RAPPORTEUR REPORT

WORKSHOP ON PUBLIC DIALOGUE ON GENOMIC MEDICINE

Published by the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO)

Author : Mark Bale

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Contents

Summary and key points

Genomic medicine will become embedded in many aspects of medicine, from diagnosis of acutely ill patients, to associated treatments such as gene therapy and genome editing, through to screening and prevention advice in otherwise healthy people.

National and regional initiatives to make genomic data accessible for clinical care and research will rely on regulation and effective, collaborative, aspects of good governance. Until now, there has been a focus on consent, medical supervision, and public information but further work should be considered to reinforce "*the importance of earning trust and stressing the role of good and transparent governance*" (preamble to the Biobank Recommendation). Guidance should also be considered on the role of the wider public and stakeholder dialogues as part of the oversight and independent review of proposals to establish large genomic databases. Dialogues should also be embedded as part of the relevant professional obligations and standards for genomic medicine to ensure non-discrimination and equitable access to healthcare.

However, genomic medicine should not be offered to the public before effective public dialogues have taken place with all stakeholders and sectors of the population. In accordance with the Convention on Human Rights and Biomedicine (Oviedo Convention), such dialogues must include attention to human rights principles relating to health, notably equitable access to health care and the prohibition of discrimination. Any public engagements should be planned and resourced so that marginalised and vulnerable groups are involved, and a wide range of views are heard and acted upon.

Public dialogues on new and complex technologies like genomic medicine have a two-way educative function for organisers and participants which bridge the gap from the early stages of development of genomic medicine through to its appropriate application in public health systems. For dialogues to be effective, they must be organised on a continuous basis.

Previous examples of public dialogues on genomic medicine serve to underline issues of fairness, equity, social justice, equal moral worth, and solidarity at the local, national, and global level. The concepts of altruism and solidarity identified in the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) are especially important for young people because "we all have a genome", as stated by one of the young participants during the workshop. In biomedical research, in return for citizens' altruistic donation of samples and data there needs to appropriate and fair application of the results into publicly funded healthcare. This addresses the priority referred to in the Strategic Action Plan to "*promote a dialogue between the public, practitioners, and policy makers on how to incorporate the principle of reciprocity in the governance of genomic medicine*".

Background & objectives

Genomic medicine involves an analysis of the DNA of patients to inform clinical decisions. This form of personalised medicine depends on insights derived from large genomic and health databases. Many countries have local or national databases, there also plans to make them interoperable in Europe (1 Million Genome Initiative[1]) and globally (Global Alliance for Genomics and Health[2]).

The governance of new technologies and their applications in the field of health is one of the key pillars of the Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO). The Action Plan highlights that governance models are needed to safeguard the protection of human rights throughout the process of biomedical research and implementation. This includes ongoing dialogue between the public, scientists, and policy makers so that developments are robustly deliberated, democratic, and legitimate. Broad and informed public dialogue helps to reflect the interests of patients and the public.

The Guide to public debate on human rights and biomedicine is a valuable resource when planning and organising public dialogues. The Guide refers to the speed of developments, opportunities for data mining and new conditions for access to healthcare that are relevant to genomic medicine. As an example of how important public dialogues are the Guide cites a common concern about genomic medicine:

[1] European '1+ Million Genomes' Initiative | Shaping Europe's digital future (europa.eu)
[2] https://www.ga4gh.org

> "*… the generation of standardised or complete genomic data sets, and access to certain services may imply that all data are stored. … 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*."

Public dialogues should be a major contribution to the governance of genomic medicine. They can build opportunities for two-way public participation or involvement in decision-making processes (e.g. at the stage of mapping the possible policy options), and can help to build capacity and promote opportunities for participation in governance (e.g. patients' panels).

In accordance with the Strategic Action Plan, the workshop on public dialogue on genomic medicine, held on 10 November 2022, pursued the following key objectives:

- Promote a common understanding of genomic medicine, to distinguish it from other fields of medicine, to grasp the various issues that it raises.
- Explore how public dialogue facilitates information, open exchanges, and better understanding of issues in genomic medicine, having regard to their implications for human rights, and for bioethical principles, such as solidarity, altruism and reciprocity.
- Consider the extent to which patient and public interest plays a role in the development and regulation of genomic medicine and, to this end, what level of public involvement and/or oversight is needed.
- Understand the prevalence of public dialogue on genomics both in member states and at the international level, reflecting on who the key stakeholders are, why do they matter and how to make their engagement count.
- Discuss how public dialogue can be employed to anticipate innovations and the need for regulation in genomic medicine.

The workshop focused on the value of public dialogues between different publics, researchers, healthcare professionals and policy makers in creating a shared understanding of the opportunities, as well as of the challenges of genomic medicine. This report of the workshop summarises the discussions and contributions from experts and young people. The full video of the meeting is on the workshop webpage. This report also identifies some relevant overarching principles and key lessons for future work on this important topic.

Opening remarks

Siobhan O'Sullivan, Chair of the Steering Committee for Human Rights in the fields of Health and Biomedicine (CDBIO), outlined how genomic medicine can provide opportunities to improve how we understand and treat disease, both in terms of the discovery of new pathways of disease, and in providing new treatment targets. Reliance on genomic medicine does however raises issues about ethics and governance, including:

- What constitutes truly informed consent when individuals agree to having their genome analysed?
- Who owns genetic information and who should make decisions about what results are returned and how they are used?
- How can privacy be assured? What outcomes matter most to patients, their families and the broader public?

A key determinant as to whether people will participate in genomic medicine is trust and trustworthiness. This involves robust governance measures – as noted in the Strategic Action Plan: "*Governance frameworks are necessary to optimise the chances of stimulating innovation that contributes to human flourishing, whilst minimising applications that have negative consequences for individuals and society."* Good governance, in turn, requires transparency and accountability that is built upon clear regulations which guarantee equitable access to genomic medicine. The risks to people being discriminated against because of their genetic information also needs to be addressed, especially because of the legal and ethical implications involved.

Public dialogues involve multiple actors allowing for a collective approach to shaping the governance and regulation of genomic medicine. Public dialogue also empowers individuals to promote and assert their agency when it relates to the use and sharing of their genomic data.

Session I: What is public dialogue on genomic medicine, why is it important and when is it most important to carry out?

Anne Cambon-Thomsen, University of Toulouse

Anne Cambon-Thomsen began by setting out what dialogue is, when it should occur and why it is important. It is both a dialogue made in public and a dialogue that involves the public. It can include consultation, participation, involvement, empowerment, deliberation, exchange, co-construction and debate. However, debate as often practiced in policy making and legislation can be too short, and with less listening than dialogue suggests. In whatever form it takes, dialogues must be organised, publicised and most importantly the results used (also called 'actionability') in decision-making and governance.

Genomic medicine is a matter of public policy in the health domain – at a personal, family and population level. It is an example of the use of 'big data' and there is often a circular relationship between biomedical research and clinical care. But there have been historical abuses and there is a perceived link between genetic or genomic information and its misuse in areas such as eugenics and genome manipulation.

With so many potential stakeholders, the neutrality of dialogues may not exist. It is important to be clear who organises public dialogues, who defines their objectives and topics, and who ensures clear and transparent use of their results. People need to be informed, recruited, and prepared for discussions on such a complex topic. The wider public may need to be informed of potential

applications or misapplications of genomic medicine as they otherwise may be unconcerned until the proposals are put into practice.

When to organise dialogues is also an important consideration. There is a time lag between when a technology may be ready for introduction and when the practical issues or challenges are evident. Public dialogues are therefore a continuous action – it may be relevant to hold them when early research or application decisions are apparent, as the evidence develops and at the time of public policy decisions.

The establishment of Open Science[3] should provide opportunities to make *scientific knowledge openly available, accessible and reusable for everyone*; to open scientific knowledge to *societal actors* beyond *the traditional scientific community* and support *open engagement of societal actors and open dialogue*.

In conclusion, Anne Cambon-Thomsen repeated that public dialogues are a process rather than an event, they are an essential aspect of democratic societies and of specific importance in ensuring trust between researchers, the public and policy makers.

Rapporteur's remarks

The opening session reinforced the importance of human rights principles for health, as referred to in the Oviedo Convention. This includes the primacy of the human being, the protection of an individual's right to privacy, to know any information collected about health, and to provide informed consent to the use and sharing of genomic data.

The development of genomic medicine, and the equitable access to its results, requires effective dialogue carried out in a continuous and sustainable manner. This should be reflected in law and policy to ensure equitable access to healthcare for everyone, including future generations.

Consequently, public dialogue should be considered as a key collaborative element of good governance, public policy making and management that engages people constructively across agencies, government, and the private and civic spheres in order to carry out a public purpose[4].

[3] UNESCO Recommendation on Open Science

[4] Integrative Framework for Collaborative Governance | Journal of Public Administration Research and Theory | Oxford Academic (oup.com)

Examples of public dialogues – results, consequences and lessons learned

- **Derick Mitchell**, Chief Executive Officer, Irish Platform for Patient Organisations, Science & Industry
- **Vivienne Parry**, Science Broadcaster & Head of Public Engagement Genomics England
- **Petra Verhoef**, Theme coordinator, Rathenau Instituut
- **Eva Winkler**, National Center for Tumor Diseases, Heidelberg University Hospital
- **Borut Peterlin**, European Society of Human Genetics (ESHG)

The first panel summarised relevant examples of public dialogue. Derick Mitchell outlined the 2022 Citizen's Jury on the Future Use of Genomics in Ireland. Petra Verhoef covered the Dutch DNA-dialogue on germline genomic editing led by the Rathenau Institute with 11 stakeholder groups. Eva Winkler spoke about public dialogue and patient deliberative forums by the German National Genome archive. Borut Peterlin gave examples from Slovenia and referred to the role of the European Society for Human Genetics. Vivienne Parry described dialogues by Genomics England on the application of genome sequencing in healthcare (including the role of the Participant Panel).

The dialogues took different forms, the Irish Citizens Jury involved 24 citizens addressing the future use of genomics; the opportunities and challenges and the sensitivity of genomic information compared to other health information. In the Netherlands, there was a community focused dialogue on the amendment to the Dutch Embryo Law, which involved nearly 1,000 citizens in 27 moderated sessions. The establishment of the German National Genome Archive involved 20 patients in two

online events with expert support in moderated deliberative forums. Genomics England organised two Citizen Jury events – on the social contract for genomic medicine and on new-born screening and sequencing.

These dialogues were complex and required dedicated funding to ensure they were well-informed and impactful. They highlight how well organised dialogues led to positive engagement and rich discussions between experts and participants. The process and results of dialogues were of wider interest to the public and media.

Delivering effective engagement could also be a key requirement to obtain funding and support among delivery partners. In the UK, dialogues on genomic medicine also showed clear 'red lines', especially when the implications were potentially discriminatory or could otherwise affect them financially or be used for marketing and insurance purposes.

Public dialogues must allow for reactions to concerns in the design, governance or policy of genomic medicine. Dialogue could identify whether there was a 'social licence' (i.e. informal permissions granted to institutions such as governments or corporations by members of the public to carry out a particular set of activities) and public support (or not) for genomic medicine. Examples were given where the absence of dialogue on the use of health data in the UK resulted in a loss of public trust. In the Netherlands, the risk of not carrying out the dialogue would have been less well-developed political discussion of the law, and the perception that the views of citizens and their children were respected.

The specifics of public dialogues depend on whether genomic medicine is research driven or a clinical service. For research, the issues concern the trust of participants and the quality of research to inform the adoption in medicine. For a clinical service, it involves patients, the health service and governments as funders of health services. The dialogue should address whether the technology is ready to be rolled out in hospitals and what this means for other priorities for healthcare funding.

The panel emphasised the importance of focus on marginalised and lower socio-economic groups. These are not 'hard to reach' groups if organisers adapt their processes, although it takes time and resources to build trust. Some groups have poor access to health care and a mistrust of authority in general but if their views are not included in dialogues then these risks widen health inequality. In this regard, engaging faith leaders is a gateway to involving diverse communities. In the Netherlands, public dialogue between different faith leaders has also been insightful to understand how different faiths consider the emerging issues of heritable genome modification.

There were examples provided of the two-way educative effects of public dialogues, because being involved in any dialogue facilitates understanding about existing protections in medicine and society. With some decisions many years ahead, it is important to be transparent about what is being done in areas like the prohibition of-discrimination, solidarity, equity, and safety.

In conclusion, the panel identified key lessons. Dialogues are the start of a process rather than a one-off event. They need a good organisational team, and a partnership with stakeholders that can create a safe atmosphere for discussion (and that small numbers of participants can be representative of wider public views). Successful dialogues enable empowerment and engagement on the possible benefits of genomic medicine and on why more protections are necessary.

Investment in developing competencies for dialogues across all stakeholders was underlined. Germany trains and supports patient representatives through a Patient Academy. In some scenarios, scientists cannot always predict with sufficient accuracy what the future benefits and risks will be. Health professionals specialising in genomics form part of a key stakeholder group with experience in genetic information and how patients handle this in real-life. These considerations reinforce the need for broad engagement in public dialogues.

Rapporteur's remarks

The examples and discussion highlighted that public dialogues on genomic medicine are complex and require dedicated resources and funding, as well as sufficient time, to ensure they are well-informed and impactful, especially in including people who may be otherwise hard to reach. These are pre-requisites for the inclusion of everyone in public dialogues.

Public dialogues as a process rather than an event are more successful when they are carried out in a manner which is transparent and accountable, so that results are tangible and 'actionable', in other words that action occurs because of dialogues.

Open exchanges with young people – personal perspectives

- **Radosveta Bozhilova**, PhD Student (Bulgaria)
- **Darina Kachakova**, PhD, Geneticist at Molecular Medicine Centre in Medical University-Sofia (Bulgaria)
- **Zoha Panezai**, Bioscience student at the University of Limerick (Ireland)
- **Justine Macé**, Student in digital law and apprentice lawyer at the Ministerial Delegation of Digital Health (France)
- **Jimena Pinto**, Student at the Swiss School of Barcelona (Spain)

Dialogue with young people is a priority for the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO). The young panellists invited to join the workshop all have personal experience of public dialogue as participants or are involved through their research and studies. The examples they provided of the use of genomic information in research or patient care highlighted the importance public dialogue to understand concerns and to help scientists provide information on what is possible and on the necessary protections.

The young panellists felt that they are most likely to be affected by future developments in genomic medicine. Their engagement in public dialogues is important as they tend to not have experience of illness and may not see any reason to take part in them. They considered that sharing genomic data is for the common good which may in future help other young people and their families.

Engaging young people in public dialogues should start online. All forms of social media should be used to raise awareness, also involving scientists and experts. This allows experts from national centres, government, and patient representatives to interact with young people in different cities or remote areas.

Public dialogues can help to support young people's critical thinking, to help debate new technologies, like genomic medicine. Open discussion is necessary, and the organisers and participants should not be afraid of differences of opinion or disagreements when it helps to address misinformation. Dialogues in turn help young people to engage with health professionals and policy makers, to alleviate any mistrust and to tackle preconceived ideas and views (as a form of myth-busting). If young people are not included in dialogues, this can reinforce mistrust and the belief that policymakers would not engage them because they were concerned about negative responses.

As well as a wider public understanding of science, there is a need to fully engage citizens in decision-making about the best oversight and protections in order to achieve the potential benefits of genomic medicine. Even though it is only part of the issue, widespread public engagement around complex issues like genomic medicine is a form of solidarity. The point was made that "*everyone has a genome and could potentially be affected by a genetic disease and the development of genomic medicine"*. This means that decision makers and governments should undertake public dialogues from the outset to develop a more equitable health system and/or to promote the opportunity for them to join clinical trials. People generally should be engaged about how their genetic information is collected and used to embed genomic medicine throughout healthcare.

Rapporteur's remarks

Young people are most likely to be affected by future developments in genomic medicine so their engagement in public dialogues is of paramount importance. They may not have experience of illness and hence demonstrate an initial lack of interest in engaging in discussion. However, their engagement can help tackle misinformation about genomics and related health matters. Young people are also an important enabler in addressing issues such as how data are controlled and used.

Different forms of outreach and dialogue, including social media, can help to engage young people. These dialogues should be linked to wider activities on science education, online safety, privacy and how health data are safeguarded.

Two-way dialogue with all stakeholders - are we listening and learning enough?

- **Regina Becker**, Research Scientist, European "1+ Million Genomes" Initiative
- **Stefano Benvenuti**, Head of Public Affairs at Fondazione Telethon
- **Nicolas Garnier**, Head of Patient Advocacy, Pfizer Global Product Development, Oncology & Rare Disease
- **Andres Metspalu**, Director of Genome Centre, Estonia

This panel included experts who use public dialogue in different contexts. **Regina Becker** focusses on the ethical, legal and social issues of the EU 1+ Million Genomes Initiative aimed at making genomic data available across borders. As well as the technical aspects, the views of people are important for trust, transparency and to avoid the pitfalls if there is not adequate dialogue. **Stefano Benvenuti** described the charity Fondazione Telethon which relies on donations from citizens to promote research on rare disease. They foster a close dialogue across a triangle of citizens, patients and researchers. **Nicolas Garnier** leads patient advocacy for Pfizer and industry leadership of Screen4Care which aims to develop a framework for new-born sequencing. **Andres Metspalu** leads the Estonian Biobank, established 20 years ago, that now includes biological samples of 20% of the Estonian population. In common with other biobanks, it requires engagement with the public who volunteer to participate; with researchers who use the biobank and clinicians who make use of the findings.

The panel discussed the importance of dialogue which is inclusive, stressing that if a key stakeholder is absent from dialogue then this engenders a risk to the effectiveness of action that follows. There is a need for broad dialogue between all parties in the healthcare ecosystem because,

should they not be aware of its existence or express a lack of trust in it they may be excluded from it and thereby not have the opportunity to contribute to the delivery of effective care and even hampering efforts to do so. Different groups also have different perspectives: the wider public differ from patients who have experience of the difficulties of diagnosis and appropriate treatment pathways for rare disease (the 'diagnostic odyssey'); dialogue exclusively with patients does not always reflect the perspectives of the (non-ill) general population and sub-groups, such young people.

Two-way dialogue, implying a meeting of minds, can be improved through peer-to-peer engagement, for example through trained patients engaging with other patients, between different stakeholders, and between experts from different governments. In all cases, there is a need for researchers, patients and experts who can act as 'translators' and communicate with different audiences. It is important to emphasise that there can be no stupid questions posed during public dialogues! This is especially important when listening and engaging with patients from different faiths or cultures, whose views and perspectives as to benefits and risks may be different.

Genomic medicine relies on the principles of solidarity and altruism. Patients are willing to donate samples and data knowing that research takes time, and that this may not be of benefit to them personally. The principle of solidarity is also the basis of most European health systems. Open dialogues between decision makers, industry, and the public on how to provide sustainable genomic medicine services is helpful in addressing the challenge of making high cost, specialised treatments available in an equitable manner. However, there was a concern that sometimes policymakers supported the principle of dialogue but did not take effective action on its findings. Despite numerous examples of dialogues where a lack of engagement led to mistrust or a lack of uptake, there is a tendency for policy makers to prefer one-way communication (or publicity) rather than genuine two-way dialogue.

The possibility for genomic screening to support early detection and prevention in a healthy population is also a new paradigm for healthcare which needs effective dialogue and engagement, especially a clearer understanding of risk and 'actionability'. To develop the public's understanding and appreciation of genomic screening takes time and requires a very broad engagement of populations, including children. This includes the screening of new-borns and their 'right to an open future'. As they are unable to consent, it is generally accepted that children should not be screened for conditions that will only occur in adulthood.

Rapporteur's remarks

Different groups in society have different perspectives. Public dialogue is an opportunity to hear all of them. If a stakeholder is absent, then it can be argued that dialogue is unlikely to turn into effective action.

Furthermore, all stakeholders – including governments, funders, and industry - have a responsibility to engage in public dialogues on genomic medicine. The effective governance of genomic medicine depends on two-way public and patient involvement. Developing criteria to maximise outreach and inclusion in public dialogues would provide useful guidance to those responsible for organising and acting upon them.

What level of public involvement and/or oversight are needed for development, governance and regulation of genomic medicine?

- **Philippe Berta**, Professor of Molecular Genetics, Deputy for Gard and President of the Rare Disease Study Group
- **Sandra Liede**, Senior Legal Specialist Healthtech Finland, part of TIF (Technology Industries Finland)
- **Katherine Littler**, Science Division, WHO
- **Alessandra Pierucci**, Chair, Committee of Convention 108

The panel discussed how the public should be involved in the process of the regulation of genomic medicine, at its earliest stages and throughout. Based on the assumption that regulation is essential for the development of genomic medicine, suitable public dialogue and debate should be established. As a two-way process, this helps to educate the public and policy makers about new developments and ways to appropriate their development and governance.

Embedding the technologies of human genome editing or genomics in medicine will potentially affect everyone. Deciding when to engage in public dialogue, who to engage in them and why dialogue is needed, are important considerations before proceeding. There is a need to consider detailed bioethical issues such as fairness, social justice, equal moral worth, and solidarity. This also includes dialogue on acceptable types of technology and corresponding values in society. Dialogues can help to identify concerns in populations about their relationships to genomic data, to how communities view their origins and ancestry and the acceptable approaches to be undertaken. The COVID-19 pandemic led to a devaluing of scientific expertise which affected trust in scientists. As a bridge, public dialogues can help to address and facilitate understanding of different perspectives.

The panel re-emphasised that public dialogues need to be fully resourced, noting the trade-offs in time, budget, and the impact on other activities if dialogues focus on genomic medicine (the opportunity cost). Any dialogue is inevitably framed by the different objectives of stakeholders and

governments, especially where public-private partnerships are involved in the delivery of genome sequencing and analysis. Also, there can be very different perspectives even within a stakeholder group, and effective dialogue must involve trusted partnerships to ensure that different voices are heard.

The periodic review of the French law on bioethics was cited as an example to show how many people had limited knowledge of bioethical issues and the legal changes that might ensue. This example revealed a need for ever greater support for public dialogues in key debates. In the absence of a general understanding in the public, through the media and among legislators, there is a danger that organised pressure groups can shape dialogues and legislative debates from a specific perspective.

As well as legislative and regulatory processes, there is a pressing need to take responsibility, including engagement and dialogues, in developing an appropriate governance system. This responsibility should involve reflection on whether to establish a body that is trusted by all people and groups in society to facilitate governance, transparency, and public involvement. A framework for the transparency and good governance of genomic data was underlined.

Data protection authorities and ethics committees are important actors in dialogue processes who should be involved and can identify affected groups and relevant stakeholders. Common standards in data protection can provide reassurances where there is a risk of data misuse. Data protection provides a means to safeguard privacy which enables people to exercise and enjoy other fundamental freedoms, such as the prohibition of discrimination or equitable access to healthcare. It is known that concerns about individual privacy and data protection in the collection and processing of genomic data may deter genomic medicine initiatives. It can lead to defensive and restrictive governance and policies that complicate the delivery of such initiatives. Dialogues are a means to traverse these individual concerns towards a wider societal discussion about the impact of genomics on collective groups of individuals.

There were parallels drawn with biobanking which is one of the foundations of genomic medicine. Biobanks are an important long-term global resource that require funding to ensure inclusiveness, for example the H3Africa consortium. Dialogue is needed to understand different communities' relationships with biological specimens, like blood or genetic information. Biobanks are an important means of controlling sample and data sharing; there are already questions about whether participants are clear about what happens with any secondary use of the samples or data. The long-term funding of biobanks (and related genomic databases) is necessary in view of the complexity and sensitivity of the samples and data. There have also been legal challenges involving commercially funded biobanks when the controlling company changes during the life of the biobank.

The panel concluded by underlining the importance of continuous public dialogues and for engagement to start with school education that can lead to empowerment. As science flows across borders, dialogues must involve and empower populations who may not have a voice.

Rapporteur's remarks

Public dialogues are an integral part of the regulation and governance of genomic medicine.

As well as robust principles for data collection, there are key lessons to be learned from the governance of biobanks and sensitive official statistical and census records.

There is also a need for more information on safeguards surrounding genomics medicine. This includes criteria and/or principles regarding transparency of interests, explanations on the consequences of scientific progress in genomic medicine, and assurances for the protection of health data. These principles should be fully addressed by decision-makers when pursuing the regulation of genomic medicine as well as those responsible for significant new initiatives in genomic medicine.

Concluding remarks and next steps

The workshop was notable for the consistency of themes from a wide range of experts and young people. It was accepted that genomic medicine will become embedded in many aspects of medicine, from diagnosis of acutely ill patients, associated treatments such as gene therapy and genome editing, through to screening and prevention advice in otherwise healthy people.

As highlighted in the Guide to Public Debate, prepared by the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO), and as mentioned throughout the workshop, there is a knowledge gap between understanding of a novel technology and the impacts on society. There needs to be continuous dialogue, from the early stages of development through to the application in public health systems. Public dialogue can build awareness and trust but maintaining trust also means being willing to act when necessary, in response to both positive and negative responses.

There are financial and opportunity costs involved in the engagement of representative groups at all stages of the dialogue process which need to be recognised by funders and government. It is especially important to support engagement to allow for an element of co-design of new initiatives to respond to concerns that may alter the governance or design of a genomic project. The workshop highlighted the risk that a lack of effective and responsive dialogue can lead to the loss of 'social licence', which has occurred in some examples.

Two-way dialogue with all parties in a healthcare ecosystem is important to create fair and sustainable applications of genomic medicine. Dialogues also have an important role in empowering citizens and informing scientists and policy makers. The continuing involvement of young people is crucial as they will be most impacted by genomic medicine in the future. The youth panel emphasised the importance of reaching wider audiences through social media and to tackle misinformation. It was emphasised that everyone has a genome, so everyone has a valid perspective as a form of solidarity.

Public dialogue will also provide an understanding of the tolerance for types of technology and the values in society. Genomic initiatives need to consider issues of fairness, equity, social justice, equal moral worth and solidarity, at the local, national and global level. The concepts of altruism and solidarity were raised many times in relation to the establishment of databases. An altruistic donation of samples and data need to be followed by the use of that knowledge in the appropriate delivery of healthcare.

Next steps

The consensus around shared values, and the sense that everyone has an interest because we all have a largely shared genome suggest this topic merits further work. Many speakers referred to the importance of altruism and solidarity in publicly funded genomic research initiatives and clinical services. Achieving and maintaining trust are crucial to ensure that patients and citizens take up the opportunities of genomics. Trust and trustworthiness depend on effective regulation and oversight, as well as transparency about the purposes and protections in place.

Public dialogues on new and complex technologies, like genomic medicine, have a two-way educative function. These are carried out on the understanding that the application in genomic medicine should be equitable, otherwise marginalised, and vulnerable groups will be unwilling to participate in research or access to genomic medicine care.

Many of the key principles raised in the workshop are also to be found in other work of the Council of Europe. They are underpinned by the Oviedo Convention, especially integrity and fundamental freedoms, equitable access to healthcare, professional standards, and non-discrimination. There are also relevant guiding principles on governance in the Recommendation on Biobanks[5].

The workshop reinforced and added further weight to the specific protections in the Additional Protocol on Genetic Testing[6]. That instrument builds on the Oviedo Convention with a focus on consent or authorisation, quality, and medical supervision. The Protocol's key points have been developed into a successful easy-to-read information brochure that has been translated into 30 languages. However, the leaflet's emphasis on public information is not the same as public dialogue. If there is insufficient focus on a continuous two-way engagement with public and patients this may affect trust and the wider acceptability of genomic medicine (sometimes referred to as the 'social licence').

The Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020-2025) of the Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) highlights the importance of solidarity because everyone will need healthcare at some point in their lives. Solidarity emphasises the willingness to share genetic data in order to realise the common good of better healthcare. Altruism and solidarity are intertwined with the principle of reciprocity that places obligations on researchers, healthcare professionals, and the state. These include feedback on 'actionable' findings, robust governance mechanisms, and equitable access to treatments.

Some of the findings of this workshop, on access to equitable medical services, will be relevant to possible future work on equitable access to innovative treatments. Giving patients the results of clinically 'actionable' findings in healthcare (for example, screening programmes) and in research is an emerging paradigm in genomic medicine that is being raised in several national genome initiatives which may require further consideration.

[5] Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin

[6] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes

There may also be a gap requiring additional work to reinforce "*the importance of earning trust and stressing the role of good and transparent governance*" (preamble to the Biobank Recommendation) in fast moving areas like genomic medicine. Further work specific to genomic medicine might usefully build on the Recommendation's provisions on governance, access, oversight and independent review. It should emphasise the importance of public debate (Article 28 of the Oviedo Convention) and provisions contained in the modernised Council of Europe Convention for the Protection of Individuals with regard to Automated Processing of Personal Data (Convention 108+) to support the effective development of genomic medicine in national and local initiatives.

Many of the key findings of this workshop could be distilled into a practical guide to the important elements of a successful dialogue at local, national or regional level. The elaboration of a series of **'points to consider'** would support policy makers, funders and professionals who are implementing genomics in research or healthcare.

Further work on genomic medicine must reflect the principles of non-discrimination, especially on certain groups or individuals with an inherited genetic predisposition. Given the evidence from previous public dialogue that genomic medicine may impact on aspects like insurance and employment, there is an opportunity to reinforce the principles of the Recommendation on use of predictive data for insurance purposes[7]. This includes the importance of "*collective consultation*" between all parties to increase confidence and transparency.

Finally, there are opportunities to work closely with other multilateral organisations, especially the EU, WHO and UNESCO given the focus of research activities in Europe and globally. Strong international collaboration is an important element of solidarity to ensure that genomic databases are globally representative. However, there are significant funding and resource challenges in ensuring public dialogue and engagement at all levels from local to global which need to be recognised.

[7] Recommendation CM/Rec(2016)8 of the Committee of Ministers to the member States on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests.