of governance (in Danish and English, www.tekno.dk/?lang=en)

Guide No. 5 of UNESCO – on National Bioethics Committees and Public Engagement (<https://unesdoc.unesco.org/ark:/48223/pf0000371176>)

Involve – UK organisation providing advice and support for democratic participation in areas including science and health policy (in English, www.involve.org.uk/; Involve has summary descriptions of over 50 different approaches to public debate at www.involve.org.uk/resources/methods)

Sciencewise – the Sciencewise programme is the UK Government's exemplar of how to develop robust evidence on public views to inform policy development in areas of scientific and technological innovation. Established in 2004, the programme has supported over 50 dialogue projects (in English, <http://sciencewise.org.uk/>)

The purpose of this guide is to facilitate the implementation of the principle laid down in Article 28 of the Convention on Human Rights and Biomedicine according to which “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”.

Aimed primarily at government officials, public authorities, national ethics committees and other relevant institutions and organisations, the guide promotes dialogue with the public on the challenges posed by biomedical developments, including the possible concerns they raise for the integrity, dignity, autonomy, privacy, justice, equity and non-discrimination of human beings. It focuses on the need for public debate, how to prepare for it, and ways to make it effective and meaningful. It does this with reference to a selection of good practices and experiences in member states which illustrate public debate in action.

www.coe.int

The Council of Europe is the continent’s leading human rights organisation. It comprises 47 member states, including all members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. The European Court of Human Rights oversees the implementation of the Convention in the member states.