

COUNCIL OF EUROPE



CONSEIL DE L'EUROPE

Strasbourg, 18 March 2019

DH-BIO/INF(2018)11 REV

COMMITTEE ON BIOETHICS (DH-BIO)

Draft Guide on Public Debate

Prepared by the Drafting Group on Public Debate*

* It is the intention of the drafting group to prepare a shorter version of the guide to increase its reach and accessibility using only the sections highlighted in bold in this document

TABLE OF CONTENTS

I.	INTRODUCTION	4
II.	AIM AND PURPOSE OF THE GUIDE	5
III.	THE NEED FOR PUBLIC DEBATE	6
	The need for public debate in relation to health and biomedicine	6
	Why public debate is especially important now	7
	Issues that may need special attention	8
	Speed of development	8
	Opportunities for data mining	9
	Biomedical innovations that may require adapted behaviour	9
	Blurring boundaries and ambiguity of use	9
	Uncertainty about risk	10
	Biomedical developments affecting social norms or access	10
IV.	APPROPRIATE ENGAGEMENT	11
	What are the reasons for public engagement?	11
	Ethical reasons	12
	Making better decisions	12
	Building legitimacy	12
	Informing	13
	Gathering evidence	14
	Increasing participation	14
	Who are ‘the public’ in public engagement?	14
	Stakeholders	15
	Representative samples	16
	Excluded voices	16
	When is the appropriate time to engage?	16
	Upstream or downstream	17
	Circumstances	17
	Continuing debate, building capacity	17
V.	EFFECTIVE ENGAGEMENT	18
	Effectiveness through design	18
	Commitment of resources	18
	Respect for interests	20
	Accessibility and inclusion	21
	Governance	22
	Effectiveness through practice	22
	Fairness	23
	Privacy	23
	Candour	24
VI.	ENGAGEMENT THAT COUNTS	25
	Commitment	25

Accountability	26
Evaluation	26
Continuing debate	27
Embedding public debate	27
VII. CONCLUSIONS	28
GLOSSARY	30
SELECTED SOURCES	34
Literature relating to public debate	34
Organisations/ practitioners/ resources	34
Case studies and evaluations	35

I. INTRODUCTION

1. **Developments in the field of biomedicine offer significant potential benefits for individuals, for society and for future generations. The pursuit of these benefits, however, often involves significant technical and social challenges. They often require decisions to be made in the context of scientific uncertainty and conflicting values; decisions that may have far-reaching implications for different groups and individuals. Many of the developments have the potential to produce profound changes in their social and economic environment, potentially reconfiguring the norms that underwrite the conditions of common life. Therefore, the directions taken by biomedical developments, and how the risks and potential benefits are distributed, are of profound public interest.**
2. **The Council of Europe Committee on Bioethics (DH-BIO) has produced this guide to assist Member States, and decision makers within Member States (including government officials and public authorities, national ethics committees, educational and academic institutions and other relevant organisations) to promote public debate in this field. Promoting public debate helps to create opportunities for the emergence of a shared public interest from the potentially diverse interests of citizens and to connect this public interest with public policy.**
3. Public debate, as defined in Article 28 in the Oviedo Convention, encompasses different modalities of public engagement by discussion and consultation. It creates an obligation on Member States to offer the opportunity for their citizens to make their opinions count. To do so effectively, the public need information about developments in biomedicine and their possible direct and indirect implications for society, individuals and, also, future generations. They also need to have access to different forms of participation.

Public debate in relation to democracy and human rights

Articles 9-11 of the European Convention on Human Rights (ECHR) establish the rights to: freedom of thought, conscience and religion, the right to freedom of expression, and the right to freedom of peaceful assembly and to freedom of association with others.

The Council of Europe Convention on Human Rights and Biomedicine ('Oviedo Convention') exists to promote human rights, democracy and the rule of law in relation to biomedical science and the practice of medicine. The Convention acknowledges the importance of public debate in this context.

Article 28 of the Convention, entitled 'Public Debate', provides as follows:

"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."

4. **The provisions of the Oviedo Convention relating to public debate encompass two requirements that relate to engaging the public about new biomedical developments.**
5. **First, the Convention requires Member States to take deliberate steps to foster discussion about the implications of developments in biology and medicine among the public. This is important because it:**
 - **promotes informed democratic participation in matters of public interest;**
 - **ensures that the implications of biological and medical research are not hidden from the society in which it takes place; and**
 - **establishes the conditions of inclusive participation in the governance of biological and medical developments.**

Second, the Convention requires Member States to create opportunities for citizens to engage in the governance of biological and medical developments that may affect them directly or indirectly. Equally, in a democratic society, it is important for Member States to demonstrate that these interests have been considered. 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/target groups and thereby to consider their interests and understandings, with a view to making informed policy decisions.**

II. AIM AND PURPOSE OF THE GUIDE

6. **The aim of the guide is to assist public authorities in fostering public debate and engaging with the public, and to appreciate the reasons why public debate is important in the governance of biomedicine. It is intended to help them to find the most appropriate and effective approaches to public engagement according to their requirements and circumstances. However, since every topic may embody new possibilities and give rise to specific ethical and societal concerns, each engagement needs to be approached on a case-by-case basis.**
7. **The guide is addressed to those who have a responsibility to promote and initiate public debate but it should also be considered as a useful tool for other actors who are otherwise engaged in contributing to public debate. It should be useful in member States where there is an established tradition of public debate and also where the tradition, infrastructure or resources for public debate are not yet established.**

The terms ‘public debate’, ‘the public’ and ‘public engagement’

In this guide, the term ‘public debate’ is used as an overarching term to describe communicative interactions in the public sphere that address issues that affect public interest. Public debate is a process through which individuals and groups engage with each other to address issues of common importance, to solve shared problems, and to bring about positive social change. Who counts as a member of ‘the public’ is someone who is not primarily acting as an agent of political authority or of a relevant profession. In this sense, who makes up the public will depend on the issue at hand and the kind of interest and relationships they have to it. One person may have both a personal and social interest as a member of the public, and possibly also an interest through their work experience or sphere of professional interest.

Public debate may arise as a spontaneous public response to biomedical developments or be initiated by public authorities or other organisations as a deliberate ‘public engagement’ involving a defined set of activities with a specific purpose. Such processes are often related to development of new legislation or policies. However, public engagements are not only about influencing decisions or changing policy but may also have value by raising awareness in society of developments in biomedicine and of encouraging democratic participation more generally.

We may draw a fundamental distinction between ‘invited engagements’, in which a public authority seeks to engage with the public or a section of the public, and ‘uninvited engagements’, in which publics seek to promote their interests to policy makers and others with decision making powers.

- **The guide clarifies why public debate on developments in biology and medicine is important (in a contemporary democratic society) to maintain trust.**
- **The guide provides guidance to public authorities on how they might support and engage with public debate effectively.**
- **The guide helps to anticipate the challenges of ensuring effective public debate in a way that fulfils the purpose of Article 28.**

III. THE NEED FOR PUBLIC DEBATE

The need for public debate in relation to health and biomedicine

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

9. **Public debate can strengthen the role of citizens in the shaping and governance of their society. We may say that public debate is therefore debate that is in public, with the public and for the public.**
10. Biomedical developments require long-term strategic decisions that raise questions of collective values, aims and visions of the 'good life', including questions about how benefits are and 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 attend adequately to these broader and longer-range questions.
11. Given the potential effect on the lives of individuals, it is important that the public are informed about such developments and can formulate, communicate and interrogate their views. This is important not only in order to take part in shaping the policies and strategies for the society, but equally to build the competence of individuals to make informed decisions about their own health and welfare. It is correspondingly important for policy makers to be aware of the different opinions and diverse values among the public in order to respond to them.
12. A key purpose of public debate is to bring forth a 'moral community', through communication, engagement and association among people. 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. Public debate contributes to a more robust basis for decision making while helping to identify issues of concern that may warrant actions in response.
 - ➔ **Public debate is important to maintain public trust in governance and policy making.**
 - ➔ **Public debate contributes to the responsible introduction of new biomedical developments and technologies in the health sector.**
 - ➔ **Public debate provides a measure of legitimacy and support for ethically difficult decision-making.**

Why public debate is especially important now

13. **The structure of social relations and the way in which 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.**
14. **In some cases, regulatory frameworks addressing the risk, effect and societal implications do not exist or are have not kept pace with technical developments. Some technologies are under continuing development and that leads to applications that have not been foreseen, may be difficult to define and may, therefore, fall outside existing regulatory frameworks.**
15. 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. When risks and side effects become known, they often come to light only through practical experience. By that time, it may be hard to undo them, especially if the developments are widely diffused or entrenched in societal infrastructures or human culture. In other words, by the time a society realises the consequences it may be too late to change the course of development within the biomedical field. Responsible approaches to biomedical innovation recognise a duty to anticipate and inform the public about developments that have a profound impact on their lives and societies, and involve them in guiding decisions towards an acceptable outcomes (for instance how and under which circumstances to use a new technology).

16. 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, incubated self-reinforcing discussions among homogenous groups, encouraged intolerance of criticism and excused the rejection of evidence in favour of opinion. The reinvigoration of public debate where contrary opinions can challenge each other with the tools of evidence is an important counterbalance to such developments.
17. In these circumstances, it is particularly important that interests should not be appraised only through aggregated opinion, which offers no such challenge or accountability. 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.

EXAMPLE: PUBLIC DEBATE IN GERMANY CONCERNING GENOME EDITING (2019) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

Issues that may need special attention

18. **Some aspects or characteristics of developments in biomedicine may bear on their ethical appraisal in a distinctive or fundamental way.**

Speed of development

19. **The speed of development may cause situations where legislation seems to be lagging behind. ‘Law-lag’ can arise from the difficulties legislators face in keeping up with rapid developments within biotechnology and properly assessing their implications. This can create uncertainty for everyone concerned.**
20. In introducing new methods where there is no long-term experience and little certainty about outcome or impact, careful ethical consideration is needed to set a long-term strategy to control their use within socially acceptable limits.
21. Two examples of areas in rapid development that need to be addressed by legislators are genome editing and artificial reproduction technologies (ART). Genome editing may challenge existing regulatory frameworks and new ART technologies may raise new ethical and societal issues that were not foreseen by the legislators.

Opportunities for data mining

22. **The application of digital technologies creates opportunities for data mining.- This potential, when combined with new biomedical technologies, may present a challenge to the current human rights framework in several ways. For an individual, it may become difficult for them to comprehend 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.**
23. Biomedical innovations such as *precision and genomic medicine* and the research that supports them, increasingly rely on access to large and detailed data sets, often from a variety of sources. Integrating large amounts of data from different kinds of sources may make the re-identification of the person concerned possible. Effective anonymisation to protect privacy and confidentiality may no longer be possible.
24. Access to medical services could require making available substantial massive amounts of personal information. This can challenge norms of confidentiality and the utilization of personal data for medical research, and may require a renegotiation of the relationship between privacy and public interest.

Biomedical innovations that may require adapted behaviour

25. **Whereas biomedical innovations can free people from the burden of disease they may also require them to adapt to the options available in particular ways. Requirements for behavioural modification suggest that there is a need for wider reflection on the implications of adopting new approaches.**
26. One example of such implications is the amount of genetic information that may need to be shared to receive certain treatments. For instance, genetic testing may in the future involve the generation of standardised or complete genomic data sets, and access to services may imply that all data is stored. Storage of a person's genome data implies storage of knowledge that, with increasing scientific understanding, could be provide information about predisposition to disease or even certain behaviours. Refusal may entail opting out of services in a way that could leave and individual without access to the best available standard of care.

Blurring boundaries and ambiguity of use

27. **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 apply or create ambiguities in the application of regulatory categories, 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.**
28. An example of technologies finding applications in different fields for different purposes is in neurotechnology. EEG neurofeedback technologies has been offered in the clinic and in trials as a possible treatment for conditions such as ADHD. These technologies are also offered outside the health care system: neuroheadsets using EEG technology to record brain activity can be purchased to monitor alertness or relaxation, or to play

games based on brain activity. When such EEG devices are brought to the market for non-medical purposes, they are not seen as medical devices, and thus fall outside existing regulation on medical devices. An example of a technology that produces findings of ambiguous status is direct-to consumer genetic testing, where information about genetic predispositions with health relevance is provided outside a health care context and without proper counselling.

Uncertainty about risk

29. **Biomedical innovations 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 reliably identified or where there is no clear understanding of how to describe or evaluate them.**
30. An appropriate response to large margins of uncertainty may be to broaden the appraisal of emerging biomedical technologies. Public debate can help to bring to the surface the different impacts and externalities, and reveal differences in the ways they are valued by different publics.

Biomedical developments affecting social norms or access

31. **The uptake of biomedical developments can lead to profound changes in social norms. Such effects may not have been anticipated when allowing technologies to drive reconfigurations of health care services. Another aspect is equality in access to health care, in ensuring that all people have the same opportunity to benefit from biomedical technology.**
32. The 'normalisation' of prenatal diagnosis as a routine examination, in combination with simplified abortion methods, has led to the birth of people with Down's syndrome almost disappear from some societies. The diffusion of this technology can have a potentially significant effect on expectations on pregnant women and heightens the risk of marginalisation of a minority with that diagnosis. 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.
 - ➔ **Public debate can be particularly important around developments that have a profound impact on society and individuals, developments that may fall outside the existing regulatory frameworks, and developments that represent unknown risks or have an unpredictable effect on society.**
 - ➔ **Speed of technological development raises uncertainty about whether existing legal frameworks will be sufficient to ensure safe and ethically acceptable implementation. Public debate can be an important source for setting appropriate standards for governance and provide a reference for development of governance.**
 - ➔ **The large volume and variety of data, and opportunities for data mining with many biomedical technologies calls for appropriate protection of information privacy, a need to inform the public, and debate on the risks and possibilities modern technologies offer in this context.**

- **Public debate can usefully broaden the basis of appraisal of new developments where the consequences of those developments are uncertain.**
- **There is good reason to involve the public in debate about developments that may lead to changes in social norms and where there are risks of increasing inequalities and marginalisation of certain groups; it can help to find appropriate and acceptable mechanisms to protect minorities and ensure equality of access to developments in biomedicine.**

IV. APPROPRIATE ENGAGEMENT

- 33. Reflecting on a number of key considerations before initiating an engagement activity can help to identify an approach that will best meet the interests of all participants. Understanding which approaches are likely to be most appropriate and effective in any particular case is perhaps the most fundamental challenge for policy makers and others who want to initiate public engagement activities.**
34. 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 described in the glossary, illustrated by the examples interpolated in the text and further elaborated in the sources provided at the end of the document.) Often it will be valuable to use a mixture of methods and to pursue more than one kind of activity. None, however, offers a complete or definitive way of identifying the content of the public interest.
35. In this section, we provide a set of questions to help those seeking to promote public debate and to engage with the public think about what actions and approaches can be most effective. The most effective engagement does not necessarily serve the instrumental objectives of one set of participants; different participants will have different motivations for engaging in debate and may hope for different outcomes.
36. Those initiating public debate should be encouraged to consider where their priorities lie in relation to a number of different dimensions, and to be realistic about what they might expect from a given type of initiative (both what can be achieved and what cannot be achieved).

What are the reasons for public engagement?

- 37. Perhaps the first question for those considering initiating public engagement concerns their reasons for engaging with the public.**
38. Although there are good reasons for engaging the public in questions about the governance of many developments in biomedicine, this is not always the case. More often, the reasons for doing so are obscure or confused. Engagement should never be undertaken without reflection, as just a 'box-ticking' exercise, since this is unlikely to serve the interests of anyone involved and could even encourage public distrust.

39. Inevitably, there will be more than one reason for any given engagement initiative. Nevertheless, to make engagement more effective it is useful first to reflect on the reasons for engaging and why engagement might be an appropriate course to take.

Ethical reasons

40. **One reason for public engagement 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.**
41. In the case of developments in biomedicine, the scope of those potentially affected extends to the whole of society.
42. A development that engages people's human rights or challenges implicit social norms is likely to be one in which public debate is not only desirable but mandated.
- **Consideration should be given to whether a development raises issues that engage the human rights of members of society.**

Making better decisions

43. **Good decision-making requires consideration of broad questions of vision and value that 'experts' are not always well placed to answer.**
44. Professional or 'expert' advice is often limited in scope and questions about application of new developments are not necessarily technical questions ('is it safe, effective, useful, economical?') so much as moral and political questions ('is the risk acceptable?' 'who should decide?').
45. It can be useful to explore variant social narratives about biomedical developments using deliberative approaches to open up questions in ways that can challenge professional assumptions and interrogate the framing of questions being addressed and underlying values.
46. Open public consultations can help to 'crowd source' expert input, or identify unorthodox considerations that may not be present in the mainstream, owing to socialisation and 'groupthink', and which can help to challenge assumptions constructively.
- **Consideration should be given to the range of interests that could be engaged, particularly any that may not be obviously represented among stakeholders, and the real nature of the decision to be made.**

Building legitimacy

47. **Public engagement can also offer a way to determine the acceptability of a proposed development or prepare the way for implementation.**
48. Before the broad acceptability of a development can be determined it is first necessary that people are aware of it. Engagement might occur further 'downstream', where developments are awaiting implementation, or perhaps where the question is about transferring new technology in from other jurisdictions.

→ **Consideration should be given to what steps it is reasonable to take to inform the public about developments in biomedicine and the level of input that would provide assurance that decisions affecting the public had legitimacy. What are the objectives of public engagement?**

49. **Different people will have different interests in the process which should be respected for reasons of both morality and prudence.**
50. Public engagement (and debate more generally) is a two-way process of communication. The nature of the exchange – what is communicated, by whom, to whom – may differ, and any initiative will very likely involve multiple kinds of exchange.
51. People's willingness to engage may depend on there being a positive benefit to engagement.

Informing

52. **The objective of engaging the public might be to inform about new developments in biomedicine in order to stimulate debate or to lay the foundation for further consultation or participation.**
53. In some cases, public participation has been assumed to depend on the possession of a certain degree of knowledge or understanding of technical matters (a view that gave rise to initiatives to promote 'public understanding of science'). But how much technical knowledge is really needed for publics to engage meaningfully with questions of public interest? **The point of engagement should not be simply to educate the public in biomedicine but to explore the interaction between biomedical developments and social understandings and values. Bringing the engagement onto these terms helps to redress imbalances of knowledge and power that can occur when publics engage with experts or officials.**
54. Social norms rely on implicit knowledge to guide choices and behaviours. In most states the media play an important role in consolidating and curating social knowledge, making this knowledge explicit in relation to current events and issues, as well as digesting new information and expertise. A free press plays an important role in the governance of public life (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 they often approach reporting from a particular 'angle' and often try to engage emotional responses. The media may often be responsible for 'hyped' 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 engaging the public. Social media can support and extend the function of the public media but insofar as they produce self-referential 'bubbles' or 'echo chambers' they can just as easily reinforce prejudice and misinformation.
55. Biomedical researchers themselves have an important role to play in communicating with the public about developments in biomedicine. Engagement between researchers and the public helps to foster public trust in science and allay public fears that scientists are pursuing research without regard to the interests and values of society. Experts may require specific training in how to communicate their work to non-specialist publics.

Public engagement (for example, speaking to the mainstream press) may be seen as part of researchers' public obligation, particularly if their work is publicly funded, and might be made a condition of grant making. Early and continuous engagement with research can be achieved by e.g. funding and promoting seminars, development of webpages and educational material for schools.

→ Consideration should be given to **the information needs of the public and the roles of different actors as information providers**. The involvement of researchers themselves and trustworthy or balanced media may help to foster a culture of trust in science and technology.

Gathering evidence

56. **The objective of the public engagement might be to gather evidence of public views to support decision-making. If evidence of public views is to be used to support or inform decision making it is important to understand what kind of evidence it is and what kind of support it offers.**

57. It is important to know to what extent the evidence will represent informed conclusions or 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 secure they are, and in what ways and for what reasons they might alter over time. 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.

→ **Consideration should be given to what kind of evidence will be relevant (e.g. quantitative or qualitative) and how the use that is made of the evidence will be justified.**

Increasing participation

58. **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 participatory governance of new technologies.**

59. Participation has a number of benefits, both procedural and substantive, including increasing legitimacy through representation and ensuring conformity with social values. However, in such cases it is most important to understand the relationship between the members of the public involved and the broader public whose interests are engaged (see next section).

→ **Consideration should be given to building opportunities for engagement into decision making processes (e.g. at the stage of strategic mapping) and for building capacity and measures for continuing participation in governance (e.g. patients' panels, etc.).**

Who are 'the public' in public engagement?

60. **While it may not be possible or necessary to involve everyone, who is actually involved in public debates is important, particularly if it is the case that some who**

might wish to participate are unable to do so. When thinking about the public, it is useful to consider how that participating public is composed, what interests they represent and whether there are barriers to participation for certain groups.

61. To speak of 'the public' can often imply homogeneity whereas, in reality, all societies embrace diverse social interests and perspectives to some extent. It also suggests that 'the public' exists independently of the issues in question, although it may be more helpful to see publics as being constituted by an issue in which they have a common (though not necessarily coincidental) interest. Not all issues, however, affect the interests of everyone to the same extent (although questions of public policy potentially affect everyone in a way that entitles them to a voice in public debate).
62. Some publics, such as participants in open consultations and uninvited public debates may be self-selecting but many invited engagements, particularly those that have the purpose of eliciting public views, use carefully constructed samples based on demographic information and following established social science methodologies.

Stakeholders

63. **The views of those with direct interests will be relevant in public debate on biomedical developments but many people may also be indirectly affected. To the extent that developments in biomedicine potentially transform opportunities for all the general public will have an interest.**
64. The intended public may be those with a direct interest (often referred to as 'stakeholders') rather than those who are disinterested – after all, why should those without a stake in the outcome influence the conditions for those for whom it really matters? While the views of those who may benefit are important, there are potentially others who may suffer harms, either directly or indirectly, for example, from changes in the types of services available to the public or the way in which they are provided. Developments in biomedical science can be socially transformative as well as benefitting individuals. There is often, therefore, reason to consider very carefully those who may be indirectly as well as directly affected.
 - ➔ **Consideration should be given to identifying or mapping affected or interested groups. It is important not to assume that, for example, civil society groups or patient interest groups – much less those who are most voluble on public and social media – speak for all of civil society (or for all patients).**
 - ➔ **Consideration should be given to those potentially affected with low impact but possibly (or eventually) high frequency as well as those affected with high impact but at low frequency. It should be borne in mind that those people might be remote in space and time from the initial implementation of a development (and more complex steps might need to be taken to find ways of representing their interests in debate).**

Representative samples

65. **In developments that potentially engage the interests of everyone, it is usually neither practical nor necessary to engage a whole population. A carefully formed representative or stratified sample can give a helpful indication of the range of public views.**
66. While biomedical developments may affect existing patients, there are many more people who are potential patients, although many of those might not yet realise it. At a basic level, any decision that affects an allocation of resources can affect the distribution of benefits across a society.
67. Except where infrastructure exists to support a national referendum, it is usually impractical to engage a whole population. Furthermore, without a culture or tradition of holding national referenda on issues other than the election of parliamentary representatives' or careful preparation it can also be disastrous to do so. In most cases, it may therefore be appropriate to involve a representative sample of the population in question.
- **Consideration should be given to the relevant parameters for representation where engagement is with a representative sample of the population.**

Excluded voices

68. When initiating public engagement, it may be necessary to take special steps to incorporate excluded voices (for example those who may be socially excluded or traditionally marginalised). In many societies, for example, minority ethnic communities may not enjoy equal access to the public sphere. Some relevant sections of a population might be inadvertently excluded from public debate or even deliberate public engagement initiatives in ways that engage their human rights, or compound existing forms of social and political exclusion.
- **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. If the issue is one that disproportionately affects the interests of certain sections of the population engagement professionals or community organisations can help to engage with those groups, particularly socially excluded groups or people in positions of vulnerability.**
- **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 overseas territories, etc. Making use of existing networks and infrastructures can facilitate access.**

When is the appropriate time to engage?

69. **In a healthy democracy, public debate is a continuous process rather than an event, although different kinds of initiatives may be appropriate in different contexts and at key junctures.**

70. Engagement initiatives should be seen within the broader context of public debate relating to issues in biology and medicine, and public debate, likewise, within the broader context of democratic politics. Participants should not feel like the decision has already been made and 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.

Upstream or downstream

71. 'Upstream' engagement has been advocated as a way to increase the potential for exerting social influence on the aims and directions of research and implementation, with the aim of making science more socially responsible.

→ **Early engagement can help to shape research and innovation trajectories but it is more likely to be framed around values, hopes and fears, and 'visions of the good life' than around specific implementation questions.**

Circumstances

72. Quite often public debate is initiated in connection with a public inquiry with the intention of providing proposals for amendments to law or public policy. When the initiative for the inquiry is politically controversial, there is a greater need to consider timing carefully and to avoid the likelihood that participants will adopt a political stance in place of a reflective engagement with the issues.

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

Continuing debate, building capacity

73. Invited public engagement initiatives are usually bounded and purpose orientated. But public debate does not have to culminate in the production of a single decision at a particular point in time. Continuing public debate and engagement may be valuable in monitoring and evaluating the implications of decisions, invigorating the public sphere and building capacity and confidence that can carry through into future engagements. This can lead

→ **The process of successful public engagement might suggest that there is value in continuing public participatory governance or research or services (e.g. patients' panels).**

74. **The main message of this section is to reflect carefully on the limitations of the initiative design, to evaluate how effective it has been in practice (see below) and what the public meaning of the outcomes amount to. A principal failing of engagement in public policy is that more significance or the wrong significance is attached to the outcome than the activity actually warrants.**

V. EFFECTIVE ENGAGEMENT

75. **For engagement to be effective, it should be meaningful, valuable and consequential for all those involved. Participants should recognise that their individual contribution has been considered even if they do not agree with any conclusion that may have been reached as a result of the process as a whole.**
76. This section is about how to secure and improve the quality of invited public engagement. The quality of engagement is related to, but distinct from, any judgement about whether the process of engagement is appropriate to a contingent aim or situation (see previous section) or how well the outcome of any initiative meets the expectations of its sponsors or participants (next section).
77. Effective engagement provides individuals with access to public life in a way that can stimulate interest, create opportunities for empowerment and foster trust among citizens, and between citizens and public authorities. Ineffective engagement may not merely fail to produce these effects but risks giving rise to their opposites: disinterest, mutual suspicion and, ultimately, a sense of alienation from public life.
78. The effectiveness of public engagement can be increased by attention to principles of design and conduct. Below, some key principles are identified along with suggestions and examples of how they can be put into practice.

Effectiveness through design

79. **The key design principle for effective invited engagement is enablement of participation. The most important features concern how the design expresses or manages the power relations among those involved, including the various participants and those initiating or sponsoring the initiative. This can be improved by creating an environment and process that are adequately resourced, inclusive and enabling.**
80. Allowing sufficient time for public debate may often be at odds with the need to make a policy decision on a pressing matter. Often the reasons for urgency are contingent (for example, to do with securing reputational or economic advantage), and urgency may be mitigated by foresight and anticipation. These pressures 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, (e.g. where risks and consequences are poorly defined) and where there is significant ambiguity about meanings and values the people attach to the issue. Over-hasty decision making in these circumstances runs the risk of simply deferring or displacing debate that may become more divisive or disruptive later.

Commitment of resources

81. In order to enable participants to contribute meaningfully, invited engagements need to be adequately resourced. Public engagement can be expensive (although this is not always or necessarily the case). At the very least, the resourcing needs to be adequate for the approach taken. Adequate resourcing demonstrates the commitment of public authorities to engaging citizens. Inadequate resourcing or 'cutting corners' can

undermine public engagement and lead to outcomes that can be worse than not engaging at all.

82. As well as adequate financial support, it is important that sufficient time is available to allow citizens to participate fully in engagement initiatives. 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 conclusions. This ensures that people engage with genuine views rather than prejudices or 'nonattitudes'.

→ **Resisting pressures to reach hasty conclusions and allowing time for debates to develop may be more prudent in the long run, especially when the issues to be debated are complex.**

EXAMPLE: PUBLIC DEBATE IN IRELAND CONCERNING ABORTION AND THE REPEAL OF THE EIGHTH AMENDMENT TO THE CONSTITUTION (2018) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

→ **Thinking of engagement as part of a policy process from the beginning, rather than an optional 'add-on' exercise, can help to ensure engagement serves the purpose of informing the policy-making process.**

EXAMPLE: PUBLIC DEBATE IN DENMARK CONCERNING THE FUTURE OF THE HEALTHCARE SYSTEM (2008) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

→ **Having decided on an appropriate approach to engagement, it is important to review whether sufficient resources can be committed. (It may be better not to embark on an initiative than to use an inappropriate approach or to cut corners. Approaches can be designed to meet more limited requirements, but overreaching and over-claiming may be counterproductive.)**

→ **Engagement that serves the interests of all participants can also lead to sharing cost burdens. (For example, resources might be expanded by working in partnership with public interest bodies, although diligence will need to be exercised to ensure that such an arrangement does not compromise the integrity of the partners or the process.)**

→ **The value of resources can be maximised by making use of existing organisational infrastructures although, again, care needs to be taken to account for embedded power structures and barriers to inclusion.**

EXAMPLES: PUBLIC DEBATE IN FRANCE ON THE LAW ON BIOETHICS (2018) / THE CONSTITUTIONAL WEEK IN POLAND TO INFORM AND DIALOGUE WITH CITIZENS (2018) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

Respect for interests

83. Effective engagement usually requires that participants believe that it is worth their while to participate, and that doing so will serve their interests in some way. Respecting the interests of participants, rather than treating them merely as a means to the ends of those initiating the engagement, is in any case, a normative requirement of public engagement.
84. In the case of public opinion research, participants' interests may be respected by rewarding them financially for participation. The rewards of democratic engagement, however, more often lie in the opportunity to influence public decision making (see next section) and to exercise control over the conditions of common life. For effective democratic engagement it is necessary for participants to believe that they have a stake in the outcome and to believe that participation offers them a genuine influence over that outcome. This means that those initiating invited engagement must implicitly and conditionally relinquish some power to the participants in exchange for their commitment.
- ➔ **Framing questions for debate in an unbiased way or, better, enabling participants to frame the questions in a way that is most meaningful to them and agreed between them can help to maintain trust in the impartiality of the exercise.**
 - ➔ **Participants' interests may be respected by involving them in the design of the process or the framing of the issues it addresses (co-design), although this may be in tension with the contingent aims of policy.**
 - ➔ **Respecting interests may require empowering participants to determine what information they consider to be relevant and to obtain it (for example, by having the ability to choose additional experts or evidence to inform their views).**

EXAMPLE: PUBLIC DEBATE IN IRELAND CONCERNING ABORTION AND THE REPEAL OF THE EIGHTH AMENDMENT TO THE CONSTITUTION (2018) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

- ➔ **Consider the balance between participants from different points of view.**

- It can help to empower individual participants and marginalised subgroups to involve independent, impartial and professional facilitators and intermediaries.
- If the engagement initiative is not mandated (for example, if it is simply for research and detached from meaningful policy influence, the participants may feel they do not have a stake in the process and be less active.
- The initiative can also be one where engagement is mandated but where the design of engagement is inappropriate and not sufficiently empowering.

Accessibility and inclusion

85. **Participants need to be enabled to engage effectively through the careful establishment and maintenance of a setup that is not structured to advantage one set of interests rather than another. This applies just as much to the design of a questionnaire as to the physical accessibility of a venue.**
86. To speak of ‘public debate’ can also imply a public space where ‘the public’ can express its interest 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. Often public engagement takes place in very private and controlled spaces into which the public are invited (see ‘invited engagement’); equally, publics may organise their own private spaces that are inaccessible to others (membership organisations, associations, trade unions, social media bubbles etc.) The site of ‘public debate’ should, necessarily, be accessible to the public, but a number of factors can limit accessibility.

EXAMPLE: PUBLIC DEBATE IN FINLAND WITH REGARD TO CITIZENS’ INITIATIVES TO THE PARLIAMENT (2012-) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

87. Public debate takes place through the medium of language. Access to the language of debate, however, may not be equally distributed. Despite the social right to education, literacy remains an issue in all states. This can be compounded by the use of technical terms and jargon, particularly with developments in biomedicine. Those for whom the local language is not their first language (e.g. recent immigrants, women in certain ethnic communities) may require interpreters. Some who lack native language skills or basic education may be less adept with written communication or interfaces that require technical skill or resources (such as online platforms).
88. Differences in language capability can be particularly significant where there is less mediation (for example in online platforms, certain public media, and social media). But interfaces may also present a problem: older people, 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. 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.

89. Accessibility of physical venues might cause difficulty for participants with restricted mobility (for example wheelchair users and those with baby carriages). Absence of facilities such as restrooms, prayer rooms or a nursing room, lack of free parking or accessibility by public transport can also exclude. The absence of a hearing loop or the presence of acoustic interference may make a venue unsuitable for a discussion with many participants.

- ➔ **Initiators may need to take special steps to engage socially marginalised groups.**
- ➔ **Having identified the scope of the ‘public’ (see above) consideration should be given to what may be required not only to enable the intended publics to participate but to enable them to participate on an equal footing with others.**
- ➔ **Engagement needs to be inclusive and welcoming. This might mean, for example, avoiding days on which some people are required to undertake religious observances, accommodating or compensating those with work commitments or childcare responsibilities. There may be a need to take specific steps to counteract insidious forms of social exclusion, for example working with specialist recruiters and community-based groups.**

EXAMPLE: PUBLIC DIALOGUE IN THE UK ON BRAIN SCIENCE, ADDICTION AND DRUGS (2007-2008) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

Governance

90. It is important that mechanisms are built in to invited engagement initiatives to ensure that they respect and promote the interests of participants/ publics and public authorities and, if necessary, adapt in order to do so. This governance role should be separated both from the practical management and delivery of initiatives, and from the initiative’s commissioners, sponsors or addressees.
- ➔ **Some form of governance, independent from the initiating public authority, sponsor, commissioner or organisation, should be part of the design of invited engagements. This might take the form of an independent oversight group or a person with independent authority.**

Effectiveness through practice

91. **The key principle for effective engagement 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 engagement cannot be assured by design alone but requires engagement to be conducted in accordance with principles of procedural justice.**

92. Procedural measures can help to counteract imbalances or inequalities among those involved, including those participating in and those initiating or sponsoring the initiative, and give legitimacy to the process.

Fairness

93. Respect for all participants is important. This may involve paying special attention or taking special steps to encourage and enable 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 of engagement should be the issue to be debated and not on the person debating it.
94. In particular, respect for ethnic, cultural, religious and socio-demographic differences should be maintained, demonstrating equal entitlement of all citizens to have their views taken into account. Demonstrating respect and fairness encourages conditions in which trust and therefore effective engagement is more likely to develop among participants.
- **Moderation or independent, impartial and skilled facilitation can help to ensure that all participants have a fair opportunity for their views to be heard, and mitigate asymmetries of social, political, educational and economic power.**

Privacy

95. Personal, lived experiences of individuals can offer important insights alongside aggregate data or impersonal evidence. Individuals may find their personal experiences are 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, where anonymity does not undermine the aims of the engagement, might be desirable, for example to protect participants from media intrusion.
96. The participation of some individuals may expose them to vulnerability, stigmatisation, discrimination or even direct harm. This can be particularly important to consider where the engagement involves the participation of children and young people. Many biomedical developments engage issues that impact disproportionately across differences of gender, age and health status/ disability, which entails a risk of compounding structural inequalities if disadvantaged groups cannot engage fairly in debating them.
- **Where participation of particular publics is important (for example, those directly or more significantly affected by a proposed measure) and direct participation poses a threat to their privacy, alternative means of enabling participation could be considered (for example, video links, trusted intermediaries or written submissions).**
- **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.**

EXAMPLE: PUBLIC DIALOGUE IN THE UK ON BRAIN SCIENCE, ADDICTION AND DRUGS (2007-2008) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)11 REV ADD]

Transparency

97. Transparency is an important aspect of fairness. Public authorities and participants alike should be transparent about their aims and interests in sponsoring or participating in public engagement, and the sources of any funding. Because of their interests it is often appropriate for sponsors of initiatives to involve independent actors or ‘honest brokers’ to conduct engagements on their behalf.
98. Relevant interests are not limited to public interests. Personal interests should also be taken into account as hidden personal interests of participants, experts or stakeholders can undermine trust and the credibility of the outcome of the debate. Having an interest in the issue at hand should not, however, prevent involvement; on the contrary, it is a reason for involvement but, on matters of public interest, it should not entail privileged influence.
- **Transparency can be improved by sponsoring/ commissioning public authorities, experts and participants in public engagement disclosing any relevant interests they have in the initiative or its outcome. This might be achieved by formally documenting interests in a record that is available for inspection or informally, for example, as participants new to a debate introduce themselves to others for the first time.**

Candour

99. It is important that participants engage candidly and in good faith, rather than ‘gaming’ public debates for private interest. This is particularly important where questions of fact and evidence are relied on in debate and when expert testimony is involved. Honesty about sources and the declaration of possible conflicts of interest are important. The use of clear, non-technical and unambiguous language is important to avoid misunderstanding; use of evaluative language or selective reference to facts by experts presented as impartial risks distorting debate.
- **Those offering expert evidence should make an effort to explain any uncertainties and limits of technical knowledge. Sometimes expert cross-examination or the participation of experts with contrary views can help to achieve balance where impartiality is unlikely.**
- **It is important to ensure that the balance of expert opinion is fairly represented, and that solid evidence-based knowledge is given due attention. Non-specialist members of the public should not be required to adjudicate between contradictory expert testimony although they may need to appreciate the margins and weight of disagreement.**

- **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.**

Public interest

100. The aim of public engagement in relation to fundamental questions of health and biomedicine may be to identify the overall public interest from engagement among the interests of a range of publics.
101. Public authorities and their agents (researchers, experts, facilitators) should be accountable for acting in accordance with accepted principles of probity in public life, for example principles such as selflessness, integrity, objectivity, accountability, openness, honesty that are found in codes of conduct for the discharge of public office in many states.
- **Identifying or setting out principles of conduct to be observed can help to increase transparency and support accountability.**

VI. ENGAGEMENT THAT COUNTS

102. For public debate to make a difference there needs to be a functional connection between public engagement and the governance of health care and biomedicine, so that the public are empowered to influence the conditions of their collective future in a way that is appropriate in a democratic society with specific institutions, culture and traditions.
103. The previous section concerned the quality of the engagement itself; this section concerns the further impacts of engagement and how to optimise these. These further impacts are of two sorts: on the developments that are the subject matter of public debate (for example, giving rise to new policies) and, reflexively, on the integrity of the public as a social body and, therefore, on the capacity of the public to participate in governance through democratic processes.

Commitment

104. For engagement to be effective, it is important that both publics and public authorities have a stake in the process (see section V above). On the part of the public authority, this stake is demonstrated by a commitment to the process of public debate and by taking account of the outcome. Taking account of the outcome does not mean simply acting in accordance with the outcome of a process, whatever that is determined to be. However, from the outset, there should be transparency about the how an engagement initiative is expected to relate to matters of public policy under consideration, how any outcomes will be taken up into public policy and what account participants and the wider public can expect to receive of this.

- **Commitment may be demonstrated by public authorities setting out explicitly what is open for debate (and what is not open for debate, and why) and what influence public engagement is expected to have. These matters should be clearly stated and could be recorded at the outset.**
- **Understanding between publics and public authorities may be improved by face-to-face encounters, for example, where participants are invited to present the outcome of discussions to policy makers or to question public authorities on how they propose to take forward the issues discussed.**

Accountability

105. There is an implicit obligation on any democratic state to account for its decisions to its citizens. Those responsible for initiating public engagement should provide feedback on their conclusions from the public discussion and how the views of the public were taken into consideration in subsequent policy-making and/or other related decisions or processes.

- **Accountability may be demonstrated by publishing information about the ways in which public engagement has informed the decisions or practice of public authorities, for example via websites and public media. As well as enabling independent scrutiny, this can help to encourage future participation and to break down barriers between publics and public authorities.**
- **Publishing and disseminating information about an engagement initiative, 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 participation.**

EXAMPLES: PUBLIC DEBATE IN PORTUGAL ON END OF LIFE (2017-2018) / PUBLIC DEBATE IN FRANCE ON THE LAW ON BIOETHICS (2018) - see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

Evaluation

106. The process and the outcome of invited engagements should be evaluated whenever possible. Evaluation should address the effectiveness of the engagement (see section V above) as well as how well the engagement initiative met the aims and expectations of participants and commissioning authorities, including a reflection on the added value of the citizens' contribution.

107. This 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 initiative. It will also serve as a reference and provide valuable information when organising future initiatives.

- **Setting evaluation criteria, measures and framework at the outset and, so far as possible, agreeing these at an early stage with participants helps to give confidence in the integrity of the process.**
- **Confidence in the bona fides of those initiating public engagement 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 engagement could publish a reflection on the exercise so that others are able to review and discuss it.**
- **Evaluation can be supported by feedback from participants (collected, for example, via a simple questionnaire at engagement events or by the inclusion of suitable questions as part of an engagement instrument or process). Depending on the nature of the process, evaluators may inform their conclusions by undertaking qualitative interviews with participants.**

Continuing debate

108. Public engagement should ideally contribute to socially constructive discourse that is reflected in the decisions and policy making of governments and the public authorities. An experience of effective engagement can also help to foster political engagement 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.

- **Engagement in a specific context may give rise to further opportunities there may be for continuing involvement of participants. For example, networks and connections developed in the course of engagement initiatives might lead on to involvement in future initiatives (providing they are maintained consistently with the privacy of individuals involved).**
- **Aside from the legacy of connection between people and publics ('social capital'), public debate may also generate tangible social resources in the form of records of events and reference documents on which future debate can build. Capturing 'learnings' can be helpful for both the public and the initiator of public engagement.**

EXAMPLE: PUBLIC DEBATE IN PORTUGAL ON END OF LIFE (2017-2018) - see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

Embedding public debate

109. A society in which the habits of democratic participation are established through education and opportunities for public participation will be better prepared to engage citizens on questions of the governance of biological and biomedical developments.

110. Institutions mandated or committed to support public engagement, whether national ethics committees, independent organisations or public authorities, regulators and advisory committees, can help to promote public engagement, maintain a continual level of public engagement with developments in biomedicine and provide institutional mechanisms to put engagement into practice. Such organisations can help to bridge the gap between implicit social norms, which form the moral fabric of a given society but are rarely articulated and challenged, and the need to address urgent policy questions arising in relation to the emergence of novel biological and biomedical developments.

→ **Adequately resourced and politically supported national ethics committees or similar bodies can have an important role in fostering public debate, carrying out engagement and securing its impact.**

→ **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 both provide suitable venues for debate and help to invigorate those sites as sites for social interaction. This can help to counteract the fragmentation of public debate in social media.**

EXAMPLES: AWARENESS WEEK IN CYPRUS ON (I) BIOETHICS, MEDICAL ETHICS AND SCIENTIFIC RESPONSIBILITY (2017), (II) BIOETHICS DIMENSIONS OF AGEING (2018) / PUBLIC DEBATE IN DENMARK CONCERNING THE FUTURE OF THE HEALTHCARE SYSTEM (2008) / PUBLIC DEBATE IN FRANCE ON THE LAW ON BIOETHICS (2018) – see addendum to the draft guide which contains country examples of public debate [doc DH-BIO (2018)16 REV ADD]

VII. CONCLUSIONS

111. Showing respect for the interests and views of citizens is a cornerstone of democratic societies. Questions relating to developments in biomedicine are often complex and can challenge the ethical norms that organise social life. The response to these questions can profoundly shape the societies of tomorrow. Article 28 of the Oviedo Convention (on ‘public debate’) was drafted with the conviction that the direction of an ethical development is not only a question for experts or authorities, but for a society as a whole.

112. In fact, 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 contemporary 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 put forward the views of their citizens represented to them through open debate in the public sphere.

113. 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 public engagement initiative, nor any mixture of public engagement 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 self-sufficient nor an end in itself.

GLOSSARY

Aggregative methods – voting, polling... (cf. 'deliberative methods').

Café Scientifique – also 'conversation cafés'...

Citizen – a natural person, the subject of a state, therefore having an interest in the governance of that state and enjoying legal rights protected by that state.

Citizen's Assembly

Citizens' Inquiry – a variation on citizens' assembly where a group of citizens are brought together to conduct an inquiry on a specific subject, usually reporting their recommendations to policy makers. (Example: HGC [Citizens' Inquiry into the Forensic Use of DNA and the National DNA Database](#) (UK).)

Citizens' Jury – a deliberative exercise involving randomly selected members of the public, having some similarities to legal proceedings that involve a 'trial by jury'. Between 12 and 24 randomly selected participants are invited to hear evidence relevant to a proposition or 'charge' and give a 'verdict', although it is also usual to record their deliberations.

Citizens' Panel – a method...

Citizens' Summit – a method...

Conflict of interest – the situation of a participant in public debate where their participation presents an opportunity to influence the outcome or effect of the debate for their own advantage at the expense of the advantage of others. [Should we refer to CoE public ethics doc on *Conflicts of interest at local and regional levels*?]

Consensus – Not all public debate aims at agreement but often there is a need to find a way forward for a group or political community that respects the rights and legitimate interests of all. There are various models of consensus formation....

Consensus conference – a method that...

Consultation – elicitation of qualitative information, typically to test policy proposals by engaging with those who have a pre-existing interest ('stakeholder consultation'), opinion or expertise. Consultation is usually open to the public (especially on matters of public policy that may indirectly affecting everyone) although respondents are self-selecting. Groups with specific interest/ expertise may be actively targeted and responses are usually submitted in written form either in print or online ('written consultation').

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

Crowd-sourcing – the harnessing of input for problem solving from any willing contributor, often online to maximise the possibilities for input.

Deficit model – now widely discredited idea that the asymmetry of knowledge between ‘experts’ and publics means that the main objective of engagement is to inform or educate to reduce this deficit in understanding (see: ‘public understanding of science’). This often includes the implication that the views of experts should have a privileged voice in public policy debates.

Deliberative methods – sustained discursive engagement (e.g. reconvening discussion groups, citizens’ juries) in which participants typically rely on principles of procedural justices, such as attending respectfully to the views of others (cf. ‘aggregative methods’)

Deliberative mapping – a method that...

Dialogue – ... (also ‘public dialogue’, ‘distributed dialogue’)

Discussion groups – ... (also ‘focus groups’)

Elicitation – techniques to obtain information from publics (e.g. questionnaires, surveys)...

Engagement – engagement is by definition a two-way process of communication, which involves participants, responding to each other’s interventions, in order to address a common challenge. [NB: There are various definitions. For example, NCCPE has: “Public engagement is a process that brings people together to address issues of common importance, to solve shared problems, and to bring about positive social change. Effective public engagement invites average citizens to get involved in deliberation, dialogue and action on public issues that they care about.”]

Excluded voices – some voices may be more difficult to attend to or less well represented in public debate as a result of the conditions of engagement or the design of an initiative. These may include voices of minority ethnic groups, demographic outliers (children, the elderly, those with low educational attainment) or those in positions of vulnerability. Depending on the question at issue, these groups may be disproportionately affected and special efforts may be required to engage with them.

Games – ... (Example: the ‘Democs’ game that involves ‘players’ selecting and discussing information relating to a public policy issue on a number of prepared cards, developed by the New Economic Foundation (UK))

Hackathon – an event at which...

Information – techniques to impart information to publics (e.g. information campaigns) ...

Invited/ uninvited engagement – invited engagement; uninvited engagement includes spontaneous debates, lobbying by industry and public interest groups and NGOs.

Kiosks/ booths – temporary interventions in public spaces, often taking the form of a display or booth that engage passers-by with advertising or conversation and provide opportunities to offer information and capture feedback. (Example: Academy of medical Sciences [‘Departure lounge’](#) – a pop-up venue for discussing death and dying deployed in a variety of public spaces (UK))

Media analysis – ... One method is social media mapping (also ‘mashups’ which combine multiple data sources).

‘Methods’, ‘tools’ and ‘mechanisms’ of public engagement – techniques of invited engagement

‘Nonattitudes’ – phantom attitudes reported in opinion polls that are offered by respondents in order to oblige the pollsters.

Participatory appraisal – a method that...

Petitions – also online petitions... in many countries, online petitions that reach an agreed threshold of signatures can automatically trigger some form of official or parliamentary process (e.g. UK)

Polling – (also ‘opinion polls’ of the sort pioneered by Gallup)

‘Public’ and ‘publics’ – many social scientists and public engagement practitioners therefore prefer the plural term ‘publics’ to the singular ‘Public’ so as not to imply homogeneity or that ‘The public’ necessarily exists in a meaningful sense independently of the issues in question.

Public debate, public engagement, public involvement, public participation – in this document the overarching concept of ‘public debate’ is used to describe a form of communication in the public sphere (that is, not in a professional context) that is aimed promoting understanding and orientating society towards decisions that affect the conditions of common life. [It corresponds to the Kantian ‘public use of reason’.]

Public dialogue – deliberative methods that involve sustained discursive interaction among participants in which, typically, the participants have a significant degree of influence over the framing of questions and/ or the selection of information.

Public engagement initiative/ exercise – an invited engagement, typically initiated by a decision-making authority to achieve specific aims. It is important that such initiatives are understood within -- and respond to -- the broader context and interests of

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 political action. In practice, it may be supported by institutions, such as social and political institutions and the media.

Public understanding of science (PUS) – this was a movement to ‘educate’ non-specialist members of the public about scientific research. It was prompted by a reaction to a number of public furores resulting from the increasing hiddenness of science (and the divergence of scientific culture) from mainstream society and the recognition that public funds were used unaccountably for scientific research. It was often inspired by the conviction that if only the public could be made to understand the objectives of science (or, rather, scientists) they would necessarily approve of them (see ‘deficit model’).

Questionnaires – more ad hoc than systematic surveys...

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.

‘Rational ignorance’ – the reasonable conclusion that, given the limitation of an individual’s influence on a public debate, it is not worth that individual’s time and effort to familiarise themselves with the detailed evidence and arguments pertinent to that debate.

Representativeness – invited engagement may be representative of the general population or of a particular subset of the population.

Surveys – cf questionnaires... online or omnibus surveys...

Town Hall meeting – A method...

Voting – an aggregative method, typical of political elections, that involves individuals casting lots (usually one per person) among a set of defined options. (Also: plebiscite, referendum)

SELECTED SOURCES

Literature relating to public debate

- Burall S (2015) Room for a View? Democracy as a Deliberative System (available at: <https://www.involve.org.uk/sites/default/files/field/attachemnt/Room-for-a-View.pdf>)
- Chilvers J (2010) Sustainable participation? Mapping out and reflecting on the field of public dialogue on science and technology (available at: <http://www.sciencewiseerc.org.uk/cms/assets/Uploads/Strategic-Research-documents/Sustainable-Participation-report-03-10.pdf>)
- Fiorino D (1990) Citizen participation and environmental risk: A survey of institutional mechanisms. *Science, Technology, and Human Values* 15:226-243
- Fishkin JS (1996) The televised deliberative poll: an experiment in democracy *The Annals of the American Academy of Political and Social Science* 546: 132-40
- Kant I (1784) An answer to the question: What is Enlightenment? in Reiss (ed.) (1991) *Kant: Political Writings* (Cambridge: CUP) (trs of: (1784) Beantwortung der Frage: Was ist Aufklärung? *Berlinische Monatsschrift*)
- Rowe G and Frewer LJ (2005) A typology of public engagement mechanisms *Science, Technology & Human Values* 30: 251-90
- Warburton D (2015) Quality in public dialogue, A framework for assessing the quality of public dialogue, Working Paper – March 2015 (<https://sciencewise.org.uk/wp-content/uploads/2018/09/Sciencewise-Quality-in-Public-Dialogue-August-2018.pdf>)

Organisations/ practitioners/ resources

- Delib** – a for-profit social venture providing a range of tools for citizen involvement
<https://www.delib.net/>
- National Coordinating Centre for Public Engagement (NCCPE)** – a website providing advice and resources to supporting public engagement by academics in the UK
<http://www.publicengagement.ac.uk/>
- Involve** – UK organisation supporting democratic participation in areas including science and health policy <https://www.involve.org.uk/> [Involve has summary descriptions of over 50 different approaches to public debate at https://www.involve.org.uk/resources/methods](https://www.involve.org.uk/involve-has-summary-descriptions-of-over-50-different-approaches-to-public-debate-at)
- 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
(<http://www.tekno.dk/?lang=en>)

Participation Compass – UK online resource for those involved in planning, running or commissioning participation activities, which includes information about methodologies and case studies (<http://participationcompass.org>)

Sciencewise: UK Government programme to encourage and support public dialogue on science and technology for policy development, providing well-established expertise and advice on deliberative methodologies with over 50 evaluated case studies (<https://sciencewise.org.uk>)

Missions Publiques: INGO organising citizens' debates on societal challenges (<https://missionspubliques.org/>)

Case studies and evaluations

Etats généraux de la bioéthique (recent periodic review of French bioethics law using multiple methods and covering a number of topics – see CCNE (2018) Rapport de synthèse du comité consultatif national d'éthique – opinions du comité citoyen, available at:

https://www.ccne-ethique.fr/sites/default/files/rapport_de_synthese_ccne_bat.pdf

GM Nation? (Widely regarded as ambitious but flawed national debate with unanticipated but far reaching consequences for biotechnology research and industry in the UK – see: Tom Horlick-Jones, John Walls, Gene Rowe, Nick Pidgeon, Wouter Poortinga & Tim O'riordan "On evaluating the GM Nation? Public debate about the commercialisation of transgenic crops in Britain", available at:

<file:///C:/Users/TEMP.NUFFIELDF/Downloads/NGS06.pdf>)

Nanodialogues ('upstream' deliberative engagements involving experts and members of the public around nanotechnology – see Nanodialogues Experiments in public engagement with science (available at:

<https://www.demos.co.uk/files/Nanodialogues%20-%20%20web.pdf>. Interesting to compare with the disrupted programme of meetings on nanotechnology in France in 2010)

Smith and Samuel, Who's talking about non-human genome editing