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11th Global Summit

of National Ethics / Bioethics Committees

Conference Report

Global Health, Global Ethics, Global Justice

World Health Organization

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Global Health, Global Ethics, Global Justice

11th Global Summit of National Ethics/Bioethics Committees
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>> PREFACE

|| It has been two years since the German Ethics Council was mandated by the Global Summit in Mexico to host the 11th Global Summit of National Ethics/Bioethics Committees in Berlin. Two years, that have seen a rapid advancement in scientific and technological progress. It shifted the boundaries of what is scientifically explorable by new tools like CRISPR-Cas9 and what is medically feasible e.g. through innovative drugs in cancer therapy or through digital applications. Such progress raises new questions about what is ethically justifiable and desirable. It also enforces the need for public debate and for providing guidance on ethical issues of national and of global concern through national ethics/bioethics committees.

The German Ethics Council was deeply impressed by the significant number of 120 delegates of national ethics/bioethics committees from 79 countries, representatives of international organizations and German ministries adding up to nearly 200 participants who travelled to Berlin to participate in this year's Global Summit. This is not only a sign of growing importance of this international meeting, it also indicates the increasing global dimension and need for exchange on bioethical issues, and the growing awareness of nations that dialogue is necessary and meaningful.

I am very grateful for the attendance of the Federal President of Germany, the reception by the President of the German Parliament and the generous financial grant by the Federal Ministry of Education and Research. With ever increasing technological advancement in medicine and in the life sciences, a strong support for ethics/bioethics committees and their international cooperation by national political institutions is of major importance.

The preparations for the Global Summit 2016 have been a joint effort by the German Ethics Council and the permanent secretariat at the World Health Organization, in close collaboration with UNESCO. The steering committee of the 11th Global Summit developed the conceptual framework and gave multiple advice. An intense

and productive working spirit has characterized our joint efforts and I am thankful for all the suggestions, comments and ideas to this year's programme. As this has been developed also with the feedback from national ethics/bioethics committees worldwide, we discussed the themes most interesting for all of them for the time being. Last but not least, I would like to express my gratitude to the external experts who contributed substantially to the Global Summit by preparing exciting background papers about the topics we will discuss.

It was a great pleasure to welcome all participants on behalf of the German Ethics Council in Berlin. We definitively experienced a successful Global Summit 2016. The following texts of this conference report highlight the topics and speeches that were presented during the Global Summit. Live videos of all sessions as well as additional documents of the summit in Berlin are available online. ||

Prof. Dr. Christiane Woopen
President of the 11th Global Summit of National Ethics/Bioethics Committees;
Chair of the German Ethics Council

>> INTRODUCTION

|| The Global Summit of National Ethics/Bioethics Committees is an international conference that was established in 1996 when the first summit took place in San Francisco. The Summit is held every two years and hosted on a rotating basis in different countries to reflect the six regions as established by the World Health Organization.

The Global Summit is the most important international meeting of national ethics/bioethics committees for dialogue and exchange on bioethical questions as well as on issues in the life sciences. The objectives of the Summit are to identify ethical issues of global concern, to provide a forum for exchange and to offer opportunities to discuss public health policies and research activities at international and regional levels.

The theme for the Global Summit 2016 in Berlin was "Global Health, Global Ethics, Global Justice" in order to illustrate the interconnected nature of public health decisions with ethical considerations and questions of justice at a world scale. The programme consequently covered various topics of global relevance including emerging and new technologies, epidemics and outbreaks, bioethical policies and bioethical law as well as raising social awareness of bioethical issues.

From 16th to 18th March 2016, representatives from 79 national ethics councils, national bioethics committees and members of international organizations working in the field of life sciences gathered in Berlin (Germany) for the 11th Global Summit of National Ethics/Bioethics Committees. The organization of the Summit was supported by a steering committee composed of representatives from national ethics councils from the six WHO regions and international experts.

This conference report serves as a summary of the discussion at the Global Summit 2016. It includes the contributions and presentations of the speakers as well as the discussion papers and the abstracts of the marketplace presentations. ||

Steering committee of the 11th Global Summit
of National Ethics/Bioethics Committees

>> ACKNOWLEDGEMENT

|| The local organizers wish to express their gratitude to all individuals and institutions who enabled the successful realization of the 11th Global Summit of National Ethics/Bioethics Committees in Berlin at the Berlin-Brandenburg Academy of Sciences and Humanities. Without their help and support this event would not have been possible in the way that we and the participants from all over the world experienced it. The manifold compliments that we received during and after the Global Summit were happily accepted in the name of all who formed part of the overall team of which everyone contributed with its respective share to fully realize this unforgettable event.

First of all, gratitude is owed to the German Federal Ministry of Education and Research which – with its generous financial support – prepared the ground for all activities and, moreover, made the participation of several representatives from low- and middle-income countries possible. Additionally, the contributions of the then President of the Federal Republic of Germany, Dr. Joachim Gauck, as well as of the then President of the Federal Parliament, Dr. Norbert Lammert, were important indications of the commitment and support of German politics with regards to ethics and international cooperation.

Leibniz Hall as the location of the Global Summit 2016 was just one part of the infrastructure which was provided by the Berlin-Brandenburg Academy of Sciences and Humanities. The conference centre coordinated the facility management, technical support and translation services as well as the catering during the event.

A special thanks belongs to the volunteers and helping hands who offered their support not only during but also before and after the Global Summit. The Trio d'anches with their interpretations of Mozart's *Divertimento No. 1* and Astor Piazzolla's *Four seasons* of Buenos Aires created a unique musical programme that set the atmosphere for the Summit in Berlin.

Many thanks also belongs to the authors and co-authors of the papers that were presented during the sessions as well as to the moderators and speakers for their contributions. All thanks and gratitude mentioned so far would be of merely limited value without the presence and appreciation of the guests and participants who travelled long distances from all over the world in order to attend the Global Summit 2016 in Berlin.

Finally, gratitude is to be expressed to UNESCO and each single member of the steering committee with its president Prof. Dr. Christiane Woopen who prepared the content of the conference so extremely well. Moreover, the work accomplished by the Global Health Ethics Unit at the World Health Organization which provides the permanent secretariat for the Global Summit is the cornerstone for all activities with regards to the organization of the Global Summit. Together with UNESCO's section on bioethics and ethics of science, they created the framework for an overall very successful 11th Global Summit in Berlin. ||

Office of the German Ethics Council

>> OPENING SPEECHES

Joachim Gauck
President of the Federal Republic of Germany

Christiane Woopen
President of the 11th Global Summit of National Ethics/Bioethics Committees;
Chair of the German Ethics Council

Marie-Paule Kieny
Assistant Director-General of the World Health Organization

Thomas Rachel
Parliamentary State Secretary of the Federal Ministry of Education and Research

Joachim Gauck · President of the Federal Republic of Germany

Joachim Gauck

President of the Federal Republic of Germany

|| "There is no greater individual interest than to espouse that of the community." It is with this guiding principle of the universal man of letters Gottfried Wilhelm Leibniz that I greet you today. It is a fitting way to begin here in the Leibniz-Saal in the year when Germany is celebrating a twofold Leibniz anniversary. The 370th anniversary of the birth and the 300th anniversary of the death of the great scholar.

As a researcher, as a champion of research and as a political adviser, Leibniz embodied a conviction that also shapes your work, ladies and gentlemen. Namely, that there is an inextricable link between researchers' own yearning for new findings and the good of humanity as a whole. And where you are now meeting, here in the Berlin-Brandenburg Academy of Sciences and Humanities, Leibniz' principle of serving the common good, the "commune bonum", is particularly palpable. After all, it was he who was behind the founding of this centre of research and then became its first president. And even back then, the idea of international exchange played a central role.

Your work to promote an ethical science and this meeting are also inspired by the idea of cross-border dialogue. Combining the gaining of knowledge and the gaining of well-being, what is more across territorial and cultural borders, as a guiding principle of a responsible, ethically grounded science is today more important and topical than ever. After all, research has now literally arrived at the very core of humankind.

The success of science has cast us more and more into the role of co-authors of evolution. This in parallel increases our responsibility for Creation – the word "Creation" taking on a new meaning given the rapid development in the so-called life sciences, for example when we hear reports on new ways of technically accessing the brain or new methods of genetic engineering. There is great hope vested in this kind of research but it also triggers concerns. It seems that ambivalence and dilemmas are on the increase. On the one hand, there is the hope of finding cures to heal the

chronically ill, of success in combating hunger in the world, in fact, the hope of less suffering and fewer trials and tribulations for humanity. On the other hand, there is the concern about ruinous aberrations, for example about human dignity being undermined and fundamental human rights being violated by targeted modifications to human genetic material. Procedures involving the brain also raise questions of autonomy, individuality and identity. Or we remember the dangers posed by research on micro-organisms meaning that newly cultivated pathogens could be misused in warfare or for terrorist attacks.

What we are talking about here are the opportunities and risks of modern research that are increasingly demanding international responses – also because science and research are quickly forging closer links across borders. The tasks facing national ethics committees may vary in part, as does research in the field of life sciences in your respective countries. Yet, the awareness of new research processes and findings is spreading apace. Particularly in life sciences, the findings are often of fundamental importance for all people. The spirit of the UN Agenda for Sustainable Development, the conviction that all countries – industrialized, developing and newly industrializing countries alike – are together duty bound to make their contribution to a better world, this spirit also impacts the ethics of research. After all, bioethics questions are questions which go to the core of our shared understanding of ourselves, to what it means to be human.

That is why it is so important to bolster international debate about how our ethical bedrock can keep pace with globalization. This conference is making a major contribution to this cross-border bioethics discourse. After all, only intensive exchange can bring about agreement on a joint rulebook for bioethics. I would like to thank all participants and organizers for approaching this dialogue with such dedication.

The broad spectrum of subjects in your programme bears witness to the diversity of the challenges faced in the bioethics debate. What methods are we talking about? What opportunities and risks do they harbour? And how do we weigh up the potential advantages and disadvantages of the various new scientific possibilities? What yardsticks are we to apply to this process? And who actually checks that research is conducted in an ethically responsible manner? What role are politics and law to play here?

At the same time such questions highlight the difficult task shouldered by national ethics bodies when it comes to assessing research or formulating guidelines on reaching and dealing with research findings whose repercussions cannot perhaps be foreseen. Despite or perhaps precisely because of these unknown quantities, ethics committees can help heighten awareness of how important it is to discuss questions pertaining to research ethics. Which fields of research should be promoted, where do we draw the line? Are we setting the right priorities? Are we paying enough attention

to spheres of research that were neglected for a long time, even though they are key to the survival of millions of people, first and foremost the poor?

Improved health and better living conditions are not least the result of priorities set in the past, also financial priorities. Ethically sound research and research policy also mean further stepping up efforts to provide healthcare in developing countries. Epidemics such as Ebola and Zika leave absolutely no doubt as to the urgency of this task. I am pleased therefore that this is one of the focal points of your conference.

Together, you are helping raise awareness of the entire spectrum of bioethics questions. The discussion on research ethics needs to be given considerable space in the public sphere: in schools, at universities, in the media as well as in scientific organizations. After all, it is only if the citizens feel increasingly able to understand, to assess and to consider what is behind key terms such as genome editing or Human Machine Interface, what is happening in research fields such as nanotechnology, synthetic biology or systems medicine, that society can re-connect with research. And how could research live up to its social responsibility without constant and public scrutiny as to whether it is actually serving humanity?

Of course, there is no simple answer to this, nor can bioethics provide such an answer. But with our research ethics infrastructure which we are working on at national and international level, we do have an important navigation system. The *Universal Declaration on Bioethics and Human Rights* issued in 2005 is an important step in the right direction. Human rights, I am convinced, provide a strong and good foundation for the further development of global bioethics. Historic and cultural influences clearly play an important role when it comes to finding responses to the many different questions in the field of bioethics. But all cultures have points of reference for the idea of human rights. Not least because human rights underpin plurality, because they thus promote or at least do not hinder cultural diversity, are they recognized internationally and seen to be universal. Despite our diversity, we, the people, are united by a primordial goal: to protect and promote human dignity. This is the very heart of the idea that every human being without distinction should benefit from the same high ethical yardsticks for research in social sciences.

As scientific and technical possibilities grow, the question of what developments we can reconcile with our view of humanity will become ever more pressing. And this is a question that concerns us all. Science, society and politics need to play their part. At national and international level, we need ongoing efforts to ensure reflections and regulations on bioethics keep up with science and research. Allow me to wish you strength and inspiration for this weighty task. May you be like Leibniz who upon wakening had so many good ideas that sometimes even a whole day was not enough time to think them through and commit them to paper.

Thank you very much and let me wish you a successful conference. ||

Christiane Woopen · President of the 11th Global Summit of National Ethics/Bioethics Committees;
Chair of the German Ethics Council

Christiane Woopen

President of the 11th Global Summit of National Ethics/Bioethics Committees;
Chair of the German Ethics Council

|| Thank you very much, Mr. President, for your profound speech. We deeply value your appreciation of the Global Summit and your support for our joint effort to foster health, ethics, and justice on a world-wide scale.

This brings me to this year's Leitmotiv: "Global Health, Global Ethics, Global Justice". This title unfortunately does not describe the present shape of our world. But it expresses a powerful aspiration. This aspiration has moved all of us to be here and to engage in an international encounter. Hopefully, our debates will form the basis for future action which makes this world a better place. But how can we work as national ethics/bioethics bodies in the fields of health and life sciences to make the best possible contribution to such progress? In the few minutes I have, let me stress two features that I believe to be crucial.

National ethics committees provide a space for independent moral deliberation, for a debate guided by moral values and the strength of moral arguments and not by the advocacy for partisan interests and by power politics.

National ethics committees allow for moral pluralism under the umbrella of universal ethical claims.

As to the first one, value orientation: Scientific and technological progress in medicine and in life sciences like genome editing in human embryos and digitalization of all our data as well as challenges to health care like Ebola- and Zika-outbreaks confront us with new challenges. We must fully understand them and we must carefully assess their impact from all relevant perspectives. When the picture is clarified that far, the relevant moral values and ethical principles must be identified, considered and balanced. On that basis, we are finally in a position to give reasonable guidance on future action.

Here are a few of those challenges and all of them will form the subject of our debate in the days to come: How can we guarantee a proper access to decent health care

for all people? Is it ethically justified to change the genome of a human embryo, thus also changing the genetic makeup of future generations? What is necessary to protect the privacy of individuals in times of digitalized health research and health care? Who is responsible in terms of political or legal action and which procedures are just and equitable? How to find and implement effective measures and mechanisms to strengthen the commitment of such an important document – which the President already mentioned – like the *Universal Declaration on Bioethics and Human Rights* from 2005?

Well, it is easily said that "ethical principles" should be guiding us on all those difficult questions. In fact, the reality looks quite different. Still too often, the striving for a person's scientific career, for the financial profit of a commercial enterprise or just for power thrust ethical considerations and even human rights away.

I assume and I trust that all of us being here and attending the Global Summit of National Ethics/Bioethics Committees agree on the priority of value-oriented reasoning and acting – while at the same time also taking into account justified individual, economical and political interests. The debates in our committees should provide examples for how value-oriented debate can take place with regard to other societal challenges as well. Think of all the crises, which are currently setting our world on fire: war, terrorism, waves of refugees, hatred of foreigners, humiliation of women, financial crises and intolerable global inequalities concerning the access to fundamental goods. Ethics in contrast to violence, hatred, subjugation and egoism acknowledges one fact: The fact that deliberating with other human beings is the morally only and best way we have in order to find good solutions to the challenges for our societies and our global community. In doing so, national ethics/bioethics committees also become places where we can show what positive energy humans can develop if they work together. "Fraternité is not only the goal but also the means" – as my colleague Hans van Delden, president of the International Bioethics Commission at UNESCO, phrased it.

Let me now turn to the second feature, moral pluralism and universal ethical claims: I am convinced that national ethics/bioethics committees regardless of their different scopes and constitutions are – or at least can be – the paradigmatic places in society to highlight the paramount importance not only of ethical guidance as such, but also of the need for and the limits of moral pluralism under the umbrella of universal ethical claims.

To accept the primacy of ethical categories and the universality of ethical claims does not mean of course that all of us will find the same answers to a specific question and the same solutions for a specific problem. Universality does not mean uniformity. Though, together with a lot of philosophers I am convinced that there is a kind of common morality as expressed in some fundamental moral rules and ethical

principles like "do not kill", "do not deprive from freedom", or "respect dignity and autonomy". These rules and principles underlie the human rights enshrined in the *Universal Declaration of Human Rights*, as proclaimed by the United Nations General Assembly in Paris almost 70 years ago.

But – what these rights exactly mean and how moral rules and ethical principles are to be applied in specific fields of research and health care is a matter of controversy. There are a lot of differences in beliefs, preferences, images of the human nature, perceptions of benefits and harms, the balancing of conflicting values, and so on. Often different religious or cultural backgrounds result in quite diverse, sometimes even opposite ethical premises and convictions. To accept this diversity is not tantamount to a relativistic approach to ethics. On the contrary, it is perfectly compatible with its universal claim. Some controversy is thus not only justified, but even desirable and enriching. Yet, as well there are also limits of a reasonably defensible moral pluralism as well as limits of permissible ways to deal with moral disagreement. There is for example no ethically defensible reason to exploit vulnerable people in clinical research for the sake of financial gain. There is no ethically valid reason to deny higher education to women. And it is not an ethically justifiable way to use violence in order to suppress those who have unwanted moral beliefs.

National ethics/bioethics committees can and should help to delineate the area of necessary consensus and the area of justified moral disagreement by elucidating the exact understanding of a given problem, by weighing possible benefits and harms in a transparent way, by revealing the respective premises and by arguing for one or if appropriate for more than one solution in a culture-sensitive way. Fostering and integrating societal debate is of major importance throughout this effort.

On the global plane, moral pluralism is even more inescapable in light of the various ways of living, the different cultures, religious beliefs, societal structures and political systems. That does not mean however, that a reference to a cultural background or to religious beliefs is an ethical argument in its own right. Rather disagreements with regard to the interpretation and application of universal human rights have to be justified by thorough analysis and deliberation.

Let me come to a last point of my introduction – a brief reflection, or rather a personal and emotional concern regarding the word "global". Global sounds very big. Global means that there is a huge world with issues touching all of the countries – either because every country has to deal with a specific issue locally, or because a challenge is a cross-border-issue from the beginning like an epidemic outbreak or the big data technology, which can only be effectively regulated internationally or at least regionally.

Perhaps I may tell you a private experience. Last Friday I was invited to a literature festival in Cologne, my home city. We listened to the readings of extracts from

novels and poems about all sorts of crises – marital, financial, maturation, and so on. At one point when listening to all the personal feelings and thoughts about the private past and future I caught myself thinking: "Wow, these protagonists are all just moving within their narrow individual horizons. What a small world they are living in." As you will understand my last weeks were dominated by the preparation for this Global Summit and obviously I thought that I was dealing with the 'big world', much bigger than my own small life. But then I suddenly became aware of something that is actually self-evident, but all too quickly forgotten: The global scale of health, ethics and justice must not conceal, that in the end it is always the individual human being in his or her social environment who is affected in his or her possibility to live a life in freedom and dignity according to his or her own assumptions about what is a good and meaningful life. What happens in the 'big world' and seemingly far away is eventually affecting billions of 'small individual worlds'. And in the end it is these billions of individual human beings who constitute our common 'big world' by living their lives, building societal institutions, developing technologies and shaping our common future.

That being said, it is obvious for me, that national ethics/bioethics committees can usefully transcend the great many individual horizons in order to work together for the sake of global health, global ethics and global justice, which, in the end, are relevant for every area of society. This precious possibility entails a responsibility and together we should try to live up to it.

After these preliminary thoughts I'm coming to the end – an end full of gratitude and appreciation. First of all I want to thank the two secretariats of the Global Summit: the permanent secretariat of WHO with Abha Saxena, Reva Gutnick, Andreas Reis and Patrick Hummel – and the secretariat of the German Ethics Council especially with Joachim Vetter, Christian Hinke, and Christian Jolibois. All of them prepared this Global Summit with huge dedication, patience, and prudence. UNESCO supported this work constantly and very constructively – thank you very much Dafna Feinholz.

Another thanks goes to the steering committee. From our first telephone conference on 13th April 2015 we have been working together intensively in drawing up this program, finding the right issues together with the national ethics/bioethics committees of the six WHO regions etc. etc. We learnt that global communication is basically possible by WebEx, even though for some there are still major technical problems. My deep appreciation goes to Mohamed Ben Ammar from Tunisia, who also had been president of the 9th Global Summit 2012 in Tunisia, to John Ayotunde Bewaji from Jamaica, to Anoja Fernando from Sri Lanka, to Khem Karki from Nepal, to Simon Langat from Kenya, to Bagher Larijani from Iran, to Laura Palazzani from Italy, to Sangeun Park from South Korea, to Manuel Ruiz de Chávez from Mexico,

who had presided over the 10th Global Summit in 2014 in Mexico, to Aissatou Touré from Senegal, and to Nikolajs Zeps from Australia. I also want to give thanks to Hugh Whittall from the United Kingdom and Aamir Jafarey from Pakistan, who served on the steering committee as our advisors. We gratefully experienced that it was a very good idea indeed to have you with us!

Furthermore I want to express my deep gratitude to all the experts, who developed the thought-provoking and comprehensive background papers for our sessions, and to those who constructively commented on the papers. I am impressed with the results. They will be a very fruitful starting point for our discussions the next days.

Thanks as well to the Berlin-Brandenburg Academy of Sciences and Humanities for this splendid location and infrastructure to host the Global Summit.

Last but not least I want to thank the German Ministry of Education and Research. With its financial support it was possible to prepare and to host this Global Summit and additionally to give travel grants to 18 representatives of low and middle income countries.

So, thank you all so much for preparing this and for being here – you made it possible that this Global Summit might become a great success. It's up to all of us now, that it can hopefully contribute to making this world a better place – for the sake of fostering global health, promoting global ethics, and implementing global justice – eventually for allowing all individual human beings to live a life meaningful and happy. Let's make it happen – together.

Now it is my pleasure and my honour to officially declare the 11th Global Summit of National Ethics/Bioethics Committees open. ||

Marie-Paule Kieny · Assistant Director-General of the World Health Organization

Marie-Paule Kieny

Assistant Director-General of the World Health Organization

|| Dear Mr. President, dear Prof. Woopen, chair of the German Ethics Council, honourable ministers, distinguished participants, chairpersons and members of national ethics/bioethics committees, councils and commissions, Ladies and Gentlemen.

It is an honour to address you today and I would like to thank the German government for its leadership and general support to this Global Summit. Two years ago, at the Global Summit in Mexico, Germany was unanimously selected to host the 2016 Global Summit of National Ethics/Bioethics Committees. Today, we are proud to be here as are so many others whom you have recently opened your borders and hearts to.

Albert Schweitzer, another great humanitarian and physician wrote that the first step in the evolution of ethics is a sense of solidarity with other human beings. These are very wise words. Why? Well, because we share a common humanity, as Prof. Woopen was saying. A common planet to use and protect and a common destiny, because we must recognize this need to live in solidarity. We must develop rules and laws that are grounded on justice and fairness. We must agree on global ethical norms that govern health and healthcare around the world.

The WHO constitution in 1948 states that, I quote, the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. End of quote.

This is a strong statement built on a strong ethical claim. WHO's role in promoting public health in its member states places effects at the heart of its mandate. One of WHO's six core functions is to develop ethical and evidence-based policy options. This is why I am particularly pleased, that already in the year 2000, the national ethics committees asked WHO to host the secretariat of the Global Summit.

As you know, the precious issues of our time, from epidemics to poverty, from climate change to the scientific possibilities of emerging technologies, all require

ethical reflection and demand ethical responses from all of us. Policy makers and public health practitioners tasked with addressing these issues must take difficult decisions. Decisions that are at the intersection of scientific knowledge and all values as part of the human community. Their decision-making, our decision-making must be supported by evidence and an ethical analysis. They must ensure that fair processes have been applied and their policies and projects are grounded in a well-balanced benefit-risk-assessment.

But what does this mean concretely? I would like to use the Ebola epidemic as an example. Some of you may know that I was quite heavily involved in the Ebola response, together with my dear colleague Prof. Bah Sow here. When the world was struggling to contain this epidemic and we neither had any vaccine or therapeutics to offer to those who needed it, one of the first questions of the global health community was whether it was considered ethical to use untested vaccines and drugs during an epidemic. And when the affected countries were losing their dedicated and hard-working healthcare workers to the epidemic, the question that needed to be answered was: What are the appropriate obligations to health workers during an epidemic? These were real-world questions with equally real consequences.

We needed bioethics to deliberate on the issues and to guide our actions and our policies. WHO convened an ethics panel to guide its global policy. National ethics committees, when, where they existed also advised their countries on the most ethical approach to be taken. And just as we finished responding to the Ebola epidemic, another one has reared its head: The Zika epidemic has brought with it a new set of questions that demand an ethical reflection and I look forward to hearing the debate on ethics and epidemics in your session later today.

The work of bioethics committees and commissions is inclusive. You bring together the best minds from many disciplines to come to a consensus on difficult questions and insure that public health practice respects the universal principles of ethics and human rights. One of a central task of national ethics/bioethics commissions and of ethicists is to inform health policy making and the drafting of new laws and regulations. That is why I am particularly pleased to see that this gathering will be reflecting on the intersection of bioethics and the law and look forward to know the outcome of your discussions on this very important topic.

However, bioethics and bioethical reflection should not be the purview only of national bioethics committees, nor be the footnote to public policy as it often times is. I am of your opinion that bioethics reflection should be the purview of all citizens and should be embedded in all policy making. This will indeed ensure that governments and countries have decisions that are not only informed by the deliberation of ethics committees, but also by a critical public reflection.

For this to happen, countries need to take active steps to popularize bioethics and the faculty of independent and critical thinking on these aspects. National ethics committees can play a big role in this and I am pleased that this Summit has devoted the time and space to hear about the experiences of those ethics committees that take this task seriously. For those countries that do not have the relevant expertise, I am pleased that the Global Summit is held regularly, providing a platform where the national ethics committees can share their experiences and learn from one another.

I also hope that this platform will provide the impetus for the formation of national bioethics committees where they don't exist and for the countries like Germany, that have a wealth of experience and expertise to share its experience with countries that are trying to establish their bioethics committees.

There is no shortcut to addressing the issues of the day and thinking forward. The world is at a critical junction today and globally accepted ethical norms are more needed than ever to respond to the critical health-related challenges. New technologies, whether it is genome editing or big data in health, are revolutionizing the very nature of how we think of ourselves and the ways how humans interrelate with each other.

These developments do not respect any national boundaries and their governance has to be on the international level. I am keen to hear how different countries manage this challenging area in an ethical manner. But technology is not all. People are the key, and respecting the dignity of human beings is fundamental.

The World Health Organization recognizes the importance of people-centred politics as it pursues its agenda for improving the health of all people. The sustainable development goals give us the tools to improve health in a holistic and comprehensive matter. The 17 sustainable development goals are broader and more ambitious than the millennium development goals presenting an agenda that is relevant to all people in all countries to insure that no-one is left behind.

The new agenda requires that all three dimensions of sustainable development, economic, social and environmental are addressing an integrated manner. Almost all of the sustainable development goals (SDGs) are either directly or indirectly related to health. Universal health coverage, one of the top priority of global health policy, is in itself an ethical endeavour. Reaching the SDGs is a huge task and as ambitious as they are, they are not only aspirational.

The goals and targets accepted by the world will stimulate action over the next 15 years in areas of critical importance for humanity and the planet. In moving towards these goals, countries will need to rely on the guidance of a national ethics committee. The world community and WHO will greatly benefit from the deliberation of a global summit over the next days and I wish you all the best of success. Thank you very much. ||

Thomas Rachel · Parliamentary State Secretary of the Federal Ministry of Education and Research

Thomas Rachel

Parliamentary State Secretary of the Federal Ministry of Education and Research

|| Dear Prof. Dr. Woopen, dear Dr. Kieny, dear members of the national and international ethics committees, Ladies and Gentlemen. I am delighted to be able to welcome you on behalf of the Federal Government of Germany as well as on behalf of the Federal Ministry of Education and Research to this 11th Global Summit in Berlin.

Now, as I look around here, I see that this event is keeping up with the times. Representatives from about 100 countries from around the globe have come here together under the topic of "Global Health, Global Ethics, Global Justice" in order to discuss current bioethical questions.

I would like to cordially congratulate Prof. Dr. Woopen for having managed to invite so many international participants here to the German Ethics Council in Berlin to this Global Summit. As a representative of the Federal Ministry of Education and Research in Germany, I find one aspect particularly important in this dialogue and this is the one related to research and to research results.

The world is moving closer together and we all know that globalization offers enormous opportunities. We all benefit from mutual scientific and technological exchange. It is easier today to collaborate, it is easier to bring the brightest minds, the best men and women together, but, at the same time, we see ourselves confronted with global challenges as well. And this, of course, is also true for research policy. Two of these current challenges that are highly relevant for the bioethics discussion will be a topic of your conference: namely, emerging technologies in the life sciences on the one hand and epidemics and outbreaks on the other.

It is obvious that it has become increasingly rare to find national responses to global challenges such as infectious diseases, marine pollution or climate change. However, where global responses are needed, we want to take part in shaping them. With our research funding, the ministry makes an active contribution to this by trying to bring together the very best scholars and researchers from all over the world

in order to enable them, in the end, to develop common sustainable solutions in view of these global challenges.

Now, how can global collaboration in science and research be shaped successfully? I would like to give you some examples. Last year, in October 2015, the conference of the G7 Science Ministers was held here in Berlin. The ministers followed up on what the heads of governments and states of the G7 had agreed upon at Schloss Elmau short-time prior to that conference. They focused in particular on poverty-related diseases, such as tuberculosis, malaria or Ebola.

It is highly necessary to develop new drugs, vaccines or diagnostic options for these diseases, and I do believe that publicly funded research and development plays a pivotal role in combating these diseases, as the pharmaceutical industry is, due to the lack of a market, unfortunately not very active in this field. Therefore, the Ministry has just opened a tender for the promotion of products to prevent, diagnose and treat neglected and poverty-related diseases. Many of these poverty-related and neglected diseases are zoonoses – meaning diseases that can be transmitted from animals to humans – which cause epidemics consistently. Take the examples of avian influenza, SARS or MERS. All of these diseases have a particularly high potential to endanger the health of a large number of people or animal populations worldwide. Only a very intensive research in zoonotic diseases will help us in the future to be prepared for a global response to such diseases. This is why in January of this year, the Ministry has launched a funding initiative that aims at researching the root causes of these diseases and that focusses also on developing new treatment options. Especially people in poor regions of the world will be benefit from this work.

Apart from the already mentioned examples, the Ministry is continuously engaged internationally in manifold ways as well. This intensified international collaboration is bearing fruit already. More and more publicly funded research projects are linked by international networks and here we are not only thinking about the European research area, but far, far beyond of that.

As an example, I would like to mention the Africa strategy that we have agreed upon in 2014. Here it is our concern to create a sustainable basis for our planned cooperations. Africa, Ladies and Gentlemen, is a continent of opportunities. And, at the same time, Africa – maybe even more than any other part of the world – faces various global challenges. The spread of pathogens, a recent example being the Ebola crisis, is in this regard surely only one of the challenges. We strive for sustainable structures for cooperation and close networks with the different partners in Africa. A comprehensive understanding about clear framing conditions for international cooperation becomes thereby a central key for its success.

Our international engagement shows us clearly that scientific collaboration does not only need joint technical or scientific standards, but also requires reliable

framework conditions. Connected to this is also the question about the ethical foundations of our actions.

On what values do we actually base our international initiatives and cooperations on? How do we accommodate adequately the plurality of different cultures, religions and legal systems? How do we prevent, that on the one hand, diversity turns into arbitrariness? How do we deal with the potential tensions between science and research on the one hand and global health, global ethics and global justice on the other? The national ethics committees, and this means all of you as participants of this Global Summit, are key players in this process. And the Global Summit is an essential element of this international.

At the same time, human dignity should ultimately always be at the centre. You know that science considers itself basically with an international self-understanding. If we look at the development in different countries, we can say that the science community has very often been a pioneer of international collaboration, by the way not only of political collaboration, but far beyond that.

I am convinced that freedom of research is ultimately a very essential basis in order that progress and prosperity may develop in countries. And freedom of research is doubtlessly also an indispensable element in the quest for finding the truth. At the same time, freedom always implies responsibility. At least, that is the way I see it. Scientists should not only ponder which opportunities exist, but they also need to reflect on potential risks related to their experiments. Also, scientists have the responsibility to deal with the potential ethical implications of their work.

But, what is the relationship between global, local or individual responsibility? In a world growing together, research needs suitable framework conditions. Framework conditions – and that is the difficulty – that are accepted by all partners and by the respective societies as well. And, we feel this, here in Germany, in Europe, and many other countries too, that in pluralistic societies, it is becoming increasingly difficult to agree on common values or points of reference.

How can such a framework then be established successfully beyond a single society on a global scale? How can a targeted discourse succeed with partners who have to some extent very different ethical, cultural or philosophical backgrounds? In the international research landscape in particular, we have to think about to what extent we need to include bioethical reflections. This is particularly evident in the current discussion on genome editing and its application in the human germline.

It is to be welcomed that scientists from this particular research field have themselves initiated a discussion on this matter and we all feel that there is a very broad based debate taking place now within societies. It is primarily the international science community that discusses a responsible way of dealing with human genome

editing, and we need this international discourse in order to look at these upcoming questions from various ethical and cultural angles.

In Germany, the Federal Ministry of Education and Research has supported for many years already the ethical, legal, philosophical and social aspects of modern life sciences. Those are our so-called ELSA funding core areas. In this context, the Ministry supports the establishment and maintenance of a competitive international research community in Germany in order to contribute to this debate. We help to ensure that upcoming issues related to the rapid progress in the life sciences are examined appropriately. At present we perform these activities intensively on an international level as well. With around 3.5 million Euros, we support research projects with regards to ethical, legal and social aspects of genome editing. And we expect as a result, well-founded, knowledge-based analyses and findings in various areas of application of genome editing that will be fruitful for the national and international discourse as well.

The discussion on genome editing clearly shows – in particular when it comes to the very dynamic and oftentimes less predictable developments in life sciences – that these issues attract the interest of the general public. How do we deal with the increasing technological feasibility, especially when it concerns the fundamental interaction of mankind with itself? Frequently, not only in individual countries but also internationally, a balance has to be found that accommodates the striving for new knowledge, on the one hand, with ethical limitations on the other.

International institutions, particularly UNESCO and the WHO, have contributed to achieving understanding on a global level. In this context, I would like to mention the *International Declaration on Human Genetic Data* and the *Universal Declaration on Bioethics and Human Rights* as examples of important UN declarations that were adopted. However, the process of negotiating a worldwide ban of cloning at UN level also exemplifies that different ethical-legal foundations can restrict a global understanding. When making these considerations we have to take care about how to use the opportunities of research, while, at the same time, preserving important societal restrictions. Especially in basic research, we often do not know which perspectives may develop at large due to specific research findings. Not only action but omission as well may therefore be ethically problematic.

Ladies and Gentlemen, the question of what I am allowed to do and what I am not, poses itself in life sciences frequently with a special practical urgency. And this even more, when we deal with the beginning or with the end of human life. The great Protestant theologian Dietrich Bonhoeffer has put it in a nutshell as follows; I quote: "Es ist sehr viel leichter, eine Sache prinzipiell als in konkreter Verantwortung durchzuhalten." [In short, it is much easier to see a thing through from the point of view of abstract principle than from that of concrete responsibility.]

There is probably a lot of truth in this quote. And this basic idea is therefore a guiding principle for the Federal Ministry of Research because it has to bear in mind – also in its role as legislator in the parliament – with practical responsibility an adjustment between different values.

In the Federal Republic of Germany but internationally as well, we look back on a solid and long-standing tradition of bioethical debate. It is not least due to the German Ethics Council, chaired by Prof. Dr. Woopen, that has contributed significantly to this with its publications, with its debates, with its events. And I would like to take this opportunity to cordially thank all present members of the German Ethics Council for their substantiated work over the last years that was caringly moderated by its chair Prof. Dr. Woopen. Correspondingly, you brought forward the ethical debate in Germany and contributed to making it clearer, more transparent and more orientated towards criteria. Thank you cordially for your commitment at this point.

Ladies and Gentlemen, for these two days of the Global Summit, I wish you an open and a constructive exchange in this extraordinary atmosphere of diversity. Again, I would like to express my special gratitude to the steering committee and to the German Ethics Council for an excellent preparation of this event, both in terms of content and organization. I wish all of you and all of us a successful event with the aim of making this world a little bit more philanthropic. Thank you very much. ||

>> REPORTS ON THE GLOBAL SUMMIT

Report on the 10th Global Summit 2014 in Mexico
Manuel H. Ruiz de Chávez

Report by the Permanent Secretariat of the Global Summit at WHO
Abha Saxena

Manuel H. Ruiz de Chávez · President of the 10th Global Summit of National Ethics/Bioethics Committees; Chair of the National Bioethics Commission of Mexico

Report on the 10th Global Summit 2014 in Mexico

Manuel H. Ruiz de Chávez

|| I would like to express my gratitude to the German Ethics Council for the wonderful job of organizing this meeting as well as the steering committee, the WHO and UNESCO. It is my pleasure to convey warmest greetings on behalf of the Government of Mexico. To Christiane Woopen, I offer my sincere congratulations for the outstanding leadership in this Global Summit.

The 11th Global Summit is an important occasion for Mexico and Germany, not only because of the happy coincidence in the succession of this international meeting, but of the celebration of the year of Germany and Mexico, which opens an extraordinary opportunity to extend the collaboration between our commissions.

The 10th Global Summit made it possible to exchange views on bioethical issues of global interest, contributing to common understanding and consensus building, as well as to assist other nations in strengthening their own bioethical institutions.

We had the opportunity to address some of the most pressing challenges of our societies: dilemmas in determining which new technologies should be adopted by healthcare systems; concerns regarding management, proper use and privacy of large amounts of information and personal data; major ethical questions that arise in implementing a universal health system; as well as ethical aspects of research involving vulnerable population with focus on children.

Even as medical technologies are ushering in a new area of opportunities, global issues of distribution make it a challenge to ensure that potential benefits are allocated justly. While justice invokes duties to report on risks and benefits in clinical trials equitably, the direction of health research requires our input as well.

The system of biomedical research and development is pressured to cut basic science and "blue sky" funding in favour of targeted funding, capable of producing return. This is why most biomedical research focuses on well-established markets rather than for emerging or even basic medical needs in the world.

Bioethics is founded on duties that medical researchers and practitioners owe to the public. Considering our institutional arrangement, health policies and methods of provision, duties of physicians may be threatened by modern methods of research and provision of care.

Bioethics lies at the nexus between science and delivery of medical care to individuals. Governments, medical organizations and public choice have their role in determining the level of care available and bioethics has a role in discussing these critically.

Many of the problems in health today stem from a lack of access to favourable social and economic conditions. Since health needs are not limited to medical services, it is necessary to insure adequate nutrition and optimal living conditions, as well as to promote healthy lifestyles, among other social actions.

We are concerned that many of the effects of global climate change will impact vulnerable populations the most, and create conditions that exacerbate health disparities. There are high stakes at risk: scarcity of resources will increase competition between social groups and displacements, droughts and heat waves will trigger hunger, thirst and diseases, in addition to important economic losses. Social conflict should not be ignored since it goes hand in hand with the disproportionate exploitation of natural resources.

Problems of wealth disparity in general are also legitimate issues of concern for bioethics. Modern phenomena of basic science and distribution of resources must be considered in the context of general issues of global economic justice. We need to reassess priorities and embrace the foundations of bioethical principles. Global justice demands it.

The 10th Global Summit in Mexico gathered over 130 specialists in ethics, bioethics and health from 57 countries, including official delegates from national ethics/bioethics committees and international organizations, along with members of the states bioethics committees of Mexico and special guest observers.

The meeting was the result of the work started in Mexico in December 2011 with the support of the WHO, the Secretariat of Health and the National Council for Science and Technology of Mexico, which allowed to hold this meeting and to issue a grant for members of commissions from low- and middle-income countries.

The session "Global Ethics: Challenges and Prospects" was also held, in which international organizations WHO, UNESCO, Council for International Organizations of Medical Sciences, the Council of Europe, the European Commission presented their respective agendas and support for national commissions. Steps were also taken for the establishment of the first official steering committee and the incorporation of UNESCO.

A series of meetings took place for assessing common challenges and opportunities in each region, in addition to establishing work methods to strengthen national

ethics committees and to foster regional networks. The market place sessions, started in Tunisia, allowed for a greater interaction in Mexico between presenters and audience in addressing issues of common interest. 17 presentations were made.

The summit is not only a forum for addressing issues of global concern in bioethics but also a valuable opportunity to establish bonds of collaboration and to follow-up on agreements reached. Each Global Summit should continue building upon the works of the previous years, just as the bridge between the summits in Tunisia and Mexico.

It is my privilege to present the outcome of our joint work from two years ago at the Global Summit in Mexico. You may review in more detail the highlights of this meeting in the official publication that was handed out at the registration, as well as the conference video which is available online through the channel of our commission.

Mexico was honoured to have hosted this gathering in 2014 and it is my pleasure to confirm this day our commitment to a better world. ||

Abha Saxena · Coordinator of the Global Health Ethics Unit at WHO

Report by the Permanent Secretariat of the Global Summit at WHO

Abha Saxena

|| It is a pleasure for me to be here to report on the work of the secretariat of the Global Summit. After Dr. Ruiz de Chávez' fantastic video, I want to continue with what we did after Mexico in order to reach here. In this work, I was helped by my valuable team. What we had to do after June 2014 – and the work started actually at the Mexico summit itself – was to identify the new steering committee as soon as possible, as each steering committee of the Global Summit works for the particular Global Summit that it has been established for and after that, a new steering committee must be formed.

We agreed and we realized that it would be very much more effective if the Global Summit is guided together, both by WHO and UNESCO, and working together with the host national ethics committee. So we had discussions, extensive discussions with the UNESCO on ways of working together and how we could make an impact. And I am glad to report, I am very pleased to report, that part of the reason why we have a much better inclusion of national ethics committees and a greater participation by national ethics committees as an outcome of that discussion. So thank you Dafna Feinholz from UNESCO.

We had preliminary meetings with the German Ethics Council which started actually in Mexico. But our first official meeting took place in Geneva on 4th December 2014, when members of the German Ethics Council came to WHO to discuss with us. A formal invitation was sent by WHO to the chair to start the process of developing the next summit and finally, the chair of the German Ethics Council, Prof. Christiane Woopen, met with our Assistant Director-General in a meeting that was held in April 2014 and that set the scene for the beginning of the next summit.

The steering committee for Mexico actually continued its work until April 2015, until the new committee was set up. The previous committee actually helped in January 2015 to send a call for nominations for the new steering committee of the Global

Summit and by March 2015, the new committee was established. This was based on the following process.

Discussions were already held during the regional meetings in Mexico were all regions met in separate meetings and had discussions as to who might be the next member on the steering committee. We also received nominations from the countries based on the call that we had sent out. The secretariat looked at all past Global Summits and evaluated the contributions of various national ethics committees to the previous Global Summits. A fact that persons who had contributed much more to Global Summits would of course qualify them to at least have a better chance of being on the steering committee. We had to manage the regional language balance within the region as well and we needed to maintain continuity from Mexico to Berlin in order to see that not all members were new and there would be to steep a learning curve.

I am proud to say that the first steering committee, when it was established in March 2015, actually met for the first time in April 2015. And when I say met, everything happened on the internet, so it was all by WebEx-meetings and virtually that we met. This committee has two members each from the six WHO regions, the countries that were represented are Senegal, Kenya, Italy, Germany, Jamaica, Mexico, Iran, Tunisia, Nepal, Sri Lanka, Australia, South Korea, and of course the two international organizations that are ex-officio members of the steering committee, WHO which I was representing and Dafna Feinholz from UNESCO.

We also agreed for this steering committee to actually include two advisors. This turned out to be a very good idea because sometimes, when the steering committee members were at a loss or when there was a division and we were not sure whether we should do this or that, our advisors were fantastic. Hugh Whittall and Aamir Jafarey, you gave us fantastic guidance and you provided the sort of the moderating role for the steering committee, so thank you very much.

In April 2015, we actually hired a consultant to support the work of the organization of the Global Summit, so Reva Gutnick joined us at the WHO, at the headquarters. That was a fantastic support as well, because as the Global Summit increases in its scope of work, the scope, the work that the secretariat has to do also increases and we really needed support. So for Mexico, we did not have any extra support and it was the secretariat, which was doing everything else plus the Mexico summit. And here, we had somebody actually come in and take over some of the responsibilities and that was really good.

What did the steering committee do from April 2015 to March 2016? One of the biggest problems that we have at the secretariat is organizing a mailing list. National ethics committees, members and chairs change very often and most, many national ethics committees do not have an institutional address. Accordingly harmonizing the mailing list always takes a couple of months.

The team for 2016 was suggested by the chair of the Global Summit. As soon as the new committee was established, Prof. Woopen took up the chairpersonship of the steering committee and in April 2015, she suggested the team and the steering committee members agreed almost unanimously immediately.

The steering committee suggested departure from earlier Global Summits in two important ways. First of all, in the past, we invited all countries to suggest different topics and then the steering committee identified which ones to take up from that. The problem was that we ended up with a huge list of topics which may or may not have relevance to each other and it was difficult to decide six, four topics from that huge list. Subsequently the steering committee decided to take an opinion from the national ethics committees. The steering committee sent out eight topics and the national ethics committees were asked to select two. That made the process much easier.

The second departure that the steering committee agreed upon was to commission academic papers on the topics that were decided, rather then to have groups of national ethics committees to prepare and develop papers which we found was taking up a lot of their time in developing the papers and perhaps not without always having the time to do it. In addition, sometimes, the contents of the papers were more policy-oriented, but not necessarily academically oriented. The according idea was that if we had academically oriented papers, then the national committees would have a chance to share their opinion on how those views were actually to be converted into policy. Finally we had the papers presented or developed by academicians rather then by ethics committees and we have two discussants for the papers from national ethics committees.

The steering committee met twelve times between April 2015 to March 2016, which was a large amount of time that was spent on this and thanks to the WebEx-support that we could provide. I think, it worked reasonably well. There were hitches, but it was fine and I think we can work better on it and improve it for the next summit.

What the steering committee did with support of the secretariat was to develop the next survey and to identify the topic experts for the background papers and the reviewers for those papers, as each paper was reviewed by a peer reviewer. The steering committee identified the discussants as well and communicated with them. Finally the steering committee developed the concept papers to guide the topic experts and the discussants. For each meeting, the secretariat provided the usual support that secretariats provide to steering committees or to committees.

I thank Dr. Rinie van Est, Prof. Laura Palazzani and Prof. Jorge Linares for the papers that they have developed as well as Dr. Aissatou Touré, who has agreed to present the WHO guidance document that was developed with the help of ethics experts and which is going to be discussed at this meeting.

In the past, the steering committee did not have a structured way of working and we decided that we have been around long enough to actually provide a structure in order that the next steering committee does not have to do everything from scratch. Now the members of the steering committee have some of the guidance documents, some templates and some things to start their work. Several documents were developed and we could do this because we had a consultant working for us, so thank you, Reva Gutnick for all the work that you pertained.

Now I would like to share with you what the progress looks like. The Global Summits were started in the 1996, the first Global Summit was held in San Francisco where we had 18 ethics committees. Now in Berlin we have participants from 82 countries. The number is growing literally from one Global Summit to the next. If we compare the summits from Mexico to Berlin, you see again a steep rise in the number of national ethics committees that attended Mexico and from the good work that Mexico did, to Berlin, we had another rise in the number of participating ethics committees.

And one of the things why we had such a great increase in the number of ethics committees is, of course, that the Global Summit is doing well. Another thing is that we decided at the beginning of April 2015 not only to have UNESCO send out invitations to the national ethics committees, but WHO and the German Ethics Council sending out invitations as well. So, there were three organizations which spread the good word about what we are doing and that we want all national ethics committees to come and to be part of it. That really helped. So, thank you for all our collaborators and thank you, Prof. Christiane Woopen.

Many of you might want to know, what will be next. Berlin is happening and I am sure that it will be a great summit. I am sure that the discussions will be very good, but we want to plan for 2018. The steering committee already thought about that and asked us to send out a request for the expression of interest to host the Global Summit 2018. At the same time the steering committee also developed criteria to identify the next venue and decided to weight each of the items equally.

Four countries responded: India, Jamaica, Senegal and Tanzania. For these, the general criteria that the steering committee had put up, it was that the Global Summit should already have not been held in that region and the national ethics committee should have attended at least one Global Summit in the past. Those were the basic minimum criteria that national ethics committees had to satisfy before they could be considered to be the next venue. Based on this, India and Senegal were short-listed.

The specific criteria were the following five: The country should be a priority region; it should have demonstrated ability to raise funds; there should be evidence for the support for the organization of the summit, not only from the government, but from professional bodies and other organizations within the country; it should have

experience and ability to host a major international event and it should have been active in advising government on ethical issues and the networking at regional and international level. Each criteria was given a weightage of 20 percent.

These five criteria need to be satisfied by national ethics committees before they can be considered for the next venue. Accordingly the recommendation of the steering committee for the next venue is Senegal. ||

>> SESSION I: EMERGING AND CONVERGING TECHNOLOGIES

Session Summary

Rules for the Digital Human Park
Rinie van Est

Country Perspective from Iran
Ehsan Shamsi Gooshki

Country Perspective from New Zealand
Barry Smith

Discussion Paper
Rules for the Digital Human Park
Two paradigmatic cases of breeding and taming human beings:
Human germline editing and persuasive technology
Rinie van Est, Jelte Timmer, Linda Kool, Niels Nijsingh, Virgil Rerimassie, Dirk Stemerding

Joyce Ikingura (Session Chair), Rinie van Est, Ehsan Shamsi Gooshki and Barry Smith (from left to right)

Session Summary

|| Rinie van Est from the Dutch Rathenau Instituut opened the debate with the presentation of the results from the paper that he and his co-authors prepared concerning new technologies in the areas of genetic engineering and digital society. Under the provocative headline *Rules for the Digital Human Park*, van Est spoke about two paradigmatic approaches to – as he polemically put it – the "breeding and taming of human beings". By this he meant the new methods for genome editing and the so-called persuasive technologies that by means of big data and smart devices increasingly determine our everyday life. According to van Est, the central question is to what extent the implicit social and moral rules entailed by such new technologies can be made explicit and changed. Further, one has to speak openly about the accelerating and decelerating factors that have an influence on the development and dissemination of these technologies and to find a good balance between these factors.

As accelerators for the development of new genetic engineering techniques, van Est mentioned, among others, research and reproductive freedom as well as economic factors; as decelerators: safety risks, caution in accessing the human genome, and the rights of prospective children to an open future. With big data, on the other hand, attractive possibilities for more user comfort and participation, economic development and public safety are to be weighed against concerns in the areas of data protection, freedom and fairness.

Ehsan Shamsi Gooshki from the National Committee for Ethics in Biomedical Research of Iran advocated in his co-presentation for developing international guidelines for such technologies. Such guidelines, which could be initiated by international organizations like WHO or UNESCO, are an important aid in the international harmonization of bioethical supervision of new developments and can also be used on the national level as valuable aids in the formation of own programmes, according to Gooshki. The second co-speaker, Barry Smith from New Zealand, shifted the

spotlight onto the special challenges that arise when one wishes to adequately take into account social and cultural diversity in bioethical debates and illustrated this through examples of the participation of indigenous population groups in Australia and New Zealand.

The subsequent discussion with the delegates focused mainly on the question of where boundaries to the new technologies should be set. The answer to this – here the discussants agreed – can only be dynamic, since the assessment of what is acceptable changes with scientific-technical, societal and also economic development. The discussion trended towards saying that one has to be prepared for such changes and to keep the discourse lively. ||

Rules for the Digital Human Park

Rinie van Est

|| The title of the discussion paper is *Rules for the Digital Human Park*. It is inspired by a lecture given by the philosopher Peter Sloterdijk at the end of the 20th century which was called *Rules for the Human Zoo*. Sloterdijk's lecture caused a fierce media debate in Germany, partly because he used straightforward, controversial terms, like "the domestication of man". Sloterdijk claimed that "the domestication of man is the great unthinkable, from which humanism from antiquity to the present has averted its eyes". So actually he said it is taboo to think about the domestication of man. But his claim was that we *should* think about that topic, and have a debate about it. He also used terms like "taming" and "breeding" human beings. Sloterdijk said that the thesis of humanism is that people can be tamed by letting them read books. If you let people read the right books, you get good people. He also signalled that in the context of human reproduction technology plays an increasingly important role. In fact, we are developing the technical means to genetically engineer our offspring. We should discuss that as well. What is the role of technology? What kind of choices should we make? What kind of rules should we have for the human zoo? I prefer to use the word "human park".

What has happened since Sloterdijk held his lecture? In these last 15 years, we have become very intimate with technologies. The Rathenau Instituut wrote an essay about the ongoing merger between humans and technology, which was titled *Intimate Technology. The Battle for Our Body and Behaviour*. We do not use technology only to intervene in our bodies, but more and more, we use information technology to intervene in our behaviour. This means that besides "breeding" technologies, we also have developed "taming" technologies. So, next to "taming" ourselves by means of passive books, persuasive texts, we can use persuasive information technologies. Accordingly, we studied two paradigmatic cases: human germline editing as an example of a "breeding" technology, and persuasive technology, as an example of a

"taming" technology. The central question in our paper is: to what extent are the rules of the digital human park being debated and created? We address that question by looking at the two technologies I have just mentioned.

Big data plays a central role in the domestication of man by means of technology. If we look at big data, it is helpful to look at the so-called value chain of big data. First, one needs to collect the data. The second step of the value chain presents the analysis of that data. And then the third step is to apply this knowledge. If you apply this idea to human beings, you notice that as a first step, we are measuring human beings on a large scale. Secondly, we are using these huge amounts of data for profiling people, and thirdly we use that information to intervene in the bodies and social lives of people. So you can measure, analyse and intervene, and then measure, analyse and intervene, and so on. In this way a cybernetic loop is created. At the Rathenau Instituut we observe that we are developing and closing all kinds of cybernetic loops. That is an important message today. We are living in an era of digitalization of human life, in which we are closing various types of cybernetic loops. Let us use that perspective to look at human germline editing. This view will also give us an idea of how fast these technological developments are going.

In the 1990s, we started the Human Genome Project and thus started to develop the technologies to map the human genome on a massive scale. About a decade later the complete genome of one human being was read. And now, again 15 years later, so 25 years after the Human Genome Project started, scientists have experimented with editing the genome of a human embryonic cell. 25 years!

We need to think about the next 25 years. CRISPR, as a huge technological breakthrough, and the social and ethical debate surrounding it, presents a good starting point for doing that. In our paper we reflect on the discussion about human germline editing. We find that historically the possibility of intervening in the human germline – closing the cybernetic loop – has always been a very important issue in discussing the future (social and ethical implications) of genetic engineering technologies. In the 1970s, the arrival of in-vitro fertilization already led to a debate about the possibility that one day in the future people could use biotechnologies to intervene in the human germline. Thus the idea of a "designer baby", a term that came up only at the end of the nineties, has played a key role in the public imagination and in ethical debates, since at least half a century. (The case of persuasive information technology, which I will discuss later, shows that the dominance of such an interventionist view in the debate is by no means self-evident.)

In the current debate on human germline editing everybody agrees that the current technology is not safe. This consensus on safety implies that everyone agrees that this technology should not be applied at this moment in time. But there is a tension, we think, already appearing in the debate, because some say, well, it is not safe, but maybe

it will be safe in the future and we like this ambition of editing the human germline. At the same time there are people who are really questioning the desirability of that development. In fact, in the debate on human germline editing, two ethical perspectives are apparent. According to Berry discussions about human genetic engineering have historically been framed by a so-called 'reductionist pluralist' view versus a 'holist communitarian' one. What divides these two perspectives is a tension between an individually versus a collectively oriented morality. These two ethical perspectives can be traced back in the two different regimes of biomedical rulemaking: the medical ethics regime versus the human rights regime. On the one hand the medical ethics regime has a strong focus on individual choice. The basic question in this regime is whether a particular intervention in the human body satisfies criteria of safety and informed consent. And in the context of reproductive medicine, parents should have the right and the reproductive freedom to choose whether they would like to use this technology or not. This regime is thus strongly focused on informed consent and supports an individual's right to make choices. From this perspective human germline editing, when it can be applied safely and effectively, will be ethically acceptable and morally desirable, especially when it may alleviate potential suffering of a future human individual.

On the other hand, we can find the holist communitarian perspective clearly expressed in universal and constitutional human rights principles, enshrined in a number of international declarations and conventions on bioethics, human rights and the human genome. The human rights perspective sees genes as public resources that constitute a collective 'heritage' or 'patrimony' involving the unity and dignity of all human beings. The human rights regime thus holds that we should not only look at the implications of human germline engineering from an individualistic point of view, but also from a societal perspective. The societal implications ask for extra caution and collective and anticipatory oversight. Set up along this way of reasoning, the *Convention on Human Rights and Biomedicine* only allows research, preventive, diagnostic or therapeutic interventions in the human genome if its aim is "not to introduce any modification in the genome of any descendants".

The discussion at this moment is not played that hard because of the consensus about the fact that human germline editing at the moment is not safe. But a lot of scientists think that in the future it will be technically possible to safely engineer human embryos. What will happen then? We expect that the medical ethics regime, that is founded on the individual right to procreate and the parent's right to reproductive freedom, will pave the way for clinical applications of human germline editing. Such a situation would really calk the debate. That implies the need to strike a balance between the individually and collectively oriented moralities. Or in other words, to strike a balance between the values institutionalized in medical ethics and the international human rights and human genome framework.

Let us now turn to persuasive technology. Let me name just some events to show the speed of the development in the field of IT. In 1989 the internet was already there, but it was only used by a small group of people. In that year the internet protocol kick-started the worldwide web. 15 years later Facebook was launched and we started to use the internet as a social medium. We gave away – for free – a lot of data about our social networks, behaviour and who we are. Then, in 2007, not even 10 years ago, we started to use smartphones in a massive way, meaning that we have the computer always with us.

That is where this merging of information technology and human beings kind of started. We are now in the stage that the environment – because of these smartphones and all kinds of other ITs – is becoming smarter and smarter. So, for example, there is an experiment in Eindhoven, a city in the Netherlands, where they currently experimenting with applying smart light in a district where a lot of young people go out at night. So, they use a lot of sensors to monitor the crowd and smart light to influence their behaviour, to try to make these young people less aggressive, when necessary.

We currently see two big trends. The first trend concerns the increasing transparency of the individual, because of the pervasive application of sensor technologies throughout our everyday environments; and the fact that all the data collected can be analysed by increasingly sophisticated technologies, capable of revealing patterns and predicting attitudes, emotions or behaviour. Individuals thus are becoming more and more transparent. The second trend is that digital smart environments are becoming more and more opaque. For example, if you go to the internet and you look up a website, at the same time 30 to 40 websites or companies are monitoring what you are doing. So while the individual is rendered increasingly transparent, the ability to understand and scrutinize the calculations and analysis performed in the intelligent systems around us becomes increasingly problematic.

What does this mean for rule-making on information technology? For a long time, only the first trend, the increasing transparency of the individual, has been on the public and political agenda. And related to that trend, there has been a longstanding debate on IT and privacy and autonomy, which started in the sixties and seventies. Then, at the end of the seventies, early eighties, some ethical and regulatory guidelines were set up. In particular, within the regulatory frameworks of the Council of Europe, the OECD and the European Union the dimension of control over personal data, or *informational privacy*, became increasingly important. One could say that we use the notion of informational privacy and the related fair information principles to deal with the first trend. Both the OECD and European Union strived for a balanced consideration of both privacy and the need for economic growth and international trade.

Because smart environments provide many ways to profile us and intervene in our lives, we need to pay a lot of attention to the second trend. For example, profiling also provide means to discriminate and also exclude people. Moreover, this type of data analysis can be used to steer our behaviour. In fact, it might even be used to anticipate our preferences, steer these preferences and even anticipate our behaviour. This type of technological interventions put on the table a lot of ethical issues and regulatory challenges.

Inspired by Sloterdijk's wakeup call at the end of the last century, our paper reflects on "the rules for the maintenance of the human zoo". Since digitization plays a central role in our current society, we studied rule-making in the digital human park, by looking at two technologies: human germline editing as core example of a "breeding" technology and persuasive technology, as a core example of an electronic "taming" technology.

A first conclusion may be that the role of technology in the "breeding" and "taming" of people has neither gone without ethical reflection nor public or political debate. Moreover, to a certain extent a conscious "breeding" and "taming" politics can be discerned. In other words, rules for the maintenance of the digital human park are being debated and created, both on the national, regional (for example European) and global level. But, if you look at it from a global level, you see a kind of fragmented patchwork of policy instruments and governance structures. As a result, the rules that exist on a national or even regional level only have limited enforceability in a global political economy.

In the debate on human germline editing and persuasive technology a complex set of values plays a role. Rule-making requires thoughtful balancing between different individual and collective values and the related interests of different actors. If we consider values as drives of a certain socio-technical development, some values may be denoted as accelerator values that legitimize a certain development, while other values act more like brake values.

With regards to human germline editing relevant values like safety, individual right to procreate and the parent's right to reproductive freedom act as accelerator values, while risk, human genome as common heritage of mankind and a child's right to self-determination or an open future act as brake values. On the short term the fact that human germline editing is not safe eases the discussion. But it is well conceivable that it will once be possible to safely genetically engineer embryos. Such a situation will really bring the conflict between the break and accelerator values to a head.

The rise of smart persuasive environments asks for a new balance between privacy and economic development. This requires us to rethink and conceptualize anew what we mean by privacy and how it can be safeguarded. The fair information

principles, which stem from a period with manual collection and automatic processing of personal data, are no longer sufficient to deal with the real-time collection of data via sensors and smart environments. The agency and opacity of smart environments force us to move beyond informational privacy, and look for ways to control how these environments not only collect data, but also profile us and steer our behavior. In other words, besides fair information principles, we need fair profiling and persuasion principles. ||

Country Perspective from Iran

Ehsan Shamsi Gooshki

|| The amount of change that technology has on human being lives is unimaginable. It impacted our environment and our social, familial and individual life dramatically, to the extent that it could be claimed we live in a completely different world, where historically well-recognized concepts such as humanity, personhood, life and death are subjects to serious challenges and debates, beyond classic geographic and political borders and even beyond what has been known as "cultural diversity". Today the language of technology is the most popular language, which connects humans and constitutes a universal society. Regulating this great new world, what Dr. van Est and colleagues truly called "techno-human park" is a source for universal concerns.

Addressing the concerns of making rules for new technologies in practice or research requires introductions of conducting documents such as research ethics guidelines in national and international levels. Because of the complicated nature of new emerging and converging technologies, ethics authorities such as health technology assessment units or research ethics committees are hardly able to properly review proposals for approving the use of such technologies or preforming research in such fields. Here the role of international documents, issued by WHO, UNESCO, the World Medical Association, Council for International Organizations of Medical Sciences and the like, are crucial. Such international guidelines could empower the above-mentioned national authorities to evaluate new technological applications or research. In addition, national bodies would be able to use such guidelines as a base for including local concerns and developing their own national documents. Despite the presence of valuable international documents such as the *Universal Declaration of Human Rights*, we need more specified guidelines for each case, to explicitly explore the application of human right standards in daily practice or research. Even more specific guidelines such as the *Declaration of Helsinki*, for organizations that conducts clinical research, need to be more specified to be useful in case of new emerging or

converging technologies. It is important that such specific guidelines also need to enjoy an acceptable level of authoritativeness. It seems that the present process of developing ethical guidelines for various research and practice fields cannot sufficiently respond to the increasing need for international conducting standards for regulating new technologies. We think that a new inter-agency system inside the related UN sections, especially WHO and UNESCO, should be implemented to overcome this problem. Even recommendations of these international bodies could be very useful for the member states.

Accomplishment of this important mission by the above mentioned organizations requires using clearer language and conceptual frameworks and expanding such concepts beyond the distinction between "medical ethics vs. human rights" regimes. Dr. van Est and colleagues labelled the medical ethics regime as reductionist, pluralistic and individual-oriented, while in their explanation, the human rights regime is characterized as communitarian and societal rather than individual. In my view, reducing medical ethics to a personalized patient-oriented regime is not a complete interpretation of this discipline. In addition, labelling human rights conventions and declarations as holistic communitarian documents is in conflict with their main aim for protecting each human's basic rights. As I understand today's medical ethics in its general sense, it includes holistic societal concerns of public health ethics or health care ethics. Although we usually use the language of "rights" and corresponding "commitment" inside the medical ethics discourse, I see the human right approach as the wider ground and underpinning for today's medical ethics and not as a separate regime. Furthermore, it seems necessary that human rights standards need to be more and more specified into the field of biomedical ethics context to repair the practical gap between medical ethics standards and human rights requirements.

One strategy that would help us to do better evaluation of new emerging technologies is increasing transparency in the various contexts and dimensions. Ensuring such transparency requires infrastructures on the national and even institutional level. Only the presence of transparent and well-established independent research ethics committees (RECs) would be able to relatively guarantee transparent research in the new emerging fields. It seems that an international accreditation system for RECs could be an option. Today RECs structure suffers of discrepancy in different states. Unfortunately, in some countries, there is not a national regulatory body for RECs and this situation has led to forming symbolic RECs that only issue approvals for research to make the publication possible. Here, the most important infrastructure is to have really independent RECs, which are accredited by an external accreditation system. Furthermore, even in the presence of acceptable RECs, the limitations of such committees prohibit them to supervise the research process and the penetration of REC evaluation hardly goes beyond approving the proposals. For overcoming

this problem the scope of RECs role and the extent to which they can penetrate needs to be redefined explicitly by international and national authorities. During the past two years in Iran, the secretariat of the National Committee for Ethics in Biomedical Research at the Ministry of Health and Medical Education has implemented a nation-wide accreditation system, in which all RECs that approve biomedical research are connected within a national system. I will explain this system in today's marketplace in more details. This transparency should also be considered in the other side that develops new technologies and export them to other countries.

Here, the general international strategy of the ethics/bioethics sector toward new technologies directly influences the following activities. Such strategy seems to have two main options: the "open window" vs. the "banning" strategy. In an open window policy, the default option is to allow the application or research on new certain technologies through a conducted and regulated way. For example, ethics committees or ethics boards do not only prohibit certain research such as human germline editing for therapeutic use, but also recommend the best possible way to protect moral norms and ethical standards while doing such kind of research. I recommend this position because according to the previous experiences, the banning strategy usually does not work. Closing all doors leads to an accumulation of expectations in the field. We need to seek for ways to redirect research/practice towards the "right" direction before such activities find their ways towards the wrong way. The biomedical ethics sector, including biomedical ethicists, need to work in a more integrated and institutionalized way to show, and even open, the right ways. The ethics sector is obligated to move towards a more active system for biomedical research conduct than the present passive model. This is a shift from retrospectively responding to the raised ethical concerns to a prospective system that conducts future trends. Reaching such position seems to be hard, but not impossible. This strategy would help to change the image of RECs from being a body for setting limitations to a position that provides protection.

In the case of doing research on new emerging technologies or research which aims at converging previously introduced technologies to create a new area, the issue of risk-benefit sharing needs more deliberations. It is obvious that studying or applying new technologies have some sets of risks and benefits, but it is important to see who is at risk of harm and who enjoys potential benefits. The issue seems more important when we see that the main promoters of new technologies are almost always companies residing in developed and rich countries, where the benefits will be there, while the risks are imposed to many other inhabitants of usually developing countries. The risks and benefits for target populations of IT companies who collect and analyse data and pharmaceutical companies who do clinical trials are usually not distributed in a fair and justified way. In addition, the issue of "induced need"

resulted from testing or introducing a new technology needs to be addressed here, which is sometimes strong enough to deviate a considerable portion of limited financial resources of the health system or GDP to a new emerging technology and related products. In some cases, this may happen indirectly by the means of INGOs that are delivering services in developing countries.

Finally, what we need to remember is the fact that new technological movements have changed our societies including the people. For biomedical research, the field I am more engaged in, this change has a great impact. Doctors and researchers need to believe the changes of humans' awareness and expectations that cannot be compared with the past decades, a phenomenon that directly affects clinical research and clinical practice. We need to move as fast as possible from a paternalistic system in which research is done on human subjects to a more ethically acceptable system of conducting research in cooperation with human participants. It seems that our societies' members want to be our research partners rather than our research instruments. ||

Country Perspective from New Zealand

Barry Smith

|| The background paper prepared for this session by Dr. van Est comprehensively sets out the key features of the landscape around emerging and converging technologies. By way of a response to this paper, my intention is to concentrate only on selected aspects, and to frame my thoughts on these matters in terms of the ethical tensions faced by countries like Australia, Canada and New Zealand, whose populations contain indigenous peoples that have experienced the process of colonization at the hands of British political and economic interests beginning in the mid to late 18th century.

One of the impacts of this history has been the deeply embedded social and health inequality that still persists to the present. These disparities create a backdrop of ongoing concern that shape discussions across a range of ethical conversations that take place in these countries. In the New Zealand context, and by way of an update, considerable energy has been directed over the past five years at implementing changes to the ethics review process for health research affecting both structure and process and prompting numerous statements of concern. For example, one of the changes which drew criticism was the instruction to ethics committees to separate the science from ethical analysis and for discussions to concentrate only on the latter.

Overall, the impact of this focus on change has drawn attention away from specific debates on topics being explored in today's session towards conversations shaped largely by the content of applications being considered by ethics committees, such as issues associated with research on vulnerable populations. Thus, the background paper covering big data and germ line editing could be useful in generating discussion within New Zealand on an area that presents important ethical challenges.

But, to keep the record straight, I should mention that a lot of detailed work has been done in the New Zealand context on the legal implications of genomic research. With regard to big data, some matters have received attention as the country

continues to explore the concept of integrated healthcare while also working towards better cross-sectoral and cross-agency relationships aimed at improving the wellbeing of New Zealand children. But let us turn to the ethical concerns associated with the use of big data and germ line editing taking each theme in turn.

Around big data I feel we need to think seriously about the risks attached to the frequent overstating of the reliability and robustness of the analytics associated with big data analysis. Here, the ethical implications lie around the potential to promote changes to social and health policy based on inadequate evidence and gross overgeneralizations that derive from the view that the more data you have, the more watertight your findings. The fact is that whilst we have 'rules' for the way in which we collect and manipulate data – and I'm wearing a statistician's hat here – we do not have the same level of agreement with regard to the way we interpret information. The approach taken to this task is generally left to the individual investigator with their own theoretical predilections with the disjunction between data collection and interpretation being critical to the discussion of issues that Dr. van Est has raised for us. Indeed we might ask whether there is actually a pressing need to 'refresh' our analytical approaches given that much health research has involved the use of small, not large, numbers or alternatively has been based entirely on the application of qualitative methodologies.

Secondly, there is always the temptation for researchers to indulge in 'hunting', 'snooping' and 'fishing' about which we have talked a lot over the years. The key implication and concern is that analysis is not being generated out of an intervention logic by which we define important health questions. Here, ethical issues emerge out of the potential misuse and waste of scarce resources for health research, with protection against this requiring the existence of crystal clear terms of reference that are strictly adhered to by those entities who fund research. But analytically, the big data issue has to do too with the limited utility regarding the discovery of correlations between diverse variables and, in statistical terms, the frequent failure to determine whether these connections might actually be spurious.

Thirdly, there is the issue that I refer to as the 'degradation of privacy'. This concept has to do with questions as to how many different bits of information about an individual is required for an observation to become a serious threat to an individual's right to privacy. Of related concern are the implications of the obvious potential in the big data space to be able to build a more complete picture of an individual citizen, simply because data is able to be extracted from a variety of sources, each relating to a different social function within the nation-state.

Moving now onto the area of germ line editing, there has been much concern, well captured by Dr. van Est's paper, over the potential use of CRISPR-Cas9 technologies and other such approaches. The expert paper provides an informative rundown of

the state of play regarding this technology and from this overview, it seems clear that there are key ethical evaluations needed around a number of elements.

First, it seems that there are actually only a small number of published studies that claim the use of the technique. The immediate and obvious conclusion to be drawn from this is that the state of knowledge in this area is clearly at a very early state of maturation which should generate reservations regarding the wider application of this technology at the present time.

Secondly, and added to the fact that we are in this 'early knowledge' state, is the concern that the technique is also easily applied. Taking these two things together should lead to the hearing of rather loud ethical alarm bells. However, the corollary to this caution is that new technologies are frequently viewed as a key means to improving health outcomes, which is an essential and pertinent focus especially where health inequalities are seen to align with differences in ethnicity or some other major social construct.

Thirdly, this ethical unease is augmented when there is the probability of making a mistake in an area that has reproductive implications that could be long term. Working with non-inheritable somatic cells is one thing whereas dealing with material that has the potential to shape inheritable characteristics is quite another.

Fourthly, a casual search of legal structures and laws relating to the use of this technology suggests that there exists considerable variability across different jurisdictions. This situation suggests there could be value in organized conversations, such as at a summit like this, with the aim of utilizing mutual learning in the development of comprehensive sets of regulations to protect humankind from its own uninhibited ambition and/or carelessness.

However, the ultimate ethical tension may arise from the possibility that the control of technology could again rest with elites. If this is the case there will likely be an exacerbation of the extent to which benefits from, and access to, new health interventions will be distributed in a way that ignores the tenets of social justice while potentially increasing the amount of health disparity.

A related consequence concerns the extent to which resources could be drawn towards this technology and away from a focus on ways to achieve more equitable outcomes through an improved understanding of the social determinants of health.

In closing, my position is that all conversations regarding ethical matters emerging from this rapidly changing technological landscape need to give much greater recognition to the importance of socio-cultural diversity so we can strive for a more just distribution of access to healthcare and the health benefits we all hope will accrue from this. Moreover, as we face challenges across the globe in terms of the rising fiscal demands on our health systems that are being generated out of changing demographic profiles and the employment of new technologies, our search for

solutions must emerge from society-wide debate and not just from dialogue generated by vested and siloed interests within the health and technological communities.

Ultimately, and whether we like it or not, these solutions will continue to be enacted and implemented through socio-political and not just scientific processes. Our hope of course is that each of these domains will see the advantage of working towards a state of synergy and mutual understanding. ||

Discussion Paper

Rules for the Digital Human Park

Two Paradigmatic Cases of Breeding and Taming Human Beings:
Human Germline Editing and Persuasive Technology

Rinie van Est, Jelte Timmer, Linda Kool, Niels Nijsingh, Virgil Rerimassie, Dirk Stemerding

1 The digital human condition

> „For all previous millennia, our technologies have been aimed outward, to control our environment. […] Now, however, we have started a wholesale process of aiming technologies inward. Now our technologies have started to merge with our minds, our memories, our metabolisms, our personalities, our progeny and perhaps our souls."
>
> Joel Garreau (2004, 6) in *Radical evolution*

1.1 Being intimate with technology

We have become very intimate with technology (van Est 2014). We welcome technology to nestle itself between us, into us and very close to our bodies. Through these technologies we constantly inform the outside world about our body and behavior. We are monitored from the cradle to the grave: our mobile phones can indicate when the ovulation takes place, we use caloric intake apps, and smart devices are made to count our heartrates, register what we gaze at and check out whether the emotions we show are true or false. Even before birth, still in the test-tube phase, we are able to identify genetic defects or talents in embryos created through in-vitro fertilization (IVF). Consequently, our bodies and our behavior have become objects of technological intervention. Recent developments in the field of persuasive technology and human germline editing illustrate this.

This human-machine merger presents a new phase in the information society, which is enabled by the digitization of life. A key characteristic of information

technology (IT) is that it blends with all kinds of existing technologies and processes (Castells 1996). We would like to discern four important types of IT convergences (see Table 1). Digitization of production processes is enabled by mechatronics; the mix of mechanical engineering and electronics. Digital communication presents a second form: information and communication technologies combine in 'ICT', enabling for example the mobile internet. Many IT firms and authorities expect that over the next two decades the internet will converge with the physical world. Physical products will be expanded with an internet address, sensors, computational power, and communication facilities. The Internet of Things implies the digitization of the physical world. Finally, IT is blending with biology or living systems, including humans. From a technological perspective this implies that information technology, aided by micro- or nano-sized components, fuses with bio- and cognitive technology. This is often popularly termed NBIC-convergence.

Table 1: Overview of four crucial IT convergences

Convergence	Areas converging	Digitization of
Mechatronics (robotics)	Mechanical engineering and electronics	Production processes
ICT (including the internet and mobile telephony)	IT and communication technologies	Information and communication processes
Internet of Things (info and nano *or* bits and atoms)	Internet and physical world	Value chains
NBIC convergence (nano, bio, info, cogno)	IT and biology	Life processes, including human biological, cognitive and social processes

(van Est & Kool 2015, 47)

In essence, NBIC convergence implies an increased interaction between the life and physical sciences, which constitutes two bio-engineering megatrends: biology becoming technology and vice versa (van Est & Stemerding 2012). Biology becoming technology points to new engineering tools which allow for more far-reaching interventions in living systems, allowing the human body and brain to be controlled as if they are machines. Human germline editing clearly fits this first trend. The second trend "technology becoming biology" entails the engineering ambition to introduce lifelike features, such as self-repair, cognition and learning, into technology. This is illustrated by persuasive technology, which assumes a human-like style of agency aimed at for example anticipating on or influencing human behavior.

When we look at our own techno-human condition, NBIC enables the digitization of human life, including physiological, cognitive and social processes, and supports

three tendencies. First, human beings are more and more seen as machines, which can be maintained, repaired and even upgraded. Next, machines get more and more human-like features. And third, machines penetrate into our privacy and social life and increasingly influence how humans interact. These tendencies all decrease the distance between ourselves and technology. In this digital age, we humans have become techno-humans, mixtures of man and machine, cyborgs. This intimate technology revolution creates a battle for our body and behavior and therefore brings up many political and ethical questions, and one of the most sensitive relates to technologies that aim to alter our germline or behavior.

1.2 Being conscious about breeding and taming

> „The domestication of man is the great unthinkable, from which humanism from antiquity to the present has averted its eyes."
>
> Peter Sloterdijk (2009, 23) in *Rules for the Human Zoo*

We seem to have difficulties truly facing the defining impact technology has on our human condition, and taking explicit responsibility for its governance. The German philosopher Peter Sloterdijk met with a lot of opposition when in 1999 he dared to talk in terms of 'breeding' and 'taming' human beings in his Elmauer lecture *Rules for the Human Zoo*. According to him, humanism has always been about "the taming of men", by means of the instructive value of books: "[Humanism's] hidden thesis is: reading the right books calms the inner beast (Sloterdijk 2009, 15).

Sloterdijk claims that besides 'taming' people into being right citizens by means of persuasive texts, we are developing the technical means to genetically engineer our offspring. Instead of ignoring technologies, like prenatal embryo selection and human germline editing, there is a need to debate about how humanity could best use these new breeding technologies.

Strangely enough, Sloterdijk did not problematize the actual taming of people, although there are many technological means to 'tame' people besides books: think for example of electronic lifestyle coaches, which help their users attain personal goals, for example weight loss, financially healthy behaviour or environmental awareness (Kool et al. 2015). Maybe this gap reflects the state of the art of the technology at the end of the 20th century. When Sloterdijk summoned his colleagues to fundamentally reflect on "rules for the maintenance of the human zoo", he was probably aware of the Human Genome project as an early example of the convergence between biology and IT, but not about the fact that a new vision of the future role of computer

technology was being concocted: ambient intelligence (cf. Aarts & Marzano 2003). The term 'ambient intelligence' (AmI) refers to invisible 'smart' technology embedded into the everyday human environment, or even the human body itself. Since then the AmI-vision has strongly shaped the European IT research agenda, and now dominates the innovation strategies of most of the global IT companies. The technologies in place to make environments 'smart' and adaptive are sensors, internet, cloud technology, big data, machine learning, et cetera. According to Verbeek, these information technologies challenge us "to tame the taming" (Verbeek 2009, 239). So besides a conscious breeding politics, we also need to develop a conscious politics of 'taming' human beings by means of technologies.

1.3 Being domesticated by big data

The digitization of human life (as partly driven by NBIC convergence) is delivering the technologies to domesticate human beings. Digitization is guided by an informational or cybernetic worldview, that is guided by programmability and manipulability (de Mul 1999). Cybernetics assumes that mechanical, organic, cognitive, and social processes can all be described in digital terms, and that by simulating such processes it will be possible to intervene in them. Whereas the raw materials of the industrial revolution were cotton, coal, and iron ore, people form the raw material of the intimate technology revolution (van Est 2014). We are first being digitally measured, think about digital data on our genetic makeup, thoughts, feelings, preferences, conversations, and whereabouts. These data are not gathered without purpose, but are often used to profile human beings in all kinds of ways with the explicit goal to intervene into human processes. These three steps in the digitization of human life – measuring, profiling and intervening in humans – link directly to the three general processes that make up the value chain of big data: collection, analysis and application (cf. Roosendaal et al. 2014). The three processes together create a digital or cybernetic feedback loop.

Table 2 illustrates schematically how in the field of breeding and taming, we as human beings use big data to digitally domesticate ourselves. In the domain of breeding, the DNA code plays a central role. Collecting the DNA of human embryos created through IVF and mapping and storing this genetic data in a biobank is a necessary step before analyzing an embryo's genetic profile. Such genetic diagnosis can lead to embryo selection prior to implantation, but is also needed for human germline editing for either somatic or research purposes. A biological sample that can be analyzed for DNA structure and protein levels can also be applied in the domain of taming humans. Personal genetic information can be used to determine the chances

of getting ill and provide incentives for preventive lifestyle changes. There are many ways to measure and diagnose the health condition of a person, and increasingly these biomedical technologies are applied outside the medical domain, for example by personal health devices or smart clothes (van Est et al. 2014). Besides bodily functions, digital technology can quantify various types of behavior, emotions and activities. Based on the analysis of all these data smartphone apps may offer advice about many aspects of our lives, ranging from finances, eating and car driving behavior, relationships and social interactions with others, to lifestyle and energy consumption (Kool et al. 2015).

Elaborating on Sloterdijk's notion of the human zoo or park, it is fair to say that we are living in a techno-human park, and given the increasingly pervasive role played by digitization therein, we might as well say that we are living in a digital human park.

Table 2: Some examples of digital human domestication through big data

Type of human domestication	**Digitization of human life / Big data value chain**		
	Measuring humans / Data collection	**Profiling humans / Data analysis**	**Intervening in humans / Application**
	Measuring humans	Profiling humans	Intervening in humans
Breeding human beings	Mapping the human genome through DNA sequencing	Genetic profiling	Human germline editing prior to implantation
	Mapping the human genome	Preimplantation genetic diagnosis (PGD)	Embryo selection prior to implantation
Taming human beings	Genetic testing, e.g. direct-to-consumer	Personal genetic testing report	Lifestyle management (prevention)
	Physiological aspects, e.g. heart rate, blood pressure, glucose rate	Personal health diagnosis	Lifestyle management (prevention)
	Cognitive, social and emotional aspects	Social, emotional and behavioral profiling	E-coaching, neuro-marketing
	Consumer behavior	Consumer profiling	Personalized advertisements

1.4 Two paradigmatic cases

In this paper we examine to what extent the rules of the digital human park are being debated and created on national, regional (in particular European), and global levels.

We aim to get to grips with the processes of rule-making for the domestication of human beings. To do that we reflect on two paradigmatic cases of breeding and taming technologies, namely human germline editing and persuasive technology, respectively. We describe the ethical debates evoked by recent developments in those two fields and reflect on those current discussions by means of a longer term perspective. One important historical line, in this respect, is drawn by the human rights perspective. For example, in response to the horrors of the Second World War, the *Universal Declaration of Human Rights*, was adopted and proclaimed in 1948 by the General Assembly of the United Nations. We will study to what extent the human rights perspective is shaping how society deals with breeding and taming technologies.

Chapter 2 describes the ethical debate evoked by new developments in the field of human germline editing. We study the extent to which the current debate reflects the long-standing debate on 'designer babies' and the use of genetic technologies for doing medical research, and the extent to which new issues are raised. We analyze how earlier technological developments, like recombinant DNA and IVF, triggered ethical and political debates, and to what extent these led to (inter)national regulatory frameworks that anticipated new technological capabilities. Some argue, however, that as long as the anticipated technologies are not yet safely into place, it is relatively easy to ban them. But what will happen when, as in the case of human germline editing, technology catches up? Will it put pressure on or strengthen existing frameworks?

Chapter 3 focuses on persuasive technology. Like many technologies, persuasive technology is enabled by a wide set of other technologies, ranging from sensors to robotics, and artificial intelligence. We will describe how persuasive technology leads to new types of ethical issues, in particular new types of privacy-related issues. In contrast to genetic engineering technologies, which have been debated from an ethical perspective for over four decades, intimate information technologies, like persuasive technologies, have rarely been acknowledged by the political system as needing critical ethical reflection and political debate.

Having considered the two paradigmatic cases, in chapter 4 we draw some conclusions about how humanity, so far, is making the rules for the digital human park.

2 From mapping the human genome to editing the human germline

> „It has been only about a decade since we first read the human genome. We should exercise great caution before we begin to rewrite it."
>
> Eric S. Lander (2015, 7) in *Brave New Genome*

Our genetic makeup has become a potential object of technological intervention. Artificial reproductive technologies, in combination with the mapping of the human genome, have created an ever-widening window for diagnosis, screening, selection and modification of our genetic traits. With this development, the long conceived and debated possibility of germline engineering is almost coming within reach. This prospect has again become the subject of vigorous debate as a result of the emergence of CRISPR[1], a technology which enables the 'editing' of the genome in living cells with unprecedented ease, low cost and promised precision. This chapter seeks to understand the debate that has been stirred by the new prospects for human germline engineering in the context of an already long-standing bioethical debate; a debate which not only has been responding to, but also has been anticipating the increasing possibilities for engineering human biology and the human genome. We discuss how current regimes of regulation are informed by the human rights perspective and ask ourselves how to deal with the new prospects for human germline editing in the light of these established regimes?

2.1 Redesigning the human genome

Although genome sequencing and genome-wide association studies have over the years provided more and more information on the human genome, until very recently it was difficult to act upon that information by intervening in a genome (Baltimore et al. 2015). The revolutionary promise of CRISPR is that it provides us with the tools to specifically and efficiently adapt the genomes of bacteria, plants and animals. When applied to humans, this may involve both somatic and germline applications. One example of a somatic application would be the modification of stem cells designed to replace white blood cells that heighten resistance to HIV. CRISPR may also be used to modify human embryonic DNA in order to adjust specific mutations associated with genetic disease. In 2015, Chinese scientists reportedly tried to genetically edit a human embryo (Liang et al. 2015). Such changes to the human germline would have implications not only for the individual that would emerge from the embryo, but also for its genetic heirs. Consequently, the discovery of CRISPR seems to give Sloterdijk's (2009) appeal at the end of the 20th century to constitute rules for 'breeding' human beings new relevance.

Interestingly, when Sloterdijk made his plea, human breeding rules that anticipated the possibilities of human germline engineering already had been or were being

1 CRISPR-Cas9 in full. See Liang et al. 2015. Later in 2015 an alternative to the Cas9 enzyme, Cpf1, was described as even more promising (Zetsche et al. 2015).

established. In particular, these rules were developed within the context of human rights frameworks. For example, the UNESCO *Universal Declaration on the Human Genome and Human Rights* (1997) states that the human genome should be seen as "part of the common heritage of humanity". And according to Article 13 of the *Convention on Human Rights and Biomedicine* (Oviedo Convention) drafted by the Council of Europe in 1997, an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is "not to introduce any modification in the genome of any descendants". Moreover, within the European Union, we can find a shared rejection of eugenic practices and cloning of human beings, both deemed to be in violation of human dignity, according to Article 3(2) of the *Charter of Fundamental Rights of the European Union* (2000).

Let us return for a moment to the CRISPR technology. In March 2015, rumors first appeared that a group of Chinese scientists had endeavored germline modification of human embryos. In anticipation of this feat, two papers by prominent scientists were published in *Nature* and *Science* respectively, which both emphasized the need for a cautious approach and argued that clinical applications are currently not justifiable, neither ethically nor scientifically (Lanphier et al. 2015; Baltimore et al. 2015). This was soon followed by the publication of a paper by Liang et al. in April 2015, describing the use of CRISPR in a largely unsuccessful attempt to genetically edit a human embryo, from which the researchers concluded that the technique is still "too immature" and to which scientists, ethicists and policymakers were quick to respond (Liang et al. 2015; Cyranoski & Reardon 2015).

Why, if the experiment was basically a failure and the possibility of human germline engineering has long been foreseen, and rules have been set up in anticipation of this potential, did the Liang paper stir such commotion? One reason is no doubt that the actual occurrence of genome editing in human embryos drives home with force the realisation that this is a real potential: we really do have the technological capability to change the genetic makeup of humans. Indeed, the new and emerging gene editing technologies are pushing the agenda towards the possibilities and dangers of human germline engineering, thus challenging the rules that have been established about the human genome from a human rights perspective.

2.2 Safety and desirability

The unprecedented possibilities of CRISPR create opportunities for scientists in any part of the world to do all kinds of experiments, raising and amplifying the fundamental question of what types of human genome editing should be allowed. After

the publication of the aforementioned paper by Liang et al. (2015) scientists, policy makers and ethicists were quick to take on this question emphasizing the need for reflection on the possible implications (Cyranoski & Reardon 2015). In this section we discuss the legal and ethical perspectives on human germline editing put forth in response to this paper.

Calling for caution

As mentioned earlier, in anticipation of the research by Liang et al. two papers were published advocating a cautious approach to germline editing and arguing that clinical applications are currently neither ethically nor scientifically justifiable. The paper by Lanphier et al. (2015) was unambiguously titled *Don't Edit the Human Germ Line* and called for a moratorium on both research and clinical applications, arguing that human germline editing may lead us down a slippery slope:

> „Many oppose germline modification on the grounds that permitting even unambiguously therapeutic interventions could start us down a path towards non-therapeutic genetic enhancement. We share these concerns." (Lanphier et al. 2015, 411)

Lanphier et al. (2015) are themselves involved in somatic applications of CRISPR, and fear that germline applications of CRISPR will induce anxieties among the general public, possibly resulting in a ban on both somatic and germline applications.

The second paper by Baltimore et al. (2015) also discouraged genome modification for clinical application in humans. However, the authors recommend that it is important to

> „[e]ncourage and support transparent research to evaluate the efficacy and specificity of CRISPR-Cas9 genome engineering technology in human and nonhuman model systems relevant to its potential applications for germline gene therapy. Such research is essential to inform deliberations about what clinical applications, if any, might in the future be deemed permissible." (Baltimore et al. 2015, 38)

These scientists thus argue that given the potential for important health care services, the door on further research should not be entirely shut.

Two conflicting views

These two positions roughly represent two conflicting perspectives dominating the debate on CRISPR and human germline editing. On the one side, there are those who applaud the ambition of germline editing, but counsel caution because of safety issues. This position seems to be the dominant point of view. Other commentators,

however, are very sceptical of the entire enterprise and reject human germline editing as a legitimate goal. Thus, Francis Collins – director of the US National Institutes of Health and genomics pioneer – argues that human germline editing constitutes a line that should not be crossed. In his view,

> „[a]dvances in technology have given us an elegant new way of carrying out genome editing, but the strong arguments against engaging in this activity remain. These include the serious and unquantifiable safety issues, ethical issues presented by altering the germline in a way that affects the next generation without their consent, and a current lack of compelling medical applications justifying the use of CRISPR/Cas9 in embryos." (Collins 2015)

This quote captures in a nutshell most of the worries expressed in the debate on human germline editing. Other pleas for caution appeal to the same recurring themes: safety, current lack of convincing applications, respect for human dignity including the fundamental rights and freedoms of future generations, and slippery slope arguments. However, the different arguments latch on to different issues: those that refer to the present safety risks of CRISPR technology, and those which question the desirability of any human germline editing. As we will see, the relative weight of these arguments varies according to whether we have clinical applications or research in mind.

Clinical application

Concerning the possibility of a clinical application for human germline editing there is perhaps universal agreement: at this time no expert suggests that clinical application should currently be pursued. The technology is nowhere near safe enough to confidently apply it to actual, living human beings. Of course, as the technology progresses, we may reach a point where it is possible to edit the genome without also causing a number of unintended mutations, although it is not certain whether the technology would ever be entirely safe. And even if the technology is perfected, its applications will likely be limited to those instances where we can predict the outcome with relative certitude. Monogenic diseases, such as cystic fibrosis, beta-thalassemia or Huntington's disease might conceivably be prevented by means of germline modifications. However, for the vast majority of cases where this might be an option, there are already safe alternatives available, notably preimplantation genetic diagnosis, enabling the screening and selection of IVF embryos for genetic disease (Lander 2015). Applying CRISPR to correct multifactorial susceptibilities for disease, or perform enhancements, seems unlikely in the near future. In particular, the prevention of Alzheimer's, cancer or schizophrenia would require much more

knowledge of how multifactorial diseases are caused and what processes underlie the mechanisms leading to illness (Khoury et al. 2013). The expectations, however, vary widely with regard to the question whether multifactorial diseases will soon – or ever – be a feasible target of human germline engineering (Berry 2015; Bosley et al. 2015; Savulescu et al. 2015).

Research on human embryos

Notwithstanding the unanimous rejection of clinical applications of human germline editing at present, there is far less consensus on whether genome editing research on human embryos should be pursued. On the one hand, it is claimed that research on embryo genome editing may have "tremendous value" in fundamental biological research (Hinxton Group 2015). Accordingly, scientists Eric Lander and George Church claim that given the potential benefits, research could and should not be stopped: "Today's debate concerns not research (which should proceed) but clinical applications to human beings" (Lander 2015, 7).

On the other hand, colleagues have argued that there is a line that should not be crossed (Lanphier et al. 2015; Collins 2015). Arguments against human germline editing research sometimes refer to the genome being 'sacrosanct' (Cyranoski & Reardon 2015) or to dangers of the technology that are insufficiently clear. Lanphier et al. (2015) also argue that there are symbolic reasons not to pursue this type of research: such a course may send a clear message that germline engineering is considered morally inappropriate and raise public awareness of the fundamental difference between somatic and germline applications.

The reasons that are brought forward against human germline editing research tend to relate to the nature and future of human 'existence'. For example, Pollack (2015, 871) argues:

> „This opening to germline modification is, simply put, the opening of a return to the agenda of eugenics: the positive selection of "good" versions of the human genome and the weeding out of "bad" versions, not just for the health of an individual, but for the future of the species."

To a proponent of human germline editing research this indirect charge of eugenics may seem a stretch, or even an insult. It is not likely that a scientist who subscribes to human rights and accepts the principle of free choice and self-determination will identify with the "agenda of eugenics". And indeed many of the reactions to fundamental objections of this kind have been decidedly dismissive. For example, to the previously mentioned slippery slope argument, Savulescu et al. (2015, 476) respond: "Nearly all new technologies have unpredictable effects on future generations." To

the argument that future generations are unable to consent, Harris (2015) replies that this is also true of any other decision with respect to procreation. In short, the proponents of human germline editing research seem not to be impressed by these more fundamental objections. Maybe this is because the current debate in many respects resembles the long-standing debate on human genetics. In the next section, we will therefore dig somewhat deeper into that historical context in order to better understand the current discussion on human germline editing.

2.3 Two conflicting ethics

For decades ethicists – and other experts – have anticipated the possibility of human genetic modification (Bonnicksen 1994; Carter 2002). In the 1970s, for example, the emergence of IVF technology prompted discussion on the ethics of engineering the human genome (Kirby 1984). When during the 1980s preimplantation genetic diagnosis (PGD) became a serious option, concerns about the possibility to select specific traits were pitted against arguments on the benefits of this technology in combating serious diseases (International Bioethics Committee 2003; President's Council on Bioethics 2004). The notion of the 'designer baby', which emerged in the late 1990s, has served as a powerful image in public discussions about the challenges of reproductive genetics.

Two ethical perspectives

The history of this debate shows an ongoing tension between two different positions each of which are deeply entrenched in distinct foundational and value-laden beliefs. Some applaud the prospect of reproductive genetic engineering, only counselling (pre)caution because of safety issues, while others are much more sceptical and reject the whole idea as a legitimate goal. Now, in 2015, the discovery of CRISPR has once more rekindled this debate. Berry (2007) suggests that discussions about human genetic engineering have historically been framed by a so-called 'reductionist pluralist' perspective versus a 'holist communitarian' one. From a reductionist pluralist standpoint value choices should be made by the exercise of free choice and associated ethical and policy problems can be reduced by achieving a balance of benefit over risks. This view holds that "the issues posed for procreation and parenting by this novel technology (of germline engineering) are the same as for any other bio-medical technology" (Berry 2007, 26). For the holist communitarians, however, this utilitarian risk-benefit approach is inadequate because it does not take into account what is at stake for humanity and society as a whole. They therefore want to engage in a debate about what "the community will abide when it comes to revising the genomes of its

future members" (Berry 2007, 27). What divides these perspectives is not, in Berry's view, the usual distinction between utilitarian and deontological thinking, but a tension between an individually and a collectively oriented morality. Whereas an individually oriented morality honours free choice, emphasizing parental autonomy in reproductive decision-making, a collectively oriented morality emphasizes the need for public deliberation and for an anticipatory ethics that is answerable to community norms (see also Bonnicksen 1994).

Medical ethics versus human rights regime

These two perspectives can also be recognized in the two different regimes of biomedical rule-making firmly institutionalized in the 1980s and 1990s on the national and international level: the medical ethics regime versus the human rights regime. The reductionist pluralist view has predominantly taken shape in a *medical ethics* regime of regulation founded on procedures of institutional review and the principle of individual consent. The basic question in this regime is whether a particular intervention in the human body satisfies criteria of safety, informed consent, and, in the context of reproductive medicine, also parental rights and reproductive freedom. In these terms, human germline engineering may be deemed ethically acceptable, especially when a particular intervention may alleviate potential suffering of a (future) human individual (Carter 2002; Hinxton Group 2015).

The holist communitarian perspective is clearly expressed in universal and constitution-like *human rights principles*, enshrined in a number of international declarations and conventions on bioethics, human rights and the human genome. These declarations and conventions represent, as Bonnicksen (1994) has pointed out, the search for a transnational ethics based on the assumption that genes are public resources that constitute a collective genetic 'heritage' or 'patrimony' involving the unity and dignity of all human beings. The implications of human germline engineering are thus societal rather than individual, warranting extra caution and needing collective and anticipatory oversight. In response to the current debate, the UNESCO International Bioethics Committee (2015, 12) called for a temporary ban on genetic editing of the human germline, in order to first "consider all the possible consequences on human rights and fundamental freedoms as well as on the future of humanity itself". A more prohibiting position can be found in the legally binding European *Convention on Human Rights and Biomedicine* which only allows preventive, diagnostic or therapeutic interventions in the human genome if its aim is "not to introduce any modification in the genome of any descendants" (Committee on Bioethics 2015).

Besides the ideological tension between the two regulatory regimes identified above, these regimes also differ in terms of impact. The medical ethics regime has been strongly institutionalized in medical ethics commissions both on the

international and national level. In contrast, there is no such unequivocal impact of the human rights principles enshrined in the international human genome declarations and conventions. A recent survey of relevant legislation and guidelines in 39 countries showed a strong diversity in policies with regard to human genome editing (Ledford 2015). Although many countries have rules that ban germline editing for clinical use, such restrictions are not always legally binding. In other countries rules are more ambiguous and in the countries where clinical use is banned, research is usually allowed. Thus it remains to be seen how current restrictions and guidelines will be affected by new achievements in the field of gene editing. As the Stanford lawyer and ethicist Hank Greely dryly remarked in a comment on official statements that forbid changing the genome: "It wasn't hard to renounce something that you couldn't do" (Regalado 2015).

2.4 Rule-making on breeding

In this section we reflect on human germline editing as a paradigmatic case of breeding technologies. Human germline editing is a genetic engineering technology which relies on the power of computer technologies. Its development is guided by an informational world view, and the current situation can be characterized by means of the value chain of big data. The grand scale project to digitize the human genome started in 1990. This is the first step in the digital or cybernetic feedback loop which consists of big data collection, analysis and application. In 2001, 90 percent of the complete sequence of one human genome was known. Only fourteen years later, genome editing in human embryos – the third step in the cybernetic feedback loop – has actually occurred. Safety concerns are paramount in the current debate about human germline engineering and in this respect there may still be a long way to go before clinical applications become a real possibility. However, some scientists strongly believe that the technical barriers concerning the safety and efficacy of the new CRISPR technology will be solved in the near future (Bosley et al. 2015; Regalado 2015; Buxton 2016). How should we deal with the new prospects for germline engineering? What rules do we need to tame the breeding of human beings?

Our analysis shows that in considering this question society does not have to start from scratch. Ethics is often said to lag behind technological developments, but in the case of human germline engineering it is the other way around. This is largely because the interventionist view that our genetic techniques and data could one day be used to design human babies has historically played a key role both in the public imagination and in ethical debates on biotechnology. Instead of a lack of rules, we have found two important, and significantly different, ethical perspectives and

regimes that suggest guidelines for using human germline editing: the medical ethics regime and the human rights regime. So in the event that this technology can be made acceptably safe and effective, we can expect an increasing tension between these two different regulatory values and regimes.

The medical ethics regime – with its emphasis on individual consent and parental reproductive choice – will pave the way for clinical applications of human germline editing. For example, Carter (2002) argues if and when human germline editing can be applied safely and effectively, it will be ethically acceptable and morally desirable. Since germline editing aims to alleviate suffering it satisfies the principle of beneficence and will bestow "a great deal of responsibility on the parents of an embryo in deciding whether GLGM [germline manipulation] would provide the best possible treatment for a genetic predisposition" (Carter 2002, 77). Indeed, assuming that the science will continue to progress rapidly, the international Hinxton Group (2015) expects there will also be "pressure from individuals wishing to use the technology for their own medical, reproductive and other needs".

Consequently, the new prospects for germline engineering will increasingly challenge the internationally established human rights and human genome framework, which articulates that no-one can claim ownership of the human genome as an individual (European Group on Ethics in Science and New Technologies 2016). The aims of germline editing do not only concern the rights and interests of individuals from current generations, but also individuals from future generations. In other words, human genome editing raises questions that cannot be dealt with only in terms of medical ethics principles relating to safety, informed consent and individual reproductive rights. In terms of the international human rights and genome framework, discussions about germline editing also need to take into account the human genome as a common heritage. Indeed, as expressed in the concluding statement of the recent International Bioethics Committee's report (2015, 29) on the human genome and human rights, this implies a collective responsibility: "What is heritage of humanity entails sharing both of responsibilities and benefits." This position does not exclude the possibility of germline engineering, but emphasizes the need for proper public and political reflection and engagement (see also Jasanoff et al. 2015).

Thus, in facing the prospect of human germline engineering, the main ethics governance challenge is how to move beyond a rising and antagonistic debate between proponents of individual freedom and choice and communitarian modes of thought. As Berry (2007) points out, debate across incommensurable systems need not be endlessly fruitless: tension between opposed systems can yield productive change. In other words, in decisions about how far we should go in tinkering with the human genome there is a need to strike a balance between the values institutionalized in medical ethics and the international human rights and human genome framework.

3 From big data collection to profiling and persuasive environments

> „[D]ata protection authorities have a crucial role in preventing a future where individuals are determined by algorithms and their continuous variations."
>
> European Data Protection Supervisor (2015, 13) in *Towards a New Digital Ethics*

While genetic profiling, genome editing and germline interventions work towards altering our biological make-up as breeding technologies, digitization is also powering taming technologies aimed at altering our behavior.

In the era of big data the individual is becoming increasingly transparent as a result of the boundless amounts of personal data that are being collected and processed. Online tracking technologies collect detailed profiles of internet users and through social media websites users add even more personal information. And in the physical world numerous smart devices – ranging from smart phones and fitness trackers to smart thermostats, cars and smart public transport cards – are designed to record data on virtually every aspect of our behavior. All these data points can be employed by businesses and governments to infer preferences, anticipate behavior, and personalize environments and information streams. The ever-expanding universe of big data thus powers invisible decisions about the ads and news feeds we see on our screens, how our smart environments interact with us, whether we are suitable for a loan, or whether we might have criminal intents (Manyika et al. 2011; Devlin et al. 2012; OECD 2013).

As such a process of (1) big data collection, (2) analysis, and (3) application emerges, and thus a digital or cybernetic feedback loop is created. In other words, human behavior is (1) read through sensors and tracking technologies, (2) which is subsequently used as the input for data analysis and profiling technologies, and (3) then affects the individual through automated algorithmic decisions, interventions or feedback mechanisms. Central to this process are the profiles that are distilled from big data. Data is abstracted from individuals, matched and mixed with data from other sources and other individuals, and recombined into personal profiles that are used to infer our needs and possible intents. This process of analysis and profiling is not at all transparent and is therefore hard to scrutinize, making it difficult for the individuals to grasp or correct the manner in which they are acted upon by a technological environment. This inscrutability is further exacerbated when the decisions made based upon these profiles are automated through algorithms (cf. Pasquale 2015; Hildebrandt 2012; Kool et al. 2015). So while individuals are becoming increasingly transparent, our technological environment is becoming ever more opaque.

This raises questions as to the extent people are 'truly' able to make autonomous decisions in so-called smart environments, whether the reasoning of smart systems

can be evaluated, scrutinized and corrected, and to whether it is still possible to act without being subject to, and influenced by, profiling. These questions are part of a longstanding and ongoing debate about the societal impacts of information technologies. Historically this debate has a strong focus on privacy, and also relates to individual autonomy. To understand the issues and ethical questions currently raised by big data, profiling and pervasive smart technologies, we first need to understand the history of this debate. From there we discuss how developments in big data and profiling challenge our present ethical and regulatory frameworks. Finally we reflect and briefly look forward on what is needed to address these issues.

3.1 Return of the ethical perspective in the privacy debate

The exponential growth of the data universe has led to vigorous debates about how this data should be dealt with. The lengthy discussions surrounding the proposed European *General Data Protection Regulation* set to replace the *Data Protection Directive* (95/46/EC) provide a clear example. The current debate centers on privacy and data protection as control over personal information and is strongly motivated by economic considerations. Initially however the debate about data was fueled by broader notions of privacy and the idea of privacy as a human right. We will argue that the return of such an ethical perspective within the debate on the societal impact of IT is urgently needed to safeguard human rights and dignity as we move into a hyper-connected digital age.

The Western debate about privacy is often traced back to the seminal article by Brandeis & Warren (1890) entitled *The Right to Privacy*, in which they argued – facing the advent of the 'mobile' camera – it was time to secure to individuals the right 'to be let alone'.[2] Since then, many interpretations and conceptions of privacy have been formulated. No agreed upon definition exists (Solove 2006). Some conceptions emphasize control over the sharing of personal information (cf. Westin 1967), others emphasize the ability to limit access to the self (from others, such as the state), or stress the importance of privacy as a necessary precondition for personhood, autonomy, intimacy and human dignity (DeCew 2015; Solove 2006).

In addition to its value for individuals, scholars have pointed out that privacy is also a public and social value. Serge Gutwirth points to the relationship between privacy and other fundamental values in Western democracies, such as freedom of

2 Solove (2006) explains: The 'right to privacy' was first articulated in response to information technology developments (photography and sensationalist 'yellow journalism') by US Supreme Court justice Louis Brandeis and Samuel Warren.

speech, freedom of association, and the balance of powers (state versus citizens). Privacy is as such a cornerstone of western society, affecting individuals' self-determination, autonomy of relationships, behavioral independence, existential choices and self-development and the ability to resist power and behavioral manipulation (Gutwirth 1998).

While avoiding a fixed definition, the protection of privacy is part of many conventions, treaties, laws and regulations. In the governance of privacy, the Council of Europe played a defining role, being one of the first institutions to put the protection of privacy on the international policy agenda. The Council of Europe was established in 1949 with the goal of strengthening democracy, human rights and the rule of law throughout its member states. Inspired by the *Universal Declaration of Human Rights* (1948), it drafted in the 1950s the *European Convention on Human Rights* in which Article 8 provides a right to respect for one's private and family life, home and correspondence. In the late 1960s the Council established a Community of Experts to advise on the protection of privacy with regards to modern computing advances. Following these efforts the *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* was adopted in 1981. For the first time this provided an international legal text which outlined the basic information privacy principles (Bennet & Raab 2006).

Over the years, data protection moved from the context of human rights, to being intrinsically linked to the promotion of economic activity and the operation of international trade. Digital data started to become more important to business operations because of the rise of the computer. As a result, economics started to drive the privacy and data protection debates and ensuing regulatory frameworks. In the late 1970s a transatlantic conflict on privacy protection and international trade emerged within the OECD. Negotiations led to the OECD *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (1981). These guidelines represented an important consensus on basic so-called "fair information principles", like collection limitation, data quality, purpose specification, use limitation, security safeguards, openness, individual participation and accountability. Adequate data protection was seen as a way to enable the free flow of information. The same type of considerations shaped the European *Data Protection Directive* (95/46/EC) in the mid-1990s. At the time, it was feared that differences in data protection regulation would impede the free flow of information and as such obstruct the EU's internal market (Bennet & Raab 2006).

The *Charter of Fundamental Rights of the European Union* (2000) – building on the *European Convention on Human Rights* (1950) formulates a right to privacy (Article 7) next to a separate right to data protection (Article 8). The right to privacy put forward in the charter is more substantive in nature than the right to data protection

and offers protection against excessive interference in people's private lives and against restrictions on the freedom and autonomy of individuals (Gutwirth & Gellert 2011). This becomes clear from the approach of the Court of Justice of the European Union (cf. Gutwirth & Gellert 2011). Data protection regulations mainly offer procedural safeguards, by defining the rules governing the use of personal data (i.e. fair information principles), but offer no substantial safeguards. For example, a defined purpose for data collection could be so broadly formulated that it can be considered privacy invasive (van Lieshout et al. 2012).

Within the regulatory frameworks of the Council of Europe, the OECD and the EU the dimension of control over personal data, or *informational privacy*, has become increasingly important. The informational privacy perspective offers protection to the individual. Behavioral profiling, however, uses data from individuals to create profiles on a group level. Group profiling largely escapes the scope of data protection regulation because the profiles contain aggregate data that are not related to a specific individual. Such profiling can however have far-reaching effects on individual privacy when the individual is matched to a specific profile (cf. Citron & Pasquale 2014; Zarsky 2013). For instance when an individual matches the group profile of a criminal or a potential deviant, this will evidently affect how she will be treated. Big data, profiling and the emerging 'Internet of Things' urgently show that the debate about privacy and how to protect it, should again be informed by a wider perspective that accounts for broader notions of privacy as well as values such as autonomy. In a recent opinion the European Data Protection Supervisor (2015, 4) stressed the importance of privacy for the protection of human dignity and stated that: "In today's digital environment, adherence to the [data protection] law is not enough; we have to consider the ethical dimension of data processing."

In the next section we describe how advances in big data, profiling and the Internet of Things challenge our current conceptions of privacy and autonomy, and urge us to rethink how these values are to be protected in a digital age. The two trends outlined above – individuals becoming ever more transparent, while our digital smart environment is becoming ever more opaque – structure our discussion.

3.2 The transparent individual

The increasing transparency of the individual results from two developments: (1) the pervasive application of sensor technologies throughout our everyday environments; and (2) the fact that all the data collected can be analyzed by increasingly sophisticated technologies, capable of revealing patterns and predicting attitudes, emotions or behavior.

In the past two decades numerous surveillance technologies have penetrated our life-world (Strand & Kaiser 2015). First of all, legitimated by fear of terrorism, the reach of the surveillance state has expanded enormously. At the same time, a big-data business culture has developed in which industry seems to take for granted, in the name of efficiency and customer convenience, that people can be treated as data resources. This commercial surveillance culture has come to flourish in the virtual world, where businesses have grown accustomed to follow every user's real time Web behavior. With the advent of the Internet of Things this culture of surveillance may well penetrate the physical world. The pervasive use of sensor-equipped technologies is already colonizing personal space to an unprecedented degree. Think of wearable fitness armbands that people use to keep track of activity patterns, heart rate, and stress, e-readers that track peoples reading speeds and habits, or smart home devices that can track TV viewing habits, energy expenditure patterns, food consumption patterns, and even assess moods[3]. As a result more and more actions in the physical world are becoming digitized and therefore traceable and trackable, thus creating the possibility of an environment in which no action goes unmonitored.[4] Big data analysis may make the individual transparent, since even mundane data points can reveal interesting facts about a person. A person's gait, for example, can be analyzed to uniquely identify him or her, or to predict the future risk of cognitive decline and dementia in older adults (Verghese et al. 2007). The behavioral data gathered through smart devices can reveal far more than just our daily patterns and activities. Predictions can potentially be made about mental illnesses, health, or even if partners might get a divorce (Mayer-Schönberger & Cukier 2013; Matheson 2014; Ciarelli 2010).

To grasp the effect of such an panoptic environment we need to look beyond the narrow concept of informational privacy. Much has been written about continuous monitoring and the effects of surveillance (cf. Lyon 1994). Several authors have suggested that continuous monitoring can have deteriorating effects on the development of identity, individual self-determination, and agonistic opinions fundamental to the functioning of democracy (Schwartz 1999). Westin (1967) states that when individuals know their actions are constantly being monitored, they find it much harder to do anything that deviates from accepted social behavior. This is also knows as the 'chilling effect' of surveillance. Rule et al. (1980) explain that informational privacy and data protection do not provide an adequate framework to deal

3 EmoSpark AI home console (http://emospark.com).

4 It is important to note that there are discrepancies between different parts of the world. In the western world, the opening up of the self is to some extent voluntarily. State initiated projects in for example China and India raise different surveillance issues.

with these types of questions since they only produce fairer and more efficient use and management of personal data, but cannot contain the ever widening collection of data on individuals. This raises questions about the continuous monitoring that smart environments may introduce, and how to deal with their possible detrimental effects.

Face and emotion recognition technologies provide an interesting example. They extend the abilities of technical systems to analyze people and better adapt their actions to our states. But they might also erode a person's ability to keep her thoughts and feelings private. Through analysis of facial expressions and nonverbal communications accurate predictions can be made about a person's emotional state, such as whether someone is nervous, happy, or telling a lie. Current face reading technology can already distinguish authentic from false expressions with an accuracy of 85 percent, while humans average 55 percent (Andrade 2014). According to Andrade the freedom to not tell the truth 'is an essential prerogative of our autonomy as human beings'. He argues that technology undercuts our autonomy when it takes away the choice to tell the truth or to refrain from showing our true emotions. In this case, developers and customers assume that there is a 'truth' that can be measured and analyzed through technology, while 'truth' is a concept that is often subject to multiple interpretations. If such an assumption becomes widely shared, it would according to Andrade, undermine the ability of people to refrain from telling the 'truth', which is considered a vital part of our social interactions, like when people tell a white lie just to be nice to others.

Technology can thus reveal things that we don't want to reveal ourselves. More than infringing on our personal space, technologies that analyze our social and emotional behavior can be argued to infringe on our mental and psychological space. Boire (2004, 5) therefore calls for cognitive liberty: "Cognitive liberty is civil rights for the mind, a legal protection for what and how you think, whether you express your thoughts or not. In many ways, this aspect of cognitive liberty follows from what Warren and Brandeis articulated over 100 years ago: privacy includes a right to psychological integrity."

Accordingly, several privacy scholars have argued that our concept of privacy should also include privacy of thoughts and feelings. Finn et al. (2013, 5), for example, would like to see that "People have a right not to share their thoughts or feelings or to have those thoughts or feeling revealed." Although the academic debate on privacy is responding to the new ethical dilemmas that arise because of technologies that increase the possibilities of companies and governments to analyze and infer our thoughts and feelings, the attention for this within the regulatory arena, with its focus on the narrow concept of information privacy, is still rather limited.

3.3 The opaque smart environment

While the individual is rendered increasingly transparent, the ability to understand and scrutinize the calculations and analysis performed in the intelligent technological systems around us becomes increasingly problematic. The digitization of behavior has led to the fact that people are represented by countless digital profiles in the databases of social media sites, search engines, smart devices, governments, data brokers, stores, marketing agencies, et cetera. These digital collections of data points can be endlessly shared, recombined, and analyzed beyond our control. French philosopher Gilles Deleuze (1992) describes how in the context of digital technology, we have gone from being individuals – irreducible and indivisible entities – to in*dividuals* that can be digitally divided and subdivided endlessly.

Zarsky (2013) argues that the lack of control and transparency of these processes of analysis and application could pose a serious threat to our autonomy. Because a person is not aware of the profiles that are being applied to him, it is impossible to scrutinize how they shape our lives. This could lead to a so-called 'autonomy trap' where a person is steered by the smart environment to act in ways that he or she wouldn't have chosen otherwise. Hildebrandt (2015) adds that a future smart environment might even detect a latent disposition of which a person is not even aware and adapt the environment accordingly, thereby undercutting her ability for conscious reflection on her behavior. She asserts that although our behavior is largely determined by automated cognitive processes, our ability to call them into conscious reasoning and reflect and review them, is what turns us into autonomous agents who are capable of living by their own law, and who can be held accountable for their actions (Hildebrandt 2012, 43). The fact that the automated algorithmic decisions made by technological systems operate outside of our ability for conscious reflection undermines our ability, to object, reflect or reject those computer decisions, and as such corrodes our autonomy within these smart environments. The Facebook experiment in which the number of positive and negative messages in user's news feeds was manipulated provides an example of how changes in algorithms can influence peoples moods and behavior without their conscious awareness (Kramer et al. 2014).

An example of a current smart environment that aims to steer social behavior is the nightlife street Stratumseind in the Dutch city of Eindhoven (Kist & van Noort 2015). As part of the experiment called *Stratumseind 2.0*, the street has been equipped with a wide range of sensor technologies. Cameras detect deviant behaviors of individuals or groups of people, microphones monitor for spikes in sound that suggest aggression, social media traffic is monitored, and through ambient light feedback the people on the street are nudged to act in accordance with the rules of the nightlife street. While the municipality's intentions are likely honorable, such

intricate technological systems that operate and make decisions in the background, are opaque and hard to criticize or object to. For instance when a person is flagged by algorithms for possible deviant behavior, the affected person has little way of knowing why his behavior triggered a certain response.

Citron & Pasquale (2014) use the example of automated credit scoring systems to show how people judged by automated algorithmic systems have very limited possibilities neither to assess whether that judgment was correct nor to object to it. A credit score is based upon data from multiple sources, through an opaque process in which the different inputs are rated to arrive at a single credit score. While an algorithmic system might provide a seemingly objective 'score', prediction or profile, these systems are never neutral and can contain serious biases. A study by Carnegie Mellon University, for example, found that male job seekers were much more likely to be offered Internet ads for high profile executive position than equivalent female job seekers (Datta et al. 2015). The researchers could not determine what caused the discrimination due to the limited visibility of the workings of the ad-ecosystem. Dormehl (2014) cites the example of US resident John Gass, who had his driver's license revoked by an automated facial recognition system that had wrongly flagged his driver's license as a fake id. The Registry of Motor Vehicles claimed it was the individual's responsibility to clear his name in the event of a mistake and argued that the advantages the system offered in protecting the public, far outweighed the inconvenience to the wrongly targeted few. These two examples highlight the opaqueness, the risks of systemic bias and error, and the disempowered position of the individual in relation to algorithmic systems.

In its study *Big Data* (Podesta et al. 2014) the White House stresses the importance of preserving core values, including privacy, fairness, non-discrimination and self-determination. Citron & Pasquale (2014, 6) state that "If scoring systems are to fulfill engineering goals and retain *human values* of fairness, we need to create backstops for human review". As part of the coming European *General Data Protection Regulation*, data controllers will be obliged to inform individuals about the existence of profiling and its envisaged consequences, and individuals will have the right not to be subjected to automated decision making in case it has significant effect on their lives.[5] This could provide important protection for the individual but will only work when a sociotechnical infrastructure of tools and mechanisms to deliver meaningful transparency is developed. Furthermore, algorithms and profiles are often protected by means of trade secret or intellectual property that might hamper these transparency

5 Council of the European Union, *Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) – Preparation of a general approach* (9565/15, 11th June 2015).

enhancing rights (Hildebrandt 2012; 2015). Hildebrandt (2012) argues transparency enhancing tools (TETs) should be developed to inform people of how they have been profiled by smart systems around them, and what the consequences of this profiling are. For instance, the people subject to automated credit scoring, or automated online talent scouting should be informed of the way different data points of their distributed online identities have resulted in an automated software agent making a certain decision. In his visionary work on computing in the 21st century, Weiser (1991) remarked "The most profound technologies are those that disappear. They weave themselves into the fabric of everyday life until they are indistinguishable from it." As technologies in the age of the Internet of Things move more and more into the background, designing meaningful transparency mechanisms might prove a big challenge. Nevertheless, such transparency mechanisms seem to be essential to protect human autonomy.

3.4 Rule-making on taming

In this section we reflect on rule-making on persuasive technologies as a paradigmatic case of taming technologies. Persuasive technologies are information technologies that aim to influence human behavior. Therefore, we placed the upcoming debate on smart persuasive environments in the tradition of the longstanding discussion on the impact of IT on data protection, privacy and autonomy. We will use the value chain of big data – the digital or cybernetic feedback loop which consists of big data collection, analysis and application – to get to grips with the current situation.

In a nutshell, we argue that in the 1960s and 1970s, the debate focused on data collection and control over personal data (informational privacy). In the 1980s and 1990s there came more attention for data profiling and privacy concerns (cf. Vedder 1998). Today, however, data profiling and the way it is used to intervene in the lives of people, and applied to steer people's behavior, demands our full attention. This realization that the cybernetic loop has come full circle forces us to acknowledge that, besides control over personal data, people need control over how smart environments shape their behavior.

This chapter described two main trends: individuals are becoming ever more transparent, while at the same time our digital smart environments are becoming ever more opaque. The first trend relates to the process of data collection and makes it harder, or even impossible, for people to control their personal data. The second trend refers to the increasing role played by big data profiling and smart feedback environments, and the fact that their opaqueness hampers people from even seeing how they are being influenced. Both trends lay bare weaknesses of current regulatory

frameworks and force us to look for a new balance between economic development on the one side and safeguarding individual human values, like privacy, autonomy and equal treatment, on the other.

Need to control personal data

In the 1960s and 1970s, sensitivity to privacy in Europe and the United States increased among citizens and politicians. The issue at stake was the digital registration of personal data, which was mainly collected by manually filling in forms. As we saw, a call for the protection of privacy caused rules to be debated and created, on national, regional and global levels. On the one hand, the human rights perspective plays an important role in those rule-making processes. In this respect, the *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* as organized by the Council of Europe in 1981, has historically been quite influential. This convention framed privacy in terms of informational privacy. In order to protect personal data in practice the fair information principles were formulated with regard to the collection and processing of data.

This perspective informed the OECD and EU frameworks, but information privacy was not the only perspective influencing them. Namely, during the 1980s data protection became intrinsically linked to the operation of international trade. Both the OECD and EU frameworks tried to strike a balance between economic values (free flow of information between states in order to optimize international trade conditions) and the human rights perspective on privacy.

As individuals become ever more transparent, the aim of the above regulatory frameworks to control personal data is becoming more and more unreal. A first weakness concerns the limited enforceability of data protection rules in a global political economy. Recent rulings, however, such as the rulings of the European Court of Justice on 'safe harbour' in October 2015 (C-362/14), and on the territoriality and applicability of EU rules to a search engine in May 2014 (Google Spain SL, Google Inc. v. Agencia Española de Protección de Datos, Mario Costeja González, C-131/12) – show that EU data protection laws can be enforced. Besides, there is the growth of a generic surveillance culture, where not only states employ surveillance technologies on a massive scale, but also firms and citizens. From a technical point of view, we have witnessed an immense growth in the ways people can be monitored: from geolocation to recognizing emotions. These new technologies require us to think about how we can secure and protect privacy of thoughts and feelings, which are essential to be able to autonomously develop our identities and our relationships with the world around us. Finn et al. (2013) describe new types of privacy for the information society, such as privacy of personhood, privacy of thoughts and feelings, and privacy of location and space. Securing protection for

these 'new' dimensions of privacy presents a big socio-cultural, political and regulatory challenge.

Need to control profiling and smart environments

Profiling and the rise of smart persuasive environments challenges our privacy and autonomy at an even more fundamental level. Namely, current data protection frameworks have focused on data collection and the fair use of data and are led by the fair information principles to safeguard privacy. At the time these principles were articulated the virtual world was seen as a rather inactive add-on to the physical world. Over time these principles have been examined and found to be still valid for a future of new technologies and globalization (Article 29 Data Protection Working Party & Working Party on Police and Justice 2009). Nevertheless, nowadays the offline and online worlds have merged, forming an on*life* world (Floridi 2015); in other words IT has changed from being a tool to becoming a defining characteristic of our lives. Moreover, the IT system has become a cybernetic system, and has assumed a kind of artificial agency. As a result, smart environments powered by big data-driven artificial intelligence, provide many ways of profiling people and subtly steering their behavior. The consequences of this radically new situation for human rights like privacy have not yet been given enough attention in public, political, ethical or human rights debate, let alone been well thought-out.

Profiling forms one challenge, since current regulatory frameworks on data protection are designed to offer protection at the level of the individual, while profiling technologies tend to operate on a group level. An important regulatory challenge, therefore, is how protections can also be designed on a group level. Secondly, non-transparent smart environments raise fear for the Kafkaesque scenario of a seemingly arbitrary smart environment that interferes with our preferences and anticipates our behavior. Above we have argued that if we are not able to find mechanisms to increase transparency and control over automated profiling and decision making software agents, we might find ourselves in an 'autonomy trap'. Finally, the value of equal treatment may be under threat. Therefore, policy makers need to think about ways to prevent discrimination and exclusion in the on*life* world.

Need to update the ethical debate

Amongst scholars there is discussion whether current regulatory frameworks are able to safeguard our human rights in this digital era. The new European general data protection regulation aims (amongst other things) to strengthen individuals' rights, and strengthen responsibilities and accountability for those that use and apply personal data. The arrival of the on*life* world challenges us to move beyond the current concepts of data protection and informational privacy, to a broader perspective

which takes into account values like autonomy, fairness and human dignity. But before regulatory frameworks can be adapted, there first is a need for an ethical debate amongst companies, scientists, NGOs, governments and politicians. Just like in the 1970s, the ethical and human rights community should take leadership and start to develop this highly needed broader view on smart environments and privacy informed by fundamental human rights and values.

4 Rule-making for the digital human park

Inspired by Sloterdijk's (2009) wake-up call at the end of the last century, this paper reflects on the "rules for the maintenance of the human zoo". Since digitization (of human life) plays a central role in our society it is fair to say that we live in a *digital* human park. This digitization process is guided by an informational worldview, and constitutes of a myriad of cybernetic feedback loops that consist of measuring, profiling and intervening in humans. NBIC convergence strongly increases the measurability, analyzability and make-ability of human life. Related to this, the collection, analysis and application of big data plays a major role in the way we domesticate ourselves.

The digitization of human life has developed to such an extent, that we are challenged to develop a conscious politics of breeding and taming. To study how man so far has dealt with this challenge, we researched human germline editing and persuasive technology as two paradigmatic cases of breeding and taming technologies, respectively. In this concluding chapter, we first reflect on the two cases and conceptualize rule-making on breeding and taming as an ongoing balancing act between individual and collective values. We also put forward the question of where, in a world in which humans are becoming more and more intimate with machines, the human self is located, and related to this where human rights should be located.

4.1 Global incoherent regulatory patchwork

A first conclusion may be that the role of technology in the breeding and taming of people has neither gone without ethical reflection nor public and political debate. Over the last half a century the debate on designer babies and IT and privacy has been on the public radar almost continuously. New technological breakthroughs in the field of biotechnology (ranging from rDNA, cloning, gene sequencing and synthesizing to CRISPR), and information technology (ranging from data storage, sensors, mobile phones, machine learning and face recognition) over and over light up

these debates in the media, as well as among citizen groups, artists, and technical, ethical, legal and policy experts.

Moreover, to a certain extent a conscious breeding and taming politics can be discerned. In other words, rules for the maintenance of the human park are being debated and created, both on the national, regional (e.g. European) and global level. With respect to rule making at least three layers can be distinguished: basic human rights, legal instruments, and social and cultural rules. There is a complex interplay between those levels. For example, in the field of IT and privacy the *Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data* (1981) organized by the Council of Europe drafted the fair information principles, which could be used as a kind of moral template by the OECD and the EU to set up more binding regulatory frameworks.

At the beginning of their study on the global governance of privacy, Bennet & Raab (2006) outlined four possible visions of privacy: the surveillance society, an incoherent and fragmented patchwork, a world of privacy haves and have-nots, and a trading-up to global privacy standards. At the end they conclude that the second scenario is the most plausible: "a more chaotic future of periodic and unpredictable victories for the privacy value as the spotlight focuses on a particular practice for a brief period and then moves on" (Bennet & Raab 2006, 295). The same counts for the global governance of human genome editing. Sparked by new developments, like IVF, embryonic stem cells and reproductive cloning, there have been various waves of legislation. This has resulted in the current regulatory mosaic, where in some countries, experimenting with embryos is a criminal offence, whereas in others almost anything is allowed (Ledford 2015). So although a conscious breeding and taming politics can be discerned at the level of nation-states, it so far results in a rather fragmented patchwork of policy instruments and governance structures. As a result, the rules that exist on a national or even regional level only have limited enforceability in a global political economy.

4.2 Rule-making as a balancing act between values

In the debate on human germline editing and persuasive technology a complex set of values plays a role (see Table 3). Rule-making requires thoughtful balancing between these different individual and collective values and the related interests of different actors. If we consider values as drivers of a certain socio-technological development, some values may be denoted as accelerator values that legitimize a certain development, while other values act more as brake values that are used to legitimize slowing down, setting the conditions for or even banning a certain development.

Human germline editing: Unsafety favors the brake values

In the debate on human germline editing, safety plays a central role. There is consensus among scientists that this technology is not yet safe enough. Preventing harm is an important value and the current risks involved clearly hamper the application of human germline editing, but also favors other brake values in the current debate. One influential view – see for example UNESCO *Universal Declaration on the Human Genome and Human Rights* (1997) – claims that the human genome should be seen as part of the common heritage of mankind and should not be commercialized. The child's right to self-determination or an open future is another, both individualistic and collective, value that is often used to oppose human reproductive cloning and human germline editing. These values conflict with the individual right to procreate and the parent's right to reproductive freedom.

So far, the notion of the human genome as a common heritage of humanity dominates the human rights perspective on designer babies. New technological breakthroughs like gene editing are used as windows of opportunity to reinforce the importance of that collective value. For example, the UNESCO International Bioethics Committee (2015) called for a temporary ban on genetic editing of the human germline. Some actors will agree with this view for pragmatic reasons: to avoid that the debate on banning human genome editing might lead to a ban on research. Without such a ban on research, the technologies needed to genetically engineer human embryos will further develop. It is therefore imaginable that once it will be technically possible to safely genetically engineer human embryos. Such a situation will really bring the conflict between the brake and accelerator values, as summed up in Table 3, to a head.

Persuasive technology: The need for striking a new balance

Exactly that has been the case in the field of IT and privacy since the early 1980s. Before that time the human rights perspective on privacy reigned supreme. But afterwards there was a pragmatic need within the OECD and European Union for a balanced consideration of both economic development as a collective value and privacy as both a collective and individual value. The rise of smart persuasive environments asks for a new balance. This requires us to rethink and conceptualize anew what we mean by privacy and how it can be safeguarded. The fair information principles, which stem from a period with manual collection and automatic processing of personal data, are no longer sufficient to deal with the real-time collection of data via sensors and smart environments. The agency and opacity of smart environments force us to move beyond informational privacy, and look for ways to control how these environments not only collect data, but also profile us and steer our behavior.

Table 3: Overview of various values that play a role in the debate on human germline editing and persuasive technology as paradigmatic cases of breeding and taming humans		
Type of human domestication	**Individual and collective values as drivers**	
	Accelerator values	**Brake values**
Breeding of humans (human germline editing)	• Safety • Individual right to procreate • Parent's right to reproductive freedom • Economic development • Freedom of inquiry	• Risk • Human genome as common heritage of mankind • Child's right to self-determination or an open future • Avoiding commercialization of human genome
Taming of humans (persuasive technology)	• Economic development • Public security • Convenience • Empowerment	• Informational privacy • Autonomy/self-development/personal freedom • Fairness • Privacy as a collective value

4.3 Machines in humans, humans in machines

> „Rather than opening up practices of the Self, allowing individuals to shape their own lives, Big Data repositories providing reference data (standards for normality) become an electronic panopticon, a molecularised super-ego, the 'voice of conscience' of the terabyte age, the Big (digital) Other."
>
> Hub Zwart (2015) on 4th May 2015 in Strasbourg, France

The case studies showed a marked difference in the way we deal with human germline technology versus persuasive technology. Although the technology to genetically engineer human embryos is far from being mature or safe, the interventionist view – the view that our genetic data could one day be used to design human babies – has for long played a key role in the public imagination and ethical debate on biotechnology. Decoding the human genome – the first step in the cybernetic loop – is directly linked to the possibility of intervening in the human genome. Or as the transhumanist Gregory Stock bluntly argues: "We have spent billions to unravel our biology, not out of idle curiosity, but in the hope of bettering our lives" (quoted in Garreau 2004, 115). In contrast, the focus in the field of IT has historically been on the collection and processing of big data. And only recently is it being realized that the interventionist view – using data profiling to intervene in human behavior – has to be taken very seriously. So what explains this difference between the way we debate and make rules concerning breeding and taming technology?

This relates to two separate ways in which breeding and taming technologies merge with human beings. Breeding technologies, like human germline editing, intervene in the human body. DNA technologies are invasive technologies that work *inside* the body. Here machines and humans merge in a classical way: technology is put into humans. Although in the field of artificial intelligence, human-machine symbiosis has been prophesied since its beginnings (cf. Noble 1997), this phenomenon so far has not played a significant role. Information technologies were seen as mere gadgets that operate as human tools *outside* the body. We seemingly did not realize that by digitizing human life we were putting humans into machines; by filling in databases we constituted "an additional self" (Poster 1990). Gelernter (1993) used the term "mirror world" to describe this process: the collection of digital representations or profiles of our physical body and behavior in the real world that can be found in the virtual world.

These digital mirror copies provide reference data of who we are and what we might become and provide reference data about what is normal or absurd, good or bad, beautiful or ugly, strong or weak genetic make-up. The digitization of human life thus shapes how we see ourselves and others and the way we behave. By putting humans into machines, we have become "subjects of the normalizing gaze of the Superpanopticon" (Poster 1990, 97f.). Since our digital profiles are stored in the databases of governments, medical centers, social media sites, search engines, marketing agencies, data brokers et cetera, we have become potentially more transparent to ourselves and many others. Our additional digital selves do not belong exclusively to us, and are to a large extent beyond our control; they may empower us, but may also work to our detriment.

4.4 Human rights enhancing machines

> „Machines are my posse. They are my machines, my body. Machines serving me should be a civil right. Now the machine is serving Google."
>
> Dave Ackley (2015) on 8th October 2015 in Leiden, The Netherlands

We conclude that a conscious human breeding and taming politics indeed is required. To a certain extent such a politics can be discerned, but so far has led to a fragmented patchwork of policy instruments and governance structures. There is a clear need for moral guidelines on the global level that may not be enforceable, but may guide national efforts to steer developments in the field of human germline editing and persuasive technology. We agree with Greely (Regalado 2015), who

said that it is not hard to renounce human germline editing when it still unsafe. But when this technology becomes almost a hundred percent safe, the voice of the proponents will become much louder. Smart persuasive environments are already working around us and force us to strike a new balance between economic development and privacy. Whereas human germline editing is an example of putting technology into humans, persuasive technology is an example of putting humans into technology. We need to understand that both types of human-machine interaction are in need of careful ethical guidance. This was taken for granted for biotechnologies (biology becoming technology), but also applies to intimate information technologies (technology becoming biology), especially when they seek to steer our behavior.

Finally, the ongoing merger of human and machine raises the profound question of where the human self is located (cf. Lyon 1994, 18). This question is relevant because by definition human beings hold human rights, and not machines. But as humans and machines grow increasingly intimate, it becomes harder to assess the limits of the human body and of the self. Accordingly, it becomes harder to determine the boundaries of the human subject which holds human rights. If we put technology, such as deep brain stimulation electrodes or DNA, into our body, does it become part of ourselves? And does safeguarding our bodily integrity also apply to those technologies? It is easy to imagine that in the case of deep brain stimulation bodily integrity as a human right belongs to the human being, including the electrode. But what if that electrode is connected to the internet? Or similarly, what if we put more and more intimate digital data of ourselves (body, brain and behavior) into machines?

We should take very seriously the fact that through these processes we are creating additional selves. This raises the question whether these digital selves should be considered part of the human self, and therefore should hold human rights? What does this imply for safeguarding human rights and where should such safeguarding take place? Academics in the privacy field plea for designing privacy into smart systems. Recently, this idea has become a more prominent issue on the agenda of policy makers. According to Klitou (2014, 263) the premise behind privacy by design is that it is "likely more effective to enforce laws/rules at the manufacturer/design-level, as opposed to the user-level". Privacy by design, or privacy enhancing technology, is an example of the broader concept of value sensitive design, which tries to take account of all kinds of relevant human values, including basic human rights, when designing technology. Maybe one day it will be a basic human right to be served by machines that enhance human rights.

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Annex: Concept paper for emerging and converging technologies

Emerging and converging technologies in the biomedical field challenge national ethics committees (NECs) to anticipate, identify, and find ways of responding to or managing the ethical issues that arise from these complex technological innovations and convergences, many of which have implications for human rights and human dignity.

The Council of Europe's recently published *Report on Ethical Issues Raised by Emerging Sciences and Technologies* (2015) provides a useful model for reflection and moving forward. The report frames the main issues and ethical concerns and then uses the notion of 'paradigmatic cases' to work through the implications and ethical concerns of specific technologies.

Two broad types of technologies are increasingly identified by NECs as needing attention: big data and germline interventions / human genome editing. The Global Summit paper would use these two broad types of technologies as paradigmatic cases of emerging technologies with each discussed in turn against the background of a broad view on emerging ethical challenges through technical innovation.

While the main purpose of this paper is to provide NECs with an up-to-date background of the issues and how they may be approached, a secondary purpose is to move towards recommendations/points to consider on these two – and perhaps other – technologies. The paper should be only as technical *vis-à-vis* the specific science of each technology as is necessary in this paper for the Global Summit of National Ethics/Bioethics Committees. The paper should be of interest to NECs from developed, transitional and developing countries.

Some of the specific points that would be useful for NECs and should be incorporated include:

- What are the implications of big data for health interventions and delivery? For the relationship between patients and physicians? For society in general?
- What are the implications (current and in the future insofar as we can imagine them) of germline interventions / human genome editing? What are the potential benefits and what are the risks of CRISPR-Cas9 techniques?
- What are the ethical and also legal implications of altering human genomes?
- What ethical guidance and policies/opinions/laws have been, and which should be developed to foster advantages and avoid disadvantages of emerging technologies?
- Are current consent procedures adequate?
- When is encouraging restraint the desirable ethical approach and when does it overly restrict innovation?
- Which features are necessary to make governance mechanisms sufficient? Are there examples from countries?
- Considering the global dimension of the issue, there is a need for guidelines and regulation on an international level. What aspects should be considered in reaching such an agreement?

>> SESSION II: EPIDEMICS AND OUTBREAKS

Session Summary

The WHO Guidance for Managing Epidemic Outbreaks
Aissatou Touré

Why Communication? The Lessons Learnt from the MERS Epidemic in South Korea
Sangeun Park

Ethical Aspects Presented by the Advent of the MERS-Co Virus Outbreak
Imad Aljahdali

Discussion Paper
WHO Ethical Guidance for Managing Epidemic Outbreaks
WHO Global Health Ethics Unit

Ritva Halila (Session Chair), Aissatou Touré, Sangeun Park and Imad Aljahdali (from left to right)

Session Summary

|| Epidemics and trans-border illnesses were at the focus of the second round of contributions. Aissatou Touré from the Institut Pasteur in Dakar, Senegal initially introduced the WHO's new ethical guidelines for dealing with epidemics, which also emerged in reaction to the Ebola crisis. "From Ebola, we learned that we need fundamental guidelines on how we should deal with the outbreak of such illnesses", said Touré. Up to now there have been such documents only for certain pathogens, such as the flu virus and HIV. Touré described how the new WHO guidelines were worked out over several years in an intensive coordination process and also explained the key messages. "What we identified as the most important factor in dealing with epidemics is a structured approach", she emphasised. Correspondingly, alongside the requirements for an adequate and ethically based health service, the 14 guidelines focus above all on the role of research and the responsibility of governments and the community of nations towards those who stand on the frontline in fighting epidemics. The paper also responds, according to Touré, to the needs of especially vulnerable groups and to dealing with biological samples in technically quite-diversely equipped states.

In his co-presentation, Sang Eun Park from the South Korean National Bioethics Committee went into more detail on three guidelines from the new WHO document, which deal with ethical demands on local and national governments as well as international organizations and with communication of risks during an epidemic. By example of the spread of the MERS virus in South Korea, Park pointed out how serious the consequences of inadequate or delayed communication can be. They not only contributed to the more rapid spreading of the virus, but also led to trust being lost in public authorities. South Korea has learnt from the mistakes in the meantime and introduced initial steps for improved risk communication. Imad Aljahdali from the National Committee of Bioethics of Saudi Arabia likewise reported on experiences

with the MERS virus, which began to spread from the Arabian Peninsula in 2012. Since 2014 there has been a "command and control centre" that can immediately send a rapid-reaction team in situ and that is committed especially to providing current and transparent information to the populace and to those persons working in health professions. Aljahdali emphasised the importance of good communication by doctors and researchers, also over social media. With a view to the researching of epidemics, he spoke sharply against attempts to patent virus sequences and related biological information.

In the quite lively subsequent discussion, many delegates expressed their approval for the need for action identified by the speakers. In combating epidemics, it is necessary to make advances in transparent communication, fair and rapid sharing of relevant samples and data and quite generally in the building up of trust. In the process it has also become clear that precisely poorer states with already scarce resources in these areas are reliant on international aid. ||

The WHO Guidance for Managing Epidemic Outbreaks

Aissatou Touré

|| We are presenting to you a draft of ethical guidelines that have just been devised by our team and we need a lot of feedback so that we can come up with a more refined document that meets everybody's expectations.

First of all, let me explain how that procedure was realized. Perhaps you still remember the Ebola crisis. It had its peak in August 2014. This was also the time when many questions emerged regarding, for example, new treatments, methods that were not validated or tested yet. The WHO then established a working group on ethics. This group was to ponder the ethical questions related to the Ebola outbreak. A number of documents were published by this working group.

At a meeting in Geneva, the working group took stock of what they had done. And on that occasion, they found out that in the case of Ebola there had been some overarching ethical questions that had already been relevant for other pandemics as well, but there were also some differences. What happened with Ebola is that it caused a lot of transformation. Many things that people had taken for granted suddenly appeared not to be applicable any more, and this raised a number of questions.

During that very important conference, we gave a presentation and we talked about the lessons to be learned from Ebola. One of the conclusions that came out of this was that we need guidelines, general guidelines, on how to deal with epidemics and such outbreaks, so that we do not have to devise specific documents on a case-by-case basis. Such documents do exist, for example for Influenza, as published by the WHO, and also for HIV. What we wanted was to have a more long-term approach and a more general document that could be applied to different kinds of diseases.

This first working group was also supported by a number of other experts who first came together in Dublin. During that first meeting, the intention was to first of all review existing guidelines. There were already a number of guidelines in Europe,

in the United States and internationally, and it was Carl Coleman who first tried to get an overview of everything that was already in place.

We then had a second meeting and based on Carl's ideas, we discussed what could be the substance of these guidelines. This is of course quite a difficult task. We spent two to three years working on these guidelines. Then we published a document which was to be rather general, so that people would be able to adapt it to their respective situation, but at the same time, we also wanted it to be specific to a certain extent. We also established a drafting committee at some point because we realized we needed to have more of a debate and agreement on wording and to make sure that we include all the suggestions coming from different sources.

We then tried to compose a final draft. We wrote an introduction, presenting the key issues and questions to be answered. That was not an exhaustive list, but it enabled us to focus on some issues. We then tried to deal with some questions that matter in relation to epidemics, and we then chose three areas to work on. Of course you might ask whether this was the right choice, but in the end we had to make a decision and get to work. We tried to get some order and structure into these guidelines, and we did have to change the sequence and order on several occasions. We always thought that the first mentioned guideline must also be more important than the others. But we found out that this is not in fact true. They are all equally important. It is just that you have to choose one guideline with which to start.

What we found most important when it comes to dealing with epidemics is to have a structured approach. So, we decided that the first guideline should be on adequate public health and health system response in line with ethical principles. We then addressed a second very important issue for epidemics management: research during epidemics. We collected a number of comprehensive questions that were related to the healthcare system and to research.

We believe that national governments and the international community have a very special responsibility, because we believe that the principle of solidarity is the key, especially in the case of epidemics. Epidemics do not stop at country borders and therefore there is a necessity to act in unison. In our document, you find a list of obligations and responsibilities. Especially vis-à-vis those who work in the field of health: the response workers, the healthcare workers. We are saying very clearly that this is not just about doctors, physicians, and nurses, but that this is about all people taking an active role in combating the disease. This might also be aid workers, cleaning staff, or the people involved in organizing the funerals of the deceased.

Then, in chapter two, we address the topic of the local communities, as you cannot contain an epidemic if you do not work with the local people, if you do not communicate transparently. Often in those countries where we see epidemics outbreaks, the resources are already under strain, and that strain becomes even more severe in

a crisis. Somebody needs to make a decision how resources are to be allocated and sometimes that is quite a dramatic choice.

We talked about the different conditions and situations where ethical questions need to be considered. We wanted to make sure that certain vulnerable groups receive special attention and we wanted to be sensitive regarding sex and gender. Because we know that in times of epidemics, there is very often increased pressure, for example, on women. At least in our countries, it is mainly women who look after ill people. Accordingly, this document lays down some principles concerning women.

We are also trying to address which ethical questions matter in more general terms, and not only in a situation of crises or epidemics. We are not only relating our guidelines to bioethical research, but we also relate them to economics, social sciences, or biomedical research. We would like to see ethical principles considered in all of these areas. If that does not happen, there might be new problems.

In times of crisis, you need to respond very quickly. You need to build up capacity, and, as a matter of fact, you also need ethics committees that have enough resources and capacity to deal with the challenges. But then, there is another issue as well. How can you strike a balance, if, for example, the drugs at play are not sufficient? Research has to play a role in this, and our guidelines here are directed at or addressed not only to the people managing the epidemic, but also to those doing the research and doing their specific work. It is very difficult here to draw a line between research, surveillance, and public health monitoring.

As a next step, we looked into issues that are related to particularly vulnerable groups. We then dealt with issues of gender. Another question concerned the transfer of data and how to deal with biological specimen: how to collect and store them. There are countries that do not have the capacity to store specimen in their own country. This in itself brings up further ethical questions and difficulties. We ended by discussing other issues that were very controversial. These questions are presented throughout the document, at the beginning of each chapter. We very much welcome feedback on them. ||

Why Communication? The Lessons Learnt from the MERS Epidemic in South Korea

Sangeun Park

|| The lessons learned from the MERS epidemic in South Korea is the topic of my speech. I will focus on public ethics and risk communication in the emergence of an epidemic which are related to WHO guidelines No. 1, 2, and 13. No. 1 is the "Obligations of national governments and the international community", No. 2 regards "Community engagement and communication plans" and No. 13 deals with "Rapid data sharing".

Table 1 of my presentation shows that there had been 186 MERS infection cases. Of these people infected, 38 patients died, and more than 16,000 people were released from quarantine. On 20th May, the first case of MERS was reported in South Korea. After only two or three weeks, MERS had spread intensely.

Figure 1 presents the timeline of the primary patient before isolation and the location. The primary case, the patient's visit to the local clinic and after that to a hospital and then a tertiary hospital, and the red-coloured number means the cases of infection by hospital. Figure 2 illustrates a transmission tree and that the MERS corona virus had spread from the primary case. This emerging infectious disease threatened South Korea's public health with potentially three generations of transmission. The number of the first order infected cases is 39. And second order infected cases are 104, and third order infected cases are 7.

As the figure indicates, patients No. 1, 14, and 16 infected considerably more patients than usual cases. We can see clearly that the MERS corona virus spread in South Korea is largely attributed to this super-spread event. At that time, media called them as super-spreaders. This is a kind of a stigmatization which is itself another ethical issue. If the authorities had revealed the names of the potentially infected hospitals at the proper time, 39 patients who ended up with secondary infections might have been able to protect themselves through preventive actions, including avoiding the hospitals completely.

There are numerous reasons why authorities in South Korea missed the opportunity to successfully control the spread of MERS in its early stages. First they overlooked the importance of a proactive public communication regarding risk, which is key to the effective management of an infectious disease. According to WHO's *International Health Regulations* (2005), one of the core capacities needed to protect against and to control the spread of a disease is risk communication. The term risk communication is defined by the WHO as the real-time exchange of information, advice, and opinions between experts, or officials, and the people who face the threat to their survival, health, economy, or social wellbeing.

Since the first confirmed case, which involved a 68-year-old man who had travelled to Bahrain, the South Korea authorities have been criticised for not publicly sharing information such as the names of all hospitals that the initial patient, and the subsequent patients, had visited. They were reluctant to announce this information because they worried about possible panic in the neighbourhoods surrounding the hospitals.

Second, in the face of this emergency, the public had been disappointed by relevant authorities' behaviour which had downplayed the risk of MERS after the first confirmed case. As the disease continued to spread, authorities lost the public's trust and had a difficult time not only controlling the outbreak but also mending their relationship with the public. Rumours about infected patients resulted in public panic. For example, people used SNS to share information about MERS. However, much of this information being posted on SNS, including how to protect against MERS, was inaccurate. A lack of trust in authorities led them to believe SNS instead, which prevented the public from adopting correct protective behaviours.

This is a photo from the Time Magazine. It was taken at a wedding in June last year in Seoul, attendees are wearing surgical masks to protect themselves from MERS. This photo symbolizes just how much MERS was taking over South Korea at that time.

In times of urgency, such as a MERS epidemic, a central government may need to make decisions in the absence of sufficient evidence. Ethical considerations in the context of public health can play an important role in building public trust. Responding appropriately to an outbreak of an infectious disease requires proper protocols specific to the disease, as well as public relations.

However, in times of ethical values, in the case of the epidemic in Korea, there was no reliable rationale for the judgment using decision making. Republic of Korea and WHO Joint Mission was conducted for 5 days, from 9th to 13th June last year. The joint mission team consisted of 16 experts, 8 from WHO and 8 from Korea. They announced messages to the public by WHO website and delivered initial recommendations to the Korean government. WHO Director-General Dr. Chan visited Korea and had a press conference about MERS in Korea, too.

According to public message, there had been an open and candid exchange of information and experience including the provision of detailed information about the outbreak and control measures put into place, as well as discussion of existing challenges. And they explained that whenever an emerging pathogen like the MERS virus appears in a new setting, a timely and the thorough investigation is critical, particularly to assess whether the virus transmissions are changing and to insure implementation of the most appropriate control strategies.

The Korea and WHO MERS joint mission sent the initial recommendation to the Korean government. Infection prevention and control measures should immediately be strengthened in all facilities across the country. Close contacts of MERS cases should not travel during the period when they are being monitored for the development of the symptoms. Any patient with positive responses should be promptly reported to public health authorities and managed as a suspected case while the diagnosis is being confirmed. A strong consideration should be given to re-opening schools, as schools have not been linked to the transmission of the MERS corona virus in the Republic of Korea or elsewhere.

At the 9th meeting of the Emergency Committee, convened by the WHO Director-General under the *International Health Regulations* regarding MERS corona virus, the committee noted the assessment of the joint mission regarding the main factors contributing to the spread of the MERS corona virus in the Republic of Korea were: First, the lack of awareness among healthcare workers and the general public about MERS. Second, suboptimal infection prevention and control measures in hospitals. Third, close and prolonged contact of infected MERS patients in crowded emergency rooms and multi-bed rooms in hospitals. Fourth, the practice of seeking care at multiple hospitals, so called "doctor shopping". Fifth, the custom of many visitors or family members staying with the infected patients in the hospital rooms, facilitating the secondary spread of infections among these contacts.

Afterwards, according to WHO suggestions, the Korean government reformed 'National Infection Prevention and Control System'. Figure 3 shows the outline of the emergency operations centre. We established a new organization, an office of communication, under the Centres for Disease Control and Prevention, and we set up an immediate response team. So, the emergency operations centre should communicate with the office of communication about the management of risk through public expert media communication. So we reformed this system, planned the coordination and official communication, and placed several departments under the office of communication, which are risk assessment, international cooperation, resource management, etc.

The National Bioethics Committee of Korea is a presidential commission. Among 20 members of the committee, six members are ministers, so ministers of health,

science, law, education, family, and industry. Last August, the Korean National Bioethics Committee reviewed and evaluated the MERS crisis regarding ethical aspects. The topics was the 'MERS crisis and bioethics'. Now the future role of the National Bioethics Committee in Korea involves building and maintaining trust and providing moral vision underpinning the healthcare policy and international cooperation network.

The infectious disease spread into the whole country, much like epidemics in Africa. In two years, an African country will host the Global Summit. Together with the African countries we understand just how important the international community is, and we should emphasize this. Finally, because each country has a unique capacity for its own surveillance, different strategic levels are needed for appropriate decision making in overcoming the medical crisis. The current MERS outbreak in South Korea requires a system based on trust that combines public engagement with core capacities of the government for appropriate and effective surveillance and response. This efforts may be the first steps in South Korea's journey to join the ranks of advanced countries regarding public health. ||

Ethical Aspects Presented by the Advent of the MERS-Co Virus Outbreak

Imad Aljahdali

|| A brief introduction about the experience that we had in Saudi Arabia with MERS-CoV will be the topic of my presentation. In the Middle East, MERS-CoV started in 2012. At the time we did not know what this virus was. It reached its peak in April 2014. Just imagine that during that period we had the Hajj, the biggest mass gathering challenge. The risk at that time was not people bringing viruses from their home countries, but instead people getting infected while visiting Saudi Arabia. According to our surveillance system, we have recorded 1,338 cases; 56 percent recovered, 42 percent passed away.

What did the Ministry of Health in Saudi Arabia do when it responded to MERS-CoV? The first thing that we did was to establish the command and control centre in 2014. Basically what we have is transparent communication, as we have a very strong surveillance system. In the command and control centre, we have what we call a rapid-response team. If there is an outbreak in a certain hospital, our rapid-response team will go to that city right away and support that hospital in that local area.

A process of transparency and involving local international experts was very important. WHO Centres of Disease Control and Prevention were involved with us, they gave us the experts, they came and visited our hospitals, and we worked together, even at the research level. Funds and support for research was given by the government.

With MERS, we had a strong health promotion campaign addressing both the public and healthcare workers. Because we have found that healthcare workers need to change the way they do things at work and in their lives. They think that they are immune to infections and that because of this they can see any patient. But one has to discuss this issue with them.

The more we knew about the virus, the more we revised our case definitions. We sent this through our command and control centres to the hospitals in other areas,

revisiting their engineering controls and their infection control practices. What helped us, even before we knew exactly what virus we were dealing with, was to decide whether it was an airborne transmission or a droplet transmission.

When it started, we assumed that we were dealing with airborne transmission, and then, later, we found out it was more like a droplet transmission. We focused on building human capital capacity within intensive care units, and introduced new programmes, such as extracorporeal membrane oxygenation to save lives. This artificial lung technology was a new experience for us in Saudi Arabia. We were the first to use it to help against MERS-CoV. The medical intervention that we have done in the intensive care units helped us save lives.

We are lucky in Saudi Arabia that we have started building our human capital capacity in different specialty areas, whether it is in physicians, support staff or nursing, and most of our physicians are North Americans or Europeans. I belong to the Royal College of Physicians and Surgeons of Canada – I was in Edmonton. And we are very proud, for we have dealt with a lot of healthcare systems throughout the world and have brought that world of knowledge and capacity to the medical services during Hajj. So, we had Hajj in 2014, in 2015, in 2016. Imagine, we had people coming to Saudi Arabia and leaving to return home. And luckily enough, we did not have any MERS-CoV case return back from the Hajj to another country.

The challenges at the time were the people's perception and belief systems. Just as people love dogs here, people in Saudi Arabia love their camels. As they are so passionate about their camels, you have to be sensitive when you talk to them and make clear suggestions: what things they can do; how they can prevent the cycle of transmission; what do they need to know about the new virus; what preventive methods can they use; what are the risks.

We were updating our risk assessments and dealing with the phobia, the panic and stress. People were not visiting hospitals, they were panicking. What we did was to deal with the stress rather than to deal with their panic. We thought that if we make sure to be very transparent from the start, and we got better at this over time, giving comprehensive information to the public, they would understand more about the virus and they would know better how to protect themselves and not panic.

Dealing with the news media – local and international – now, that was a tough one, because you are dealing with science and politics, NGOs and mixing subjects. For physicians things are often very simple and clear. We usually do not have to deal with politics, so we say it as it is, do the right things and try to be very transparent. That is what we do. But to learn how to talk to the media and the local press about this sensitive issue of MERS-CoV, we had to take some classes and get some training.

Almost all of us have Twitter accounts. We have followers and we usually talk through our Twitter accounts and in this way we build trust. If you are late in

addressing an issue, it becomes very, very difficult to build trust within the community. Research in bioethics was a challenge, and this is the first case that I am going to talk about. Case No. 1 is the real stuff. On 13th June 2012, this patient was admitted in a private hospital in Jeddah. The patient suffered from pneumonia and renal failure and died without an identified cause. The consulting physician at the time sent samples out of the Kingdom of Saudi Arabia, without a material transfer agreement (MTA). We did not know about this at the time. He sent the samples to a medical centre in Europe, which then identified the new corona virus.

As a country we did not know what was going on from June to September of that year. Soon, the European lab started sharing the corona virus sample with other laboratories across the world, under a material transfer agreement. So, the lab took the MTA and sent it to other labs. It also applied for a patent on the corona virus gene sequence, and that is the real challenge of the new corona virus. Back then in September, we wanted to develop vaccines, but there were already patents related to the virus that you had in Saudi Arabia. This delayed a lot of things. These restrictions meant to preserve ownership of the virus samples and protect the ability to obtain intellectual property rights on research.

Did the consultant have the supervisory and ethical approval to send the clinical sample out of the country? How were the samples accepted without an MTA and did the receiving lab challenge him on this before accepting the samples? These are just questions. The patent, actually was applied for on 23rd September 2013, at a global level: the United States, Europe, Singapore, and Korea. But there is no patent yet, because we challenged that even at the WHO level. After that the question was discussed in the media whether you can patent a disease, and there was controversy around this.

Dr. Chan asked, why scientists would send specimens out to laboratories in a bilateral manner and allow other people to have international patent rights regarding a new disease, rather than sharing it through the WHO. She went on to say that no intellectual property should stand in the way of you, the countries of the world, to protect your people. That is the position.

Another case, case No. 2 was in Indonesia. At this time, the researcher had lost the fight through the Dutch court regarding the virus. But Indonesia argues for viral sovereignty, that the virus belongs to the country and that the country should not be forced to share it with the world community, because if they do share it with the community, then the developed countries will more quickly develop vaccines and screening tools, which will subsequently cost poor countries a lot of money to protect their people. This is the other extreme, viral piracy asking for a patent on a naturally occurring sequence, delay of research of diagnostic tests or vaccines.

Case No. 3 was in the United States and is related to a genetic company which discovered breast cancer I and II. They patented it in 1994 and had the right of

diagnostic and screening test for it which cost 2,000 US dollars or more. It took seven years for NGOs and others to take it to the court. Finally, and the ruling was in June 2013, the US Supreme Court held that the DNA was isolated from a human body, so it is not patentable, not a subject matter under US patent law. The court said that Myriad Genetics had not created anything, actually. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Beautiful ruling from the United States. Millions of US women now have access to affordable genetic screening. Until recently it cost around 3,000 US dollars, now, after the ruling, it is only 200 US dollars or less.

Maybe it is because of publications that people are competing. Discoveries in research, business, maybe a monopoly, protection of countries, that is the other extreme, that is why countries are not sharing. The bottom line is that Dr. Chan called upon the delegates of the World Health Assembly to stand against international patents blocking epidemical response.

We need to review and update the WHO resolutions that we have related to epidemics and to summarize them. We look back into the convention of biological diversity, the *International Health Regulations*, under governance of WHO, when it comes to epidemics and the protection of bioethics. The suggestion is that we propose that, as the WHO document actually states, countries that have resources to provide foreign assistance should devote a portion of foreign aid to academic preparedness, providing technical assistance, as well as avoidance of practices that slow down proper response. Number two: Clear stand on patenting genome-related diseases or patents should not be communicated to scientific communities and governments, especially with legal presenters that involve such a request. ||

Discussion Paper

WHO Ethical Guidance for Managing Epidemic Outbreaks

WHO Global Health Ethics Unit

This guidance does not represent the final document as published by WHO. This is a draft that was presented at the 11th Global Summit for discussion.

1 Introduction

This guidance grew out of discussions at the World Health Organization (WHO) about ethical issues raised by the Ebola outbreak. The WHO Global Health Ethics Unit's work with Ebola response began in August 2014, immediately after Ebola was declared a "public health emergency of international concern" pursuant to the *International Health Regulations*. That declaration led to the formation of an ethics panel, and later an ethics working group, which was charged with developing ethics guidance on issues and concerns as they arose in the course of the epidemic. Throughout these discussions, it became apparent that the ethical issues raised by Ebola mirrored similar concerns that have arisen in other global disease outbreaks, including SARS, pandemic influenza, and multidrug-resistant tuberculosis. Previous WHO ethical guidance has focused on each of these outbreaks in isolation, without considering ethical issues that might have arisen if the epidemiological circumstances had been different. The purpose of this document is to look beyond the specific issues particular to a particular epidemic pathogen to focus on the cross-cutting ethical issues that apply to epidemic outbreaks generally. In addition to setting forth general principles, it examines how these principles can be adapted to different epidemiological and social circumstances.

While many of the ethical issues that arise in epidemic outbreaks are the same as those that arise in other areas of public health, the context of an outbreak raises additional complexities. Decisions during an outbreak need to be made on an urgent

basis, often in the context of scientific uncertainty, social and institutional disruptions, and an overall climate of fear and distrust. Often, the countries most affected by epidemic outbreaks have limited resources, underdeveloped legal and regulatory structures, and health systems that may already be strained beyond capacity. Within this context, it will often be impossible to satisfy all urgent needs simultaneously, forcing decision-makers to engage in difficult ethical trade-offs. Moreover, time pressures and resource constraints may create pressures to act without the kind of inclusiveness and transparency that an ethical decision-making process demands.

This guidance document focuses on ethical issues that arise specifically in the context of epidemic outbreaks. It is meant to complement, not replace, existing guidance on ethical issues in public health. It should therefore be read in conjunction with more general guidance on issues such as public health surveillance, research with human participants, and addressing the needs of vulnerable populations.

2 Relevant ethical concepts

Ethics involves judgments about how "we ought to live our lives, including our actions, intentions, and our habitual behaviour" (World Health Organization 2010, 5). The process of ethical analysis involves identifying relevant values, applying them to a particular situation, and making judgments about how to weigh competing values when it is not possible to satisfy them all. This guidance document draws on a variety of ethical values, which are grouped below into seven general categories. These categories are presented merely for the convenience of the reader; other ways of grouping ethical values are equally legitimate.

Equity: Equity refers to fairness in the distribution of outcomes. Key elements of equity include treating like cases alike, avoiding discrimination and exploitation, responding to those who are especially vulnerable to harm or injustice, and providing something in return for contributions that people have made (often referred to as "reciprocity").

Utility: The value of utility refers to the maximization of benefits. It encompasses the concepts of proportionality (balancing the potential benefits of an activity against any risks of harm) and efficiency (achieving the greatest benefits at the lowest possible cost).

Meeting basic needs: Ethics requires attention to meeting the basic needs of individuals and communities, particularly basic humanitarian needs such as nourishment, shelter, good health, and security.

Respect for persons: Respect for persons means treating individuals in ways that are fitting to and informed by a recognition of their morally relevant qualities. A

central aspect of respect for persons is respect for autonomy, which requires letting individuals make their own choices on the basis of their own motivations, without manipulation by external forces. One way this value is manifested is in the principle of informed consent, under which a competent individual authorizes a course of action based on sufficient relevant information, without coercion or undue inducement. Respect for persons also includes paying attention to values such as dignity, privacy and confidentiality, as well as social and cultural beliefs and important relationships, including family bonds.

Liberty: Liberty includes social and political freedoms, such as freedom of movement, freedom of peaceful assembly, and freedom of speech. Many aspects of liberty are protected as fundamental human rights.

Solidarity: Solidarity is a social relation in which a group, community, or nation stands together. The value of solidarity justifies collective action in the face of common threats. It also supports efforts to overcome inequalities that undermine the welfare of minorities and groups that suffer from discrimination.

Procedural justice: Procedural justice requires a fair process for making important decisions. It includes the elements of due process (providing notice to interested persons and an opportunity to be heard), transparency (providing clear and accurate information about the basis for decisions and the process by which they are made), inclusiveness/community engagement (ensuring all relevant stakeholders are able to participate in decisions), accountability (assuming responsibility for decisions), and oversight (ensuring appropriate mechanisms for monitoring and review, including systems for appeals).

The application of ethical values should be informed by evidence as far as it is available. For example, in determining whether a particular action contributes to utility, decision-makers should be guided by any available scientific evidence about the action's benefits and harms. When specific evidence is not available, decisions should be based on reasoned, substantive arguments and informed by evidence from analogous situations, to the extent this is possible.

In balancing competing values during epidemic outbreaks, countries should be mindful of their obligations under international human rights treaties. The *Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*[6] are a widely accepted framework for evaluating the appropriateness of limiting fundamental human rights in emergency situations. The Siracusa Principles provide that any restrictions on human rights must be provided for and carried out in accordance with the law and in pursuit of a legitimate objective

6 UN Commission on Human Rights, *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights* (E/CN.4/1985/4, 28th September 1984).

of general interest. In addition, such restrictions must be strictly necessary and there must be no less intrusive and restrictive means available to reach the same objective. Finally, any restrictions must be based on scientific evidence and not imposed in an arbitrary, unreasonable, or discriminatory manner.

For both pragmatic and ethical reasons, maintaining the population's trust in epidemic response efforts is of fundamental importance. This is possible only if policymakers and response workers act consistently act in a trustworthy manner by applying procedural principles fairly and consistently, being open to review based on new relevant information, and acting with the genuine input of affected communities. In addition, the success of the response effort depends on the willingness of all members of the global community to act in solidarity, with recognition that all countries share a common vulnerability to the threat of infectious disease.

3 Guidelines

(1) Obligations of national governments and the international community

Questions addressed:

- How can national governments help prevent and respond to epidemic outbreaks?
- Why do countries' obligations during epidemic outbreaks extend outside their own borders?
- What obligations do countries have to participate in global surveillance and preparedness efforts?
- What obligations do governments have to provide financial, technical, and scientific assistance to countries in need?

National governments can play a critical role in both preventing and responding to epidemic outbreaks, by improving social and environmental conditions, ensuring well functioning and accessible health systems, and engaging in public health surveillance and prevention. Together, these actions create conditions inimical to the spread of diseases with epidemic potential. In addition, they help ensure that an effective public health response will be possible if an epidemic occurs. Governments have an ethical obligation to ensure the long-term capacity of the systems necessary to carry out these functions.

Countries have obligations not only to those within their own borders but also to the broader international community. As the UN Committee on Economic, Social and Cultural Rights (2000, 12) has recognized, "given that some diseases are easily transmissible beyond the frontiers of a State, the international community has a

collective responsibility to address this problem. The economically developed States parties have a special responsibility and interest to assist the poorer developing States in this regard."

These obligations are grounded in the ethical principles of beneficence, justice, and solidarity. They also reflect the practical reality that epidemics do not respect national borders, and that an outbreak in one country can therefore put the rest of the world at risk. Countries' obligations to consider the needs of the international community do not arise solely in times of extreme emergency, such as epidemics. Instead, they require ongoing attention to ameliorating the social determinants of poor health that can contribute to epidemic outbreaks (e.g. inadequate systems of water and sanitation).

The following are key elements of countries' international obligations:

- ***Participating in global surveillance and preparedness efforts:*** All countries should carry out their responsibilities under the *International Health Regulations* to participate in global surveillance efforts in a truthful and transparent manner. In addition, countries should develop preparedness plans for epidemic outbreaks and other potential disasters.
- ***Providing financial, technical, and scientific assistance:*** Countries that have the resources to provide foreign assistance should devote a portion of foreign aid to epidemic preparedness and response efforts, including support for research and development on diagnostics, therapeutics, and vaccines for pathogens with epidemic potential. This aid should supplement ongoing efforts to build local public health capacities and strengthen primary health systems.

(2) Community engagement and communication plans

Questions addressed:

- Why are community engagement and communication critical components of epidemic response efforts?
- Who should be involved in designing communication plans?
- What is the media's role in epidemic response efforts?
- What are the hallmarks of a transparent, accountable, and inclusive decision-making process?
- What should decision-makers do with input they receive during community engagement activities?

All aspects of epidemic response efforts should be developed through fair and inclusive procedures, and should be supported by ongoing communication with and engagement of the affected communities. In addition to being ethically important in its own right, attention to fair process and communication is essential to maintaining trust and preserving social order.

Communication plans should seek to ensure that individuals understand the nature and justification of public health efforts and the steps they can take to protect themselves from harm. Such plans should be designed in cooperation with a broad range of local stakeholders, in order to ensure that messages are relevant to the local context and consistent with other health-related messages the community receives. Those responsible for designing communication strategies should seek to anticipate and respond to misinformation and to minimize the risk of stigmatization and discrimination.

The media will play an important role in any epidemic response effort. It is therefore important to ensure that the media has access to accurate and timely information about the disease and its management. Governments and nongovernmental organizations should make efforts to help support media training in relevant scientific concepts and techniques for communicating critical information without raising unnecessary alarm. In turn, the media has a responsibility to provide fair and balanced reporting.

The following considerations are relevant to designing and implementing community engagement and communication strategies:

- ***Transparency:*** The ethical principle of transparency requires that decision-makers publicly explain the basis for decisions in language that is linguistically and culturally appropriate. When decisions must be made in the face of uncertain information, the uncertainties should be explicitly acknowledged.
- ***Accountability:*** The public should know who is responsible for making and implementing decisions so that they can challenge decisions they believe are inappropriate.
- ***Review and appeal mechanisms:*** Those who believe that a decision is unjust should have access to reasonable processes for review and appeal.
- ***Inclusiveness:*** All persons who could potentially be affected by a decision should have opportunities to make their voices heard, either directly or through legitimate representatives. Special attention should be given to ensuring that persons from historically marginalized and vulnerable groups are able to contribute to the decision-making process. Public health officials should recognize that members of these groups might be distrustful of government and other institutions and should make efforts to engender a climate of trust.

- ***Openness to diverse perspectives:*** Communication should be designed to facilitate genuine two-way communication, rather than as merely a means to announce decisions that have already been made. Decision-makers should be prepared to revise their decisions based on information they receive.

(3) Obligations related to diagnosis, treatment, and prevention of infectious disease

Questions addressed:

- Do patients (or their authorized proxy decision-makers) have the same right to receive information about the risks, benefits, and alternatives of medical interventions during epidemic outbreaks that they have in non-outbreak situations?
- Can it ever be appropriate to override an individual's refusal of diagnosis, treatment or preventive measures during an epidemic outbreak?
- What circumstances might it be justified to override an individual's refusal of diagnosis, treatment or preventive measures during an epidemic outbreak?
- What procedural safeguards should be provided before overriding an individual's refusal of diagnosis, treatment or preventive measures during an epidemic outbreak?

Individuals who are offered diagnosis, treatment, or preventive measures for infectious disease should be informed about the risks, benefits, and alternatives, just as they would be for other significant medical interventions. The presumption should be that the final decision about which treatment to accept, if any, belongs to the individual patient. For patients who lack the legal capacity to make treatment decisions for themselves, decisions should generally be made by appropriately authorized proxy decision-makers, with efforts made to solicit the patient's assent in appropriate circumstances.

Providers should recognize that, in some situations, the refusal of diagnosis, treatment, or preventive measures might be a choice that is rational from the perspective of a competent individual. If an individual refuses to accept an intervention, providers should seek to understand the reasons underlying the patient's refusal and make sensitive efforts to overcome those concerns.

In rare situations, there may be legitimate reasons for overriding an individual's refusal of diagnosis, treatment, or preventive measures. Decisions about whether to override a refusal should be grounded in the following considerations:

- ***Public health necessity of the proposed intervention:*** A mentally competent individual's refusal of diagnosis, treatment, or preventive measures should not be overridden unless there is substantial reason to believe that accepting the refusal would pose significant risks to the public health, that the intervention is likely

to ameliorate those risks, and that no other measures for protecting the public health – including isolating the patient – are feasible under the circumstances. The requirement that the intervention is likely to ameliorate the public health risks makes it inappropriate to require individuals to accept unproven experimental interventions that have not yet been proven to be safe and effective.

- ***Existence of medical contraindications to the proposed intervention:*** Some interventions that may pose low risks for the majority of the population can pose heightened risks for individuals with particular medical or social conditions. Individuals should not be forced to undergo interventions that would expose them to significant risks in light of their individual medical circumstances.
- ***Feasibility of providing interventions to an unwilling patient:*** In some cases, it may be impossible to provide an intervention to an individual who is unwilling to be an active participant in the process. For example, standard treatment for tuberculosis requires the patient to take medication on a regular basis for 6 to 12 months. Without the patient's cooperation, it is unrealistic to expect that such a lengthy treatment regimen could be successfully completed. In such circumstances, the only realistic way to protect the public health might be to isolate the patient until he or she is no longer infectious.
- ***Impact on community trust:*** Overriding individuals' refusal of diagnosis, treatment, or preventive measures can backfire if it leads members of the community to become distrustful of health care providers or the public health system. In many cases, the harm caused by undermining trust in the health care system may outweigh any benefits that imposing unwanted interventions may achieve.

Objections to diagnosis, treatment, or preventive measures should not be overridden without giving the individual notice and an opportunity to raise his objections before an impartial decision-maker, such as a court, administrative review panel, or other entity not involved in the initial decision. The burden should be on those proposing the intervention to show that the expected public health benefits justify overriding the individual's choice. The process for resolving objections should be conducted in an open and transparent manner, consistent with the principles discussed in Guideline 2.

(4) Allocating scarce resources

Questions addressed:

- What type of resource allocation decisions might need to be made during epidemic outbreaks?

- How do the principles of utility and equity apply to decisions about allocating access to scarce resources during epidemic outbreaks?
- How does the principle of reciprocity apply to decisions about allocating access to scarce resources during epidemic outbreaks?
- What obligations do healthcare providers have toward persons who are not able to access life-saving resources during epidemic outbreaks?
- What procedural considerations apply to the application of resource allocation principles during epidemic outbreaks?

Epidemic outbreaks can quickly overwhelm the capacities of governments and health care systems. Difficult decisions about allocation of services, equipment, medicines, and public health activities (e.g. surveillance, health promotion, community engagement, etc.) will need to be made if available supplies are insufficient to meet the need. Epidemic outbreaks also compete for attention and resources with other important public health issues. For example, one of the consequences of the Ebola outbreak was a reduction in access to general health care services due to a combination of a greater number of patients and the sickness and death of health care workers. As a result, deaths from tuberculosis, HIV, and malaria increased dramatically during this period (Parpia et al. 2016).

Countries should prepare for such situations by developing guidelines on the allocation of scarce resources in outbreak situations. These guidelines should be developed through an open and transparent process involving broad stakeholder input, including patients' representatives or associations, and they should be incorporated into formal legal instruments that establish clear priorities and procedures. In developing these guidelines, countries should be guided by the following considerations:

- ***Balancing considerations of utility and equity:*** Allocation decisions should be guided by the ethical principles of utility and equity. The principle of utility requires allocating resources in the manner that will maximize benefits and minimize burdens, while the principle of equity requires attention to the fair distribution of benefits and burdens. In some cases, an equal distribution of benefits and burdens may be considered fair, but in others, it may be fairer to give preference to those who are worse off, such as the poorest, the sickest, or the most vulnerable. It may not always be possible to fully achieve both utility and equity. For example, establishing treatment centers in large urban settings promotes the value of utility because it makes it possible to treat a large number of people with relatively few resources. However, such an approach conflicts with the principle of equity if it means that no resources will be directed to isolated communities in remote rural areas. There is no single correct way to resolve the tensions between utility and

equity; what is important is that decisions are made through an inclusive and transparent process that takes into account local considerations and values.

- ***Defining utility on the basis of health-related considerations:*** In order to apply the ethical principle of utility, it is first necessary to identify the type of outcomes that will be counted as improvements to welfare. In general, the focus should be on the health-related benefits of different allocation mechanisms, whether defined in terms of the total number of lives saved, the total number of life years saved, or the total number of quality-adjusted life years (QALYs) saved. For these reasons, while it might be ethical to prioritize those who are essential to managing an outbreak, it is not appropriate to prioritize persons based on social value considerations unrelated to carrying out an effective emergency response.
- ***Paying special attention to the needs of vulnerable populations:*** In applying the ethical principle of equity, special attention should be given to individuals and groups that are the most vulnerable to discrimination, stigmatization, or isolation, as discussed further in Guideline 7.
- ***Fulfilling reciprocity-based obligations to those who contribute to epidemic response efforts:*** The ethical principle of reciprocity implies that society should provide support to those who face disproportionate burdens in protecting the public good. This principle justifies giving priority access to scarce medical resources to frontline workers who assume risks to their own lives to help others in need.
- ***Providing supportive and palliative care to those who are unable to access life-saving resources:*** Even when it is not possible to provide life-saving medical resources to all who could benefit from them, efforts should be made to ensure that no patients are abandoned. One way to do this is to ensure that adequate resources are directed to providing supportive and palliative care.

The application of allocation principles should take into account the following procedural considerations:

- ***Consistent application:*** Allocation principles should be applied in a consistent manner, both within individual institutions and, to the extent possible, across geographic areas. Decision-making tools should be developed to ensure that like cases are treated alike, and that no person receives better or worse treatment due to his or her social status or other factors not explicitly recognized in the allocation plan.
- ***Resolution of disputes:*** Mechanisms should be developed to resolve disagreements about the application of the principles, including procedures for breaking tie votes in the event they arise. Persons who believe that allocation principles have been applied inappropriately should have access to impartial and accountable review processes.

- ***Separation of responsibilities:*** To the extent possible, the interpretation of allocation principles should not be entrusted to clinicians who have pre-existing professional relationships that create an ethical obligation to advocate for the interests of specific patients. Instead, decisions should be made by appropriately qualified individuals who do not have personal or professional reasons to advocate for one patient over another.

(5) Public health surveillance

Questions addressed:
- What role does surveillance play in epidemic response efforts?
- Should surveillance activities be subject to ethical review?
- What obligations do those conducting surveillance activities have to protect the confidentiality of information collected?
- Are there any circumstances under which individuals should be asked for consent, or given the opportunity to opt out, to surveillance activities?
- What obligations do those conducting surveillance activities have to disclose information to the affected individuals and communities?

Systematic observation and data collection are essential components of emergency response measures, both to guide the management of the current outbreak and to help prevent and respond to outbreaks in the future. Even if these activities are not characterized as "research" for regulatory purposes, an ethical analysis should be undertaken in order to ensure that persons whose information is being used are protected from physical, legal, psychological, and other harms. Countries should consider developing organized systems for ethical oversight of public health activities, commensurate with the activity's objectives, methods, risks and benefits, as well as the extent to which the activity involves vulnerable groups. Regardless of whether such systems are adopted, ethical analysis of public health activities should be consistent with accepted norms of public health ethics and be conducted by individuals or entities that can be held accountable for their decisions.

Ensuring high-quality, ethically appropriate surveillance is complicated by at least two factors: First, the law surrounding surveillance across jurisdictions may be unnecessarily complex or may contradict itself between jurisdictions (Dumez et al. 2008). Second, surveillance activities will occur across jurisdictions with varying levels of resources, thus placing strains on the quality and reliability of the data (Barnett & Sorenson 2011; Sturtevant et al. 2007). These issues are likely to be exacerbated

during an epidemic, creating an urgent need for careful planning and international collaboration. Specific issues that should be addressed include the following:

- ***Protecting the confidentiality of personal information:*** The unauthorized disclosure of personal information collected during an epidemic outbreak (which can include not only names but also other potentially identifying information such as addresses, diagnoses, family history, etc.) can expose individuals to significant risks, particularly in a context where isolation and quarantine are being used. As such, information generated through surveillance activities should not be shared with individuals or organizations that do not require it for public health purposes, and any disclosures without individual consent should be limited to the minimum needed. Use of surveillance data for research purposes must have the approval of a properly constituted research ethics committee.
- ***Assessing the importance of universal participation:*** Public health surveillance is typically conducted on a mandatory basis, without the possibility for individual refusals. This is because collecting complete records on the entire population is usually necessary to ensure the scientific validity of epidemiological information. Collecting surveillance information on a mandatory basis is ethically appropriate as long as a legitimate and accountable government authority has determined that universal participation is necessary to achieve the activity's public health objectives. However, it should not be assumed that surveillance activities must always be carried out on a mandatory basis. Those responsible for designing and approving surveillance activities should consider the appropriateness of allowing opt outs in light of the nature and degree of individual risks involved in the activity and the extent to which allowing exceptions would undermine the activity's public health goals.
- ***Disclosing information to individuals and communities:*** Regardless of whether individuals are permitted to refuse to participate in surveillance activities, the process of surveillance should be conducted on a transparent basis. At a minimum, individuals and communities should have access to information about the type of information that will be gathered about them, the purposes for which the data will be used, and any circumstances under which information collected may be shared with third parties. In addition, information about the outcome of the surveillance activity should be made available as soon as reasonably possible.

(6) Restrictions on freedom of movement

Questions addressed:

- Under what circumstances is it legitimate to restrict individuals' freedom of movement during an epidemic outbreak, through mechanisms such as isolation, quarantine, travel restrictions/bans, border control, and social distancing?
- What living conditions should be assured for individuals whose freedom of movement has been restricted?
- What other obligations are owed to individuals whose freedom of movement has been restricted?
- What procedural protections must be established to ensure that restrictions on freedom of movement are carried out appropriately?
- What obligations do policymakers and public health officials have to inform the public about restrictions on freedom of movement?

Restrictions on freedom of movement, including isolation, quarantine, travel restrictions/bans, border control, and social distancing, can play an important role in controlling many epidemic outbreaks; in these circumstances, their use is justified by the ethical value of protecting community well-being. However, the effectiveness of these measures should not be assumed; in fact, under some epidemiological circumstances, they may contribute little or nothing to epidemic control efforts, and may even be counterproductive if they engender a backlash that leads to resistance to more appropriate control measures. Moreover, all such measures involve significant burdens for individuals and communities, including direct limitations on fundamental human rights, particularly the rights to freedom of movement and peaceful assembly.

In light of these considerations, no restrictions on freedom of movement should be implemented without careful attention to the following considerations:

- ***Reasonable basis for imposing restrictions:*** Decisions to impose restrictions on freedom of movement should be grounded on the best available evidence. No such interventions should be implemented unless there is a reasonable basis to expect that they will significantly reduce morbidity and mortality. The appropriateness of any restrictions should be continuously reevaluated in light of emerging scientific information about the epidemic. If the original rationale for imposing a restriction no longer applies, the restriction should be lifted without any delay.
- ***Least restrictive means:*** Any restrictions on freedom of movement should be designed and implemented in a manner that imposes the fewest burdens reasonably possible. For example, home-based isolation or quarantine should be considered

before confining individuals in institutions. Similarly, requests for voluntary cooperation are generally preferable to mandates enforced by law enforcement authorities. Greater restrictions should be imposed only when there is a substantial basis for believing that less restrictive measures are unlikely to be sufficient to achieve important public health goals.

- ***Consideration of costs:*** The fact that a less restrictive alternative involves greater costs does not, in itself, justify relying on more restrictive approaches. However, costs and other practical constraints (e.g. logistics, distance, available workforce) may legitimately be taken into account in determining whether a less restrictive alternative is feasible under the circumstances, particularly in settings with limited resources.
- ***Ensuring humane conditions:*** Any restrictions on freedom of movement, particularly those that are not voluntary, should be backed up with sufficient resources to ensure that those subject to the restrictions do not experience undue burdens. For example, individuals whose mobility is restricted (whether through confinement at home or in institutional settings) should be ensured access to food, drinking water, sanitary facilities, and medical care. It is also essential to address the significant psychosocial burdens of confinement on individuals and their loved ones. This requires not only providing individuals with basic necessities but also ensuring that they have adequate physical space, opportunities to engage in activities, and the means to communicate with the outside world. When individuals are confined in institutional settings, mechanisms should be put in place to minimize the risk of violence (including sexual assault) and nosocomial infections. At a minimum, persons who are quarantined because they have been exposed to the pathogen responsible for the epidemic should not be put at heightened risk of infection because of the manner in which they are confined. In making decisions about the circumstances and conditions of confinement, special attention should be given to the heightened needs of vulnerable populations, as discussed further in Guideline 7.
- ***Addressing financial and social consequences:*** Even short-term restrictions on freedom of movement can have devastating financial and social consequences for individuals and their families. Countries should consider providing financial support to households that suffer financial losses as a result of inability to conduct business, loss of a job, damage to crops, or other consequences of restrictions on freedom of movement. In some cases, this support may need to continue for a period following the end of confinement. In addition, efforts should be made to support the social and professional reintegration of individuals for whom confinement is no longer necessary, including measures to reduce stigmatization and discrimination.

- ***Due process protections:*** Individuals whose liberty has been restricted should have access to mechanisms for challenging the appropriateness of those restrictions, as well as the conditions under which the restrictions are carried out. If it is not feasible to provide full due process protections before the restrictions are implemented, mechanisms for review and appeal should be made available without excessive delay.
- ***Equitable application:*** Restrictions on freedom of movement should be applied in the same manner to all persons posing a comparable public health risk. Individuals should not be subject to greater or lesser restrictions for reasons unrelated to the risks they may pose to others, including because of membership in any disfavored or favored social group or class (for example, groups defined by gender, race or religion). In addition, policymakers should seek to ensure that restrictions are not applied in a manner that imposes a disproportionate burden on vulnerable segments of society.
- ***The importance of communication and transparency:*** Policymakers and public health officials have a duty to communicate the rationale for any restrictions on freedom of movement, as well as regular updates on the implementation of such measures, both to the public at large and those whose movement has been restricted. Communication strategies should be designed to avoid the stigmatization of individuals whose liberty has been restricted and to protect such individuals' privacy and confidentiality, particularly in the media.

(7) **Vulnerable populations**

Questions addressed:

- Why are some individuals and groups considered vulnerable during epidemic outbreaks?
- How can vulnerability affect persons' ability to access services during epidemic outbreaks?
- How can vulnerability affect persons' willingness and ability to share and receive information during an epidemic outbreak?
- Why are stigmatization and discrimination particular risks during epidemic outbreaks?
- In what ways might vulnerable persons suffer disproportionate burdens from epidemic response efforts, or have a disproportionate need for limited resources?

Some individuals and groups face heightened susceptibility to harm or injustice during epidemic outbreaks. Policymakers and epidemic responders should develop

plans to address the needs of such vulnerable groups in advance of an epidemic outbreak and make reasonable efforts to ensure that their needs are adequately addressed. Doing this requires ongoing attention to community engagement and the development of active social networks between community representatives and government actors.

Efforts to address the needs of vulnerable populations should take into account the following:

- ***Difficulty accessing services and resources:*** Many of the characteristics that contribute to social vulnerability can make it difficult for individuals to access necessary services. For example, persons with physical disabilities may have mobility impairments that make travelling even short distances difficult or impossible. Other socially vulnerable persons may lack access to safe and reliable transportation, or may have caregiving responsibilities that make it difficult for them to leave their homes. Resource limitations can also limit vulnerable persons' ability to obtain necessary resources, such as nets for reducing the risk of contracting a mosquito-borne disease.
- ***Need for alternative communication strategies:*** Some types of vulnerability can impede individuals' ability to transmit or receive information. Communication barriers can stem from a wide range of factors, including but not limited to illiteracy, unfamiliarity with the local language, vision or hearing impairments, or lack of access to Internet and other communication services. These barriers can make it difficult for individuals to receive necessary public health messages or to participate fully in community engagement activities.
- ***Impact of stigmatization and discrimination:*** Members of socially disfavored groups often face considerable stigma and discrimination, which can be exacerbated in public health emergencies characterized by fear and distrust. Those responsible for epidemic response efforts should make efforts to ensure that all individuals are treated fairly and equitably regardless of their social status or perceived "worth" to society.
- ***Disproportionate burdens of epidemic response measures:*** Even when public health measures are designed with the best of intentions, they can inadvertently place a disproportionate burden on vulnerable population. For example, quarantine orders that prevent individuals from leaving their homes can have devastating consequences for persons who need to travel to obtain basic necessities such as clean water or food. Similarly, social distancing measures such as school closings can place disproportionate burdens on children who depend on going to school for access to regular meals.
- ***Disproportionate need for limited resources:*** Accommodating the needs of vulnerable populations will sometimes require the use of additional resources. In

some cases, these additional resources will be relatively minimal, such as when sign-language interpreters are hired to make community engagement forums accessible to persons with hearing impairments. In other cases, they may be more substantial, such as when mobile health teams are assembled to dispatch vaccines and treatments to hard-to-reach rural areas. It is legitimate to take costs into consideration in determining whether a particular accommodation is warranted under the circumstances; indeed, the principle of utility (discussed elsewhere in this document) demands that such assessments be made. However, despite the importance of conserving limited resources, the ethical principle of equity may sometimes justify providing greater resources to persons who have greater needs as a result of conditions beyond their control.

(8) Addressing sex- and gender-based differences

Questions addressed:

- How are sex and gender relevant to epidemic response efforts?
- How can sex and gender be incorporated into public health and surveillance?
- How can social and cultural practices about sex and gender affect epidemic diseases?
- Must reproductive healthcare services be made available during an epidemic outbreak?
- How are sex and gender relevant to communication strategies during outbreaks?

Sex ("biological and physiological characteristics"[7]) and gender ("socially constructed roles, behaviours, activities, and attributes"[8]) can have a significant impact on the spread, containment, course, and consequences of epidemic outbreaks. Sex and gender differences have been associated with differences in susceptibility to infection, different levels of health care received, and differences in the course and outcome of illness (World Health Organization 2007). Addressing sex and gender differences in epidemic planning and response efforts requires attention to the following considerations:

- ***Sex- and gender-inclusive surveillance programs:*** Public health surveillance should systematically seek to collect disaggregated information on sex, gender,

7 World Health Organization, *What Do We Mean by "Sex" and "Gender"?* http://www.who.int/gender/whatisgender/en/index.html.

8 Ibid.

and pregnancy status, both to identify differential risks and modes of transmission and to monitor any differential impact of an epidemic disease and the interventions used to control it. Countries should establish pregnancy registries during epidemics in order to improve the treatment and management of pregnant women in future outbreaks.

- ***Sex- and gender-inclusive research strategies:*** Researchers should make efforts to ensure that studies do not disproportionately favor one sex or gender over the other, and that women who are or might become pregnant are not inappropriately excluded as research participants. During an outbreak, research on experimental treatments and preventive measures should seek to identify any sex- or gender-related differences in outcomes.
- ***Attention to social and cultural practices:*** Gender-related roles and practices can affect all aspects of epidemic diseases, including risk of infection, morbidity and mortality, and differences in health-seeking behavior and the use of health services, and vulnerability to interpersonal violence. Policymakers and epidemic responders should seek to identify and respond to these factors, drawing when possible on relevant anthropological and sociological research.
- ***Ensuring the availability of reproductive health care services:*** Whether or not they are currently pregnant, women of childbearing age should have access to a full range of reproductive health care services during an epidemic outbreak. If there is evidence that an epidemic disease creates special risks for pregnant women or their fetuses, women should be informed of these risks and have access to methods to minimize them, including contraception and access to safe abortion. Reproductive counseling services should be made available, including services designed to help women make informed decisions about whether or not to carry a pregnancy to term.
- ***Sex- and gender-sensitive communication strategies:*** Those responsible for developing and implementing communication strategies should be sensitive to sex- and gender-based differences in how individuals access and respond to health-related information. Separate messages and communication strategies may need to be developed to provide relevant information to particular subgroups, such as pregnant women or nursing mothers.

(9) Frontline response workers' rights and obligations

Questions addressed:

- What obligations does society have to protect the health of frontline workers who participate in epidemic response efforts?

- What obligations does society have to provide material support to frontline workers who participate in epidemic response efforts?
- To what extent do these obligations extend to the workers' family members?
- What considerations should be taken into account in determining whether individuals have an obligation to serve as frontline workers during epidemic outbreaks?
- What special obligations do workers in the health care sector have during epidemic outbreaks?

An effective epidemic response depends on the contribution of a diverse range of frontline workers, some of whom may be working on a volunteer basis. These workers often assume considerable personal risk to carry out their jobs. Within the health care sector, frontline workers range from health care professionals with direct patient care responsibilities to traditional healers, ambulance drivers, laboratory workers, and hospital ancillary staff. Outside the health sector, individuals such as sanitation workers, burial teams, and persons who carry out contract tracing also play critical roles. Some of these workers may be among the least powerful members of society, who have little control over the type of duties they are asked to assume.

A subset of frontline workers may have duties to assume a certain level of personal risk as part of their professional or employment commitments. This is particularly true for workers with professional qualifications, such as physicians, nurses, and funeral directors. As discussed further below, even for these individuals, the duty to assume risk is not unlimited. However, many frontline workers are under no such obligations, and their assumption of risks should be regarded as beyond the call of duty (i.e. "supererogatory"). This is particularly true for sanitation workers, burial teams, and community health workers, many of whom may have precarious employment contracts without any social protection, or work on a volunteer basis. Regardless of whether a particular individual has a pre-existing duty to assume heightened risks during an epidemic outbreak, once a worker has taken on these risks, society has a reciprocal obligation to provide necessary support. It is essential that the criteria and procedures around frontline workers' rights and obligations be established during the pre-epidemic planning period, in order to ensure that all actors are aware of what can reasonably be expected if an outbreak occurs.

At a minimum, fulfillment of society's reciprocal obligations to frontline workers requires the following:

- ***Minimizing the risk of infection:*** Individuals should not be expected to take on risky work assignments during an epidemic outbreak unless they are provided with the training, tools, and resources necessary to minimize the risks to the extent reasonably possible. This includes complete and accurate information about

the nature of the pathogen and infection control measures, to the extent that information is known, updated information on the epidemiological situation at the local level, and the provision of personal protective equipment. Countries, with the support of international experts, should establish the minimum standards that should be applied in the care and treatment of patients affected by the epidemic, including for home-based care. Healthcare workers have an obligation to ensure that care and treatment standards do not fall below these minimums. Regular screening of frontline workers should be put in place to detect any infections as quickly as possible, in order to minimize the risk of further transmission to colleagues, patients, families, and community members.

- ***Appropriate remuneration:*** Frontline workers should be given fair remuneration for their work. Governments should ensure that public sector workers are paid in a timely manner, and they should make efforts to ensure that actors in the private sector fulfill their own obligations to pay their employees and contractors. If necessary, the international community should provide additional aid to ensure that frontline workers receive fair compensation for their efforts. In addition to fulfilling the ethical value of reciprocity, providing fair remuneration to frontline workers reduces the likelihood that such workers will seek to supplement their income by taking on additional jobs in the community, which could increase the risk of disease transmission to themselves and to community members. Fair remuneration for frontline workers includes the provision of financial support during periods in which workers are unable to carry out their normal responsibilities because of infections acquired on the job.
- ***Priority access to health care:*** Frontline workers who become sick, as well as any family members who become ill through contact with the worker, should be ensured access to the highest level of care reasonably available. In addition, countries should consider giving frontline workers and their families priority access to vaccines and other treatments as they become available.
- ***Support for reintegrating into the community:*** Frontline workers may experience stigma and discrimination, particularly those involved in unpopular measures such as isolation or burials. Governments should support efforts to help such workers become reintegrated into the community, including job placement assistance if needed.
- ***Assistance to family members:*** Assistance should be provided to families of frontline workers who are required to remain away from home in order to carry out their responsibilities or to recuperate from illness. Death benefits should be provided to family members of frontline workers who die in the line of duty, including those who were volunteers or "casual workers."

As noted above, some workers may have professional or employment-based obligations to work during epidemics. However, even for these individuals, the duty to assume risk is not unlimited. In determining the scope of workers' duties to assume personal risks, the following factors should be taken into account:

- ***Reciprocal obligations:*** Any professional or employment-based obligation to assume personal risk is contingent on society's fulfillment of its reciprocal obligations to workers, as outlined above. If those reciprocal obligations have not been met, frontline workers cannot be expected to assume a significant risk of harm to themselves and their families.
- ***Risks and benefits:*** Frontline workers should not be expected to expose themselves to risks that are disproportionate to the expected public health benefits their efforts are likely to achieve.
- ***Equity and transparency:*** Those responsible for assigning frontline workers to specific tasks should ensure that risks are distributed among individuals and occupational categories in an equitable manner, and that the process of assigning workers is as transparent as possible.
- ***Consequences for nonparticipation:*** Frontline workers should be informed of the risks they are being asked to assume. Workers who are unwilling to accept reasonable risks and work assignments may be subject to professional repercussions (for example, loss of their jobs), but additional punishments, such as fines or imprisonment, are generally unwarranted. In assessing the consequences for nonparticipation, employers should recognize that it may sometimes be necessary for workers to balance other obligations, such as duty to family, against job-related responsibilities.

In addition to the issues addressed above, persons working in the health care sector have additional obligations to the community during an epidemic outbreak, including the following:

- ***Providing accurate information:*** During an epidemic outbreak, the public will rely on the health sector for accurate information about the epidemic pathogen, including how it is transmitted, how infection can be prevented, and what treatments or preventive measures may be effective. If health care workers provide information about the epidemic, they should do so only from reliable sources and avoid spreading unsubstantiated rumors or suspicions.
- ***Avoiding exploitation:*** In the context of a rapidly spreading life-threatening illness with no proven treatments, desperate individuals may be willing to try any intervention offered, regardless of the expected risks or benefits. Health care

workers have a duty not to exploit individuals' vulnerability by offering treatments or preventive measures for which there is no reasonable basis to believe that the potential benefits outweigh the uncertainties and risks. This duty does not preclude the appropriate use of unproven interventions on an experimental basis, consistent with the guidelines set forth in Guideline 12.

- ***Resisting corruption:*** Corruption in the health care sector – which is always a serious concern – may be exacerbated during epidemic outbreaks if large numbers of individuals are competing over access to limited resources. As in non-epidemic situations, health care workers must not accept or give bribes or engage in other corrupt activities. Mechanisms should be put in place to track and manage corrupt activities in a timely and expedient manner. One of the ways to reduce incentives for corruption is by ensuring that governments and health care institutions fulfill their reciprocal obligations to healthcare workers, as outlined above.

(10) Ethical issues in deploying aid workers

Questions addressed:

- What ethical issues arise in selecting workers for deployment during epidemic outbreaks?
- What obligations do sponsoring organizations have to adequately prepare aid workers for their missions?
- What obligations do sponsoring organizations have regarding the conditions of deployment?
- What obligations do sponsoring organizations have to coordinate with local officials?
- What obligations do aid workers have before, during, and after deployment?

Governments and aid organizations that deploy workers in epidemic outbreaks have ethical obligations to both the workers themselves and the affected communities. These obligations include the following:

- ***Fairness in selection of workers for deployment:*** The selection of individuals for deployment should be based on a fair and transparent process. Individuals who object to assignments should have an opportunity for review and appeals.
- ***Provision of necessary training and resources:*** Aid workers should be provided with appropriate training, preparation, and equipment to ensure that they can effectively carry out their mission with the lowest risks practicable. Training should include preparation in psychosocial and communication skills, and in

understanding and respecting the local culture and traditions. This should include training and resources for managing challenging ethical situations as well.

- ***Clarity about conditions of deployment:*** Aid workers should be clearly informed of the conditions of their deployment, including the level of health care they can expect if they become ill, the circumstances under which they will be repatriated, available insurance, and whether benefits will be provided to their families in case of illness or death.
- ***Coordination with local officials:*** To the extent possible, foreign governments and external aid organizations should deploy workers following discussion and agreement with local officials or, if this is not possible, with international organizations like WHO.
- ***Avoidance of "disaster tourism":*** Aid workers, particularly those from foreign countries, should be deployed only if they are capable of providing necessary services not otherwise available in the local setting. It is inappropriate to deploy unqualified or unnecessary workers solely to satisfy those individuals' personal or professional desire to be helpful.

Aid workers also have their own ethical obligations. In addition to those outlined elsewhere in this document, these obligations include the following:

- ***Adequate preparation:*** Aid workers have an obligation to ensure that they are adequately prepared before embarking on a mission. If they believe that they have been inadequately trained or lack necessary equipment, they should make their concerns known.
- ***Adherence to assigned roles and responsibilities:*** Aid workers should understand the roles and responsibilities they have been asked to assume and should not undertake tasks they have not been authorized to perform.
- ***Regular communication:*** Aid workers should provide clear and timely information to both their sponsoring organizations and to local officials.
- ***Attention to appropriate infection control practices:*** Aid workers should be vigilant in adhering to infection control practices, both for their own self-protection and to prevent further transmission of disease. Aid workers should follow recommended protocols for monitoring symptoms and disclosing their health status (including possible pregnancy), both during their service and after. For foreign workers, this obligation continues upon return to their home countries.

(11) Research during epidemics

Questions addressed:

- What is the appropriate role of research during an epidemic outbreak?
- How might the circumstances surrounding epidemic outbreaks affect the ethical review of research proposals?
- How might the circumstances surrounding epidemic outbreaks affect the process of informed consent to research?
- What methodological designs are appropriate for research conducted during epidemic outbreaks?
- How should research be integrated into broader epidemic response efforts?

Carefully designed and ethically conducted research is a critical component of an effective public health response to epidemic outbreaks. In addition to clinical trials evaluating experimental treatments or preventive measures, other types of research – including diagnostic, epidemiological, anthropological, and implementation studies – can play a critical role in reducing morbidity and mortality and addressing the social and economic consequences caused by the outbreak. Research conducted during an epidemic outbreak should be designed and implemented in conjunction with other public health interventions. Under no circumstances should research compromise the public health response to an outbreak or the provision of appropriate clinical care.

In general, the ethical issues raised by research during epidemic outbreaks are not substantially different from those arising in research in other situations. As in non-epidemic situations, it is essential to ensure that studies are scientifically valid and add social value; that risks are reasonable in relation to anticipated benefits; that participants are selected fairly and participate voluntarily (in most situations following an explicit process of informed consent); that participants' rights and well-being are adequately protected, and that studies undergo an adequate process of independent review. Any clinical trials must be prospectively registered in an appropriate clinical trial registry. These obligations stem from the basic ethical values of beneficence, respect for persons, and justice. They apply to all fields of research, from basic virological experiments to biomedical, public health and social science studies, and are explained in detail in numerous international ethics guidelines,[9] all of which apply with full force in outbreak situations. All actors in research, including researchers,

9 See, e.g., World Medical Association, *Declaration of Helsinki* (1964, last revised in 2013); Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) and *International Ethical Guidelines for Epidemiological Studies* (2009).

research institutions, research ethics committees, national regulators, international organizations, and commercial sponsors, have an obligation to ensure that these principles are upheld. Particular issues that may take on greater urgency when conducting research in an outbreak situation include the following:

- ***Dealing with time pressures:*** The need for immediate action to contain an epidemic outbreak may make it impossible to adhere to the standard timeframes for research ethics review. National research governance systems and the international community should anticipate this problem by developing mechanisms for expediting ethics review in emergency situations, without undermining any of the substantive protections that ethics review is designed to provide. One option is to authorize the advance review and approval of generic protocols for conducting research in outbreak conditions, which can then be rapidly adapted to particular contexts.
- ***Addressing limitations in local research ethics capacity:*** In addition to time constraints, countries' capacity to engage in local research ethics review may be limited during outbreaks because of lack of expertise, diversion of resources to epidemic response efforts, or pressure from public health authorities that undermines reviewers' independence. International and nongovernmental organizations should assist countries in overcoming these challenges by, for example, sponsoring collaborative reviews involving representatives from multiple countries supplemented by external experts (Coleman et al. 2015).
- ***Confronting fear and desperation:*** The climate of fear and desperation typical of epidemic outbreaks can make it difficult for ethics committees or prospective participants to engage in an objective assessment of the risks and benefits of research participation. In an environment where large numbers of individuals are becoming sick and dying, any potential intervention may be perceived to be better than nothing, regardless of the risks and potential benefits actually involved. Those responsible for approving research protocols should ensure that studies are not initiated unless clinical equipoise is present, and that the risks have been minimized to the extent reasonably possible. In addition, researchers and ethics committees should recognize that, during an outbreak, prospective participants may be especially prone to therapeutic misconception – that is, the mistaken view that research is primarily designed to provide direct benefits to the individual participants, as opposed to developing generalizable knowledge for the potential benefit of persons in the future. Indeed, researchers themselves may sometimes fail to distinguish between engaging in research and providing ordinary clinical care. Efforts should be made to dispel the therapeutic misconception to the extent

reasonably possible, but it should be acknowledged that, even when such efforts are made, some prospective participants may still not fully appreciate the difference between research and ordinary medical care, and that this should not preclude their enrollment. Researchers should be well informed about the medical, psychological and social support systems available locally so that they can guide participants in need towards these services.

- ***Addressing other barriers to informed consent:*** In addition to the impact of fear and desperation, other factors can pose challenges to researchers' ability to obtain informed consent to research, ranging from cultural and linguistic differences between foreign researchers and local participants to the fact that prospective participants in quarantine or isolation may be cut off from their families and other support systems. To the extent possible, consent processes should be developed in consultation with local communities and implemented by locally recruited research workers/staff. In some situations, it may be necessary to develop rapid mechanisms for appointing proxy decision-makers, such as during outbreaks of diseases that affect cognitive abilities, or when an outbreak leaves a large number of children as orphans. Finally, in some cases, epidemic outbreaks may require the use of certain types of research designs that may not be compatible with the usual process of obtaining individual informed consent from all research participants. For example, research on the most effective means to respond to an epidemic may require introducing different interventions at a population level (e.g. evaluating the effectiveness of different social distancing strategies), or the same investigational intervention in different areas at different times (e.g. stepped-wedge vaccine trials). These type of studies are typically not conducted with individual informed consent, as allowing individual members of a community to refuse to participate would make it impossible to conduct the study altogether. Under these circumstances, ethics review committees should consider the appropriateness of waiving individual informed consent and substituting alternative protections, such as seeking authorization for the research from community leaders.
- ***Gaining and maintaining trust:*** Failing to build and maintain community trust during the process of research design and implementation, or when disclosing preliminary results, will not only impede trial recruitment and completion but also may undermine the uptake of any interventions proven to be efficacious. Engaging with affected communities before, during, and after a study is essential to building and maintaining trust. In environments in which the public's trust in government is fragile, researchers should remain as independent as possible from official public health activities. If government workers are themselves involved in conducting research, they should inform participants of this fact. Researchers

who observe unethical practices carried out in the name of public health or emergency response efforts should promptly report them to ethics committees or other independent bodies.

- ***Selecting an appropriate research methodology:*** Exposing research participants to risk is ethically unacceptable if the study is not designed to provide interpretable results. It is therefore imperative that all research be designed and conducted in a methodologically rigorous manner. All scientifically recognized methodologies and study designs should be considered, including placebo-controlled studies, innovative adaptive designs, and, under some circumstances, open-label studies. The choice of research design should be commensurate with the resources and expertise available at the research site and should take into account factors such as prior knowledge about safety/effectiveness in animals and humans, number of doses likely to become available, ease of administration and monitoring, and additional support required (e.g. monitoring of chemical chemistry). In addition, research designs should take into account the local context of the research, so that whatever methodology is chosen is acceptable to the community from which participants will be drawn.
- ***Including local researchers as genuine partners:*** Including local researchers in all aspects of the design, implementation, analysis, and publication of research can help ensure that studies adequately respond to local realities and needs. Involving local researchers as partners may also help build long-term research capacity in affected countries and promote the value of international equity in science.
- ***Integrating research into broader epidemic response efforts:*** National authorities and international organizations should seek to coordinate research projects in order to set priorities consistent with epidemic response efforts, and to avoid unnecessary duplication of effort or competition among different sites. Researchers have an obligation to rapidly share results (including preliminary results) with public health officials and the wider international response effort, without waiting for publication in scientific journals. Journals should facilitate this process by allowing researchers to rapidly publish information with immediate implications for public health without losing the opportunity for subsequent consideration for publication in a journal.[10] Researchers have an obligation to share information collected as part of a study if it is important for the ongoing response efforts, such as information about hidden cases and transmission chains, or resistance to response measures. As part of the informed consent process, researchers should

10 World Health Organization, *Developing Global Norms for Sharing Data and Results during Public Health Emergencies*. http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en.

inform potential participants of the possibility that their information might be shared in this manner.

- ***Ensuring that research does not drain critical health-related resources:*** Research should not be done if it will take away resources, including personnel, equipment, and health care facilities, from other critical clinical and public health efforts. To the extent possible, resources that are used for research should be made available locally to strengthen patient care services. For example, equipment that has been brought into the country from abroad for research should be maintained locally after the research is completed.
- ***Assuring equitable access to the benefits of research:*** As recognized in existing international ethics guidelines,[11] individuals and communities that participate in research should have access to any benefits that result from their participation. Research sponsors and host countries should agree in advance on mechanisms to ensure that any interventions developed in research will be made available to the local population without undue delay.

(12) Emergency use of unregistered interventions outside of research

Questions addressed:

- Under what circumstances is it ethically appropriate to offer patients unregistered interventions outside of research during epidemic outbreaks?
- If such interventions are provided, what should individuals be told about them?
- What type of ethical oversight should be conducted when unregistered interventions are offered outside of research during epidemic outbreaks?
- What obligations do those administering unregistered interventions outside of research have to communicate with the community?
- What obligations do those administering unregistered interventions outside of research have to share the results?

Effective interventions do not exist against many pathogens, but for some pathogens, there may be unregistered interventions that have not yet been evaluated for safety and efficacy in humans but have shown promising safety and efficacy in the laboratory and in relevant animal models. Ideally, such interventions should undergo testing in the context of clinical trials that are capable of generating reliable

11 See, e.g., World Medical Association, *Declaration of Helsinki* (1964, last revised in 2013); Council for the International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research involving Human Subjects* (2002).

evidence about safety and efficacy. However, in the context of an outbreak characterized by high mortality, in the an absence of proven effective treatments, and where it is not possible to initiate clinical studies immediately, it can be ethically appropriate to offer individual patients unregistered and experimental interventions on an emergency basis outside of research, provided that their use is monitored, documented and shared with the wider scientific community. Such Monitored Emergency Use of Unregistered and Experimental Interventions (MEURI)[12] may only be authorized by an appropriately qualified scientific committee specially established for this purpose. Providing a given intervention under MEURI can be justified by the ethical principle of respect for patient autonomy – enabling individuals to make their own risk-benefit assessments in light of their personal values and goals. It is also guided by the principle of beneficence – providing patients with available and reasonable opportunities to improve their condition, including measures that can plausibly mitigate extreme suffering and enhance self-preservation. Importantly, the emergency use of unproven interventions outside of research should be guided by the following principles:

- ***Scientific basis:*** Unregistered interventions should not be used outside of research without the agreement of an appropriately qualified scientific advisory body, based on a rigorous evaluation of the laboratory and animal data that exists. Only investigational products that adhere to Good Manufacturing Practices should be eligible candidates. In n selecting among eligible candidates, priority should be given to those that meet minimum data requirements, show the best benefit-risk assessment, are available, and pose limited or no logistical challenges for distribution and use in the relevant setting.
- ***Effective resource allocation:*** The use of unproven interventions under MEURI should not preclude or delay the initiation of clinical research and should not divert attention or resources from the implementation of effective clinical care or and public health measures that may be crucial to control an epidemic.
- ***Minimizing risk:*** Administering unproven interventions necessarily involves risks, some of which will not be fully understood until further testing is conducted. However, any known risks associated with the interventions should be minimized to the extent reasonably possible. Some examples include administration of interventions under hygienic conditions, using standard safety precautions,

12 The WHO Ethics Working Group coined the term MEURI to distinguish the use of unregistered interventions in emergency situations from other situations in which investigational interventions may be used outside ongoing clinical trials (such as "compassionate use" or "expanded access"), as well as from the use of registered interventions for purposes beyond the approved indication (commonly known as "off-label use") (World Health Organization 2014).

with close monitoring and access to emergency medications and equipment; and provision of the necessary supportive treatment.

- ***Collection and sharing of meaningful data:*** Physicians overseeing the administration of unproven interventions outside of research have a moral obligation to collect all scientifically relevant data. Knowledge generated through the use of unproven interventions, including all aspects of care, should be shared transparently and rapidly with public health authorities and the international scientific community, so that maximum information is obtained about the interventions' safety and efficacy. Information should be described accurately, without overstating benefits or understating uncertainties or risks.
- ***Importance of informed consent:*** Individuals who are offered unproven interventions on an emergency basis should be made aware that the intervention might not benefit them and might even harm them. The process of obtaining informed consent to the emergency use of experimental interventions outside of research should be carried out in a culturally and linguistically sensitive manner. The emphasis should be on the substance and understandability of the information conveyed and the voluntariness of the patient's decision, rather than on the use of any specific forms or procedures. The ultimate choice of whether to receive the unregistered intervention must rest with the patient, if the patient is in a condition to make the choice. If the patient is unconscious or too unwell to understand the information, proxy consent should be obtained from a family member or other authorized decision-maker.
- ***Need for community engagement:*** The emergency use of unproven interventions must be sensitive to local norms and practices. One way to try to ensure such sensitivity is to rollout rapid community engagement teams to promote dialogue about the potential benefits and risks of receiving interventions that have not yet been tested in clinical trials.
- ***Importance of ethical oversight:*** MEURI is intended to be an exceptional measure for situations in which initiating a clinical trial is not feasible, or for persons who are not eligible to participate in an ongoing trial. They should not be used as a means to circumvent ethical or regulatory oversight of experimental interventions. Thus, mechanisms should be established to ensure that MEURI undergoes ethical oversight through regular research ethics committees. One goal of this oversight process should be to ensure that researchers do not seek to disguise systematic clinical research as a series of unrelated case studies.
- ***Fair distribution in the face of scarcity:*** Promising investigational interventions are unlikely to be available in large quantities, which means that choices will have to be made about who receives each intervention. Countries should establish

mechanisms for making these allocation decisions, taking into account the principles discussed in the chapter in this document on Allocating Scarce Resources.

(13) Rapid data sharing

Questions addressed:
- Why is rapid data sharing essential during an epidemic outbreak?
- What are some of the key ethical issues related to rapid data sharing?

The collection of data is an essential part of epidemic response efforts. Activities that generate data include public health surveillance, clinical research studies, individual patient encounters, and epidemiological, qualitative, and environmental studies. The ethically appropriate sharing of data is critical for identifying causal agents, predicting disease spread, evaluating existing and novel treatment and preventive measures, and guiding the deployment of limited resources.

All individuals and entities involved in epidemic response efforts should cooperate in efforts to share relevant and accurate data in a timely manner. The need for rapid data sharing is heightened during outbreaks due to the urgency of the situation, the compromised response capacity of local health systems, and the important role of cross-border collaboration. Ongoing communication between data sources and recipients is critical to identify information priorities.

Key ethical issues related to data include protecting the confidentiality of personal information, ensuring that individuals and communities have access to information about how their data will be used, and creating governance systems capable of protecting the interests of all relevant stakeholders, particularly when data are shared internationally. These issues are discussed more extensively in other chapters of this document, particularly Guidelines 2, 3, and 5.

(14) Collection of biological specimens

Questions addressed:
- What are the risks associated with the collection of biological specimens during epidemic outbreaks?
- What obligations do those involved in collecting biological specimens have to consult with the community?

- Are there any circumstances under which individuals should be asked for consent, or given the opportunity to opt out, to the collection of their biological specimens?
- What considerations should be taken into account in transferring biospecimens outside the institutions that collected them, whether domestically or internationally?

Biological specimens may be collected during an epidemic outbreak either in the context of surveillance (e.g. determining who has been exposed to a novel pathogen, identifying the prevalence of drug-resistant bacteria), in research (e.g. developing new vaccines or interventions), or from leftover samples initially taken for clinical care. Specimens may be analysed in laboratories on site or sent other regions or countries. After they are analysed, they may either be discarded or stored for future use.

The ethically appropriate collection of biospecimens depends on creating and maintaining the trust of affected communities. Doing this requires time-consuming but necessary relationship building, consultation, and education, as well as the establishment of policies, practices, and institutions capable of commanding public confidence and trust. The willingness to commit to the work of building such relationships prior to an outbreak will help avoid ethical problems and controversies after the fact.

In addition to the general principles discussed in the chapters on Public Health Surveillance and Research during Epidemics, specific considerations relevant to the collection of biological specimens during epidemic outbreaks include the following:

- ***Risks of stigmatization and discrimination:*** Individuals who provide biological specimens for testing may face stigmatization or discrimination if their samples reveal undesirable health information, such as the presence of an infection or a genetic susceptibility to future disease. In many cases, these risks can be minimized by protecting the confidentiality of individuals' identities, but ensuring confidentiality may not be possible when only a small number of people are being tested or when the purpose of testing is to institute isolation or quarantine. Moreover, the risks of stigmatization and discrimination extend not only to individuals who test positive, but also to members of the individuals' family and broader communities. For example, if a particular disease is found to be disproportionately present in samples taken from a particular community, all members of that community may face stigmatization and discrimination, including individuals who are not actually infected with the disease.

- ***Community consultation:*** In light of the risks associated with the collection and storage of biological specimens, such activities should not be undertaken without a prior process of community consultation. This process should include representatives of all segments of the community potentially affected by the collection.
- ***Disclosure of information:*** Before individuals are asked to provide biospecimens for public health purposes, they should be given access to information about the purpose of the collection and the ways in which the specimens might potentially be used. When feasible and consistent with public health objectives, individuals should be asked to provide informed consent or be given the opportunity to opt out from having their specimens collected. Seeking informed consent is particularly important if there is any possibility that the specimens may later be used for research purposes.
- ***Benefit sharing:*** The benefits of research using biospecimens should be shared broadly with the international community. Special attention should be given to ensuring that members of the communities from which samples are obtained will have access to any resulting benefits, including access to any interventions developed based on research with the samples.
- ***Material transfer agreements:*** Biospecimens should not be transferred outside of the countries from which they are collected without formal material transfer agreements. Such agreements should specify the purpose of the transfer, ensure that it is consistent with the donors' consent, if any, provide for adequate confidentiality protections, and ensure that the benefits of any subsequent uses of the specimens are shared with the communities from which the samples were obtained. Material transfer agreements should be developed with the involvement of those responsible for the care of patients and the taking of samples, representatives of affected communities and patients, and relevant government officials and ethics committees.
- ***International sharing of biospecimens:*** The international community should make efforts to strengthen countries' capacities to maintain biospecimens within their own borders. If it is necessary to transfer specimens internationally, appropriate governance mechanisms should be established to ensure that representatives of the country where the specimens were collected are involved in decisions about the specimens' use.

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>> SESSION III: BIOETHICAL POLICIES AND BIOETHICAL LAW

Session Summary

Biolaw and Biopolicies
Laura Palazzani

Practical Applications of NEC Guidelines
Nikolajs Zeps

Bioethical Policies and Biolaw and Its Implementation
Joseph Mfutso-Bengo

Discussion Paper
Biolaw and Biopolicies
Laura Palazzani

Jean Claude Ameisen (Session Chair), Joseph Mfutso-Bengo, Nikolajs Zeps and Laura Palazzani (from left to right)

Session Summary

|| How bioethical questions can be reflected in policy and law was the topic of the third thematic focus of the Global Summit. In her contribution, Laura Palazzani from the Italian National Bioethics Committee analyzed four possible regulatory models. In doing so, she differentiated the liberalist approach, according to which state interventions are refrained from as broadly as possible and the responsibility for bioethical questions is chiefly undertaken via the voluntary self-commitment of individuals or associations, from the liberal approach, which allows legal interventions insofar as they facilitate and foster self-determination. The utilitarian model, in turn, aims through legal regulations at maximizing benefits and minimizing harms, whereas the dignitary model emphasizes the protection of the human dignity of each single individual as the goal of state interventions. Palazzani argued that the diversity of these regulatory approaches, in combination with the likewise pronounced bioethical pluralism and the often great complexity of bioethically relevant technologies, leads frequently to major delays in the biopolitical process. Many topics have only been tackled reluctantly by politics out of fear of conflicts, and instead a strategy of waiting has been preferred, which can nonetheless lead to technological developments remaining unregulated for too long. Here, the important task belongs to ethics councils of helping to shape the deliberation process with analyses and conversations at an early stage.

Nikolajs Zeps from the St. John of God Hospital in Perth, Australia illustrated such deliberation processes through two examples from current Australian biopolitics: the selection of sex by means of pre-implantation diagnostics; and the alternatives to informed consent. In the political process concerning both topics, direct exchange with the interested public by means of public consultations has been of importance, Zeps said.

Joseph Mfutso-Bengo from the National Advisory Committee of Bioethics in Malawi presented further considerations on the different roles of ethics and law in the

biopolitical process and advocated not underestimating the significance of bioethical discourse as both a counterweight and complement to legislative power. "The law has the power to bite, but bioethics has the power to move hearts and go beyond the minimum", he said. The search for the right balance in the bioethical process was also an important main focus of the subsequent discussion. Also touched upon was how one can best deal with those transboundary biopolitical challenges that arise when procedures are forbidden in one country and permitted in the neighbouring country. ||

Biolaw and Biopolicies

Laura Palazzani

|| My presentation is on bioethics and biopolicies. We all know that the rapid techno-scientific development and ethical pluralism give rise to new issues with regard to regulation and policies, both at a national and international level. This is why we talk not only of bioethics, but also of biolaw. This word means regulation in bioethics and also biopolitics, that refers to the decision-making process of regulation in bioethics. So, the real question – the philosophical question, the preliminary question – is: Which kind of regulations should we have in bioethics, in biolaw? We need an answer to this question, because we experience a bioethical pluralism but also a biojuridical or biolegal pluralism. That is, we have different models of biolaw, of possible regulations in bioethics, and different kinds of relationships between bioethics and biolaw.

I will analyze some of the main models: the libertarian model, the liberal model, the utilitarian model, and the so-called dignitarian model.

The libertarian model is focused on the affirmation of individual freedom. In this model the absence of law is preferable in bioethics. There is an exclusion of the public intervention of law in order to defend the freedom and private choice of individuals. That is why this model calls bioethics a "space free from regulation". It means that all that is neither prescribed nor forbidden is, or may be, allowed. This is the direction of the movement of HIL, which means "highly inappropriate legislation". According to this model, biolegislation, in whatever way it may be formulated, can only be highly inappropriate. So, the preference goes to the deontological codes, codes of conduct, self-discipline of researchers, self-control of, for example, the scientific community. The implications of this model are the privatization of choices of scientists and citizens, as regards choices about life, death, pain, suffering, and so on.

The liberal model is in favour of the intervention of law in bioethics that guarantees individual self-determination. According to the liberal model, the law should

protect freedom both in the negative and in the positive sense. In the negative sense, it should not be an obstacle to freedom, and in the positive sense it should multiply options that are technologically possible. So, the liberal model is the intervention of law to guarantee self-determination of freedom. Then, there is the preference of the so-called neutral rules, which means neutral, minimal legislation, procedural rules, and above all, case law. The idea is not to intervene heavily with laws in bioethics, the only limit being when we have big damages to others, for example, possible severe risk of damages for society. Here there is acceptance in the liberal model of temporary rules that limit freedom to deal with social emergency. In this liberal model, for example, there is the claim of reproductive rights, genetic selection rights, the right to die, and so on.

Then we have the utilitarian model. It proposes the need for the intervention of law to maximize benefits and pleasure and to minimize costs and suffering for the greatest number of individuals. It is the so-called utilitarian, collectivistic perspective, that balances the best pragmatic results with social efficiency, productivity, quality of life, and well-being of individuals. The preference goes to norms that ensure quality of life. Examples of implications are, for instance, animal rights or claiming the right to euthanasia. Here, the subjects are considered to have interests because of the balance of pleasure versus pain.

Then we have the dignitarian model. In this model there is the need of the intervention of law to defend the objective dignity of each human being, considered as a person. So, if a human being is an end and not just a means, as Kant said, the preference goes to norms that ensure human equality. The principle at the centre is not self-determination, not balancing costs and benefits, but instead human equality. So, it recognizes each human being, because it is human, to be the subject and not the object of law. Some examples of the implications of this model are, for instance, claiming rights for the unborn, rights for the vulnerable, prohibiting the suppression, exploitation and violation of human life, and claiming the right, for example, to be assisted in dying. Here it is not the right to die, but only the right to be assisted in dying.

These pluralistic models of biolaw and bioregulation have many consequences also in biopolitics. That is why there is a very difficult situation, sometimes, and we have difficult delays in biopolicies because of bioethical pluralism, biojuridical pluralism, the complexity of problems in technoscience and biomedicine. All these kinds of pluralism (at ethical, legal, and even scientific level) are reasons of a delay and difficulties of policies in the field of bioethics. We know that the timing and pace of science and technology exceed the discussion and political decision-making. For this reason, we have different approaches also in policies.

One possibility is the deliberate non-intervention of politics. Politics does not intervene in the field of bioethics because of an awareness of the lack of shared values,

the lack of a consensus that would be needed in order to elaborate laws. This is one of the main problems that we have in Italy, above all, in the discussion, for example, of advance care directives or research on stem cells. A further reason is the fear that bioethical issues may prove divisive or conflictual in society because of ethical pluralism, or the prudence in front of uncertainties and unpredictability of the so-called emerging technologies. This approach may have advantages, for example, the so-called "wait and see" strategy. We just wait and we will see. But the disadvantage is that with some specific kinds of technologies, as converging technologies, the abstention of politics we may have the intrusiveness of the so-called technocracy and market.

Therefore, we have the so-called soft intervention of politics. Soft is a word that is often used now in biolaw and biopolitics. What does it mean, exactly? It means a flexible instrument, a light instrument – as regards the methodology of using the instrument –, but above all, non-binding interventions. Soft means avoidance of sanctions and preference for case law, procedural rules, temporary rules. This may create an advantage, since it has the possibility of changing the content due to ethical pluralism and the rapid transformation of science and technology. Although it may have, on the other hand, a disadvantage which is uncertainty. This is a real problem for citizens. Because they do not really know what exactly is allowed and what is not. And that is a problem above all for professionals, such as physicians and scientists. And it leaves open the interpretation to the so-called discretion of judges. This is a real problem especially in statute law systems, not so much in common law systems.

Then we have the so-called hard, or heavy, intervention of politics. This is another adjective that we often use in biolaw and biopolitics, meaning specific and detailed intervention. Specific and detailed have to do with the content, but also with binding intervention. In this case we have rules that create an advantage, namely the clarification of behaviour. So we know exactly what is allowed and what is prohibited. Further, there is a limit to the scope of interpretation for judges. There is, therefore, a specific form of certainty regarding the behaviour of both professionals and citizens. But at the same time it comes along with a disadvantage. It is difficult to modify these rules, because changing these rules takes a lot of time. We have another interesting expression in biolaw called "law-lag". The term is used to describe the difficulty and time-intensive process in law when you have heavy legislation. Here, there is the risk of law becoming obsolete or lagging behind, because of the rapid advancement of science and technology, and there is the perception that specific values are being imposed.

For this reason – because of bioethical pluralism, biojuridical pluralism, and various approaches in politics that may be different in different contexts – bioethics committees play such an important role. The important role refers to the scientific

updating activities, which are absolutely necessary, and the dialectical discussion of ethical pluralistic analyses, because of the examining of legal aspects in the normative framework, both nationally and internationally.

I believe bioethics committees, both at international and national level, must focus on these two points. First, making recommendations to governments regarding biolaw and biopolitics, which is the best way of giving advice on the way to deal with specific issues. Which kind of biolaw and biopolicy approach is preferable? What main principles and values can be identified? Second, bioethics committees play a role in the so-called citizens and public involvement.

Regarding the first point, recommendations to the government, I would like to point out the importance, methodologically, to set up a sort of ethical balance in a bioethics committee. It is not a way to find a compromise or a pragmatic agreement on specific topics, but it is a way to set up a debate – to see to what extent one ethical position is shared inside the committee, to listen to others, to answer objections, and to find the so-called minimum ethical, or maximum reachable consensus. Connected to this is also the importance of public involvement, namely, the committees' openness to society. I am referring to the fact that information dissemination, but also so-called active citizenship is growing in importance: the national committees could build an institutional platform for dialogue, allowing to inform and to educate citizens. The aim is to raise social and critical awareness in bioethics, as well as in biolegislation and biopolicies. ||

Practical Applications of NEC Guidelines

Nikolajs Zeps

|| The example of sex selection is something that has been quite controversial in Australia in the last decade, actually, because we have a prohibition on this. The first thing you might ask is whether sex selection is actually an issue. As you can see on this slide, which I just took from Google, showing the sex ratio at birth from 2012 there are certain hot spots where there obviously is sex selection going on. This is a real issue in the world. But in Australia there has been a little bit of a controversy because there are opportunities for sex selection because people are allowed to do some pre-implantation genetic diagnosis, for a particular series of diseases.

Technology has really raced ahead and enabled us to do things that were not possible ten years ago. So if you have something (regulations) that is very concrete, you cannot necessarily respond swiftly to changes in technology. The issue here is not about using the technology to, for instance avoid having a child that might have muscular dystrophy. This is a sex-linked disorder, and you do not want to necessarily have a child who will have almost certain death in a most unpleasant way. It is permitted in Australia to do sex selection where there is the risk of disorders of that nature. But arguments have been made about sex selection saying, well, this is a step too far, because if you do this using pre-implantation genetic diagnosis, you can know the sex of your child, besides the other things that you may wish to find out. The argument is really about the slippery slope idea of, well, if you allow that, then what comes next? Hair colour, eye colour? Athletic prowess? What sort of things would we be selecting people for? And we get into the eugenic arguments.

In Australia the parliament issued an Assisted Reproductive Technology Act, which calls for the National Health and Medical Research Council (NHMRC) to issue guidelines. The guidelines are taken into account and they are actually used in clinical practice. The effect is that although these are not legislated guidelines – in the sense that the guidelines themselves are not legislation – they are issued under

legislation and they have the force of law. The thing about that is that in the guidelines it says sex selection through pre-implantation genetic diagnosis is forbidden. If you want to operate as a service in Australia that provides assisted reproductive technology services, you cannot do sex selection. It is forbidden. You would have your license revoked. The Embryo Research Licensing Committee would revoke your license. That is effectively the way restriction is achieved.

We are a federation. We have a constitution and the federal government essentially issues the law and then the states can choose whether or not they want to issue their own version as State laws. The sex selection ban actually results from the guidelines issued by the Australian Health Ethics Committee, one of the principal committees established under the NHMRC Act. The Australian Health Ethics Committee issued guidelines and an accompanying statement saying this is an ethically controversial issue – that admission to life should not be just due to certain conditions that a person has, and that this somehow was removing the humanity. The guidelines are not legally binding in the sense that the guidelines themselves are not law. But they have the equivalent function, because you cannot get a license to practice unless you abide by the guidelines, and therefore, they effectively have the function of law. Now, individual states – Victoria, West Australia, South Australia – have banned sex selection. So, the next question then is, how effective is the ban?

In Australia companies like Genea are saying: "We do not do sex selection, we are not permitted to do it for these purposes." But they talk about and highlight the objections, listed on page 92 of the guidelines. It is interesting here that they use an example. They say that Genea's experience is that there is a 51 to 49 preference for girls. The issue here is really about choice. If we go to the libertarian view, then people should have a choice to do what they want. And in fact they do. It was allowed prior to 2005 and now it has been banned. People in Australia go to America, where it is permitted. I know that twelve Australian couples become pregnant every week in America, where they had a sex selection done. It is not a hypothetical question, it is in fact what is going on.

It calls into question the idea about the role of national ethics committees and the discourse that we are having here, asking: How do we have uniformity? Because if we outlaw and make it functionally impossible to do sex selection in Australia, but people can go to Thailand, the United States, wherever else and it is permitted there, then is there actually a point of us having a stance?

As you see on this next slide there is the term "family-balancing". It is put very nicely, it is "family-balancing": I have had a boy, I now would like a girl, you know, these kinds of arguments. In fact I have to say that I was quite impressed that they did have information on their websites that allowed people to make a balanced view. You could actually find out something about the laws, and in fact they quote WHO

regarding gender and genetic sex selection discrimination, they provide a link to this. It is kind of curious that they are at least trying to provide people the opportunity to think through and debate this issue for themselves.

Currently in Australia the assisted reproductive technology guidelines are under review. These guidelines are reviewed every five years and they are calling for public consultation. When it comes to public consultation – in my experience, when working on the national ethics committee – you only get a very limited amount of submissions, and they tend to be from the absolute polar sides of society. The massive in-betweens do not write anything, and you are left with those "for" and those "against". And they are vehement in the way that they articulate their arguments. So, when I was on the Australian Health Ethics Committee we were reviewing every single word in all the submissions and we had to provide an answer to parliament about how we had addressed each individual comment. We were permitted to reject a view, but we had to explain why. That is one way to have the involvement of public consultation. But you cannot please everyone. There is always going to be someone who is angry about the position that you have taken in society. But we are a pluralistic society. However, we have to fall towards the majority.

Now I am going to talk very briefly about "opt-out consent", because big data is something new for us, the purposes of collecting large quantities of data. As a person who works with large quantities of data, I can tell you that most people do not understand the complexity of how to do the analysis of the data. And we are drowning in data – we have too much data. The ethical issue is: We are collecting it, we are spending money collecting it, but we do not actually know what to do with it. And then, when you do look to do the analysis of it the problem is that it is scientifically unsound, because you have not controlled for various factors.

To overcome that, in Australia, we had a public consultation. Previously we had not permitted what was called "opt-out consent". Many of us feel that opt-out consent is not consent, because you are essentially saying to a person: "Unless you state otherwise, we are going to assume that you are happy for us to use your data." Well, the person can reasonably say: "But you never told me." We say: "Ah, but we had these leaflets, see, we had these posters, and it is on the media." But a person can still say: "I did not know." In fact, the problem with opt-out consent is that it is not evidence of anything. So, if you talk to the lawyers in my hospital, they will say: "I do not like it." Then I'll explain how that works. The chair of our Australian Health Ethics Committee, a medical oncologist, wrote a paper about this, because in epidemiology, we do not want ascertainment bias. You do need to have all of the data, if you can possibly get it. So sometimes, by not having opt-out, you are actually excluding the very population that you want to include in your analysis. So there you are introducing biases, if you do not include them – which is a real conflict.

Our national statement is issued by the NHMRC, the Australian Research Council and Universities Australia – so it is endorsed by three groups. Again, it is not law, but you cannot get funding if you do not abide by it. They literally will not give you any money from the government if you do not abide by it; so no university will employ you or run a study without abiding by it, because if just one person does not abide by it, they can close down all the funding to the entire university. Obviously no university wants that. This is a nice sticks and carrots example. So opt-out – as it was issued last year in March, in the National Statement – is about when it is feasible to contact them, but the scale is so significant that using explicit consent is neither practical nor feasible. Essentially, the ethics committees are charged with the job of evaluating whether or not the reason to have opt-out is a reasonable argument. And it talks about things like: Has the person had a reasonable amount of time to evaluate the information and is there a mechanism to obtain further information. But again, how would you ever evaluate this if you have never actually had a conversation with the person? And so, it is a little tricky. It is really only applying to very large epidemiological-type projects.

If we go to the next slide, it crosses over with quality assurance. And I am going to end now by talking a little bit about what I think is the challenge for medicine and affordability of care. If we look at quality assurance, I now work predominantly in trying to deliver healthcare and do research in hospitals. And unless we capture data about what we are doing in the hospital, we do not know that we can deliver effective and efficient and safe healthcare. There is an ethical imperative for us to be able to deliver effective and safe healthcare.

There are some ideas now that what we want to be able to do is capture large sets of data. I want to know, for instance, how many patients were re-admitted within 72 hours of discharge with a complication that we should have identified as being possible to avoid. Unless we do pragmatic trials – and we are able to capture data, create a hypothesis, test an intervention, and then feed that back into the system – we are not going to deliver effective healthcare. There is an idea that we need to change. Nancy Kass has written really beautiful work on this and I urge you to read some of her papers about this idea of changing the regulations.

I am going to end with the platform trial. I think that the future – and this is where regulation is going to be very, very difficult indeed – is that I want to be able to randomize every patient in my hospital to an intervention. That might be something like: Should they have one pillow or two pillows when they sit up in bed. It might be: Do they want their tea at 11 a.m. or not. Or it might be an actual clinical intervention. But we should be testing every single thing we do in a hospital. That is going to be a challenge about the consent process. ||

Bioethical Policies and Biolaw and Its Implementation

Joseph Mfutso-Bengo

|| What is bioethics, what is law? I think, bioethics is not law, and law is not bioethics. They complement each other – bioethics, one proposes, law, one imposes. Sometimes it is ethical to disobey unjust law, just like Nelson Mandela did who refused the law of apartheid.

The law is supposed to be a minimum standard and ethics is directed at maximisation and perfection. Both law and ethics have power. Ethics has soft power. The American philosopher Winship wrote about the moral power of ethics. One can be attempted to think that ethics has no power since law has the power to bite. It is the fear of the law which makes people respect the law, whereby bioethics has the power to move hearts reaching beyond the minimum in order to strive for excellence and perfection! Taking the example from above, apartheid in South Africa, with law alone there would be no new South Africa. The Buren, the Whites, were fearing imprisonment and black South African were angry and ready for revenge. However Mandela came in and convinced them that South Africa did not need to punish the Whites. What was needed was truth and reconciliation, not litigation, in other words what was needed at that time was healing of nation and not litigation. That is why the Truth and Reconciliation Commission was created. Mandela, using moral power, swayed angry Blacks to reconciliation. That is moral power – moral power to the point that Mandela's power has become a sort of moral brand worth billions of dollars.

Bioethics is flexible in order to achieve more: more justice, more beneficence, and more respect. Whereas with law, if it becomes flexible, it risks to become selective justice.

The law can move people and can facilitate the enforcement of bioethical theories, policies, principles, and guidelines to become best practice. In Malawi, for example, informed consent for research is part of the Constitution (s.5 of the Malawi

Constitution 1994). The philosopher Hans Jonas argued that people may change not because of pleasure, but because of pressure. There is a need that – what I call – "checklist ethics" to become ethics of transformation. Actually, ethics can become agents of change, too.

Bioethics and law have to be in a balancing pendulum – I call it ethical balancing. The weaker the internal ethical controls the stronger the external controls (the law) must be. Societies, like in Germany, where one has strong rule of law, can maintain societal order based on strong external control and social contract. However in context of countries with weak external control and governance, where one has a weak rule of law, ethics which is internal control matters most.

Why does bioethics matter and not only the rule of the law? Changing behaviours and acting correctly can be based on the fear of the law. However, law alone as means of social control or professional control is not sustainable. Laws, good skills and knowledge alone are not enough for sustainable professional behaviour without investment in the right attitude and the moral character of a person. It is general knowledge that complete permanent social control through law enforcing agencies is not possible in a democratic society that respects human rights. This is why states and organizations need to complement the regulatory and legal enforcement with moral capital, with moral instance.

Moral capital is transformative ethics because it is not only informative but also formative. By being formative it becomes transformative. It strives to promote moral behaviour change through the consideration of moral character formation/transformation that become part of any knowledge and skills transfer. In Malawi it has become clear that good skills and good knowledge alone are not enough to achieve sustainable development and professionalism. Knowledge and skills without right attitude can be dangerous and often harmful. A thief without knowledge is less dangerous than a very knowledgeable and skilful thief. Hence appropriate knowledge and skills without right attitude are not enough for compliance and global corporate citizenship.

There are three requirements for global bioethics implementation which are very important. The requirements for global health ethics implementation according to "precede-proceed behaviour change model" are threefold: Disposing, enabling and reinforcing factors. The disposing factors are vision, leadership, mind-set change, and ethics. The enabling factors are systems. The third requirement contains the reinforcing factors which are legislation and regulations, rewards and sanctions. These are crucial to ensure that ethical policy is turned into good practice.

University of Malawi has announced the mainstreaming of ethics in all disciplines. Ethics is also called moral capital when it is integrated with appropriate knowledge and skills. Goodness (right attitude) does not come from knowledge and skills but

from good character. Goodness (right attitude) without appropriate knowledge and skills cannot create good professional practice neither. The concepts of moral capital, moral dividend and moral capital containment cost have captured the attention of industry, government and educationalists in Malawi. The Centre for Bioethics in Eastern and Southern Africa (CEBESA) has developed the following instruments: Moral capital index and LEGS (leadership, ethical engagement, governance and systems) framework for implementation of policy into best practice. Leadership, ethical engagement and governance (LEG) are building blocks to run resilient and responsive systems (S). We also added to the notion of moral capital (the KAS model) for sustainable professionalism. In my book *Bioethics as Moral Capital in Africa/Malawi: Mind-building for Sustainable Development and Professionalism* I built upon the idea of moral capital of Alejo Sison, a professor of business ethics, who has written extensively about the moral capital of leaders, and why virtue matters. He writes that no amount of human intellectual or social capital could make up for the lack of moral capital among the workers for the long-term success of the enterprise or a country and that moral capital as excellence of character is a combination of virtues which are good for a particular context or profession. He only talks about virtues appropriate for a particular context. I transferred this concept into African bioethics and expanded the concept beyond virtues by arguing that without appropriate knowledge, appropriate skills, virtue alone cannot be a capital. It is when virtues or morality is integrated with appropriate knowledge and skills needed for a particular profession or organization then morality can become a capital that produces dividends (professionalism).

Hence, the KAS model of moral capital has three pillars which one must combine and integrate in order to transform morality into capital: a) appropriate knowledge and b) the right attitude c) appropriate skills.

Furthermore bioethics as moral capital is a stepping stone for the use of other forms of capital such as natural resources, financial capital, social capital, human capital. Among all forms of capital moral capital is very often ignored or forgotten. Institutions, nations and governments have invested in human capital but less in moral capital. Global lack of investment in moral capital has resulted in declining moral dividend and the dramatic rise of moral-capital-loss-containment-costs such as fraud, corruption, moral hazards, professional misconduct, and global decline in political leadership standards, inequalities, and increase of violence. Malawi in the last 22 years had invested a lot in knowledge and skills development ignoring character which resulted in having a more knowledgeable and skilled workforce. The moral gap was noticed due to an increase in moral capital loss containment cost due to corruption, fraud, moral hazards and professional misconduct. The government of Malawi has eventually realised that technical competence has to be complemented

with moral competence. Meanwhile Malawi government is propagating three ethical pillars as foundation for national development: patriotism, integrity, hard work. The agenda for increased integrity is not only based on legal control but also transformative ethics.

I will give you another example, at the global level where ethical approval and informed consent for clinical research have become the international standard for good research practice. The need of ethical approval for research and publication are good examples where bioethics has become law and a universal research requirement. There is also the *Doha Declaration* that permits compassionate use of patents for public health interests. In the context of world trade, it had been a very difficult topic with vested interests. However, using moral reasoning and persuasion as strategies of negotiation at World Trade Organization developing countries managed to persuade rich countries to allow the possibility of using the patents for widening access to essential medicines and for production of affordable generics drugs for resource constraint, developing countries. This was moral power of ethics negotiated through ethical leadership and ethical engagement.

Similarly, European Medicines Agency and US Food and Drug Administration have expanded the concept of "compassionate use" to unregistered investigation of drugs so as to allow the use of post-trial access of unregistered effective investigational drugs. This was not easy to achieve. Without ethical leadership and engagement bioethics cannot become law.

Still, there are discrepancies between law and bioethics. Sometimes lawyers can defend inequity legally, but we know for example that the 10/90 equity gap or unfair trade and other practices may currently be legally acceptable, but morally not. The democratic principle of majority rule can undermine some bioethical principles of respect of persons, beneficence and justice.

From an ethical point of view one needs to be concerned about the general decline of quality of political leadership both on national and international level. There is a growing support for demagogues. Global Summit of National Ethics/Bioethics Committees ought to take up this challenge of promoting ethical political leadership at both national and international levels. Malawian National Committee on Bioethics (NACOB) decided in their first meeting that its mandate goes beyond mere medical ethics, research ethics and covers all social determinants of human life. Ethics should address also political, equity and social issues.

At times such advocacy is confronted with a strategic dilemma and bioethics needs to be flexible to maximize beneficence and respect of life by taking all circumstances into account. For example, Malawi's constitution, like many other countries, allows death penalty as exception to the constitutional right to life. According to the Penal Code murder attracts death penalty and courts passed death sentences. Any

death sentence would need to be endorsed by the head of state according to the law. However due to ethical considerations of respect of life, no Malawian president since democracy from 1994 has ever approved the implementation of a death sentence but converted it into life imprisonment. There is a silent moratorium. Hence, death penalty is legally but not practically in force. Advocacy to abolish death sentence legally might be harmful, because the Malawi Parliament is not ready to abolish the death penalty. Hence such well-intended advocacy could be unethical since it can cause more harm than good than intended. Such discourse could lead to a harsher and stricter legislation and practice than the current one.

This example shows again that majority rule and ethics are not always compatible and that law and ethics are not always the same but interlinked. ||

Discussion Paper

Biolaw and Biopolicies

Laura Palazzani

1 Introduction: Techno-scientific progress, ethical pluralism and biolaw

The acceleration of scientific discoveries and technological applications opens up new possibilities for interventions on both human beings (at different stages of development, in different conditions) and non-human beings (animals, vegetables, environment). There are diverse levels of development of science and technologies in different countries: therefore, different issues and different priorities in the urgency of solutions and governance may emerge across regions of the world, given the existence of varying socio-economic and cultural contexts as well. The techno-scientific development raises ethical questions which require bioethical answers.

Due to ethical and cultural pluralism, the ethical answers to techno-scientific questions may be and, in fact, are very different. Contemporary moral philosophical thought is strongly marked by pluralism: moral positions differ as far as the justification of principles and values is concerned, and also, with regard to the justification of the balancing of values in conflicting situations. The heterogeneous theoretical and practical settings of the many cultures (the beliefs, conceptions of philosophy and religion, traditions, customs and habits), but also the particular way cultures relate to techno-scientific innovation, as well as the specificity of social and cultural contexts, are certainly other factors in diversification. That is why bioethics is considered a plural field of knowledge on a theoretical and practical level.

The problematic techno-scientific development on the one hand and, at the same time, the ethical and cultural pluralism on the other, gives rise to new issues concerning regulation and policies, on a national, regional and international level. Bioethics

cannot avoid referring to biolaw and biopolitics.[13] This is mainly due to the increasing need in present day society all over the world for a certain kind of 'governance', through juridical regulations and policies, related to scientific and technological progress. It aims to regulate new and emerging rights: the right to reproduce or not to reproduce, the right to either carry out testing and eugenic selection or to the integrity of one's genetic heritage, the right to know one's genetic origins, the right to be born healthy or not to be born with a wrongful life, the right to die or to be assisted in dying, animal rights, the right to a healthy environment or, more generally, environmental rights.

The theoretical models of biolaw will be examined, each of them leads to different types of regulation.

2 The relationship between bioethics and biolaw: what kind of regulation for bioethics?

The debate on biolaw revealed several lines of thought and different models regarding the understanding of the relationship between ethical pluralism and biolaw.

The libertarian model, in the name of the affirmation of individual freedom, considers the absence of law/regulation preferable in bioethics (abstensionist model), at least in some specific bioethical questions (i.e. the questions of technological interventions at the beginning and end of life). According to this perspective, it is considered more appropriate to exclude the public intervention of law, perceived as an instrument of oppression and unduly interference with subjective self-determination. This is a model of thought which asks in bioethics for a "space free from law/regulation", supposing that all that is neither prescribed nor forbidden by laws is/may be considered allowed. The absence of regulation means the legalization in fact of the praxis. What libertarians need is to a guarantee of free choice concerning life and death, health and sickness, pain and suffering, and quality of life. Each individual in this perspective, should act according to his/her "private" moral conscience, without any external ruling, above all in the form of coercive imposition. This is the movement of thought known as "Hil", or "highly inappropriate legislation", which considers that bio-legislation, in whatever way it may be formulated, can only be 'highly inadequate'. Its inadequacy lies in the oppression of individual freedom. On this basis,

13 Ethics and law interact in various ways: they may significantly overlap with one another, but they remain two different normative systems: ethics reflects on what is good or bad, and aims at promoting the fulfilment of our tendencies towards the good, law ensures human relationships and guarantees the common interests of society of peaceful coexistence.

the libertarian model considers it appropriate not to legislate in bioethics, above all in those issues in which the liberty of choice is at stake. There is a preference for regulations of deontological codes (with only non-coactive sanctions), that is codes of professional practise such as medical codes or codes of conduct, or the opinions of ethics committees, as indirect, non-binding and flexible rules and regulations, making responsibility coincide with the self-control of a community or the self-discipline of single researchers. This model proposes the removal of public intervention of law in bioethics, with the consequent privatisation of choices, reducing the biojuridical intervention to a minimum and extending the individual autonomous decision to a maximum (Engelhardt 1996; 2006).

The liberal model of biolaw calls for the intervention of the law in bioethics with the function of guaranteeing freedom, understood as individual self-determination. According to this theory, moral rights pertain to the sphere of autonomy of the bioethical choices with respect to which the law should not interfere. Biolaw should protect the external and formal conditions allowing freedom to be concretely manifested and should abolish the impediments, ensuring the means for translating intentions into behaviour. According to this model, biolaw should strengthen and broaden subjective freedom, multiplying choice options technologically possible. Biolaw, in this view, accepts ethical pluralism, seeking to elaborate "neutral" rules, without taking sides in favour or against any moral perspective, so that each individual person is free to express his/her individual option, with the only limitation being to avoid damages to others (free individuals). This model is in favour of the so-called "minimal legislation", legislation that limits itself to procedural rules to settle controversies or flexible intervention of jurisprudence – that is the case-by-case intervention of the judges. Only if there is a justified fear of possible severe and irreversible risks and damages for society, the liberal approach to biolaw focuses on drawing up temporary rules, to deal with social emergencies, which may be reviewed and eliminated if not necessary (Charlesworth 1993).

The utilitarian model in biolaw seeks to maximise benefits and minimise costs for the greatest number of individuals. It is the model of collective utilitarianism. The aim of this model is to elaborate laws that guarantee the best pragmatic result possible in relation to social efficacy and productivity increasing the quality of life and well-being and decreasing suffering. The utilitarian bioethics of the "quality of life" subordinates the value of life to the presence of quality, measurable in aggregative terms of welfare. Utility in biolaw coincides with welfare, or the best optimal balance, in comparative terms, of benefits over costs, of satisfactions over frustrations, of preferences/interests in terms of pleasure/joy over damage in terms of pain/suffering (Singer 1993).

Some critical points emerge from these models of biolaw. Only free individuals or individuals who benefit from a certain level of quality of life may claim rights, in

other words, healthy adults capable of understanding, deciding and taking action. Other individuals are entitled to secondary rights, which are provisional, changeable according to circumstances, social concerns, whether of opportunity or prudence, benevolence or sympathy. Individuals experiencing physical or psychological vulnerability (associated with either development stages or existential conditions), unable to claim their rights, are tacitly excluded from legal recognition. Embryos, foetuses, infants, terminally ill patients, mentally disabled people or those suffering brain damage, become vulnerable subjects (Palazzani 2009). According to this line of thought, the rights of scientists to conduct scientific experimentation, positive reproductive rights to have a child with technologies, the right to eugenic selection to have a healthy child prevail over the rights of the unborn and outweigh other rights. The right to decide how and when to die or the right to use technologies in order to meet individual desires prevails over the duty of the physician to cure and care.

The 'dignitarian' or 'personalist' perspective in biolaw is the one which puts at the centre of ethics the intrinsic human dignity. The law is considered in itself as an instrument for the defence of the objective dignity of each human being, considered as person. In this perspective, the concept of person is identified with the human condition itself. Every human being, either at the beginning or at the end of life, healthy or ill, able or disabled, young (minor) or old is a person and should be treated as such. Human life, in each developmental stage and existential condition, should not be exploitable for scientific or experimental purposes. Each human being must always be recognized as an end, and never just a means (Barilan 2012; Andorno 2009). In this perspective, the law cannot become a mere instrument of the individual will or the utilitarian convenience, and cannot be limited to the recording of social practices and individual claims (Andorno 2009; 2013).

Biolaw, in this sense, is based on the principle of equality, namely recognizing that each human being, for the fact of being human, cannot become the object of discrimination, but must be treated as a 'subject' (and not 'object') having an intrinsic dignity irrespective of other extrinsic considerations, related to the stage of psychophysical development reached or the capabilities and abilities they express, such as autonomy or the perception of a certain quality of life. The principle of equality is rooted in human beings, independently of their appearance and functions. Dignity is a natural fact to be recognised and not a qualification to be given or awarded. The dignity of the human being as a right means the safeguard of physical integrity, prohibiting any form of suppression, exploitation of the human body and violation of human life. The point that needs a special reflection in bioethics is the recognition of the dignity of those who – due to accidental or provisional reasons, such as age, stage of development or conditions of illness and disability, temporary or stable – are not able to carry out certain abilities or do so weakly, thus becoming

particularly vulnerable and fragile when faced with the pressures of the progress made in biotechnology.

3 The relationship between biolaw and biopolitics: different models

The difficulties encountered by politics in decision-making in bioethics are understandable because of the complexity of problems, the relentless speed of progress, ethical and legal pluralism, and the necessary interdisciplinary approach to cultural analysis. The timing and pace of science and technology exceed the pace of discussion and political decision-making. Law and politics cannot keep pace with the advance of progress, at least at a 'competitive' rate, in order to make joint decisions implying some degree of stability. Politics lacks efficiency and timeliness, which are sometimes essential for the regulation of science.

We are, currently, in front of several possible models of biopolitics.

3.1 The deliberate non-intervention of politics in bioethics and biolaw

This choice can be made for several reasons: indifference toward bioethical issues; fear that bioethical problems may prove divisive in society and jeopardize its cohesion; awareness of a lack of shared values combined with the risk of a possible regulation enforcing a one-sided ethical perspective.

In statute law countries, such a decision taken by politics not to legislate inevitably leads to judicial interventions compensating for political stalemate, whenever disputes arise in practice. In this way, case-law replaces the role of legislation, carrying the risk of discretion and creativity (the court decides on ideological grounds), along with heterogeneity. Since there is no rule of binding precedent, any judge can issue different judgments while ruling on similar cases which, occasionally, result in incoherent interpretations with reference to the legal system as well as conflicting interpretations with reference to existing laws. Moreover, unlike the latter, common law countries, where case-law traces a generally homogeneous regulatory path, the political need for a general rule enacted by the Parliament, however, comes to the fore in particular fields of bioethics, with the aim of clarifying and defining some general aspects.

Non-intervention in bioethical issues by politics can often become dangerous, due to the intrusiveness of both technocracy and the market, alongside a 'technological far-west'. These questions turn out to be all the more sensitive and challenging whenever life and health of individuals are at stake, as well as the survival of the environment and of humanity itself.

Sometimes political non-intervention in bioethics means an implicit liberal-libertarian protection of the freedom of individuals (when actions are not explicitly prohibited, they are considered allowed). Sometimes it means a conservative defence of existing law, considering that even if they do not deal explicitly with bioethical issues, their extensive interpretation may result as in a form of legally binding protection of juridical goods (for example, life or human dignity).

3.2 The 'soft' or 'hard' intervention decisions in politics

'Soft' political instruments refer both to case-law intervention or to 'light', flexible, procedural laws, which are designed to define a minimum content, while leaving more or less broad scope for the courts' discretion when interpreting and implementing rules, and for citizens to make choices between different courses of action.

A soft law initiative can prove effective, on the one hand, in ensuring flexibility within a context of ethical pluralism and rapid transformation of society; on the other hand, it can be risky, since it is likely to shape scenarios leading to uncertain and unpredictable outcomes.

The political decision to intervene with specific and detailed 'hard' legislation, governing precise questions and laying down core values pertaining to a particular ethical perspective is generally designated as the substantial interventionist paradigm. This is the case of legislative measures, when existing law is deemed silent, outdated, ambiguous and the risk of violation of human dignity arises. This model aims to establish both specific and detailed content for each subject, identifying principles and rules for the regulation of specific cases. The purpose of bio-legislation is, at least, to clarify general principles, in order to set interpretive limits for judges, while avoiding discretion and creativity of legal decisions, alongside ensuring legal certainty among both professionals in the field and citizens.

This orientation may be criticized, as the overlap or close connection between law and morality is blamed for 'imposing' one moral perspective, while delegitimizing others. It may be accused of illiberality, not taking in due consideration the demands for autonomy, and charged with obscurantism, as it may block or tend to hinder scientific progress through prohibitions. Rules based on a unique ethics can cause social fractures and need to be progressively reviewed, edited, revised, as well as becoming quickly obsolete compared to the pace of scientific advancement.

Another possible biopolitical approach may be entrusting bio-political decision-making to the majority rule, without taking a stance in relation to the different types of intervention. This policy can resolve conflict effectively by looking for a practical, although not theoretical, way out, in an effort to mediate a resolution. The majority

rule, in bioethics, may be considered as a pragmatic solution to find a solution: it lacks dialectic confrontation towards minimum shared by all values. It does not bring appreciable effects in contributing to regulatory certainty and effectiveness applied to the objects being governed. The law requires a broad political and social consensus, in order to ensure that regulatory decisions are accepted, stable and efficient.

In this regard, given the pros and cons of each possible intervention or non-intervention by biopolitics, there is a need to explore single contexts and problems drawing on a rationale for normative differentiation (prohibition vs. permission; soft vs. hard law; case-law vs. legislation). However, what is really essential is identifying a 'place' devoted to scientific updating activity, ethical pluralistic discussion and insight exchange, an in-depth examination of legal aspects in the normative framework with a view to devising a minimal set of shared standards that should be enshrined in biolaw and biopolitics. And these 'places' are, in fact, bioethics committees established at the national and international levels.

4 The role of bioethics committees: seeking shared basic principles/values

Notwithstanding existing differences in establishment, nature and structural configuration, ethics/bioethics committees play a key role, both at national and international levels, providing scientific updates, engaging in interdisciplinary discussion, and ethical-legal analysis.

On a theoretical level, there is an increasing need for an 'ethical balance', which should not be reduced to a mere compromise or pragmatic agreement. Conversely, a minimum level of shared ethical standards requires weighing principles and values at stake, in the face of real complexity, through balanced critical reflection and dialectic argumentation.

In terms of methodology, an ethical balance is achieved, at national and international levels, through a constant exchange of insights with regard to the theories and arguments held by others. This interdisciplinary and pluralistic approach succeeds insofar as every ethical concept has been adequately and consistently articulated and justified. It should be aware of existing restraints and problems, in the willingness to consider the arguments of others through dialectic and dialogic dimensions. It is appropriate to assess to what extent the position involved is shared by others, even checking it against different and opposite stances, while striving for balance in defining a set of shared/likely to be shared minimum ethical standards. It may also entail partially giving up the 'maximum' expression of one's own theory to find common ground, avoiding irreconcilable conflicts as far as possible.

The aim of the Committee's discussions is to elaborate opinions and documents with final recommendations that can contribute towards giving the conceptual instruments to governments, in order to understand the often complex, dynamic, changeable issues and their importance and urgency, outlining the possible scenarios/lines of action in social policies to be undertaken at public level. These lines of action must seek a balance between the needs of science and technology to progress and the protection of human beings.

The elaboration of minimum ethical elements for regulating techno-science draws inspiration from the horizon of fundamental human rights as a conceptual framework, which form a crucial part of national constitutions and international documents. These documents have undergone, in recent decades, a process of explicit specification and interpretation, in light of emerging issues stemming from scientific and technological development, through declarations issued by international organizations (UNESCO, WHO), conventions, resolutions, recommendations, directives, regional regulations (i.e. the Pan-African Bioethics Congress; the Asian Bioethics Association; regional organizations of American states; the European Group on Ethics in Science and New Technologies at the European Commission; the Committee on Bioethics of the Council of Europe).

The reference to human rights is guaranteed in legislation, at national level, by Constitutions; both in national legislation and case-law, by European norms and judgments of the European Court of Human Rights and the Court of Justice of the European Union. In this context, individuals, national legislation and European laws are called upon to refer to basic fundamental human rights, placed at a higher level.

The work of discussion and production carried out by committees of bioethics, along with the elaboration, interpretation and clarification of fundamental human rights, within the various international and national institutional settings, has contributed to entrenching some shared principles, such as:

- the primacy of the human being and his dignity over the sole interest of science or society; the respect for physical and psychological integrity (safety, wellbeing); the ban on exploitation and commercialization of the human body, manipulation or arbitrary use of the body and its parts (cells, tissues); the ban on physical and psychological invasiveness (i.e. using devices, experimental treatments), arbitrary and non-therapeutic eugenic selection;
- beneficence and non-maleficence: maximizing objective benefits/minimizing potential physical, psychological and social harm, applying the principle of appropriateness/proportionality (the risks should not be disproportionate to the potential benefits), from the perspective of a 'comparative risk/benefit assessment' for the protection of the subject's wellbeing and physical, social and mental health;

- the protection of freedom, in the both sense of autonomy and responsibility (counselling and informed consent to medical treatment), especially with regard to those who are facing inability or particularly vulnerable conditions (children, mentally incompetent individuals, the elderly, pregnant/nursing women or of childbearing age, prisoners, military, poor);
- justice or guaranteeing equal treatment for all, equity of access to healthcare, equality, non-discrimination and solidarity;
- precaution, caution and prudence, in the face of uncertain or risky technologies, which are likely to cause serious and irreversible damage to human beings, humanity, the environment, and future generations.

These shared values and principles do not cover every bioethical issue. Some ambiguities and conflicts persist, particularly in the context of sensitive and controversial issues at the frontiers of life (the status of the human embryo; the status of the dying person). We need to clarify, theoretically and practically, whether dignity should be viewed as absolute (always and unconditionally) or relative (varying according to circumstances); if the proportionality/disproportionality of interventions should be defined on the basis of objective and/or subjective standards; if autonomy should be interpreted either in the sense of self-determination and self-reference or in relation to responsibility towards oneself and/or others; if justice is to be understood in liberal-individualistic or constitutively social-solidaristic terms.

The committees also display openness to society, by means of an adequate dissemination of information, while, at the same time, undertaking consultation and monitoring expectations, as well as emerging concerns. Today, the role of 'active citizenship' is growing in importance, along with the need to build (institutional and otherwise) platforms for dialogue and an interdisciplinary approach to pluralist discussion, which enable dynamic updating and active interaction between experts of new technologies and citizens. Interaction aims to adequately inform and educate the citizens, alongside trying, on one hand, to prevent an irrational fear of novelty in science and, on the other hand, a blind trust as both attitudes are emotional, uncritical, non-reflective and inadequately justified. The goal focuses on raising social awareness, while enabling citizens to develop a critical consciousness, in order to ensure their participation and active involvement in bioethical reflections, drawing up biolaws and policy-making decisions.

Briefly: The aim of the Committee's discussions is to contribute towards giving the conceptual instruments to those in governments and to society, in a broad sense, so as to understand the often complex, dynamic, changeable issues and their importance and urgency, envisaging the possible scenarios/lines of action in social policies to be undertaken at public level. These lines of action must attempt, through the search for

an ethical balance, to reconcile the needs of science and technology to progress with the protection of human beings, health, environment, avoiding the shifts to a radical techno-scientism or just as radical obscurantism (anti-technoscientism).

5 The experience in Europe

5.1 The need for harmonization: regulating the beginning and end of life

Whenever considering beginning and end of life issues, we encounter considerably different approaches to regulating biolaw in the European countries. It is not possible to trace descriptively a comparative framework based upon regulatory diversification, nor get into the details of the different ethical issues involved, but only highlight and provide examples of the general paths devised. Differences clearly arise out of bioethical, biojuridical and biopolitical pluralism, as examined above.

In the context of reproductive technologies, two different orientations of biolaw and biopolitics can be identified. An orientation using claims to defend 'procreative autonomy', which tend to favour the rights of those seeking access to biotechnology, and only secondarily consider the rights of those yet unborn (the most liberal countries are Spain and England); an orientation inclined to defend 'procreative responsibility', which requires balancing the interests of the parents and the unborn child, recognizing the right to be born in a heterosexual bi-parental family setting (the most restrictive countries are Germany, Austria, Italy, France, Ireland). Concerning end of life issues, few countries allow euthanasia (the Netherlands, Belgium, Luxembourg) and assisted suicide (Switzerland, as depenalization); the recognition of the right to receive treatment and the physician's duty to care for the sick and accompany patients 'through' the dying process remains preeminent.

The fragmentation characterising the combination of legislation and case-law when comparing single States is the underlying cause of the "bioethical tourism" phenomenon, resulting in "procreative tourism" or "death tourism", i.e. the displacement of individuals claiming rights being prohibited in their country to go to the country that allows the implementation of those rights. This phenomenon increases conditions of injustice, namely the different treatment of similar conditions, giving priority to those who can afford this transfer to fulfil their desires. But it is also causing problems to judicial decision-making with respect to the recognition of rights when returning to one's Country of origin (e.g. surrogacy and problematic parenting/filiation recognition), resulting in uncertainty, alongside further fragmentation and injustice.

Conflicts among legal frameworks continue to emerge, despite the fact that European institutions (European Parliament, Council of Europe) have issued some

guidance, more or less binding, to draw up legislation in these areas (one should recall the recommendations on assisted reproduction technologies, genetic engineering and assistance in dying).[14]

The necessity to make uniform laws has been clearly recalled in documents, which play a harmonizing role in Europe. The *Convention on Human Rights and Biomedicine* (1997) of the Council of Europe expresses a set of shared values, principles and elements, although there is still some ambiguity surrounding the status of the human embryo (given the persistence of pluralist views on this sensitive issue, albeit agreeing that the creation of human embryos for research purposes is prohibited). Elements shared are: the recognition of the right to equal access to healthcare; the principle of non-discrimination against a person on grounds of his or her genetic heritage, not allowing the use of techniques of medically assisted procreation for the purpose of choosing a future child's sex, the prohibition of sex-selection (selection is only allowed where serious hereditary sex-related disease is to be avoided); the prohibition of making financial gains with the human body; the duty to assist a dying person, the duty to take into account the previously expressed wishes of the patient. The *Charter of Fundamental Rights of the European Union* (2000) refers to the value of human dignity, the right to life and integrity of the person, the right to an informed consent, prohibiting eugenic practices, the commercialization of the human body and its parts, as well as reproductive cloning.

A significant part of EU legislation, if ratified into national legal systems (not all countries have completed ratification procedures, yet the process is ongoing), become binding on States, even requiring adaptation, adjustment and overhaul of laws (with integration and/or completion). In addition to this biojuridical review mechanism, the European Court of Human Rights plays a key role, within the context of European institutional biolaw, particularly in recalling the *European Convention on Human Rights* (1950), especially Article 8 providing a right to respect for private and family life. All citizens, domestic law and the very European legislation shall make reference to fundamental human rights, which are placed at a higher level. Countries are often called upon by the Court to review domestic regulation, whenever it points out a departure from human rights, particularly from the principle of equality and non-discrimination.

14 Concerning beginning of life issues, it is worthwhile recalling: Council of Europe, recommendations 934 (1982), 1046 (1986) and 1100 (1989) on assisted reproduction and the use of human embryos for research purposes; European Parliament, resolution A2-327/88 on ethical and legal problems of genetic engineering (1989), resolution A2-372/88 on in vitro and in vivo artificial fertilization (1989), *Resolution on the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine* (1996), various resolutions against human cloning (1993, 1997, 1998, 2000). As for end of life issues, see European Parliament, recommendation 779 (1976) on the rights of the sick and dying (1976).

5.2 A new regulatory approach in front of emerging technologies

European institutions (European Parliament, Council of Europe, European Commission) have taken action at the legislative level to achieve the harmonization of legislation amongst member States, at least on some points directly related to fundamental human rights.

In these last years, the need to accelerate the regulatory process has led to formal legislation increasingly pushing towards new models of biolaw and biopolitics. European institutions started to introduce new forms of normativity, a new model of 'soft law' or "non-legally binding" instruments. On the one hand, reference on existing legislation ensures continuity and guarantees the control of techno-scientific developments; on the other, experimentation with new normative tools implements previous norms and allows to keep up with, and possibly to anticipate, the pace of innovation in techno-science. Soft laws represent a way to produce normativity quickly without going through the length of the traditional legislative process.

The regulation of the new emerging technologies, characterized by speed of development, uncertainties and unpredictability, is based on some criteria: (1) anticipation, the proactive imagination and identification of the potential scenario, possible or probable negative features and outcomes, of new technologies (through the interdisciplinary and pluralistic discussion of committees of experts); (2) analogical reasoning, namely ruling the new on the basis of its similarities to the past; (3) flexible and easily modifiable normativity, as codes of conducts, or elaboration of integrations and provisional updating of existing regulation. The process begins with the effort of building and envisaging scenarios to anticipate unknown future outcomes, while assuming that existing legislation in "similar" fields can be extensively or analogically applied to new technologies, ensuring a process of flexible modification.

This new kind of governance is oriented towards soft instruments, more easily allowing changes, adaptations and reviewing, and does not require setting up a formally complete and timely regulatory framework, which may or may not eventually take place.

The inefficiencies of the law, constantly chronologically "lagging behind" (the so called 'law lag') techno-scientific innovation and giving space to diversification due to pluralistic ethical approach, is changed by the methodology of anticipation that requires not only accelerating the pace of normativity but even being ahead of its objects. The biopolitical choice to soften the regulation, instead of regulating (interventionist model) and non-regulating or deregulating (abstentionist model), allows maintaining and conveying a sense of legitimacy and control through normativity without actually formally exercising it.

Within this context of soft normative guidance as a constituent of the new European regulatory process in front of new emerging technologies, ethics as a 'soft normativity' plays the role of 'co-productionist understanding' of social and technological change. The rise of ethics as a tool for governance acquires a special meaning. Ethics has progressively become an 'institutional practice' within the field of health but also 'beyond' health in the techno-scientific domain. The main expression of 'institutionalized moral reasoning' consists in ethics committees, established to produce policy opinions on the ethical aspects of new technologies (often meant also to include legal and social implications).

The European Group on Ethics in Science and New Technologies (EGE) may be one example of expert committee, whose role is strictly connected with the EU deliberative process. Whenever directives touch upon values, the opinion of the EGE has to be taken into account and mentioned. As EU law making process is complicated and slow, this approach brings dynamism, envisaged as a way to respond to the accelerating pace of development in the relationship between science, technology and the key values of society. Opinions of expert Bodies (as EGE) outlines the "timely manner" in which ethics advice should respond to more rapid, complex and unpredictable science and technology developments. In this sense, also ethics opinions are imitating legislative documents, see the long "descriptive" preambles of "Having regard to" and "Whereas".

6 The need for a global harmonization

6.1 The evolution of biolaw in the international context

The awareness of the harmonization of laws at the international level is gradually developing. The need for internationalization comes, in fact, from the emergence of structurally transnational problems, as they are not confined within a region or a nation (for example pandemics, human genome mapping, international trials, environmental issues). Our world and our societies become increasingly interconnected and threats to global public health increase and continue to emerge. The awareness that solutions of bioethical issues raised within a nation or a region often have, immediate or future, direct or indirect implications, that go beyond the specific historical, social and cultural conditions from which they have emerged to embrace the entire planet, appears increasingly clear. There is a need for a macro-bioethics, broadened in space, across cultures, countries, continents and in time, between distant and future generations.

There are now sources of international biolaw: codes of practices and human rights framework. There are professional codes of ethics as sources of soft law, whose

origin goes back to Hippocrates and the ethical and deontological reflections on the practice of medicine. It is a flexible regulation, subject to revision, addressed to physicians and health professionals and the universal and global international law sources.[15]

As for international law sources in bioethics, we should consider the documents (declarations) that have been developed by international organizations. The statements of international organizations on certain issues have anticipated or even replaced the statements of individual States that often, due to delays of internal politics and ethical pluralism (as previously seen), postpone or do not even get involved in internal regulation. Therefore, within the international debate, meeting places and discussions have been started, aimed at identifying minimum shared ethical elements that can serve as a reference guide for individual countries that do not have a regulation or are developing one or are going to review the existing one, and as an outline for the international community.

The theoretical framework of the evolution of international and global biolaw is the reference to human rights and the thematization of the extension and specification of human rights in bioethics. The universalistic claim of human rights has facilitated the formulation of transcultural standards; the fact that the key notions employed at the domestic and regional level to protect people from misuse in the biomedical field are already formulated making reference to human rights; the lack of any conceptual and institutional instrument other than human rights to produce an international framework of norms relating to biomedicine. The human rights approach facilitates the universal dialogue in bioethics, as human rights are conceived as entitlements that people have because of their human condition, regardless of their ethnic origin, sex, age, socio-economic status, health condition, or religious or political ideas. The recourse to human rights is a way to ground intercultural dialogue that helps bioethics to go beyond the pluralistic fragmentation that brings to the overproduction of divergent norms: human rights offer a framework and a common understanding to find common principles and values.

Since 1948, with the *Universal Declaration of Human Rights*, the United Nations Organization has adopted a number of instruments in the human rights field,

15 As for the professional ethics international documents see: the *Nuremberg Code* (1947), the *Declaration of Geneva* (1948, last revised in 2006) and the *Declaration of Helsinki* (1964, last revised in 2013) of the World Medical Association; the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) of the Council for International Organization of Medical Sciences; the *Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products* of the World Health Organization (1995); the *Guideline for Good Clinical Practice* (1996) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, as adopted by the European Union, the United States, and Japan.

implicitly or explicitly related to bioethics.[16] This trend was consolidated at the international level within the UNESCO, through the International Bioethics Committee: the *Universal Declaration on the Human Genome and Human Rights* (1997); *International Declaration on Human Genetic Data* (2003); *Universal Declaration on Bioethics and Human Rights* (2005). This last document is particularly important as a universal legal instrument, as it sets the minimum principles agreed and considered universally essential for bioethics, biolaw and biopolitics. In the Explanatory Memorandum to the Preliminary Draft Declaration (para. 11): "The Drafting Group also stressed the importance of taking international human rights legislation as the essential framework and starting point for the development of bioethical principles", as international human rights biolaw.

The principles set out, express the recognition of the duty to respect human dignity and human rights in a pluralistic and multicultural setting, given the new possibilities opened up by techno-science in the biomedical field. The recognized principles are: autonomy and responsibility, equity of access and justice, informed consent and confidentiality, respect for the integrity and vulnerability of the human person, solidarity and international cooperation, responsibility towards the environment and future generations.

As a declaration, this document falls within "soft laws", as a non-binding instrument. It is not actually and immediately binding (since it requires the consequent ratification of States), but it has or may have an indirect effect as a moral, legal and political commitment at national and regional level, and may extend such effect in the long term. As a form of soft law, it may have an influence and is potentially binding, as the initial document that begins a process that may bring gradually States to elaborate binding rules and enforceable rules for states with biolegal and biopolitical relevance.

The rapid development of soft laws as a source of international law and biolaw is evident. This gradual procedure leaves more space for interdisciplinary and pluralistic ethical discussion in the effort of achieving a theoretical consensus and a practical agreement on complex and delicate issues, which are often very dynamic in relation to the rapid scientific and technological development. The process of the "hardening" of soft laws may develop in pushing towards a treaty-making process with reference to the principles stated in the declarations, or to influence the practice of states or the creation of customary law, above all as non-binding standards are reaffirmed in international treaties or invoked by international courts to support their decisions.

16 Among them one can mention the resolutions of the General Assembly devoted to human rights faced with scientific and technological progress (*Human Rights and Bioethics* in 2001 and 2003), genetics (*Genetic Privacy and Non-Discrimination* in 2004, 2007, 2008) and human cloning (2005).

The use of a human rights framework for global biolaw has been criticized as a Western ideological cultural 'imperialism' (non relevant in non-Western cultures and societies) and as a strong individualistic construction (non sharable by communitarian perspectives).

As regards the first objections, it comes from a philosophical debate between universalists and relativists, the first one believing in the possibility to know universal minimal common values and the second sceptically rejecting the possibility to find an objective common truth. It is an historical evidence that the origin of the formulation of human rights is Western (the European Enlightenment of the end of the 18th century, notably, the American and French Revolutions), but the historical and geographical circumstance of their birth does not deny the widely accepted claim recognizing that human beings are entitled to basic rights by the mere fact of being humans. As a matter of fact, international human rights law has been elaborated and agreed upon by representatives of the most diverse countries and cultures, without the intention to impose one cultural standard, but rather to promote an ethical and legal standard of minimum protection necessary for human dignity. Human rights have been originally conceived having in mind the individual person.

As regards the second objection, it should be mentioned the recent development of international law towards a communal and collective approach, as the development of the "second generation of rights" (the right to education, to social security, to a fair remuneration, to healthy working conditions, to health care, the protection of the family and children) and the "third generation of human rights" (the so called rights of solidarity, or rights of groups, which include the right to development, to peace, to a healthy environment).

6.2 The case of international multicenter clinical trials

A specific issue that puts in evidence the need for a global biolaw is the question of globalization of clinical studies. It is one example of dramatic inequalities between individuals in developed countries and developing countries, who often have no access to safe water, new vaccines, and effective medications. Inequalities in health care have contributed to significant inequalities in health. These inequalities have led to a debate on how clinical investigators can improve health care in developing countries and reduce health disparities.

The risk is the one of "outsourcing" the experimentation, in order to reduce costs, simplify and accelerate procedures, with experimentations that involve those populations that are particularly "vulnerable" mainly because of economic underdevelopment that slows down the progress of science and technology or, even if economically

developed, unaware of ethical issues. These conditions may expose some populations to a risk of exploitation for scientific interests, which may hide commercial interests.

There are a lot of international norms on experimentation in biomedicine.[17] Yet in the field of bioethics, specific issues related to experimentation have emerged in discussions concerning this area, requiring further analysis.[18] The opinions issued by European and national committees pointed out that rules governing trials, which have developed throughout the debate, were inadequate and, therefore, would benefit from integration.[19] The application of general ethical standards of clinical trials to the different cultural context, in particular to developing countries, needs an activity of interpretation and specification, that may be helped by a community consultation in order to acquire better knowledge of local culture.

The main points that need to be recognised globally (on both ethical, legal and political level) are:

- the necessary use in research of the "worldwide best" methods, meaning the best methods available anywhere in the world;
- responsiveness and direct relevance of the clinical trial to the health real needs of the vulnerable population of the host country populations;
- commensuration of the balance of risks/benefits with the basic conditions of the population (including nutritional, epidemiological and health conditions), in reference to each individual, but also to the community, ensuring that participants enjoy potential benefits and helping health care infrastructure to support proper distribution and guaranteeing continued access to post-trial benefits and

17 Council of Europe, *Convention on Human Rights and Biomedicine* (1997); International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline for Good Clinical Practice* (1996); Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002); World Medical Association, *Declaration of Helsinki* (1964, last revised in 2013).

18 See the reports and opinions of national bodies: Comité Consultatif National d'Ethique, *La coopération dans le domaine de la recherche biomédicale entre équipes françaises et équipes de pays en voie de développement économique* (1993); National Bioethics Advisory Commission, *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (2001); Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (2002); European Group on Ethics in Science and New Technologies, *Ethical Aspects of Clinical Research in Developing Countries* (2003); Italian Committee for Bioethics, *Pharmacological Trials in Developing Countries* (2011).

19 The general ethical standards which must be considered mandatory, as substantive ethical requirements for clinical trials on international level are: the protection of all human subjects (no discrimination); the guarantee of the conditions of justice, respect of equality (in the equal access to health) and of different cultural contexts. The respect of dignity, physical integrity, autonomy of participants and justice between subjects in accordance to the good clinical practices are ensured through: preliminary verification of scientific relevance of research; protection of safety and well-being of participants; equity in the enrolling and selection of participants; balance of reasonable risks compared to potential benefits; expression of informed consent; appropriate treatment during and after the trial; compensation for direct damages to health; distribution of equal burdens and benefits.

treatment to participants and to the population outside the research context of the country where the trial is conducted, as expression of international cooperation and solidarity;

- specification of the informed consent to local customs, verifying that it is voluntary and freely given without coercion, incentives or 'undue inducement' (oral and witnessed for the illiterate, with permission of community leader or family involvement);
- building the capacity of host countries to become fuller partners in international research both on scientific and ethical levels, enhancing collaboration and creating an atmosphere of trust and respect.

It is a topic that shows how important a bioethical global consensus is in order to avoid ethical "double standard" that opens forms of discrimination. The ethical standards for research should be the same for each country and each country should benefit from the positive results of clinical trials regardless of the level of literacy, wealth, social advancement, techno-scientific progress. This is one of the concrete paths to deliver global justice in health and welfare in the framework of human rights.[20]

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20 Most recent legal references on the topic: The *Universal Declaration on Bioethics and Human Rights* (2005). The declaration recalls the general ethical principles of experimentation on human subjects – recognized in international documents, affirming that they should be applicable everywhere, without making a distinction between more or less developed countries, avoiding unequal treatment and recognizing the universal justice. This does not mean accepting a "double standard" of ethics: on the contrary, it means reiterating that the ethical standard should be "unique" as concerns principles. Trials in developing countries must meet the same ethical standards of developed countries (Article 21 b). Interventions by the European Union are more recent: Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use which explicitly deals with vulnerable populations in developing countries. The implementation of shared ethical rules requires biopolitics to take further steps forward, both at national and international levels.

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Annex: Concept note for bioethical policies and bioethical law

(This topic includes but is not limited to concerns about exploitation in countries where studies may be done or genetic data provided without commensurate benefit to the participants or countries.)

Harmonization between bioethical policies and law is crucial if each are to be effective and relevant.

- What should the relationship between bioethical policies and law be and are there models that show what it currently is in a few different places?
- How do countries set about developing and reviewing bioethical laws and policies at the national level, what role do national ethics committees and their recommendations play, and what are the mechanisms when these laws and policies need to be harmonized internationally?
- Are there specific areas where harmonization is more important than others?

>> SESSION IV: RAISING SOCIAL AWARENESS ON BIOETHICAL ISSUES

Session Summary

Social Awareness of Bioethical Issues
Jorge E. Linares

The Perspective of the Presidential Commission for the Study of Bioethical Issues
Anita L. Allen

The Singapore Experience
Chin Jing Jih

The Perspective of the Nuffield Council on Bioethics
Hugh Whittall

Bioethics Education in Turkey
Meral Özgüç

Discussion Paper
Raising Social Awareness of Bioethical Issues Including Education, Media, and Communications
Jorge E. Linares

Aamir Mustafa Jafarey (Session Chair), Meral Özgüç, Anita L. Allen, Hugh Whittall, Chin Jing Jih and Jorge E. Linares (from left to right)

Session Summary

|| The fourth and last thematic emphasis of the Global Summit pertained to bioethical discourse with the public sphere and possible ways of strengthening bioethical awareness. First of all, Jorge Linares from the National Autonomous University of Mexico advocated in his introductory talk for finding new methods of promoting dialogue between experts, scientists, bioethicists and the public. The goal is a pluralistic debate, which firstly is based on scientific facts, secondly makes use of current ethical theories and thirdly reacts sensitively to different cultures and ethnicities, Linares said. Subsequently, delegates from four WHO regions reported in a podium discussion on experiences in their countries with public discussion.

Anita Allen from the US Presidential Commission for the Study of Bioethical Issues described the activities of her commission in creating transparency in public proceedings and in attracting interested persons for a more intensive discussion by means of teaching and educational materials. Chin Jing Jih from the Bioethics Advisory Committee in Singapore pointed to particular successes in the artistic treatment of bioethical themes together with cooperation partners. He reported on an exhibition in the Singapore Science Centre; a theatre project on the topic of enhancement; as well as cinema- and discussion-evenings on films that thematized bioethical questions. Hugh Whittall, managing director of the British Nuffield Council on Bioethics, likewise praised the effectiveness of good cooperative projects. In addition to projects with museums and theatre groups, good experiences have also been made in Great Britain through collaborations with filmmakers, science festivals and a radio station for children, and there has even been a prize tendered for a poetry competition. Meral Özgüç from the Bioethics Committee of the Turkish National Commission for UNESCO in Ankara underlined the significance of bioethical professional and advanced training initiatives, especially in the university sector.

In addition to many further inspiring examples from other states, the concluding discussion turned mainly on the increasingly more important role of social media in the bioethical debate with the public and on the importance of a culturally and ethnically sensitive dialogue. It is indispensable, according to the consensus, to endeavour to hear and take seriously all relevant voices in the conversation – and also to make this visible. ||

Social Awareness of Bioethical Issues

Jorge E. Linares

|| My paper is on raising social awareness on bioethical issues including education, media and communications. According to the *Universal Declaration on Bioethics and Human Rights* of UNESCO, the member states of the United Nations had the obligation to promote their reflection on bioethical issues in educational structure and public communication as well as encouraging international cooperation to achieve a more extensive dissemination of bioethical culture in the entire world.

The paper is organized along three questions. First, national ethics committees (NECs) have the responsibility to innovate new ways of communication and dialogue between experts, scientists and bioethicists and the public within their own cultural and political context. NECs should promote a pluralistic debate – and this is my main proposal – with these characteristics: based on scientific knowledge, founded in contemporary ethical theories, and including a multicultural and pluri-ethnic dialogue.

Formal education: The purpose of education in bioethics is to cultivate critical thinking among the population, especially the youth, that will help people to improve autonomous and independent decisions regarding these problems. Such capabilities are related to the universal rights of free thought and the free development of each person, making philosophical ethics irreplaceable in bioethics education at all levels.

Why do we need philosophical education in bioethics? In moral philosophy, there is a new paradigm that extends the scope of moral consideration to all animals and the entire biosphere – current ethics cultivate non-anthropocentric moral values. Contemporary ethics also holds a cosmopolitan and multicultural vocation that considers not only the interests of the dominant western civilization but also other cultures and future generations. Bioethics as a fundamental ethical education, this is my view. Bioethics is not about predominant moral values or the enforcement of the moral values of the majority within societies, but about the construction of

transcultural and diverse moral values that recognize the individual right to make decisions about the different ways of living and dying without suffering moral oppression from the rest of the society. Education regarding bioethics should supply tools to develop autonomous deliberation about our own bodies and personal decisions in life. There should be particular attention to the bioethical rights of vulnerable groups, especially women.

Forming bioethics professionals or "bioethicists": Bioethics in higher education should concentrate only on postgraduate studies. The formation of bioethicists as professionals can only be achieved with a scientific background, because bioethical studies entail multidisciplinary, theoretical and practical perspectives. Bioethicists require post-graduate formation and experience with practical deliberation in committees of hospitals and research centres and also with public debates, if possible.

Communication media: Non-formal education should be offered in all possible modalities of media and through promotional campaigns targeting the main subjects related to bioethical issues. Science museums are a good opportunity to exchange and expand exhibits on main bioethical issues, for instance the beginning and end of life, diseases and epidemics, genetics and genomic technosciences, health systems, neuroethics, environmental ethics, ecology, conservation of biodiversity, sustainability issues and social and economic development, for example.

Critical analysis of the legal frameworks of bioethics: NECs should share knowledge with the public about the legal framework of their respective country, including rights and obligations and also restrictions and limitations within their political and legal framework. An individual's bioethical rights are not sufficiently protected or are not properly communicated to the public, neither are the rights and obligations of citizens regarding these critical issues well-known or clear.

Fostering dialogue: One of the primary objectives of the NECs is to broaden and grow social awareness regarding bioethical controversies as well as give impulses for the resolution of these controversies through democratic consensus. It is also fundamental that the NECs foster the social assessment of scientific and biotechnological innovations and discuss the risks of biotechnologies as well as the fair distribution of the technological and scientific benefits. This debate might contribute to the reduction of social economic inequalities.

Regarding the second question, the NECs could make use of citizen participation and decision-making methods such as citizen juries, consensus conferences and other models of citizen participation in the assessment of bioethical public policies or biomedical research. They can review and use models of citizen conferences in several countries since the 1980s. These modalities of dialogue between common citizens and experts had been effective methods for technological innovation assessment and for decision-making regarding technological regulations.

Promoting citizen participation on bioethics: The goal of this debate is not that the public will accept any technology that industry launches on the market. The goal is deliberative discussion of risks and benefits and fair conditions and opportunities to access the technological benefits. Scientific information has to be sufficiently and adequately disseminated and, moreover, that the interests of the predominant social groups, industries and their lobbying activities may not prevail over public and common interest.

Regarding the third question – whether NECs should take on a strong role in raising public awareness – my answer is affirmative. One of the main responsibilities of the NECs is to take a stronger role in the public sphere for the dissemination of a pluralistic understanding of bioethical issues. NECs have a duty to contribute to consolidating pluralistic bioethics that embrace true global and planetary reach, including in their ethical consideration not only all human beings but also all other living beings that we share the planet with.

What are bioethical conflicts? Within all societies, different moral conceptions and practices coexist. None of them should arbitrarily be imposed on other communities through influence on customs or through being more dominant or hegemonic in a given society. It is the duty of the NECs to help shape public debates in which the doctrinal moralities do not prevail and are not imposed as an official public morality over all citizens. That is why pluralistic bioethical debate is needed in every society. All moral decisions should be expressed in public debates and in the media, but each has to offer rational arguments and ethical values that are acceptable and shared by all moral communities. That is common moral values like the classical principles of bioethics. The NECs must encourage pluralistic bioethics that expands the individual and social rights to free decision-making, equal opportunities of human development, and universal access to healthcare and the benefits of science and technology.

Bioethics as a democratic development: The democratic character of bioethics consists in its potential to preserve and strengthen individual and collective autonomy and its ability to build ethical consensus, although not necessarily unanimous consensus. True broad social participation legitimizes ethical resolutions that have the most acceptance among different groups of citizens.

Democratic consensus on bioethical issues: Consensus agreement on bioethical issues will depend on the degree of development of an open public discussion and pluralistic debate to confront and resolve these problems and dilemmas properly. The NECs have the crucial task then to spread a global culture of bioethics. Bioethical global culture means a culture of democratic pluralism that entails recent debate with scientific grounds, that is well-founded philosophically, that enables achieving consensus and agreement among morally heterogeneous and culturally diverse communities. We live in a multicultural context that has weakened the all-rationalist

convictions about universal values and claims of absolute moralities. We need pluralistic bioethics which entails tolerance towards different moral and cultural groups within each society.

Four bioethical principles: To resolve moral conflicts in a rational and just way, common ethical principles are required and they must be established with a minimum axiological content for all moral communities – that is, the common moral values are the main goal of contemporary bioethics. First of all, autonomy (individual and collective), then justice (distributive and retributive), responsibility (civil society, social and government commitment) to face and resolve longstanding problems and future risks including ecological disasters, and precaution to prevent major technological risks (e.g. nanotechnological, biological, informational, nuclear, ecological disasters, consequences of global climate change).

Towards cosmopolitan bioethics: Bioethics can only advance as a practical reason of dialogical and pluralistic nature. It is about building a collective and global practical reason or a cosmopolitan bioethics with local and global scopes – this is the main goal for the future.

Conclusion: The future of bioethics depends on a wave of moral plurality and tolerance in our global society and institutions around the world to consolidate some pluralistic public spaces of deliberation and resolution of scientific and technological controversies related with bioethical issues. The main idea of my paper is a proposal regarding the future of cosmopolitan and global bioethics around the world based on the *Universal Declaration on Bioethics and Human Rights* and the idea of a common moral value, a minimum morality, around the world that is transcultural and heterogeneous in moral communities. ||

The Perspective of the Presidential Commission for the Study of Bioethical Issues

Anita L. Allen

|| How can national ethics committees raise public awareness? The US Presidential Commission for the Study of Bioethical Issues has addressed each of its topics using the method that we have come to call "deliberative democracy". This method, which is developed in a theoretical way in the work of our chair, Dr. Amy Gutmann and her colleague Dr. Dennis Thompson, facilitates ongoing public exchange of ideas, supporting, questioning and envisioning new policy options. Dr. Linares notes in his paper the importance of consensus and this is one of the things which our approach to democratic collaboration seeks to do.

We distinguish deliberation from debate. Debates have winners and have losers. But democratic deliberation is a collaborative problem-solving process that seeks to find common ground for the common good wherever possible and strives to adopt a pluralistic perspective on forging actionable policy solutions. Public awareness and public participation go hand in hand. One way the US commission encourages public participation is by hearing from a wide variety of stakeholders through publicly transparent and accountable mechanisms. So, we have our meetings in public. We invite learned international experts to come and talk to us as well as learned national experts. For example, during the 2014–2015 Ebola outbreak in West Africa, our commission met publicly and we heard from experts on public health, public health workers returning from deployment abroad and from advocates from the affected communities in the United States and Sierra Leone.

As this example illustrates, formulating thoroughly informed recommendations requires including diverse forms of expertise and distinct perspectives of persons and communities most affected by the policies under consideration. Each US president has the opportunity to create a new bioethics commission. President Obama's bioethics commission, compared to that of President Bush and his predecessors, is very ethnically and otherwise diverse: men and woman, black and white and brown,

Asian, Muslim, people from African ancestry, Indian ancestry, and Iranian ancestry. Military and civilian backgrounds are represented, as are physicians, a nurse, philosophers, and lawyers. Our group embodies the ideal of diversity and our approach of inclusiveness and hearing public voices reflects that same set of core values. National ethics bodies should consider ways to actively engage and encourage a public involvement and our commission has been making a priority of this.

Six of our commissions' nine written reports directly address the importance of public and professional ethics education. These reports reflect the commission's view that public engagement and education are essential. We have produced over fifty sets of educational materials for the public. These are available on our website, bioethics.gov. These educational materials are designed for a variety of learners.

One of the points that Dr. Linares appeared to make is that bioethics education should start at the postgraduate level. When should bioethics education begin? We take the point of view, that it needs to start at the beginning. Elementary school children need to be exposed to bioethics, high school students, college students, graduate and professional students in professional training need to include bioethics education. Why? Because not everybody will get to that postgraduate level and yet everybody needs to have an opportunity to know about bioethics. And why is that? Well, in my view, bioethics is for all the people. Bioethics came to exist, at least the American version, because of the mistreatment of ordinary people, ordinary people who were research subjects, ordinary people who were patients. And since bioethics arose to make the lives of those people, ordinary people, more full of dignity, more autonomy, more freedom, more respect, more privacy, it stands to reason that those ordinary people need to understand when their interests are at risk. Therefore we need to start bioethics training in our societies and at the beginning of education, as soon as possible.

How do national ethics committees know when their efforts have been successful? Because you can have fifty sets of pedagogical materials out there on the web, you can have your live stream of our bioethics meeting. We have always public outreach – be on Twitter, be on Facebook, be on Instagram, be everywhere. And how do you know though, when you are having the impact that you want to have? This is a very difficult thing to engage. But one of the things which we are going to be turning our attention to is that not only the process of trying to make sure that the public has an opportunity to learn to know, engage and inform government and experts, but also to have some metrics about when success has been obtained.

I would like to underscore the importance of never forgetting the reason why we do bioethics. Public awareness of the goals and purposes of bioethics is a paramount policy priority. ||

The Singapore Experience

Chin Jing Jih

|| Prof. Linares has outlined the philosophical principles involved in, and the need for, raising social awareness on bioethical issues. What I want to share with you is some of the things that we have done in Singapore – the applied and practical aspects of how we try to raise social awareness. I will also discuss what are some of the challenges that we face, and how we try to bring the message to the public.

The Bioethics Advisory Committee (BAC) was formed in the year 2000 by the Singapore Cabinet. One of the key objectives for the committee is public education and being a source of information on bioethical issues. Singapore is a multiethnic, multicultural and multireligious country. It is very pluralistic, and people have different religions and beliefs. But it is also a country that has moved only in the last few decades from a third world country gradually into the second and first world. Generally, people tend to think that bioethical issues belong to the "high priests of ethics" that sit on committees. There is a generalization sometimes, and a certain apathy, towards some of these issues; but there is also this trust that the government will decide what is right for the people.

The challenge is therefore: how does a committee like the BAC bring its message to the masses? The BAC realised that it needed to engage with agencies that reach out to the public. Another consideration is the mode of presentation – How do we present these topics in a manner that would appeal to our public, especially to students. Students in Singapore tend to favour science and technology related subjects, and there is a general lack of interest in humanities. How do we present bioethical issues in a way that engages their interest, and how will we be able to stimulate them intellectually to think about these issues. Most people like to read about science, but not the philosophical implications of technologies. Thus we decided that we needed to engage certain outreach agencies. Through the representations of these agencies in the BAC, we were able to establish projects that are able to engage the public, especially students.

One of the key partners of the BAC is the Singapore Science Centre which is an institution to promote interest in science and technology through a blend of exhibitions, events and educational programmes. Through our collaboration between the committee and the Science Centre, as well as with the Centre for Biomedical Ethics, we have a bioethics exhibition in the Science Centre. The Science Centre is frequented by tourists, and also by students. Schools organize regular excursions to this place and through these exhibitions, we are able to reach out to students and more, as other members of the public would also visit the Science Centre. The exhibition is not meant to impose certain views on young minds, but rather, the intention is to let them see things from a different perspective. For example, the main exhibit is a display on the commercial aspect of organ transplantation, but it is presented in stories which are told from the perspective of the patient, the family and the community at large. It tries to get students to look at the issue from different perspectives, so that they can gradually decide for themselves through the application of principles, and establish their own views. This, I think, prepares them for the next ten, twenty years, for when they become adults, to engage in very rich and fruitful discussions on some of these bioethical issues.

We also organize symposium and public forums for the public. We invite foreign experts to Singapore to share their perspectives and/or their knowledge of their topic of expertise. Singapore has a tradition of learning best practices from countries that are more established, and through these public forums, we hope to be able to widen perspectives and broaden knowledge, because before we can have meaningful discussions, we need to raise the public's level awareness on these issues. We also do students workshops, for example we had one on germline modification last year. We have had movie screenings, which are followed by discussions on some of the bioethical themes raised in the movie. For example, some of you may be familiar with the movie *My Sister's Keeper*, in which a young girl was brought into the world as a savior-sister to provide organs for her older sister who was stricken of leukemia. Through some issues raised in this movie, we encouraged the students and viewers to explore their thoughts and feelings. Accordingly, we introduced them to some fundamental principles of bioethics. We also held public forums that discussed issues raised in research involving children, for the public to be informed about some of the issues. So this is how we have approached public education and our task of being a source of information about ethical issues, national ethics committee definitively have a role in raising social awareness on bioethics.

Another initiative involves a popular drama group in Singapore that has been open to experimentation with bioethical issues. The Centre for Biomedical Ethics commissioned The Necessary Stage to produce a play called *Future Perfect*, which dealt with the theme of human enhancement through three stories about designer

babies, stem cell products and a "youth fountain serum". The play was able to draw in the crowd. After the play, scholars from the Centre for Biomedical Ethics, the dramatist, and the director engaged in a conversation with the students and the public who came to watch the play. And through that, there was a public discussion on the ethics of human enhancement.

We found that this medium of communication is far more effective than commentaries that the public may find too profound for their understanding. And this is also a very good medium for interaction. I chair the National Healthcare Group's research ethics committee which oversee the Office for Human Research Protection Program, where we also do public engagement to help people to understand what their role is when volunteering as human subjects in biomedical research, and what questions they should ask in order to protect their own rights. And these are very meaningful discussions between the public and invited experts, which usually attracted huge crowds. Again, raising social awareness is achieved through public conversations. These are the ways that national ethics committees, through the various organizations that they are linked to, can bring their messages to the public and stimulate interesting discussions.

In terms of engaging the media in the public bioethics discussion, I would like to share an example where the public got interested because of certain perceptions and fear that was carried in media reports. We have found that for some bioethical topics, the media may adopt a portrayal that evokes a very emotive response, and the way some biomedical research issues are portrayed in the public medium may create fear among people. One example for us was when we released our public consultation paper on the topic of human-animal combinations, which resulted in emotive responses from some journalists writing in our local papers. To help dispel some of these fears, the BAC organized a public forum to inform the public. We invited international experts to discuss the science behind the research, so that people would understand the potential behind the research. In many of these initial discussions, people had imagined all sorts of possibilities which were still very far away from reality. We made an effort to explain to the public that we need to balance the benefit and risk to society in pursuing such research, and our aim was to help the public to understand what were the boundaries, risks, and the protections that could be put in place to ensure that this sort of research will produce more benefits while mitigating the risks. We also met specifically with the media, to inform them about the science and the issues that need to be considered.

These engagement sessions were very useful because people got the opportunity to ask questions and clarify their doubts. By the time the report was out, I think it was received with much less emotion and much more reasoning and rationality by the media and the public. People tend to look at it from a more evidence-based perspective,

rather than with an emotional reaction, when the sum of these scientific endeavours are promoted. The BAC therefore engages with the media as often as possible, such as during the launch of our public consultations. Before we make any recommendations or issue any guidelines, we will always have a public consultation, during which we invite views from the public, experts such as researchers, the research ethics committee members, as well as the media. And after careful consideration of the feedback we received, we will release our reports. This is another instance when we engage the media, for publicity about our work and also for events that we organize.

We find such engagement of the media critical because the media has got a very deep penetrative reach into the public. The way the media frame certain issues can influence the perception of the public. Therefore, we think that engaging the media is important. I think, for us, the new frontier is social media. BAC may have to consider starting a Facebook account, or develop a website that appeals to the younger generation, because in Singapore, many young people no longer use the print media. They get information as they like, through social media, from the internet. Therefore, if we want to have effective social engagement, we have to move to where the public is going for information, and social media is certainly the fastest growing mode. Social media is going to be the new frontier for BAC. We need to think about how we can package bioethical issues in a format that is appropriate and that can be communicated even across social media.

The so-called netizens in Singapore are very active. They have very strong views. But we also know that there is a silent majority out there and the question is, how do we engage the majority? This question is very important because at the end of the day, we need to hear from as many people as possible, and solicit as many views as possible. In a pluralistic society like Singapore and like your societies, we need to bring together all these views on the principle of tolerance, as well as promoting science and the principal of proportionality. We need to be able to promote science in a way that is deemed to be acceptable by all, and to find methods of carrying out research with adequate protection in place, so that the research is deemed acceptable by social consensus.

In short I have shared with you some of the things we have done to raise social awareness of bioethics in Singapore. It is not easy, and we are still trying very hard to get the public interested, trying to frame some of these discussions in a way that is interesting and engaging. We are trying to get young students interested because they ask some of the most probing questions. That allows us to improve on our deliberations and guidelines, so that when our guidelines are translated into policy, and sometimes even into legislation, there is a general sense of acceptance since people have been given the opportunity to voice their opinions. At the end, this product is something that the general society is able to accept; and it works for the majority of society, for the good of society. ||

The Perspective of the Nuffield Council on Bioethics

Hugh Whittall

|| It seems to me that we are generally in agreement, about the things we should do, we could do, and we would like to do to engage people. Bioethics has to and does engage important public interests and is in itself a public enterprise. Of course, national ethics committees advise policy, but if we see it as a public enterprise that engages public interests then this obviously requires public involvement in a pluralistic fashion, engaging a national and international discourse. That much we all will agree. And we know that this will contribute to what is only ever a provisional resolution of issues which means that we also have to engage in continual reflection that involves people much more widely.

The question then is: What is the role of national ethics committees in this context? I will break this down into some different elements, asking: What is it that we are trying to do; and what are the ways in which we can try to do those things?

So, the first aspect of "What do we want to do?" through engaging people more widely is to get their input into our work, into our deliberative activities. I think that we should not try to claim that we are the experts who make decisions on behalf of everybody, but rather we should engage people to contribute to our own projects, to our own work.

The second is that we try to stimulate a public contribution to a policy process so that the information that goes into policy processes is not simply channelled through national ethics committees themselves but that we stimulate a public discourse in which those contributions can be made in other ways.

The third aspect of what we might be trying to do is to inform people of our own work. So, in the dissemination of our published opinions, reports and recommendations, we will of course target policy makers and decision makers, but we also want to promote an understanding of what we have done within a wider public context.

The fourth aspect of what we are trying to do is to promote a general understanding, not necessarily specific to a particular problem or a particular issue but generally, as others here have said, to cultivate critical thinking. Another phrase that is often used is "promoting bioethics literacy" – this is the capability of people to recognise, to contemplate, to think and to engage in these types of discussions.

So these are four different aspects of what it is that we might be trying to do through engaging a public. When it comes to the *ways* in which we might try to do that, I have identified three different approaches based on our own experience at the Nuffield Council on Bioethics. The first is to try to engage with people directly. In the United Kingdom, we have about 65 million citizens and it is quite difficult to sit and have a cup of tea and a conversation with every one of them, as nice as it would be. The second might be via the media, as an intermediary. And the third might be through partnerships. I would just like to speak a little bit about each of these approaches.

The first, directly speaking to an entire population, of course, becomes very difficult. In our work we carry out public consultations where we seek as many views as we can, we put information out widely, or we might target particular interest groups who we know have a particular stake in an issue, or we might use focus groups where we speak to groups representative of wider publics. All of these approaches clearly have some benefits and some value, but they also have limitations. We have, as others have, prepared educational materials that are intended to be used in schools, but with limited success. I think the materials were good, they were appreciated where they were used, but the difficulty was to actually get them into schools and into the teachers' hands. We made them freely available online, but teachers have access to thousands of online resources and what they look for are often the ones that respond directly to the questions that will be in exams at the end of the year. So, while I am not saying this could or should not be done, it has been difficult for us to make it very productive.

The second approach is through the media. We run press briefings, send out press releases, etc., and this meets with variable success. We know that the media tend to write stories largely when there is an argument of a certain nature. And the media also want to present the extremes. So, when we say, "Well, we have got quite a balanced argument here", this is not always well-reported. I think that we must work with the media and foster relationships with people working in the media so that when they do see an issue relevant to our field of work, then this is the place that they can come to discuss, to understand and to work through it. Social media is increasingly important and we are using Facebook, Twitter, and blogs to reach wider audiences. I think that we have to keep working with this, but we need to be careful. For example, with Facebook – the clue is in the name – that we are not just talking to our friends, our Facebook friends. We can have, say, 5,000 followers, but we do not know who really follows what we put out and whether it is getting further.

The third, which is one that we certainly have found important to develop in recent years, is about identifying partners. If we have limited capacity and limited ability to reach people more widely, despite our ambitions and our best intentions, it is interesting to look for partners who can work with us. At the Nuffield Council, we have done this in a number of ways. We worked with an online radio station that produced a number of two-minute radio clips directed at children aged six to twelve. These were put out through their radio station which is broadcast in London and South East England and online. And these had about 370,000 listeners. We have worked with science museums (and I went through the bioethics trail in Singapore which I think was excellent); we have partnered with theatre groups, such as Theatre of Debate in the United Kingdom who have worked with us to construct plays that they take out into schools; and we have worked with people who use our material to develop activities or stalls at different kinds of festivals. We have also worked with spoken word groups – last year we partnered with a group called Apples and Snakes which specialises in poetry, and through them we had poets working with us on a project around naturalness. These are examples of ways we can work with others who are well placed to take our work out to audiences that we might not otherwise reach.

The point is, all of these things are opportunities, but they all have certain limitations. The conclusion that I come to here is that we all agree that we would like to do all of these things and engage as many people as possible, but we have limited time and limited resources. The key is to mix up these ideas to understand what it is that we are trying to do, what is the right way to get to that, and to understand the effect of it. The question about impact and how we can measure the effect of what we do is really difficult but really important. Because if we have limited resources, then we have to be really smart about how we select *what* we do, *why* we do it, *who* we work with – these must be trusted independent partners – and *how* we understand the effect that it has had. ||

Bioethics Education in Turkey

Meral Özgüç

|| Raising public awareness is not a very common thing in Turkey because most of the biomedical issues are dealt with in a very top-down sort of approach. This is one difficulty that we have, what we tried to do was to decide how to approach bioethics ourselves. Because medical ethics is a traditional discipline – we already have research ethics committees, clinical ethics committees, but bioethics was a new world and new environment. We decided to start with education, because that would be of course the best way to start.

We had to approach education in three different ways. As most of us have a position in medical schools or science faculties, we said: "Why do we not go back and check the curricula – what are we doing regarding bioethics?" Especially in medical schools with new technologies in genetics and genomics, we realized that we were not very well equipped regarding the associated bioethical issues. So we went back and discussed with the faculty members and deans that there should be a sort of updating of the medical curricula. We did the same thing with science faculties and now we are very happy that especially in Ankara, there are two science faculties now that are teaching bioethics and which are using UNESCO's materials. We realized that as a profession, bioethics is a sort of postgraduate field. It is a field that you cannot intensely focus on when you are in secondary school, so one very good outcome of the committee's work is that, in 2013, we were instrumental in establishing a bioethics centre in one of the universities in Ankara. We hope that they will also be spreading the word and they will be doing much better research than we are capable of doing as a committee.

When we come to public awareness, we live in very volatile times. We know what is going on. So we said, okay, higher education is wonderful, but what is going to happen in the general public, in the minds of the younger ones? How should we approach them and try to cultivate the issue? So, again the committee of education

within the UNESCO commission helped us to have some meetings with teachers – secondary school teachers. They gave us some ideas of how we can approach them, how we can put ideas in textbooks, such as critically looking at principles of discrimination, solidarity, stigmatization, all the issues that we thought should be looked at an early age, if we are hoping for a better world for all of us.

Of course, when we talk about how we are going to get the public on our side and start public discussions, the media is of course a very legitimate means. However, we have this problem of educating the media as well, because media in general is not very well-versed in bioethical issues. So, we went back to the committee for communications and we asked, what can we do with the media and how can we meet some members and talk to them? During some meetings with members of the media, the very good idea was developed that within faculties of communication we should lobby for better standards of science journalism. Because most journalists do not really pay much attention too much to ethical issues because it will not give them flashy news. So, that is one new project that we are going to do together with the communication committee in order to see if science journalism can be improved in different faculties – how they approach ethics and whether we can have training sessions that include bioethical issues in their degree programmes.

There is one last thing to mention: The value of these Global Summits – because, and this is also a part of the mandate, it is so important for us to meet members of other committees and share our experiences. One of the things that we took from the Mexico meeting was to focus more on collaborating on a regional level. We are now trying to share our experiences among the Mediterranean countries to learn from each other. Before we attempt to get the entire public into ethics discussions, we think it would be very nice to collaborate well on a regional level, to be able to better reflect on the global issues. ||

Discussion Paper

Raising Social Awareness of Bioethical Issues Including Education, Media, and Communications

Jorge E. Linares

1 Introduction

According to the UNESCO's *Universal Declaration on Bioethics and Human Rights* (2005), as mentioned in Articles 23 and 24, the member States of the United Nations have the obligation to promote the reflection on bioethical issues in education, instruction, and public communication, as well as encouraging international cooperation to achieve a more extensive dissemination of bioethical culture in the entire world.

Article 23 – Bioethics education, training and information

> „In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics. […]"

Article 24 – International cooperation

> „States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge. […]"

In the same way, the declaration states that the national ethics/bioethics committees have the following responsibilities in the fields of education and communication that should strengthen public awareness and social participation in bioethics.

Article 19 – Ethics committees

„Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:
(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
(b) provide advice on ethical problems in clinical settings;
(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
(d) foster debate, education and public awareness of, and engagement in, bioethics."

2 How can public awareness be raised and how can public debate and discussion on bioethical issues and their implications be encouraged by NECs?

Despite the great diversity of roles, objectives, legal frameworks, methods of collaboration and number of members, the national ethics committees (NECs) have in common the crucial aim of promoting ethical reflection and bioethical knowledge throughout society. I think that NECs have the responsibility to innovate new ways of communication and dialogue between experts (scientists and bioethicists) and the public, within their own cultural and political context. Each commission should find in the scientific literature (including social and political sciences) (e.g. ten Have & Gordijn 2014; Bagheri et al. 2016; Solinís 2015), civil organizations, institutions like universities and parliamentarian agencies, the most successful experiences in dissemination of bioethical issues.

My main proposal is that the NECs should promote a pluralistic debate, with these characteristics: based on scientific knowledge; founded in contemporary philosophical/ethical theories, and encompassing a multicultural or pluri-ethnic conversation.

Formal education

Formal education in bioethics cannot be a direct task for the national ethics/bioethics committees. However, these committees may promote and support formal and non-formal education on bioethics, cooperating with the best universities in their own country as well as from other nations.

In my view, the purpose of education in bioethics is to cultivate critical thinking among the population (especially the youth), that will help people to improve autonomous and independent decisions about these problems. Such capabilities are

related with the universal rights of free thinking and free development of each person that all countries must warrant to their citizens. For those reasons, I think that the philosophical ethics and philosophical culture are irreplaceable in bioethics education at all levels.

Let's recall that bioethics is a modern form of ethics; sometimes said to be a form of "applied ethics", but ethics, as a philosophical discipline, has always had a practical purpose (Hottois 2004; 2001). The rationale of why philosophy is an indispensable discipline in bioethics is that the bioethical controversies are filled with philosophical questions about the status (ethical, legal or political) of natural entities (cells, embryos, bodily organs, living organisms, ecosystems, etc.), bio-artifacts (GMO, GMA), individual rights or social institutions that are the source or the effect of the problems discussed.

Therefore, along with the knowledge of the life sciences, and in general, the natural sciences, the curriculum of formal and non-formal education in bioethics, as well as public communication, should contain concepts from a contemporary philosophical perspective. Regarding moral philosophy, there is a relatively new paradigm that extends the scope of moral consideration to other animals and the entire biosphere; that ethics teaches and transmits *non-anthropocentric moral values* (in the sense of a no restriction of moral consideration only in humans and their interests). The contemporary ethics also holds a cosmopolitan and multicultural vocation, not limited only to consider the interests of current society and dominant western civilization, but also considering other cultures and future generations that will be damaged due to long-term future effects of human actions on the whole planet and on all living beings. A sound example of that kind of new paradigms in contemporary ethics and political philosophy is the work of Sue Donaldson and Will Kymlicka (2013), which argues the possibilities and conditions to incorporate other animals, domesticated and in their natural habitat, in our political and legal systems, in a similar way to the recognition of equal rights of minorities or segregated cultural groups in multicultural countries in the last few years.

And also, bioethics requires concepts and values of the so called "complexity sciences". The source of the philosophical problems in bioethics lies in the growing complexity of interactions individual/society/techno-science/environment/history/evolution, as well as from the interdisciplinary perspectives and methodologies. I may suggest as a sound reference the work of Edgar Morin, *La Méthode* (2008).[21]

On the other hand, Martha Nussbaum defends in her book *Not for Profit. Why Democracy Needs the Humanities* (2010) the fundamental role of the humanities for developing the cardinal cognitive and emotional skills in order to create these

21 And also: Morin 2005.

democratic capabilities: "the ability to think critically; the ability to transcend local loyalties and to approach world problems as a 'citizen of the world'; and, finally, the ability to imagine sympathetically the predicament of another person" (Nussbaum 2010, 6). Without those moral cognitive abilities, democracy is no longer possible. That is the necessity of universal ethical (and bioethical) values in the public education provided by the humanities.[22]

For instance, it is necessary to expand a culture of environmental sustainability and ecological justice that goes beyond the current predominant anthropocentric paradigm of our economic and technological civilization. The values of sustainability are provided by the life sciences and primarily by the environmental ethics. For example, the criticisms about the culture of excessive consumption of meat and animal products that is no longer sustainable, or the lack of recognition of the animal rights within our legal systems. The recent debates about global warming and the international agreements of Paris (COP 21) is a very illustrative case of the difficulties for arriving at global commitments of the governments and industries, and the lack of power in front of these global issues for the majority of citizens of the world.

Bioethical education at the primary and secondary levels should teach the concepts and principles so that individuals are able to make their own personal decisions. Bioethics is not about predominant moral values or the reinforcement of the moral values of the majority within a society, but about the construction of transcultural and diverse moral values (widely accepted and generally regarded by several moral groups), that recognize the individual right to make decisions about the different ways of living and dying, without suffering the moral oppression from the rest of society. The education on bioethics should supply tools to develop autonomous deliberation about our own bodies, about illness and health, disabilities and capacities, sexuality, reproduction and the convenient conditions for death.

There should be particular attention to the bioethical rights of vulnerable groups, especially women. Sexual education and the promotion of reproductive and sexual rights, including the right to legal pregnancy interruption, are priorities in contemporary bioethics debates, because of their frequently controversial nature and the strong reactions that come from the predominant conservative social groups.

At secondary education, it is fundamental to transmit to the young citizens the idea that the freedom to choose what each person does with their body and life, without affecting the rights of others, is a universal human right. For example, I know a successful and permanent campaign of the Observatory of Bioethics and Law of the University of Barcelona (Spain), titled *Libertad para decidir*[23] (freedom to choice), in

22 Also one can review: UNESCO 2007.
23 http://www.libertadparadecidir.es

brochures, internet and posters oriented to the general public and to young students at the universities.

In higher education the leading topics of bioethics should be present as obligatory themes in all the life sciences undergraduate degrees, and also in social sciences and philosophy. It is unacceptable that curricula of medicine and other life sciences in undergraduate studies don't include at least one semester or sufficient class hours on bioethical and medical ethics themes. That is currently the status in my University, by the way. National committees could supervise or certify these ethical contents in the undergraduate and postgraduate programs, based upon academic standards of quality agreed with all the universities (or associations of universities) in the national or regional context.

In my experience as a professor, bioethics in higher education should concentrate only on the postgraduate studies. The formation of professionals in bioethics (called "bioethicists") can only be achieved beginning with a scientific background and after a master's degree and doctoral studies in bioethics carried out in prestigious institutions of higher education, because bioethical studies entail both multidisciplinary theoretical and practical perspectives.

It is not convenient to form bioethics professionals in undergraduate studies, since they will only have a deficient formation at this level. To be able to understand in depth the bioethical issues and to be able to propose practical solutions, these professionals ought to be formed prior in some classical discipline: medicine, law, philosophy, social sciences, or life sciences. The bioethicists require postgraduate formation and practical deliberation experience in committees of hospitals and research centers, and also in public debates, if possible.

Communication media and non-formal education

Non formal education (non-curricular or academic) should be offered in all the possible modalities and through social promotional campaigns that target the main subjects related to bioethical issues.

Of course, those issues should not be reduced to biomedical problems or public health issues, but should include areas such as ecological crisis, environmental degradation, biosecurity, evaluation of products of pharmacological and biotechnological industries. These campaigns must have a solid scientific foundation and include a complete media plan that encompasses social networks, traditional and digital media channels to reach all sectors of society.

Also through courses and conferences in public places like science museums and centers for scientific and technological research. For example, *The Exploratorium* of San Francisco, which has some themes related with bioethics in its "live systems" and

"human phenomena" galleries.[24] Nevertheless, in science museums there is on average a lack of bioethics information, this is why it is a good opportunity to strengthen and expand exhibits in these museums about the main bioethical issues: beginning and end of life, sexuality and reproduction issues, diseases and epidemics, social factors of diseases, genetic and genomic techno-sciences, history and characteristics of health systems, neuroethics, environmental ethics and ecology, theory of evolution and biology of biodiversity, sustainability issues, and fair social and economic development. The NECs should contribute to these exhibitions with several educational programs.

For a more pertinent dissemination of bioethics, NECs may make use of all media to communicate to/with the public, but not in the form of a polarized and artificial public debate between liberal and conservative points of view, because there are usually more than two conflicting ethical positions. And not only about the most controversial issues that are hot topics in the news, but rather as a critical reflection that is permanently present in all kinds of media and Internet, conducted by professionals of communication and with the participation of scientific and bioethical experts. There are two imperative requisites to promoting bioethics adequately: pertinent and effective scientific dissemination and a balanced framework of reflection and pluralistic bioethical debate. The NECs could foster these types of dissemination with indirect incentives like grants or awards to the best programs in public dissemination of bioethics, selected by a jury of academic experts.

Critical analysis of the legal frameworks on bioethics

In addition to promoting and encouraging public debate surrounding bioethical problems, another of the committees' main activities should be to bring to the public knowledge the legal framework of their own country, including their rights and obligations, and also the restrictions and limitations within their political and legal framework. We can say that in most countries *bioethical individual rights* are not sufficiently protected or are not properly communicated to the public. The rights and obligations of citizens regarding these critical issues are not well known or clear to them. For example, the right to make autonomous decisions about their medical treatments or, at least, the right to reject them in hospitals, in case of terminal diseases; or the correct elements of informed consent that apply in research experiments.

Promoting dialogue and democratic consensus

If one of the primary objectives of the national ethics/bioethics committees is to broaden and grow social awareness about the bioethical controversies, as well as

24 https://www.exploratorium.edu/visit/galleries

impulse the resolution of them through democratic consensus, then it is also fundamental that the NECs foster, through formal and non-formal education and all kinds of media, the social assessment of scientific and bio-technological innovations, discussions about the risks of biotechnologies, as well as the fair distribution of the technological and scientific benefits, in order that this debate also might contribute to reduction of the social-economic inequalities (disparities on health, gender inequalities, ethnic inequalities and so on).

A good example of an opportunity to influence in a social debate with bioethical implications, is the current public debate in my country about the possibility of legalizing the production and use of marijuana (*cannabis sativa*), not only for therapeutic but also for recreational purposes.

3 Do NECs have a role in ensuring that it happens? Do NECs have the mandate, skills and resources to raise bioethical awareness?

My answer is affirmative. NECs have to seek the resources and to develop skills in communicating bioethics issues, besides their mandatory objectives and activities. I think that it could be possible to make use of citizen participation and decision-making methods like citizen juries, consensus conferences or other models of citizen participation in the assessment of bioethical public policies or biomedical research, mainly. I suggest reviewing models of citizen conferences and consensus conferences in countries like Denmark, France, the United States, or Brazil. Since the 1980s these modalities of dialogue between common citizens and experts have been effective methods for technological innovations assessment and for decision-making about technological regulations. The role of scientific experts has consisted in providing analysis, sound arguments, conceptual distinctions, and related pertinent data in order to inform concerned citizens. We can learn, for example, of the experience of the Danish Board of Technology:

> "A consensus conference is defined as a method of technology assessment organised as a meeting between an expert panel and a panel consisting of concerned citizens – the lay panel. The lay-panel members assess controversial and technological developments. During the conference they produce a statement in the form of a document which expresses their expectations, concerns and recommendations. The final document is written by ordinary people, and thus does not represent any special interests. It is directed at parliamentarians, other policy makers and decision makers, and the general public. […]

> The objective of a consensus conference is to bridge the gap between the general public, experts and politicians, who only rarely have an opportunity to meet. In Denmark the consensus conferences organised by the Danish Board of Technology have stimulated public debate on new technology. The final documents from these conferences have contributed to informing politicians and decision makers on citizens' views of, and attitudes towards, new technology. These conferences aim at an ideal process in which a given topic is elucidated on the basis of the finest available knowledge and discussed by the lay panel in open and unbiased dialogue. The consensus conference ensures that members of the general public, represented on the lay panel and in the audience, and the summoned experts become engaged in a dialogue with one another." (Grundahl 1995, 31)

I argue that the NECs may promote more effective and reliable procedures of citizen participation when they engage in dialogues between people and experts (including professional bioethicists) aimed at evaluating biotechnological and medical innovations, public policy on bioethics, allocation of public resources in health systems, priorities in biomedical and biotechnological research (at least, those that are financed by the States), and laws and regulations regarding bioethical issues. However, the goal of this conversational debate is not that the public will accept everything that industry and scientists will launch to the market (for instance, drugs and medical technologies), rather a true deliberative discussion of risks and benefits, social needs and fair social-economic conditions and opportunities to access the technological benefits. These forms of citizen participation imply that scientific information has to be sufficiently and adequately disseminated and, moreover, that the interests of the predominant social groups, industries and their lobbying don't prevail over the public and common interest.

Here I would like to make a remark: civil rights on bioethics (like pregnancy interruption, for example) shouldn't be submitted to referendum or approval of the social majority; whereas in the controversies of ecological or public health risk, the principle of common interest must be priority. Recently in my country, the Federal Government legally authorized the destruction of one section of the Cancun mangroves (Tajamar, at the Mayan Riviera) for the construction of new resorts and urban areas. Although that approval was legal, it is clear that it has no bioethical foundation. This ecological destruction has caused a very strong reaction of the people, both in my country and in the entire world. It has destroyed part of a vital ecosystem for the health of the local environment, and also part of the natural heritage of all humankind. For now, one local judge has suspended this project because of the public outrage.

4 Are there specific instances where NECs may take a strong public awareness raising role and how it should be done?

I might say that one of the main responsibilities of NECs is to take a stronger role in the public sphere for the dissemination of a *pluralistic understanding of the bioethical issues*. I will try to explain the fundaments of these characteristics and the general criteria I consider how they should be done.

The contemporary world is characterized by moral and cultural diversity, that is why the NECs have a duty to contribute to consolidating pluralistic bioethics that embraces true global and planetary reach, including in its ethical considerations not only all human beings alike, but also the rest of the living beings that we share the planet with and that are affected by all of our actions. Remember that bioethics has two branches: biomedical/biotechnological issues and ecological issues.

In the contemporary bioethical debate, all moral conceptions, as well as all knowledge and cultural traditions, are worthy of consideration. Bioethics is informed by both the scientific knowledge and the moral values of cultures and social traditions (religions, morals and customs). Within all societies (even more so in multicultural countries like Mexico) different moral conceptions and practices coexist: those from western modern civilization and from older cultural traditions. None of them should arbitrarily be imposed on other communities, due to their influence in customs or by being more dominant or hegemonic in a given society. Yet conflict continues to be generated by the predominance of denominational morals, mainly of Christianity and other monotheistic religious traditions, in education or social communication, as well as in the laws and rules of many countries. I point out that it is the duty of the national committees to help shape public debates in which the doctrinal moralities don't prevail or are imposed as an official or "public morality" over all citizens. All moral positions should be expressed in public debates and the media but each has to offer rational arguments and ethical values that are acceptable and shared by all moral communities; that is, *common moral values* (like the classical principles of bioethics).[25] For that reason, the NECs must encourage a *pluralistic bioethics* that expands the individual and social rights to free decision making, equal opportunities of human development and universal access to health care, at least. I would like to refer to a suitable definition of the bioethics as a profession, by John H. Evans.

25 These common moral values may come also from religious traditions, of course; but they have to obtain the consensus of several moral and cultural communities.

Bioethics as a profession

John H. Evans (2012, xxi) defines "*bioethicists* as professionals who use methods in a system of abstract knowledge wherein ethical recommendations are *not* based on their own personal values or the values of a particular group in society, but based on the values of either the individuals involved with an ethical decision or the values of the entire public. A professional is not a bioethicist if they make recommendations based upon their own values or the values of a subgroup of the public."

There are many religious groups in contemporary societies, and each of them are a social subgroup that cannot impose its values and moral concepts to the rest of society, even though it has been part of a worldwide religious tradition.

Bioethics as a profession defends four fields of "jurisdiction", as Evans says: (1) health-care ethics consultation; (2) research bioethics; (3) public policy bioethics; and (4) bioethical debates in public sphere and media ("cultural bioethics"). In my opinion, the mission of NECs is to encourage a pluralistic debate and resolutions based upon common ethical values (and which do not necessarily correspond to the values of the majority) in these four fields of action.

On the other hand, bioethical debates are a result of the heterogeneity and complexity of contemporary societies, but only begin to bear fruit in democratic societies, or societies transitioning towards regimes and political institutions of democratic nature. The democratic and *democratizing* character of bioethics lies first, in its potential to preserve and strengthen individual and collective autonomy (cultural and moral groups, minorities, vulnerable groups, and others who are segregated, stigmatized or discriminated against) and second, in its ability to build ethical consensus, although not necessarily unanimous consensus, through broad social participation that legitimizes ethical resolutions, and legal and political issues that have the most acceptance among different groups of citizens.

Achieving consensus agreements on bioethics issues will depend on the degree of development of an open public discussion and pluralistic debate to confront and resolve these problems and dilemmas properly. The national ethics/bioethics committees have a crucial task, then, to spread a "global culture of bioethics". "Bioethical global culture" means to me a culture of democratic pluralism that entails reasoned debate with scientific grounds, well-founded philosophically and able to achieve consensus and agreements among morally heterogeneous and culturally diverse communities.

For over fifty years, bioethics has been constructing a form of "practical reason" (*phronesis*, in terms of Aristotelian philosophy). It progresses if it is conversational, deliberative, public and pluralistic, because it is a new way of practical reasoning that should be prudential and "provisional" (not closed or absolute). This means that agreements reached are based on pragmatic reasons and consequentialist evidence:

provisional facts that are to be proven by social experience, so to speak, in bounded agreements recognizing that no one is absolutely right, that the approach towards the common good is the result of an intense dialogue and creative forms of social interactions.

For example, in the case of the controversy about the use of embryos as a source of stem cells for regeneration or transplantation for therapeutic proposes, the debate has led to, in one way or another, a dead end: What is the legal status of the embryo? Is it equivalent to a person or not? Can it have a purely instrumental character or not? Is it a bio-artifact or natural entity? Is it marketable or not? Who does it ultimately belong to? Nevertheless, the contemporary philosophical approach, based on an ancient conceptual distinction between "potential" (*potentia*) and "actual" (*actus*) forms of being, has reached a consensus, so that, we may conclude that embryos are not equal or equivalent to the human being after its birth, and that means its legal status must be different. A pluralistic bioethics recognizes those differences and the need for a certain kind of protection for the embryos, as a common moral value, but not as a reason for establishing a ban to use them in biomedical research.

5 Conclusion

Bioethics (both its academic dimension as well as its practical-political sphere) currently faces the challenge of overcoming the confrontation between the values of different moral communities.

The position that I defend in this paper is that the future of bioethics depends on a wave of moral plurality and tolerance in our global society and institutions around the world, to consolidate some pluralistic public spaces of deliberation and resolution of scientific-technological controversies related with bioethical issues. This bioethical process must incorporate all moral communities and involves the deepening and expanding of the historical process of modernity by which the social and political institutions of contemporary nations were created.

Contemporary societies have had to understand their irreducible cultural, religious and moral plurality. We live in a multicultural context that has weakened the old rationalist convictions about universal values and claims of absolute moralities. We need a pluralistic bioethics which entails tolerance towards different moral and cultural groups within each society. Besides, the ecological and technological problems, as well as increasing global socioeconomic inequality, force us to reach ethical agreements and legal norms to be able to coexist in a civilized way. But apparently what prevails is the aporetic dissent and lack of agreement on minimum moral content. As noted H. Tristram Engelhardt Jr. in his classic *The Foundations of Bioethics*

(1996), there is not a "canonical, content-full morality" able to solve these social and bioethical controversies (Engelhardt 1996, 288).[26]

Each techno-scientific innovation (biomedical and biotechnological also) raises doubts, fears and hopes; generates benefits and new technical possibilities, but also new risks that every society must analyze and ponder; and these evaluations, always divergent, inevitably lead to disagreements and bioethical conflicts. To resolve such conflicts in a rational and just way, common ethical principles are required; but they cannot be merely procedural or "empty" of axiological content as Engelhardt has argued, but must be established with a minimum axiological content for all moral and cultural communities. These ethical contents (common moral values) are the object of bioethical debates and the desirable goal of their agreements and consensus. For example, the four bio-ethical principles that I argued in my work *Ética y mundo tecnológico* (2008) are:

1. Autonomy (individual and collective)
2. Justice (distributive and retributive)
3. Responsibility (civil society, social and governmental commitment) to face and resolve past problems and future risks or disasters.
4. Precaution to prevent the major technological risks (nanotechnological, biological, informational, nuclear, ecological disasters, consequences of climate global change)

These four ethical principles are not thought to be universal; however, they make an unyielding frame that delimits the societal interactions and public decisions that could consider and protect the rights of all human beings, ecosystems and also other animals alike.

Therefore, interdisciplinary scientific knowledge and moral plurality (based on the four principles mentioned) could be the foundations of a bioethics capable of achieving agreements that are fundamental for solving, as much as possible, the scientific-technological controversies. In my opinion, bioethics can only advance as a *practical reason* of dialogical, public and pluralistic nature. It is about building a *collective and global phronesis* or a cosmopolitan bioethics with local and global scopes. The national ethics/bioethics committees thus have an important mission to accomplish.

26 And also: Engelhardt 2006.

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Annex: Concept note for raising social awareness of bioethical issues including education, media and communications

Biomedical issues raise complex ethical concerns that are not always immediately obvious to those not deeply engaged in understanding and analyzing those issues. This lack of awareness can leave people highly vulnerable to having their rights and dignity compromised.

- How can public awareness be raised and public debate and discussion on biomedical issues and their implications be encouraged? Examples from different countries to be provided.

- Do NECs have a role in ensuring this happens? Do NECs have the mandate, skills and resources to raise awareness?
- Are there specific instances where NECs have taken a strong public awareness raising role and how was this done? Was it successful?

>> REPORT OF INTERNATIONAL ORGANIZATIONS

Session Summary

Report of the World Health Organization
Abha Saxena

Report of UNESCO
Dafna Feinholz Klip

Report of the European Commission
Isidoros Karatzas

Report of the Council of Europe
Laurence Lwoff

Report of the Council for International Organizations of Medical Sciences
Johannes J.M. van Delden

Michel Daher (Session Chair), Laurence Lwoff, Dafna Feinholz Klip, Abha Saxena, Isidoros Karatzas and Johannes J.M. van Delden (from left to right)

Session Summary

|| Abha Saxena, coordinator of the Global Health Ethics Unit at WHO, opened the session by providing an overview about the main activities in the areas that WHO is primarily involved in: capacity building; providing ethical and evidence based advice; collaborative partnerships; and setting norms and standards. With regards to partnerships for example, WHO has established a global network of collaborating centres to support the Organization's activities in specific areas. Moreover, Saxena outlined some of the current topics that the different regional offices at WHO started to work on. These topics included ethical issues related to data sharing, data collection, data use and analysis. Moreover, healthy aging, biobanking, ethics and disasters as well as ethical aspects of migration and health were among them.

UNESCO's activities in the area of bioethics were presented by Dafna Feinholz, chief of the bioethics section of the division of Ethics of Science and Technology at UNESCO, who focused in her presentation on UNESCO's capacity-building measures. Feinholz introduced the Assisting Bioethics Committees (ABC) project, UNESCO's main programme to support the establishment and operations of bioethics committees. The programme helps countries in identifying what kind of committee they need and provides guidelines on how to constitute such a committee. Moreover, UNESCO accompanies the countries until the committee is established with a legal status and additionally provides training and education. With regards to the future work programme, Feinholz gave a short account of UNESCO's new activities in the area of big data and health, on the access to healthcare services for migrants as well as on a declaration of ethical principles in relation to climate change. Additionally, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) of UNESCO started to look into robotics ethics.

Isidoros Karatzas, head of the ethics and research integrity sector in the Directorate-General for Research and Innovation at the European Commission, called

for more collaboration between national ethics councils and international organizations working in the field of bioethics in order to avoid the unnecessary duplication of activities, and to use the resources – that are already scarce in the field of ethics – more efficiently. In a next step, he outlined some of the funding mechanisms of the European Commission for ethics research. One area of particular interest in this context was the so-called 'ethics dumping' which describes the export of unethical research practices to countries that may not have the appropriate ethics compliance mechanisms and a strong legal framework in place. Another funding mechanism related to research integrity and research misconduct with the aim of strengthening the *European Code of Conduct for Research Integrity*.

The work of the Council of Europe was presented by Laurence Lwoff, head of the bioethics unit at the Human Rights Directorate of the Council. As the reference instrument for the Council of Europe is the *Convention on Human Rights and Biomedicine* (Oviedo Convention), the main activities thus focused on developing a legal corpus around the Convention as well as further developing its principles and facilitating its implementation through practical tools. Moreover, different guides and recommendations had been developed by the Council, for example, a guide on the decision-making process regarding medical treatment in end-of-life situations, a recommendation on the processing of health-related data for insurance purposes, a recommendation regarding research on biological material of human origin as well as a statement on genome editing. For 2017, the Council of Europe was planning to celebrate the 20th anniversary of the Oviedo Convention with the aim of analysing the relevance of the convention in the light of new developments in the biomedical field.

At the end of the session, Johannes van Delden, president of the Council for International Organizations of Medical Sciences (CIOMS), presented the revision process of the CIOMS guidelines that aimed at combining the guidelines on biomedical research with the guidelines on epidemiological research in one document and, furthermore, to integrate new development and issues in the life sciences. The general purpose of these guidelines is to indicate how fundamental ethical principles and the *Declaration of Helsinki* can be applied effectively in medical research with a particular focus on low- and middle-income countries.

The subsequent discussion with the audience focused on capacity-building measures and the question of how to achieve better compliance with international guidelines in different countries. ||

Report of the World Health Organization

Abha Saxena

|| This is a presentation on the work that WHO does in the area of global ethics and health ethics. This is a presentation made also on behalf my colleagues in the regional office. So, just for those of you who may not be aware, we have six WHO regions: the African region (AFRO), the region of the Americas (PAHO), the Western Pacific region (WPRO), the South-East Asia region (SEARO), the European region (EURO), and the Eastern Mediterranean region (EMRO). We also work with a network of WHO collaborating centres for bioethics, and currently we have seven collaborating centres. We are always looking for collaborating centres in regions where we do not have any yet. Usually, it is a two-year work plan before a centre can become a collaborating centre. We have strict criteria for who can or cannot join as a collaborating centre, and we are very proud to be currently working with our seven collaborating centres: Toronto, Columbia University, Miami, Stellenbosch University in South Africa, Melbourne in Australia, Singapore and Zurich.

This is a global work plan which includes six WHO leadership priorities, but also the four functions that we are primarily involved in. This includes capacity strengthening, building evidence-based and ethical policies, collaborative partnerships, and setting norms and standards. So in relation to providing ethical and evidence-based advice, I just want to illustrate some of the things that we have been doing in this area. First of all, there are guidelines for responding to public health emergencies, which is of special concern internationally. And we do this through the international health regulation and through the development of guidelines, which Dr. Touré just presented in the last session. We are also developing guidelines in the area of surveillance, in the area of, e.g. tuberculosis management, and in other areas of public health. And in the area of research, we have since last year been in the process of developing guidelines for implementation research.

We develop normative standards at the organizational level where standard setting is related to the work in research ethics, which is managing a research ethics committee. And ethics review committees at WHO not only exist in the headquarters in Geneva, but also in almost all the regional offices. So, we are really paying a lot of attention to ethical research that is supported by the WHO. At the headquarter, we also have a public health ethics consultative group which looks at ethical issues that are related to public health issues. And that is something new that we started last year, and actually, the sort of guidance that we received for it came from countries like Canada and the United States, for example, where the Centers for Disease Control and Prevention (CDC) already have public health ethics committees. At the global level, we have developed standards for research ethics committees, and in the EMRO region, they have guidelines for the recruitment of pregnant women and minors. And I think that is a big issue in the EMRO region because of the issues related to being able to talk to pregnant women who may be minors, or who may be unmarried, and there is a big cultural issue related to that. So I think that is a great guideline to have been developed.

We work on the basis of collaborative partnerships, not only with our collaborating centres, as I just said. The Global Summit is a great example of our partnerships. The EMRO region did a survey and reached out to the national ethics committees in their region as did AFRO which did a survey, I think last year, trying to develop partnerships with its national ethics committees. We have recently started something called the Global Health Ethics Seminars. This is a series of four seminars in a year in which we identify issues of concern that the WHO is interested in. And these are webcast live to an audience – so it is like reaching out to a very wide audience in relation to some ethical issues that the WHO has concerns with. We also, of course, have collaborations with other UN agencies and other European organizations.

This is a slide with an overview of national ethics committees in AFRO region. As I mentioned, this was work that the AFRO region has done. They did this survey to pinpoint in how many countries national ethics committees exist, how many of these committees they have, whether they focus exclusively on ethics, how many draft policies, how many of them have secretarial assistance. So that is a very useful resource that we can use in order to carry out our work. EURO has also done something similar in mapping ethics reviews and clinical registration policies for health research in human subjects. And they have also drafted an action plan to strengthen the use of evidence information and research for policy making. The regional offices are doing a lot of capacity strengthening workshops in countries. At the level of our headquarter, we are concentrating mostly on developing training tools. We have a training tool on research ethics, on disaster ethics, on implementation research ethics we have a whole curriculum. And then we also worked with West African ethics

committees during the Ebola epidemic. We worked with the national ethics committees to help them build capacity to review the research during the epidemic and also to strengthen their ethics committees. The regional office of PAHO is working a lot in the area of both research ethics and public health ethics and they are doing capacity strengthening, working directly with countries and helping them establish their norms, standards and guidelines. So Carla is here and she is doing great work in the region.

Regarding our future work: We are planning to start an initiative on ethical issues related to data sharing, data collection, data use and analysis, etc. So that is going to start very soon, in the next couple of months. Healthy aging is something that we are very much interested in. Biobanking is an issue that we will also be taking up very soon. EMRO is going to be working on ethics and disasters. The EURO office is planning the ethical aspects of migration and access to health care and services. This is just to give you a few examples of the sort things that we will be working on. And that is all. I had ten minutes. I believe I finished up very quickly – you can ask me questions afterwards. ||

Report of UNESCO

Dafna Feinholz Klip

|| Thank you very much for this introduction and Christiane, as we predicted, so far this summit has been so very good. Thank you very much for putting in such hard work. It is very difficult in ten minutes to describe exactly what we do. On the one hand, many of you have heard and are familiar with the work of UNESCO, but others are not. So what I decided is to try to give a very brief overview of very general things that we do and to focus on what is likely to be most relevant for the meeting today, for the national bioethics committees.

As you may know, since more than 20 years UNESCO is working on bioethics. As the UN agency with a mandate in natural sciences, social and human sciences, education, culture and communication, it has all the ingredients that are important in bioethical reflections, including health and ethics of science and technology. And that is why we are now one section. So, the initial reflections on bioethics started in the seventies. Since then, we have developed a very strong, coherent programme that includes a very important component of education – which I am not going to address here. We have developed specific educational materials that are used in higher level education, and we are training educators how to teach ethics and bioethics. But I am not going to concentrate on these things in detail now.

A part of the cohesiveness and the beauty of the programme is that we have on the one hand the only global forum – well, this summit here is the forum for national ethics committees – but we have the only global forum for ethical reflection. Many of the representatives are members of national bioethics committees. This is the International Bioethics Committee (IBC) which has 36 experts that are nominated by the Director-General, but on their own capacities. These experts are independent, meaning that they are not representing the official position of their government. Representing the official position of their government is the role of the Intergovernmental Bioethics Committee (IGBC). Further, we have the World Commission on

the Ethics of Scientific Knowledge and Technology (COMEST). The IBC has been heavily involved and in charge of drafting the three main instruments that we have been hearing about in the last three days.

Our organization's mandate of the programme is, on the one hand, the normative one and, on the other hand, it is capacity building. One of the struggles that we have is not so much developing sound principles, but how to successfully implement them. So this is what the programme tries to do. On the one hand, we have these instruments – also looking at the bigger picture – trying to address all the main issues and the big gaps that we have in bioethical infrastructure and legislations. And this is very difficult if you want to achieve international cooperation and effectively implement principles and regulations. I appreciated very much the comments of the representative from New Zealand about how we talk about public engagement and literacy. We look at education and public engagement, the lack of fair access to the fruits of scientific and technological advancement, and of course the access to healthcare, and one of the last reports of the IBC was on benefit sharing. Inadequate mechanisms for knowledge transfer, the need for updating ethical and regulatory frameworks, particularly when it comes to genetics and converging technologies. And of course, what is one of the main topics of this Global Summit, the challenges for global ethics and democratic governance of science and technology. And I think this is because we are all striving for the common good and social justice.

So, under Article 19 of the *Universal Declaration on Bioethics and Human Rights*, which 192 countries signed, ethics committees at a different level are being established, on a national, regional or institutional level. The idea is that when they are national, they cover the wide range of issues that are included in bioethics or ethics of science and technology. So it is on the impact of health, but taking into consideration medical issues and all the other issues that are there. One of the most important things is that they try to advise governments. Since this Article refers to different kinds of committees, the UNESCO decided to concentrate more on establishing national bioethics committees that could really build the infrastructure on bioethics in the countries, and then, starting from the national bioethics committees, try to also promote the other kind of committees. But the national committees are there to foster education, to foster public engagement and debate, to advise on public policies and on any issue in bioethics, on public health or other issues.

One of the main programmes that we have is called the ABC programme – Assisting Bioethics Committees – where we help countries in their process of deciding what kind of committee they need and how to constitute this committee. We then accompany this country until their committee is established, with a legal status, and then we sign a memorandum of understanding with each of these countries. Further, we offer three years of training to each of these countries, on how to work effectively,

on issues within the field of bioethics, and on specific topics which the respective committees have chosen to focus on.

We have developed specific guidelines for national ethics committees, available in six languages and accessible online on our website. And here at this summit, in one of the rooms of the marketplace, there is a UNESCO stand where you can find all these publications in various languages. Some of them explain how to establish a committee, others explain the differences between the various committees, others deal with education, and again others address the work of ethics committees. We also have different regions – and many offices in UNESCO. I am very happy that three of my colleagues are here in the room today, from the Nairobi office, the Jakarta office, and the Lebanon office.

There are a few more things that I will only shortly mention and that you can discuss later. For some of the issues of Latin America, we have Prof. Lobos Lazzeri from El Salvador who can explain to you in more detail the work that they are doing. In Latin America in particular, committees were established with our support and some of them have already finalized their three trainings. One important thing in Latin America is that we have been able to establish a network of national bioethics committees. The second time that they met, in El Salvador, there were 20 countries and they signed a sort of agreement of collaboration – without going into more detail now.

When it comes to Asian and Arab countries, we also have been working a lot. We did a subregional workshop in Kuwait – with Jordan, Oman, Tunis, Saudi Arabia and Lebanon – to try to foster the establishment of national bioethics committees in those countries who do not yet have them and to have an exchange of experiences, challenges, and lessons learned. And we also had a request from Nepal to establish a national bioethics committee there. Unfortunately, after the two earthquakes, we had to postpone this. We went to Kazakhstan – and I am very happy to hear that Prof. Bakhyt Sarymsakova is here in the room today, so you can also speak to her later – to discuss the establishment of a national bioethics committee. Basically, they started with the idea of establishing a committee because they have a lot of problems with research, and the quality of research, but now they want to establish a wider scope committee. After doing this, we could continue supporting them with further collaboration and education. And it is the same case with Bangladesh. We have all these individuals with which we collaborate. And in all these trainings, we use the reports of the IBC.

Further, we also have other kinds of collaborations with chairs. We have UNESCO chairs in different countries and with them we are trying also to do a lot of capacity building, promotion of research, education, and other things. Here, my colleague Abdul Lamin, who is in the room today, can give you more details. And all this is

in print, as well, as I said. This is a south-south collaboration that was promoted by the chair of Brasilia, involving African and Portuguese-speaking countries, so also Latin America, Brazil, and Cuba. Part of the idea of this declaration was that they wanted to establish regional networks as bioethics researchers, scholars, institutions. All these statements you can also find in print.

Another thing I wanted to mention is that the work of the advisory bodies, that is related potentially to the work of the committees, provides some information that could be useful for national committees to use. To sum up – as I said, IBC finalized two reports, one on benefit sharing and one on human cloning, an update on ethical issues regarding human cloning. One of the main recommendations, again, was to insist on more time to reflect on the ethical implications of germline modification. I will not go into this now, but there was a press release. And then there was a joint statement on Ebola. This was circulated also among different ethics committees and it was very useful. Just to let you know, these committees are also encouraging what was discussed in the previous session: That it is important to strengthen infrastructure for people to do good prevention work.

I will now mention two publications that might be of your interest. The first publication was put together after the 20th anniversary of the programme by the secretariat – but really by 30 experts from all over the world. It is available in three languages, also accessible online. The second publication was produced by the IBC and is about the challenges of bioethics in the last 20 years. I will now come to the end of my presentation. Our focus in the next two years will be on big data in healthcare and health research, and ethical issues related to access to health services and the condition of being a refugee. And COMEST is working on ethics and robotics, and ethical issues relating to water. And to announce to you the last challenge that we are now starting to work on: the declaration of ethical principles in relation to climate change, which needs to be delivered in 2017. ||

Report of the European Commission

Isidoros Karatzas

|| I will talk very briefly about what we are doing within the European Union and the 28 member states. But of course all these activities have implications for the international activities. I can see already from what you both presented the beautiful onion of ethics – the more you peel, the more there is to peel. And we all work with the same kind of peeling methodology. What we need is more collaboration, because if you scroll down the list of all the activities that you are doing in your countries, the activities will be very similar. So we need this stronger collaboration in order to avoid unnecessary duplication of activities and use of resources, resources that are already scarce in the field of ethics. Acquire funding for and wanting to spend money on ethics is often challenging.

The European Commission funds a lot of ethics research. It funds ethics research projects because the output of this work is very important and fits into the work of the research ethics committees and of the national ethics committees. Our work does not only have the biomedical research environment in mind, but it covers all areas of research. Actually, we are talking in the European Union, and internationally, about the "tyranny" of the bioethical model. The strength, knowledge and experience that has been accumulated over a long period of time has the tendency to influence the way ethics is done in other areas, like social sciences, or security research. We are doing all this research throughout the European Union and outside and we can see, for example, that informed consent in drug dealer research is not the same as informed consent in a clinical setting in a hospital. Nevertheless, ethically, we require informed consent for most of our activities. So, we also have to be ingenious in the way that we apply the basic principles of biomedical ethics into other areas.

One of the research focuses that we are currently funding is what we call ethics dumping. How and under which conditions is research that is not allowed in Europe being sent to other parts of the world that may not have the appropriate

ethics committee structures or regulatory structures? This is not allowed – we cannot export unethical practices to other parts of the world just because our regulatory framework is more mature, or far stricter, and it does not allow this sort of work to be done here. One of the previous speakers, in one of the slides, I think emphasized collaboration and the need to enhance the local structures, because we do not operate in a silo. Everything that we do has repercussions in the rest of the world. In the previous panel, the H5N1 case was mentioned as an example where I think for the first time probably in the history of research a self-imposed moratorium on publication of research results took effect until the legal case was resolved in the courts. The legal case in the courts did not go because of ethics. It went for a beautiful piece of legislation that we have in the European Union a dual-use export regulation. So, the court decided on a case related to H5N1 based on regulation that had to do with the dual-use export control. Dual-use is basically good, that can be used for both civilian and non-civilian applications. And the court decided on this case on the basis of this regulation.

So, ethics has an effect if you like and it relates to many other areas of our regulatory framework, I will mention another example: data protection. 99 percent of the cases of ethics proposals and research funding that we support in the European Union raise issues regarding data protection, privacy, and human rights. Our scientists love to collect data, and modern technology gives them the opportunity to collect data all the time from all sources, even data that most of the time they will never need. So, immediately when they do that, and they go against the letter of regulation, immediately also ethics comes in to protect the human participants that are the human research subjects, so to speak.

I will now switch to another topic and shortly talk to you about the latest initiative of the European Commission and our commissioner for research that relates to research integrity and research misconduct. We all read the newspapers, we all see the cases that are very frequently reported, sometimes justifiably, sometimes unjustifiably. Recently we have had such cases in Sweden, in France, in Spain. Research misconduct is I would not say a preventable disease, but it is a preventable condition. And I think we have to do our utmost, and it falls within our structure, within the remit of the ethics departments in order to protect the good name of science, the good name of the researchers, and to, if at all possible, stop these incidents of research misconduct raising their ugly head very frequently, unfortunately. This is the new initiative. One of the first steps is to protect through the legal framework – thank God for the legal framework – that collaborates with ethics very frequently, sometimes successfully, sometimes not very successfully, and also to support the strengthening of the *European Code of Conduct for Research Integrity* – what we call the ALLEA/ESF code – in order to make it possible to accommodate the current needs.

Reproducibility of research results, quality of research results, conflicts of interests, and other interesting issues that are coming, open sharing of data, authorship – all these issues that we all know create a big problem for the research community and of course for all the institutions that operate in this capacity. ||

Report of the Council of Europe

Laurence Lwoff

|| On behalf the chair of the Intergovernmental Commission on Bioethics and myself, representing the secretariat of the Council of Europe, I wish to thank the German Ethics Council, WHO and UNESCO for this invitation. We have a kind of longstanding tradition of attending Global Summits, for it is always a pleasure and also a great opportunity. And as was underlying in the statement that was drafted by the secretariat of the Council of Europe for the opening of that Global Summit, I think it is important to underline the importance of the discussions at national ethics committee level for the intergovernmental work, and in particular for the Council of Europe. I know how much the opinion and the work is also feeding the discussion on an intergovernmental level.

So for those who are not familiar with the Council of Europe, I do not want to present the organization but just to let you know that one of the main objectives of the Council of Europe is the protection of human rights. It does that at the level of the 47 member states of the Council of Europe. So the activities in bioethics in which the Council of Europe has been active since the 1980s is really in line with this mission, looking at human rights protection in the particular field of biology and medicine. The work that is being done has different purposes, one being to develop a legal corpus around the reference instrument which is the *Convention on Human Rights and Biomedicine* (Oviedo Convention) – which is a legally binding instrument on an international level. The work includes further developing its principles and facilitating its implementation through practical tools – not legal instruments – such as the guide that is actually available in the marketplace concerning the decision-making process in end-of-life situations, and also to follow developments in the field of science and technology to identify possible challenges for human rights. The intergovernmental committee responsible for these activities include the 47 member states as well as observer states including Mexico, Canada, the United States, the

Holy See, and Japan, and also other international organizations, in particular WHO, UNESCO, but also the OECD and the European Union.

Now I am just going to go through some of our achievements since the last Global Summit and will then briefly touch on current activities. I am afraid this is going to be very factual, but I would be very pleased to discuss this content at break or at a time that suits you. So, the guide on the decision-making process regarding medical treatment in end-of-life situations was launched in May 2014. I just wanted to come back to this because it has been really successful in the sense that it has been much used in many different countries, which is why we made it available in 13, and soon 16, European languages. This is available on the website. It has also been referred to by the European Court of Human Rights, which is an institution of the Council of Europe, in a latest case, Lambert against France, concerning end-of-life issues. And we have two seminars organized around those issues in Turkey and Armenia this year at the request of national authorities.

Another very recent achievement is the elaboration and finalization after public consultation of two legal instruments. I would like to take this opportunity to thank those who have contributed to this public consultation, thus helping to finalize those instruments. A first instrument is a recommendation on the processing of health-related data for insurance purposes, and I think it is the first legal instrument addressing this issue. Without going into too much detail, a main concern is privacy and non-discriminations. There was also a concern about discrimination in particular with regard to the coverage of risks of social importance – but all these texts are available on the website. And the second legal instrument is a recommendation regarding research on biological material of human origin, which is actually the revision of a text adopted in 2006. This new text takes into account developments in this field with a particular focus on residual materials – so materials that come from persons not able to consent – and governance. The text was approved by the committee in December and is on the agenda of the Committee of Ministers next Wednesday.

Now, activities are ongoing in the Council of Europe regarding the elaboration of a new additional protocol to the Oviedo Convention which focuses on some very specific areas where interference with human rights is particularly high which is the situation with involuntary measures with persons with mental disorders. And a draft protocol was made public for consultation. We received a large number of replies from all the fields concerned, and a large number of those replies did refer to the UN *Convention on the Rights of Persons with Disabilities*, which led the committee to give more time for reflection in the light of those comments to see how to move forward on these topics. And that would be one of the key issues discussed at the next plenary meeting in June. Prohibition of financial gain is actually a principle laid down in

the Oviedo Convention, reiterated in this additional protocol on transplantations, and taken over by the *Charter of Fundamental Rights of the European Union* in its Article 3. This principle, which is recognized by everyone, raises a certain number of concerns as to how it is to be implemented. This came up in the context of a discussion at the Council of Europe about organ trafficking as well as at a criminal law convention on human trafficking. Because of these concerns regarding implementation, the decision was taken to set up another group to try to clarify a certain number of notions such as compensations, incentives, fees, payment, which are all relevant to the implementation of this principle. This work is actually led by a secretary of one of the member states' ethics committees, Doris Wolflehner, from Austria. They have already done a first meeting and are working towards developing further clarification regarding those key notions. We actually think this will be useful even outside the Council of Europe.

Another topic which is on the agenda of the committee, and which is quite relevant to this Global Summit because it was actually discussed this morning, is emerging technologies. And the Committee on Bioethics (DH-BIO) organized an international conference in which actually some of you participated actively last year. The objective of that conference was to identify priority human rights challenges raised by those technologies. The committee benefited from two studies. The first was by the Rathenau Institut, and I think I found a lot of commonalities in the paper presented by Dr. Rinie van Est with the study done by Rathenau for this past conference. The second report we benefitted from, by Bergen University, focused on ethical aspects. All these documents are available as a printed copy in the marketplace and on the Internet. Further, we have also benefited from a report from the rapporteur of the conference which was made available to the DH-BIO as a basis for future work. And that is exactly where we are at the moment.

There is a strategic group that has been set up and which is now preparing a proposal for action by the DH-BIO, and possibly in cooperation with other organizations, to be presented to the Committee next June for future work by the Committee itself. Possibly, I hope, WHO and UNESCO might also be interested, as well as the EU. I think this is a transversal topic which, as became very apparent during the discussions, goes beyond the limits of Europe, even big Europe. Just an example of such emerging technologies on which there was a specific action taken by the Committee: last December there was a statement on genome editing technology. This is also an issue which was raised and discussed here. This statement was emphasizing the reference value of the Oviedo Convention as a starting point for the discussion on an international level regarding the ethical issues raised by this development. And also the DH-BIO is committing itself, as part of its mandate, to look at these ethical and legal challenges raised by these technologies.

Now, these would be my last slides about the future activities and events that you are all very welcome to join. Education and training: We have a course project based on e-learning technologies. We have a whole programme in the Council of Europe addressed to legal professionals, and we want to develop a similar course on core human rights principles in biomedicine for legal professionals, but also health professionals, in the hopes of also having mixed training sessions with those two sets of professionals. We have partnerships for that project with Russia, Norway, Romania and Italy. And the idea is to make that course available afterwards for all those interested.

Collaboration: We are about to hold a high level conference on human rights and biomedicine in Moscow, on 26th April, with a particular focus on organ donations. This conference will be held in the context of the 20th anniversary of the membership of the Russian Federation in the Council of Europe. And I am pleased that one of our colleagues organizing the conference with us, who works in the health ministry in Russia, is actually here with us today, Anastasia Koylyu. I am sure she would be happy to talk to you about this conference if you are interested. And you are all invited – we sent invitations out already.

And then, to end, in 2017 there will be the 20th anniversary of the Oviedo Convention where we will organize a big international conference entitled relevance and challenges of those principles laid down in that convention. And I am sure that will be a very vivid debate, I mean we already paved the way for that this morning, I think. You will all receive invitations to that conference which will also be broadcast live. But to pave the way for that conference, we will on 5th December of this year organize – under the auspices of the Cyprus chairmanship of the Committee of Ministers – a seminar on the international case law relevant to bioethics with a focus on the case law of the European Court of Human Rights. Here we want to look at the relevance of the international legal instrument and how it was used by the court, and also to have a forward look at what – based on constitutional law and comparative analysis of constitutional case law in the member states – can be expected to reach the international judicial arena in the near future. So, this will also be broadcast live, but we would of course be very pleased if you would join us in person in Strasbourg, where there will be time dedicated to discussions and where your input will be very much valued. Thank you very much. ||

Report of the Council for International Organizations of Medical Sciences

Johannes J.M. van Delden

|| Thank you Mr. Chair. I must admit that I feel humbled after this magnitude and wealth of all the initiatives that have just been presented. I can assure you that my talk will be relatively simple because I will address only one thing. I think this is also necessary because it is the end of the day. I must compliment you for the fact that you are still in the room, still listening and not sleeping yet – I think this is already a sign that you really want to be here and that it is good to be here. And this, of course, leads me to first of all say thank you to Dr. Christiane Woopen and to the team at the German Ethics Council for organizing this splendid conference.

Now maybe I do not think I should introduce CIOMS to you as an organization, for this would probably not be very interesting. But it may be interesting for you to know how far the revision of the CIOMS guidelines has come and where we are right now. So, what is CIOMS? It is the Council of International Organizations of Medical Sciences, it is an NGO, it is a forum, and it is a body of bodies. We actually only have a few members, but all of them are international organizations of medical sciences who in turn have a great many members. So that is our background. We worked a lot in nomenclature, then moved to drug safety, and bioethics was added to that field in the late 1970s.

We have guidelines on biomedical research, we have guidelines on epidemiological research and then in 2011 we decided to start a revision of the biomedical guidelines and also to merge the two guidelines. So, we now have, in a draft, the two guidelines on biomedical and on epidemiological research combined. The purpose of these guidelines is indeed in a way to indicate how the *Declaration of Helsinki* can be used and implemented in low and middle-income countries. That has always been the intent. And indeed, those are the areas where our guidelines have been used most notably. That is also visible to us because people have volunteered to translate

the guidelines into their own native languages, which is also a great way of implementing these guidelines, of course.

Maybe first a few words about the process. You will notice that many guidelines need revisions. I sometimes wish CIOMS was a law, or that our guidelines were a law, but at other moments I am actually quite happy that they are not – because it is easier to revise a guideline than to revise a law. Guidelines can be revised and ours have been revised several times, though not as often as the *Declaration of Helsinki*, I must add. The latest version is of 2002 and so many things have happened since, such as biobanks and conflicts of interest.

So, new issues cry for a new guideline, which is why we started this revision process. We created a workgroup who met for first time in 2012 and will meet again on 1st June, precisely on the day of the meeting of the Council of Europe. I am so sorry for that, I know, we should have coordinated. The interesting thing is that after having worked with these people for three, four years, we then had a pre-final draft. Then, of course, it was of great importance to us to share it with the public, for consultation. That was done from September to 1st March, which was the deadline. We allowed a little more time after that, but it was basically 1st March. And indeed, very many comments were received. And I am very grateful for that. I can echo the Laurence's comment here, because without those comments these guidelines would really lack substance. I think, as in all of ethics, it is really about people talking to each other and finding what I would call professional fixed points on which we can agree. CIOMS is not the ruler of the world. CIOMS is not the place where things get decided. It is not the place where some authority resides that will tell you what to do. It is actually a group of experts that tries to come up with a decent proposal, and then it is the world together that decides whether or not this was a good idea. And that is what happened here and I am very grateful for that.

We are right now looking into all these comments. We will not be able to reply individually to all who have submitted a comment, simply because this would be impossible for a relatively small organization such as ours. But we will discuss the comments with the workgroup from 1st to 3rd June and then will hopefully have a final draft to submit to our executive committee. Then we hope to finalize the whole story before the end of 2016. Of course, it does not end there. Because, in a way, it only begins after our finalization of the draft. For, I hope to meet many of you in many parts of the world to talk about the CIOMS guidelines, to discuss details and how to make further improvements.

So, there are indeed 25 guidelines and all of these guidelines have bold text which is normatively strong, telling you what we think ought be done and then a lot of commentary to it in order to tell you how this is all meant. If you have the opportunity to have a closer look, you will see that there is the topic of pregnant women, the topic

of the use of biological materials – so, many of the new issues are indeed covered by the new version of this guideline.

We really hope to keep these CIOMS guidelines a living document, ready therefore to meet future challenges. That can only be done if we have thorough ethical reflection. This happened in the workgroup, but it also happened among the individuals who submitted comments, because they, too, actually formed groups to comment on the guideline, and this is a great thing. And this really helps to provide ethical guidance in real world dilemmas. So, thank you very much. ||

>> REPORT ON THE REGIONAL MEETINGS

One of the main functions of the Global Summit is to strengthen regional exchange and collaboration. To this end, the programme of the Global Summit 2016 included regional meetings in the afternoon of 18th March. Participants came together in separate meetings for each WHO region to share experiences and discuss common issues and interests. The respective regional members of the steering committee served as facilitators. Due to a small number of participants, SEARO and WPRO held their meeting together.

The agenda for the regional meetings included the following items:

1. To make suggestions for priority topics from a regional perspective to be discussed at the plenary session in 2018. In this context, ethical issues common for many countries in the respective regions and cross-border issues that require international cooperation were to be considered.
2. To discuss the potential for regional meetings in 2017, keeping in mind the goal of promoting regional summits in the years between the Global Summits.
3. To make suggestions for steering committee members from each region for the Global Summit 2018.
4. To provide feedback and general recommendations on the organization of the Global Summit.

Strengthening the role and the influence of national ethics committees (NECs) was one of the priority topics suggested by the regions. This included issues such as funding of NECs as well as capacity building and needs assessment. Closely related to this was raising awareness and promoting education on bioethical issues. Definitions of vulnerability and access to healthcare for vulnerable groups, including non-discrimination and non-stigmatisation was another topic of significance for several regions.

Of particular interest in this context were ethical issues in relation to migration and health. Additionally, biobanking and the use of genomic information including data transfer, international collaboration and benefit sharing was suggested by several regions too.

The organization of regional meetings was encouraged in all regions and specific action had been taken to nominate a host or start establishing subcommittees for the organization of such a meeting.

With regards to recommendations for the next Global Summit, a common suggestion by all regions was to allocate more time and a more visible location for the marketplace. Moreover, the introduction of parallel sessions was recommended that could focus on specific topics that are relevant for the respective regions. Also, it was recommended to have shorter presentations in general and give more space to the discussion from the audience. The idea of extending the meeting to three days was shared by many regions too. It was suggested that the additional time could be used for the marketplace and would allow for additional parallel sessions.

The following table provides an overview of suggestions and recommendations made by each WHO region.

Suggestions and recommendations made by each WHO region					
	AFRO	**EMRO**	**EURO**	**PAHO**	**SEARO/WPRO**
Suggestions on priority topics	• influence of politics and economics on bioethics • the relationship of bioethics and religion • access to health-care • the relationship between bio-ethics, democra-cy and sustainab-le development • NEC funding • capacity buil-ding and needs assessment • mainstreaming of bioethics and raising awareness • biobanking, tissue trade and transfer, data access and data sharing as well as benefit sharing	• solidarity, international collaboration and benefit sharing • resilience of health systems in responding to migration • non-stigmatisa-tion and non-discrimination in public health issues • public awareness raising and edu-cation on ethical issues	• migration and health • demographic change • vulnerable groups • experimental therapies and personalized medicine • dual-use	• public health emergencies and responses to infectious diseases • ethics of gene-tics and stem-cell research, research with medical devices and research on off-label use of devices • ethics in public health policy • migration as a bioethical issue • bioethics and climate change • organ trafficking	• managing emer-ging pathogens/ diseases • biobanking and genomic infor-mation • new technologies • definitions of vulnerability • ethical questions in the context of natural disasters • organ transplan-tation • strengthening the role and the influence of NECs
Potential for regional meetings in 2017	A subcommittee was elected to follow-up on the implementation of a regional meeting after the Global Summit. Malawi offered to host the meeting.	To be hosted in Oman in Spring 2017	Differences bet-ween a regional meeting in the context of the Global Summit and the already estab-lished NEC Forum (organized by the European Union) was discussed -> different transnati-onal organizations involved in this should work out a concept for orga-nizing a regional meeting besides the already estab-lished NEC Forum	It was suggested to hold a regional meeting in May 2017.	A regional meeting is scheduled from 23rd to 25th Octo-ber 2017 in South Korea.

Suggestions for steering committee members	Joseph Mfutso-Bengo (Malawi)	Delegates from Oman and Jordan	The former and future host country should not count as a member of a region.	John Ayotunde Isola Bewaji (Jamaica); Edgar Lobos Lazzeri (El Salvador)	All representatives agreed that they need to get approval for steering committee member suggestions from their respective council/secretariat.
General recommendations for the next Global Summit	• allocate more time to the marketplace • the panelists/ presenters spoke too long -> allow more time for contributions from the audience • add panel sessions to the programme • add an additional day to the Global Summit and make it a three-day event -> the additional time could be used, for example, to better accommodate the marketplace or allow more time for contributions from the audience	• establish partnerships between countries • explore additional fundraising options	• introduce parallel sessions • allocate more time and a better location to the marketplace, allow only for poster presentation (no PPT) • extend the meeting to 2,5 or 3 days • no need for co-presentations from NECs to the discussion papers, the presentation of the papers should be directly followed by the plenary discussion • the process to apply for and select the next host of the Global Summit should start about one year before the next Summit • next venue could be decided by electronic vote of all NECs	• find better ways to carry out the marketplace	• reports could be shorter, especially the presentation of the discussion papers, co-presentations maybe only 5 min. • make the Global Summit a three-day meeting to have more time for the marketplace and for a more fruitful discussion • two key themes that were particularly relevant for the SEARO and the WPRO region and deserve more attention: so-called brave new world topics such as surrogacy and organ transplantation • introduce parallel sessions to allow for regional discussions/discuss topics of particular interest for that region • capacity-building via a mentoring system

>> MARKETPLACE

Marketplace Sessions

Marketplace Session I

Marketplace Session II

Marketplace Session III

Marketplace Session IV

Participants at a marketplace session

Marketplace Sessions

|| The concept of the marketplace, which had been introduced at the 9th Global Summit in Tunisia in 2012, had been a valuable tool for discussion and knowledge sharing and was thus also included in the Global Summit 2016. In the breakout times between formal sessions participants were able to present, share and discuss their work, their activities or simply good practice with other delegates. Altogether, there were four marketplace sessions at the Global Summit 2016 and a total of 31 presentations. The following pages will give an overview about the marketplace sessions and provide the abstracts of the presentations. ||

Marketplace Session I

No.	Presenter	Organization	Country/ Region	Title
1	Ehsan Shamsi Gooshki	National Committee for Ethics in Biomedical Research	Iran/ EMRO	Iranian national initiative for enhancement of research ethics activities in biomedical sciences
2	Chin Jing Jih	Bioethics Advisory Committee	Singapore/ WPRO	Ethical, legal and social issues in neuroscience research: Singapore's perspective
3	Abdulmanon Saidov	National Ethics Committee in Tajikistan	Tajikistan/ EURO	National ethics committee in Tajikistan: mandate and main activities for the last decade
4	Hugh Whittall	Nuffield Council on Bioethics	UK/ EURO	An ethical approach to involving children and young people in clinical research
5	Hidenori Akutsu	Expert Panel on Bioethics, Council for Science, Technology and Innovation	Japan/ WPRO	A review of the current perspectives on the prohibition of embryo creation using induced germ cells
6	Mohammad Ahmed Hamdan	National Committee for Ethics of Science and Technology	Jordan/ EMRO	NEC: Jordan model
7	Bakhyt Sarymsakova	National Ethics Committee	Kazakhstan/ EURO	National ethics committee in Kazakhstan: achievements and perspectives for the ethical review system development
8	Joseph Mfutso-Bengo	National Advisory Committee on Bioethics	Malawi/ AFRO	Illicit global human, biological research sample transfer, trade and bio-pirating of indigenous plants and knowledge

Presentation 1: Iranian national initiative for enhancement of research ethics activities in biomedical sciences

Ehsan Shamsi Gooshki; National Committee for Ethics in Biomedical Research (Iran)

The national health system of the Islamic Republic of Iran is a comprehensive system including most health-related activities such as provision of health-care and medical services, research in clinical and basic fields, and medical and allied health-workers education. This multifaceted national health system is supervised, coordinated, and to a great extent funded by the Ministry of Health and Medical Education (MOHME). According to official reports published by Thompson Reuters, during the recent decades, Islamic Republic of Iran has achieved a remarkable growth in scientific publications, surpassing most countries in the region. This enormous increase in the number of publications in health-related fields necessitated a robust and reliable research ethics infrastructure to ensure full adherence to international ethical codes as well as Islamic principles. As a response to this need, the first official national research ethics committee (REC) was established in 1998 which was followed by foundation of different organizations and bodies such as regional RECs. Moreover, several research ethics guidelines have been published and ratified in Iran hitherto such as the first 26-clause national general ethical guideline for biomedical researches (revised later and upgraded to 31 clauses) and 8 designated guidelines for specific research projects such as fetal and embryonic research, research on vulnerable groups, randomized clinical trials, HIV/AIDS research, stem-cell research, and publication ethics. Considering the increasing rate of knowledge production in the country and emerging gaps in the field, the REC has designed a comprehensive project for further development and expansion of the current national research ethics system. This project includes:

1. A "gap analysis study" aimed at defining the current gaps in research ethics administrations and guidelines in comparison with well-developed international models.
2. Centralization of research ethics activities through integration of all Iranian research ethics institutions such as those of Iranian Food and Drug Administration, Iranian Registry of Clinical Trials (IRCT), and research and education deputies of the ministry into one single framework.
3. Establishment and endorsement of a national accreditation system for all research ethics committees.
4. Foundation of a national register for cases of biomedical research misconduct.
5. Establishment of a harmonized national post-approval study monitoring system.
6. Development of a national web-based program for online submission and cooperative review to save both time and resources.

Presentation 2: Ethical, legal and social issues in neuroscience research: Singapore's perspective
Chin Jing Jih; Bioethics Advisory Committee (Singapore)

This presentation will discuss the process and findings of the Singapore Bioethics Advisory Committee's project on *Ethical, Legal and Social Issues in Neuroscience Research*. Issues that will be discussed include: research with persons lacking mental capacity, management of incidental findings and neuroenhancement.

Presentation 3: National ethics committee in Tajikistan: mandate and main activities for the last decade
Abdulmanon Saidov; National Ethics Committee (Tajikistan)

The presentation will describe the national ethics committee's history since its establishment under the Ministry of Health of the Republic of Tajikistan, main activities and mission in the national ethical review system. Also, there will be an outline of the future perspectives and plans to strengthen the capacity and role of the national body at the country and international level to ensure the dissemination of the best practices in the ethical review and public awareness in the fields of the human subject protection.

Presentation 4: An ethical approach to involving children and young people in clinical research
Hugh Whittall; Nuffield Council on Bioethics (United Kingdom)

Much has been written as to what constitutes 'ethical practice' in clinical research – but generally from the starting point of research with competent adult participants. In May 2015 the Nuffield Council on Bioethics published the report *Children and Clinical Research. Ethical Issues*, which starts from a consideration of children and young people, of what makes their situation ethically different, and of their lived experiences of participation in research. The report was written with input from young people, parents and professionals concerned with clinical research both in the United Kingdom and internationally, and other materials to complement the report were also produced in collaboration with and for these groups. This presentation will set out the Council's ethical approach to children's involvement in research, and display the various outputs of this work including the report and summary for policy makers, a magazine and animation aimed at young people, posters, and material for training and education.

Presentation 5: A review of the current perspectives on the prohibition of embryo creation using induced germ cells
Hidenori Akutsu; Expert Panel on Bioethics, Council for Science, Technology and Innovation (Japan)

Recent progress on fertile germ cells differentiated from mouse pluripotent stem cells may lead to the successful differentiation of germ cells from human pluripotent stem cells in the near future. Gametogenesis studies performed *in vitro* have the potential to reveal causes of infertility and congenital diseases by modelling gametogenesis or the early development process. Advancing such studies provokes ideas of future assisted reproductive technologies using germ cells derived from human pluripotent stem cells. However, there are several scientific, medical, and ethical steps that must be taken before such innovative medical procedures may be realized. The Expert Panel on Bioethics of Japan's Council for Science, Technology and Innovation (CSTI) has recently reached the consensus that induced germ cells should not be fertilized even in their functional assay following over two years of discussion. The presentation introduces the current perspectives in Japan on the handling of induced germ cells from human pluripotent stem cells.

Presentation 6: NEC: Jordan model
Mohammad Ahmed Hamdan; National Committee for Ethics of Science and Technology (Jordan)

This presentation will cover vision, mission, goals, organizational chart and membership of the Jordan NEC model. Also some major programs implemented and others planned will be highlighted. Besides some best practices and lessons learnt will be discussed.

Presentation 7: National ethics committee in Kazakhstan: achievements and perspectives for the ethical review system development
Bakhyt Sarymsakova; National Ethics Committee (Kazakhstan)

The presentation will describe the national ethics committee's history since its establishment in 2008, main activities and mission in the national ethical review system. Also, there will be an outline of the future perspectives and plans to strengthen the capacity and role of the national body at the country and international level to ensure

the dissemination of the best practices in the ethical review and public awareness in the fields of the human subject protection.

Presentation 8: Illicit global human, biological research sample transfer, trade and bio-pirating of indigenous plants and knowledge

Joseph Mfutso-Bengo; National Advisory Committee on Bioethics (Malawi)

Clinical research may sometimes involve exportation and importation of biological samples and data which serve as the back bone of viable scientific or biomedical research. As emerging innovations in the fields of genetics, genomics and biotechnology increase, the value of biological samples and data creates greater demand that will lead to increased exportation of biological samples and data for technologically advanced biomedical research mostly in developed countries. Most developed countries and some developing countries have regulations and guidelines for the use and exportation of stored biological samples and data in future research. However, Malawian research ethics regulations and guidelines do not allow storage and secondary use of biological samples and data in future unspecified research. Therefore, the aim of this presentation is to address the current debate in Malawi and many African countries regarding storage, use and exportation of biological samples and data. Furthermore recommendations will be made that will protect research participants and benefit the biomedical research community in the country. The current framework of the Material Transfer Agreement partially regulates the human biological samples obtained for research purpose but is also very silent on proof of destruction of biological samples, when the research is over and on medical samples obtained for medical diagnosis that end up in in medical research centers. Therefore, I wish to recommend a special Medical Material Transfer Agreement for regulating transfer of human biological sample for medical diagnosis.

Marketplace Session II

No.	Presenter	Organization	Country/ Region	Title
1	Malamin Sonko	Gambia Government/ Medical Research Council Joint Ethics Committee	Gambia/ AFRO	Alternate informed consent procedure for clinical trials
2	Ali Bourawi	Libyan National Committee of Bioethics and Biosafety	Libya/ EMRO	Teaching bioethics: challenges and overcoming
3	Damdindorj Lkhagvasuren	Mongolian National Biosafety Committee	Mongolia/ WPRO	Mongolian current condition of biosafety and bioethics
4	Patrik Hummel	WHO		WHO ethics guidance in elimination of TB – 'The Road Ahead'
5	Evariste Likinda	Comité National de Bioéthique	Congo, D.R./ AFRO	Equité dans l'accessibilité aux services de santé
6	Manuel H. Ruiz de Chávez	Comisión Nacional de Bioética	Mexico/ PAHO	Drug policy and cannabis regulation
7	Joyce K. Ikingura	National Institute for Medical Research	Tanzania/ AFRO	Tanzanian ethical review system: experience of the National Ethics Review Committee

Presentation 1: Alternate informed consent procedure for clinical trials
Malamin Sonko; Gambia Government/Medical Research Council Joint Ethics Committee (Gambia)

The presentation will give an overview of the recently published work of Dr. Muhammed Afolabi of the Medical Research Council Unit in Gambia which focuses on the development and evaluation of a multimedia tool as an alternative procedure for obtaining informed consent in clinical trials conducted in mainly illiterate communities such as obtained in the Gambia. The tool is an audio-recorded information presentation of a clinical trial in 3 major Gambian languages. The research participants comprehension of the trial information was then assessed and compared with the traditional way of providing written trial information for participants. The results were highly encouraging. The CD of the multimedia tool will be available during the Summit.

Presentation 2: Teaching bioethics: challenges and overcoming
Ali Bourawi; Libyan National Committee of Bioethics and Biosafety (Libya)

Bioethics is a new concept that has been introduced in Libya and some countries in the Middle East and North Africa (MENA) in the beginning of 20th century. Accordingly, local governments, especially in Libya and some other countries, have focused their work on the empowerment of their local committees, but did not establish clear strategies in order to educate technical staff being able to implement bioethics concepts in their communities. Capacity building is the essential and basic step for establishing rules and concepts of bioethics that need to be taken. Some countries still have some challenges ahead and questions that need to be answered:

- What is the curriculum of bioethics in MENA?
- How can the curriculum of bioethics made compatible with their principles of laws, religious beliefs and social traditions?
- Engagement of bioethics as subject or training in universities and higher education institutions? Kind of advocacy created by local and/or national committees of decision makers in MENA?
- Trainers and their qualification to teach bioethics?
- Examples of successful trials in MENA countries?

Presentation 3: Mongolian current condition of biosafety and bioethics
Damdindorj Lkhagvasuren; Mongolian National Biosafety Committee (Mongolia)

Mongolia needs to strengthen law, responsibilities, and human resources in this sector due to increasing foreign trade and globalization. According to the problems, we are taking steps to solve for improving laws within the framework of the *Cartagena Protocol on Biosafety* to the *Convention on Biological Diversity*. The development of modern biotechnology and genetic engineering demands for regulation of crucial issues in bioethics and biosafety in Mongolia.

Presentation 4: WHO ethics guidance in elimination of TB – 'The Road Ahead'
Patrik Hummel; World Health Organization

In 2010, the WHO published its *Guidance on Ethics of Tuberculosis Prevention, Care and Control* to help guide health care workers, policy makers, patients, and civil society on a wide range of challenges related to tuberculosis (TB). The document is an important reference point for informed ethical policy-making, clinical and public health practice. Last year, the WHO adopted the End TB Strategy, which puts forth the goal of ending the global TB epidemic by 2035. Specifically, the End TB Strategy states that TB deaths shall be reduced by 95 percent, new cases shall be cut by 90 percent, and no family shall be burdened with catastrophic expenses. One of the core principles of the strategy is the protection and promotion of human rights, ethics and equity. Since the publication of the 2010 TB ethics guidance document, new challenges have emerged or gained more attention. Coupled with the ambitious goals of the End TB Strategy, the WHO has decided to update its ethics guidance document. The goal of this marketplace session is to present the global bioethics community with an opportunity to provide important input for the next iteration of the WHO's TB ethics guidance document. The presentation encompasses four of the more challenging topics to be addressed in the new WHO guidance document: migrants and displaced populations; treatment when recommended regimens are non-feasible; treatment of latent TB infection; and involuntary isolation.

Presentation 5: Equité dans l'accessibilité aux services de santé
Evariste Likinda; Comité National de Bioéthique (Congo, D.R.)

Notre participation à ce Market Place afférent au XIè Sommet Mondial des Comités d'Ethique/Bioéthique va consister en un partage sur l'une des préoccupations

majeures en République Démocratique du Congo (RDC) où la situation est caractérisée non seulement par une disponibilité insuffisante en densité de services médico-sanitaires et une limite dans leur capacité opérationnelle, mais aussi et surtout par un caractère inéquitable en terme d'accessibilité des populations aux soins médicaux.

Nous nous référons pour cela d'une part aux résultats de l'Enquête sur la disponibilité et la capacité opérationnelle des services de santé (SARA RDC 2014) qui épingle un ensemble d'indicateurs fondamentaux sur des données de l'offre et la capacité opérationnelle de formations sanitaires du système de santé, notamment les infrastructures, le personnel de santé et l'utilisation des services et, d'autre part aux résultats de l'Enquête démographique et de santé (EDS) réalisée en 2013-2014 dans le cadre du programme mondial des EDS (Demographic and Health Surveys, DHS) avec objectif de produire des résultats représentatifs au niveau de l'ensemble du pays aussi bien du milieu urbain que du milieu rural, mettant en évidence des indicateurs fiables pour l'élaboration, le suivi et l'évaluation de la mise en œuvre des programmes et politiques sectoriels du pays.

Les résultats de l'Enquête SARA 2014 en RDC montrent que le système des services de santé dans le pays n'assure pas de services suffisants pour répondre aux besoins de santé de la population. On note, en effet, qu'en moyenne, la densité des établissements de santé est de 1,3 pour 10.000 habitants, nettement inférieur à 2 pour mille, la moyenne considérée comme acceptable selon l'Organisation mondiale de la santé (OMS). L'offre de service et la capacité opérationnelle (capacités de diagnostics et aménagements de confort indispensable) est de 27% pour les services généraux dans l'ensemble du pays, de 40% pour quelques services spécifiques comme la vaccination, les soins obstétricaux de base et le paludisme pour lequel le taux atteint 70%. La plupart des autres services avec des niveaux de capacité opérationnelle à 20%, voire 10% ne donnent guère l'assurance aux usagers potentiels que leurs besoins de santé seront satisfaits.

La disponibilité des services, y compris ceux qui bénéficient d'une disponibilité relativement bonne, est compromise par les faibles niveaux de capacité opérationnelle. Les structures des soins aussi bien de base que de référence, disposent de moyens d'intervention très limités, le personnel qualifié est très insuffisant. Seulement 9% des formations sanitaires disposent d'une source d'énergie électrique et 2% disposent d'ordinateurs avec connexion à l'internet.

Le rapport de la dernière Enquête démographique et de santé (EDS-RDC II 2013-2014) évalue la population globale en RDC à 77,8 million d'habitants en 2012, sur une superficie de 2.345.000 kilomètre carré, avec une densité moyenne de 24 habitants au kilomètre carré. La majorité (70%) de la population vit en milieu rural.

Il existe d'une part une préoccupation liée à l'accessibilité aux services de santé de manière générale, et d'autre part les possibilités d'accès aux soins sont inégalement

réparties sur l'étendue du pays. En effet, l'indice moyen de capacité opérationnelle des services généraux de 27% varie entre 76% à Kinshasa, la capitale, et 11% dans certaines provinces, traduisant ainsi d'importantes disparités. Les établissements privés et les structures en zone urbaine obtiennent de meilleurs scores de capacité opérationnelle que des établissements publics et ceux qui sont situés dans les zones rurales. A quelques exceptions près, les établissements qui sont les plus aptes à fournir des services sont les structures privées et les centres situés dans les zones urbaines. Or, comme dit plus haut, la majorité des habitants de la RDC vivent dans les zones rurales, ils sont pauvres et ne peuvent se permettre de verser des frais médicaux pour obtenir des services privés. Il en est de même en ce qui concerne d'autres indicateurs comme l'accès à l'eau potable (68% de ménage s'approvisionnent auprès des sources non-améliorées en milieu rural), la disponibilité des toilettes ou de logement convenables, l'éducation ou l'information sanitaire.

L'accès aux services de santé est limité par le facteur distance qui fait que les personnes vivant en milieu rural très éloigné des centres urbains ont peu de moyen d'atteindre les centres relativement mieux équipés de la ville de Kinshasa, compte tenu d'énormes difficultés de transport pour relier les différents coins d'un pays étendu sur 2.345.000 kilomètres carré. Ces populations sont dès lors défavorisées. Bien plus, même pris globalement, 95% des Congolais n'ont pas d'assurance médicale. Une petite minorité (4%) de salariés ont une assurance fournie par l'employeur ; ceux-ci sont en fait des personnes qui travaillent dans quelques entreprises publiques ou privées plus ou moins prospères, et parmi eux 10% sont à Kinshasa. En réalité, la grande majorité de ceux qui travaillent notamment dans la fonction publique n'ont aucune assurance médicale, et leur rémunération très modique ne peut leur permettre de prendre en charge les frais médico-pharmaceutiques.

Quelques tentatives de mise en œuvre des systèmes de solidarité institutionnelle (mutuelles de santé), encore timides, sont butées à la modicité des revenus des citoyens. Nous avons dénombré 14 mutuelles de santé d'initiative privée (confessions religieuses notamment). Les cotisations très faibles (de 19 à 54 dollars US par an et par membre) ne permettent pas de couvrir adéquatement les besoins de santé comme il n'y a aucune subvention de l'Etat.

Il y a lieu de constater là un fossé entre le niveau actuel des avancées technoscientifiques dans le domaine des services de santé à travers le monde et la pratique médico-sanitaire chez nous. La majorité de la population n'a pas accès à des soins de santé adéquats. Il y a donc lieu de noter l'étendue des devoirs et des objectifs que doit s'assigner le gouvernement dans sa mission d'assurer aux citoyens des conditions de jouir du droit à la santé comme défini dans le droit international des droits de l'homme, à savoir le « meilleur état de santé physique et mentale qu'on soit capable d'atteindre » (Article 12 du *Pacte international relatif aux droits économiques, sociaux*

et culturels, 1966). Ce droit fondamental englobe les soins médicaux, l'accès à l'eau potable, l'assainissement adéquat, l'éducation ou encore l'information sur la santé.

Bien entendu, dans un contexte de ressources limitées, il y a lieu de chercher à trouver un équilibre entre plusieurs paramètres ; des questions se posent, en effet, sur la répartition des allocations entre plusieurs besoins tout aussi nécessaires, et sur les choix entre certaines technologies onéreuses face aux besoins du grand nombre. Il faudrait une compréhension approfondie des conditions du délicat rationnement lorsqu'il s'agit pour le gouvernement de choisir les priorités dans l'affectation des ressources dans les systèmes de soins de santé publics et privés.

Le comité National de Bioéthique s'attelle à l'évaluation de ces situations afin de favoriser le débat, l'éducation et la sensibilisation du public et des pouvoirs publics concernant les dimensions éthiques y relatives afin d'entrevoir des solutions aux problèmes d'équité de l'accès aux soins de santé et d'accès équitable au traitement médical.

Presentation 6: Drug policy and cannabis regulation
Manuel H. Ruiz de Chávez, Comisión Nacional de Bioética (Mexico)

The global phenomenon of marijuana consumption and production is multifaceted and involves various concerns, such as the effect on the health of individuals, public health, public order, the right to the free development of personality, among others. New attitudes towards this drug have triggered reforms in regulation in various parts of the world over the past years, however the debate is ongoing.

In Mexico, this matter took special importance from the resolution 237/2014 issued by the Supreme Court of Justice of the Nation, which grants to a group of people the right to plant, cultivate, harvest, process, possess or transport cannabis, without implying the authorization to carry out business activities, or any other provision that refers to the transfer or distribution of such substance.

The argument underlying the resolution is based on the fact that legislative measures that prohibit a number of activities related to the production and consumption of marijuana in our country disproportionately restrict the right to the free development of personality. The extent of damage to health and the respect for the right of the free development of personality, however, cannot be the only values taken into account in regulating this substance; this would be a simplification of a problem that requires more than a specific governmental policy analysis on drugs.

The development of public policies should focus on preventing human rights violations and address the problem from a comprehensive public health approach, in order to establish criteria for government intervention and regulation of a substance

that certainly represents a risk to the health of people. It is necessary to make adjustments to the whole scheme of criminal prohibition and regulation under general parameters of public health and protection of human rights of users and nonusers.

The National Bioethics Commission of Mexico (CONBIOÉTICA) has followed closely the national debate on the legalization of Marijuana, providing information and issuing statements from a bioethical approach. In this regard, the commission is currently collaborating with the Pompidou Group to gain a better understanding of the arguments and motivation for reforms in marijuana regulation, as well as considering new policy approaches to regulate cannabis by linking policy, practice and science.

Presentation 7: Tanzanian ethical review system: experience of the National Ethics Review Committee

Joyce K. Ikingura; National Institute for Medical Research (Tanzania)

The Tanzanian Ethical Review System is not common with other East African countries, or in the south and eastern region in Africa. Established in 2002, and based at the National Institute for Medical Research (NIMR), the National Ethics Review Committee (NatHREC) began to operate as the only ethics committee in the country. It was being implemented in the country after amendment of the Act of Parliament that established the NIMR (Act No. 23 of 1979). This act was amended to consider international guidelines for biomedical, socio-economic and cultural research involving human participants which are developed and updated by the WHO jointly with the Council for International Organizations of Medical Sciences (CIOMS) and that will be adapted for implementation in this country. The amendment stipulated 10 regulations to guide coordination of health research in Tanzania.

NatHREC therefore, being the only Committee operating as national ethical review model, whereby all health research to be conducted in the country, had to seek ethical clearance from one NIMR NatHREC. With time as per the regulations, some health research, medical academy, university Institutions were being established and therefore had developed capacity to conduct health research. They also were mandated to review and grant approval for health research doable at their institutions. At this stage the predominant national model for ethical review systems was complemented with a Local or Institutional Model. The ethical review system framework in Tanzania is both local and national, and the national committee is supporting other institutional research ethics committees to operate. This has been possible by developing the standard operating procedures (SOPs) for all ethics committee both national and institutional. Our experience in the ethics review system has been

working, and there is success. The institutional research ethics committees are guided by the national committee, and there is support from the regions and districts where research is being conducted.

Marketplace Session III

No.	Presenter	Organization	Country/ Region	Title
1	Andreas Reis	WHO		WHO guidance on ethics of public health surveillance
2	Michel Daher	Lebanese National Ethics Committee	Lebanon/ EMRO	Ethical issues in end-of-life care
3	Manuel H. Ruiz de Chávez	Comisión Nacional de Bioética	Mexico/ PAHO	Migrations: a bioethical issue. The case of Mexico
4	Barry Smith	Health Research Council of New Zealand	New Zealand/ WPRO	Ethical tensions between protecting vulnerable populations and generating equity in health knowledge across a population
5	Esteban Cerdas Quirós, Erna Melendez	Consejo Nacional de Investigación en Salud	Costa Rica/ PAHO	Regulación de la investigación biomédica en Costa Rica: pasado, presente y futuro
6	Daniel Piedra Herrera	Cuban National Bioethics Committee	Cuba/ PAHO	Universality of bioethics
7	Azizan Baharuddin	National Bioethics Council	Malaysia/ WPRO	Maqasid al-Shariah as a complementary framework to conventional bioethics
8	Nozimkhon Makhmudov	Uzbekistan Bioethics Committee	Uzbekistan/ EURO	UNESCO and National Bioethics Committee of Uzbekistan

Presentation 1: WHO guidance on ethics of public health surveillance
Andreas Reis; World Health Organization

Surveillance is one of the most fundamental activities of public health, involving diverse practices in areas such as non-communicable disease registers, outbreak investigations, infectious disease, health systems research, and digital surveillance. Public health surveillance (PHS) raises multiple ethical issues, and in 2014, the WHO launched a project to develop ethics guidelines for PHS. These guidelines are intended to establish a general ethical framework that is intended to be applied by governments, public health agencies and practitioners when designing public health surveillance policies and practices. In explicating the key components of these guidelines, the presentation will:

1. Provide an overview of the modalities of PHS and the ethical issues that could arise, including those that have been identified in the literature;
2. Identify ethics gaps in existing regulatory frameworks, including the *International Health Regulations*;
3. Explicate the key ethical values, these being (i) prioritising public health as public good, (ii) equity and justice, (iii) respect for persons, and (iv) accountability and good governance; and
4. Broadly explain the application of these guidelines in PHS, with focus on ethical challenges that arise at the point of data collection; use and storage; and dissemination.

These guidelines represent an important stride forward in articulating a set of animating values and procedural principles that, while beginning from the premise that public health has an affirmative duty to conduct surveillance, recognise that it must be subjected to ethical limits.

Presentation 2: Ethical issues in end-of-life care
Michel Daher; Lebanese National Ethics Committee (Lebanon)

Because of technical advances in the care of critical illness, physicians, patients, and families are often confronted with ambiguous circumstances in which medical advances may inadvertently prolong suffering and the dying process rather than bring healing and recovery. Excellent resources are available that review these issues in greater depth.

Ethical principles (respect for persons, beneficence, non-maleficence, and justice) must be defined and respected. These ethical issues are profoundly influenced by values, culture and religion.

The objectives of this presentation are to: (1) review major principles of medical ethics relevant to the care of terminally ill patients; (2) explore further the principle of autonomy and its application to advanced directives, informed consent, and medical futility; (3) characterize the ethical differences between withholding or withdrawing life-sustaining therapies and physician-assisted death; (4) define a process for communicating bad news and negotiating decisions at the end of life; and (5) examine ethical problems specific to terminal illness in light of these principles.

Patients and their physicians together face these challenging ethical issues at the end of life. Although some issues (e.g. the role of physician-assisted death in addressing suffering) remain very controversial, there is much common ground based on the application of the four major principles of medical ethics, non-maleficence, beneficence, autonomy and justice.

When ethical dilemmas occur, ethics committees must be involved.

Presentation 3: Migrations: a bioethical issue. The case of Mexico
Manuel H. Ruiz de Chávez; Comisión Nacional de Bioética (Mexico)

As neighboring State of the United States, Mexico is a country of transit, origin and destination of migration. Our country experiences a heavy flow of emigrants as well as transit migrants from Central and South America seeking to reach the United States.

This phenomenon is a direct consequence of the process of modernization and urbanization that has taken place all across the globe in the last century. In the case of Mexico, the idea of going north in search of opportunity is deeply embedded in our society. Despite all regulations and enforcement measures, migration has become an economic and social force to be dealt with: more than 90 percent of Mexicans living abroad are concentrated in a single country, the United States, and regarding currency remittances that migrants send to their families, Mexico ranks fourth worldwide.

This situation represents challenges for the governments of all nations involved, such as expanding access to health care for uninsured immigrants and ensuring protection for the rights of migrants.

Addressing this challenge constitutes the first foreign policy priority of the Mexican government. The focus of the current administration has been to establish strategic alliances between origin and host countries in order to develop public policy that allows greater possibilities for lawful territorial mobility, social benefit and improvement of the quality of life of immigrants. The Secretariat of Foreign Affairs,

through the Chancellery, is currently developing the program *Puertas Abiertas* (open doors), which seeks to strengthen the migration policy by focusing greater attention on respect for fundamental human rights, as well as to provide guidance for migrants returning home.

In this regard, bioethics represents a key factor in developing public policy on migration. Its interdisciplinary approach provides a valuable reference framework for assessing the ethical, legal and social issues related to intercultural exchange and migration, which may contribute significantly in establishing a legal framework with regard to human security and respect for the rights and dignity of those who need to come to our country, either temporarily or permanently, allowing, in turn, for a better management of legal migration and protection for migrants in vulnerable situations, as well as to prevent unlawful migration and human trafficking.

Bioethics invites us to change our views on migration and acknowledges the contributions of migrants to host societies, while promoting their social inclusion and human development, as well as raising awareness on the value of ethnic and cultural diversity.

Presentation 4: Ethical tensions between protecting vulnerable populations and generating equity in health knowledge across a population
Barry Smith; Health Research Council of New Zealand (New Zealand)

While it is totally appropriate that the participation of vulnerable participants in our populations be seriously discussed in the ethics review process, it is also important that robust knowledge about these segments of our populations be generated and built up over time. The consequence of not 'permitting' this to occur has the potential to generate higher levels of risk because of the fact that health interventions carried out on these segments of our communities are then more likely to be based on ad hoc decisions and 'traditional' knowledge rather than on substantiated research findings. In the New Zealand context, legal arguments and codes of patient rights tend to favour the former rather than the latter position in this debate.

Presentation 5: Regulación de la investigación biomédica en Costa Rica: pasado, presente y futuro
Esteban Cerdas Quirós, Erna Melendez; Consejo Nacional de Investigación en Salud (Costa Rica)

- 1972. Decreto Ejecutivo 2393 la creación del Comité de Investigaciones Médicas en Humanos y Reglamenta los ensayos de nuevas drogas y medicamentos.

- 1973. Ley General de Salud de 1973.
- 1975. Decreto Ejecutivo 5463-SPPS1, Reglamento para las investigaciones y experimentaciones en seres humanos. Con una influencia más clara de los códigos internacionales como la *Declaración de Helsinki*, se crea la figura del Comité Científico Institucional (CCI) como órgano asesor y de consulta del Ministerio de Salud en materia de investigación y experimentación en seres humanos y como responsable de la revisión y aprobación de los proyectos de investigación por realizarse en el país.
- 1998. Decreto Ejecutivo Nº 27349-S, Reglamento para las Investigaciones en Participan Seres Humanos. Se establece, por una parte, la revisión y aprobación de todo proyecto de investigación por parte un comité ético, público o privado, debidamente acreditado por el CONIS. Surgió el Consejo Nacional de Investigación en Salud (CONIS) y la red de Comités Éticos Científicos (CEC).
- 1998. La CCSS emite su primer Reglamento para la Investigación en los Servicios Asistenciales de la Caja Costarricense de Seguro Social.
- 2003. La CCSS emite un nuevo Reglamento para las investigaciones clínicas en los servicios asistenciales de la CCSS.
- 2003. Decreto ejecutivo 31078-S, Reglamento para la investigación en que participan seres humanos, el cual se ocupa más detalladamente de regular la investigación en seres humanos y de las instancias encargadas del control de estas investigaciones, principalmente los comités éticos y el CONIS.
- 2005. La CCSS emite su Reglamento para la investigación clínica en los servicios asistenciales de la Caja Costarricense de Seguro Social.
- 2010. La Sala Constitucional paraliza la realización de nuevos programas de investigaciones en seres humanos desde el 27 de enero del 2010. En la sentencia, la Sala IV afirmó que en "un tema como la experimentación con seres humanos, que incluye derechos tan importantes y esenciales como la vida, la salud, la dignidad y la intimidad de los seres humanos, exige su regulación mediante una ley", la cual debe ser aprobada por la Asamblea Legislativa.
- 2014. Ley Nº 9234 del 22 de abril del 2014, Ley Reguladora de Investigación Biomédica
- 2015. Decreto Ejecutivo Nº 39061-S del 17 de julio del 2015, Reglamento a la Ley Reguladora de Investigación Biomédica

Luego de casi 5 años de espera, en abril del 2014 se aprueba la *Ley Reguladora de Investigación Biomédica* (Ley Nº 9234) que viene a regular las investigaciones biomédicas en Costa Rica. Con esta ley se autoriza la realización de investigaciones biomédicas tanto en el ámbito público y el privado. Se crea el Consejo Nacional de Investigación en Salud como ente encargado de la regulación, supervisión y seguimiento

de las investigaciones biomédicas. Igualmente se define las funciones de los Comités ético Científicos, los cuales deben previamente ser acreditados por el CONIS, y deben asegurar entre otras cosas, que en las investigaciones biomédicas se respeten la vida, la salud, el interés, el bienestar y la dignidad humana, se cumplan los criterios de rigurosidad científica y las normas éticas que regulan la materia. El objeto de la presente ley es regular la investigación biomédica con seres humanos en materia de salud, en los sectores público y privado.

El Consejo Nacional de Investigación en Salud (CONIS) es un órgano independiente, multidisciplinario, de carácter ético, técnico y científico, adscrito al Ministerio de Salud con un grado de desconcentración máxima y con personalidad jurídica instrumental. Integrado por siete miembros propietarios, cada uno con su respectivo suplente, que durarán en sus cargos un período de cinco años y podrán ser reelegidos

1. El ministro de Salud o el funcionario en quien este delegue y su suplente, quien presidirá.
2. El ministro de Ciencia y Tecnología o el funcionario en quien este delegue y su suplente.
3. Un abogado especialista en derechos humanos y su suplente, nombrado por el Colegio de Abogados de Costa Rica.
4. Un representante de la Caja Costarricense de Seguro Social (CCSS).
5. Un representante del Consejo Nacional de Rectores (Conare) y un suplente, quien deberá ser especialista en bioética.
6. Un representante en propiedad y un suplente, agremiado de los Colegios Profesionales de Médicos y Cirujanos; Farmacéuticos; Cirujanos Dentistas y de Microbiólogos, nombrados por las juntas directivas de los respectivos colegios profesionales.
7. Un miembro propietario y un suplente en representación de la comunidad.

Algunas funciones del CONIS son:

- Regular y supervisar y dar seguimiento a las investigaciones biomédicas y garantizar la vida, la salud, el interés, el bienestar y la dignidad de las personas.
- Acreditar, registrar, supervisar y suspender(si corresponde):
  - CEC (públicos y privados)
  - Organizaciones de administración por contrato (OAC)
  - Organizaciones de investigación por contrato (OIC)
  - Investigadores que llevan a cabo investigaciones biomédicas.
- Supervisar, inspeccionar, suspender proyectos de investigación.
- Promover e impulsar la capacitación en bioética en investigación.

- Llevar un registro nacional de:
  - todas las investigaciones biomédicas que se realizan en los centros privados y públicos del país.
  - de las entidades o establecimientos de salud que realice investigaciones biomédicas.
  - investigadores.
  - organizaciones de investigación y de administración por contrato.
  - los CEC y de los investigadores, patrocinadores, OAC y OIC que hayan sido sancionados por incumplimiento de la presente ley.
  - publicaciones y presentaciones en actividades científicas de los resultados de las investigaciones biomédicas aprobadas en el país.
  - investigaciones que han sido rechazadas y las razones que fundamentaron la decisión.
  - investigadores sancionados y las razones que motivaron la sanción.

La integración del CONIS se da en diciembre del año 2004 e inicia funciones en febrero del 2015, encontrándose ante la necesidad de cumplir todas las funciones que la ley le asignaba y con limitaciones serias de recursos humanos, materiales, presupuestarios y de instalaciones físicas.

Se ha necesitado tiempo para que el CONIS, una estructura nueva vaya cumpliendo con los requisitos país en temas de administración y manejo presupuestario, pues por primera vez se han tenido que preparar formulaciones presupuestarias, definir estructuras administrativas y redactar planes operativos anuales. Todo esto ha sido posible gracias al apoyo de la Dirección de Desarrollo Científico y Tecnológico en Salud, del Ministerio de Salud.

Conjuntamente se han tenido que desarrollar acciones para dar cumplimiento a todas las funciones que la ley le asignó y que también partiendo de cero, a un año de haber iniciado sus labores el CONIS cuenta con procesos internos documentados, con regulaciones específicas para las acreditaciones de investigadores, CEC, OIC, OAC, para la temática de los cursos de buenas prácticas clínicas, entre otros.

Todo este proceso se ha acompañado en todo momento de una inmensa y variada cantidad de consultas de personas interesadas en que se les aclaren puntos específicos de la ley y su reglamento y una intensa cantidad de trámites de documentos de personas interesadas en cumplir los requisitos para acreditar investigadores, CEC, OAC y OIC. Esto ha sido posible gracias a la existencia de una secretaría técnica que brinda estos servicios, entre muchos otros, con el apoyo de la Dirección de Desarrollo Científico y Tecnológico en Salud, del Ministerio de Salud.

El futuro próximo, nos trae la urgencia de contar con regulaciones específicas como por ejemplo en el tema de investigaciones con células madre, investigaciones

genéticas, pero también se tiene la esperanza de que en este 2016, contaremos con un espacio físico y con la valiosa cooperación del Ministerio de Salud, podremos contar con más recurso humano en la Secretaría técnica lo que redundará en un mejor cumplimiento de las funciones establecidas en la ley, lo que al final redundará en que en Costa Rica se estarán realizando investigaciones biomédicas con seres humanos, de calidad científica, respetando la dignidad y los derechos de los participantes y en estricto apego a los principios bioéticos.

Presentation 6: Universality of bioethics
Daniel Piedra Herrera; Cuban National Bioethics Committee (Cuba)

The presentation is extended in order to express how the linkage of applied bioethics to a theoretical basis very much related to cybernetics remained hidden due to the dark history of this science of "communication and control in the machine and in the animal", that has led to a concept of informatization of society based on the diffusion of information and communication technologies, ignoring its implications for arriving at a society with full democratic participation.

Presentation 7: Maqasid al-Shariah as a complementary framework to conventional bioethics
Azizan Baharuddin; National Bioethics Council (Malaysia)

With the rapid advancements made in biotechnology, bioethical discourse has become increasingly important. Bioethics is a multidisciplinary and interdisciplinary field that goes beyond the realm of natural sciences and has involved fields in the domain of the social sciences. One of the important areas in bioethical discourse is religion. In a country like Malaysia, where Muslims make up the majority of the population, Islam plays a crucial role in providing the essential guidelines on the permissibility and acceptability of biotechnological applications in various fields such as medicine, agriculture, and food processing. This presentation looks at the framework of a complementary model of bioethics derived from the perspective of Islam. The framework is based on 'maqasid al-shariah' (purposes or objectives of Islamic law) which aims to protect and preserve mankind's faith, life, intellect, progeny, and property. It is proposed that 'maqasid al-shariah' be used as a pragmatic checklist that can be utilized in tackling bioethical issues and dilemmas.

Presentation 8: UNESCO and National Bioethics Committee of Uzbekistan
Nozimkhon Makhmudov; Uzbekistan Bioethics Committee (Uzbekistan)

The presentation will give a brief overview about the National Bioethics Committee of Uzbekistan and its activity. A detailed description of the practical cooperation with the UNESCO including the implementation of the participation program 2014 to 2015 (No. 7290113455) *Support of Activities of the National Bioethics Committee of Uzbekistan* will be presented. Additionally, proposals for promoting cooperations with the UNESCO, the WHO, other foreign national ethics/bioethics committees and potential partners will be made.

Marketplace Session IV

No.	Presenter	Organization	Country/ Region	Title
1	Lissette Duque	National Bioethics Commission	Ecuador/ PAHO	Public announcement and application: an Ecuadorian model for the establishment of National Bioethics Commission
2	John Ayotunde Isola Bewaji	National Bioethics Committee	Jamaica/ PAHO	Proposal for national bioethics committees to serve as overarching national ethics bodies in countries
3	Sangeun Park	National Bioethics Committee	South Korea/ WPRO	Introduction of 2017 WRPO/Asia NEC meeting in South Korea
4	Simon K. Langat	National Bioethics Committee	Kenya/ AFRO	Speeding up ethical review in multi-centre research: the case for collaboration in the Eastern Africa region
5	Manuel H. Ruiz de Chávez	Comisión Nacional de Bioética	Mexico/ PAHO	Strengthening the institutional infrastructure in bioethics in Mexico. The endeavors and challenges of CONBIOÉTICA
6	Hugh Whittall	Nuffield Council on Bioethics	UK/ EURO	(un)natural – ideas about naturalness in bioethics debates
7	Elizabeth Pike, Nicolle Strand	Presidential Commission for the Study of Bioethical Issues	USA/ PAHO	The legacy and body of work of the US Presidential Commission for the Study of Bioethical Issues

Presentation 1: Public announcement and application: an Ecuadorian model for the establishment of National Bioethics Commission
Lissette Duque; National Bioethics Commission (Ecuador)

Ecuador through the Ministry of Public Health (Ministerio de Salud Pública, MSP) established the National Bioethics Commission in Health (CNBS) in June 2013. Its members were selected by merit rating in an innovative process of public announcement and application.

MSP proceeded to the final selection of the 15 members of the commission (3 delegates MSP) of which 7 have a profile as a doctor, 2 lawyers, 3 professionals in social sciences, 1 nurse, 2 to theologians of different religious orientation. Some of them meet more than one profile. Bioethics orientation of its members is diverse: personalistic, casuistry, of virtue, based on the Latin American epistemology, or in human rights.

Since January 2014, the CNBS with the support of the MSP and Redbioética UNESCO, developed multiples activities: identifying major bioethical problems in Ecuador; statements on the use of genetic material from indigenous populations and reuse of biological samples. Also advice on the preparation of regulations for ethics committees, clinical trials, observational research, use of human genetic material, informed consent and conscientious objection was given. Additionally, meetings and workshops to promote bioethics education and training of ethics committees were held.

An evaluation suggests that the CNBS has answered the motivations that led to its creation, that it responds to the process of development and recognition of individual and social rights and to the need for its own bioethics recognizing the vulnerability of countries producing science, technology and bioethical philosophy.

Presentation 2: Proposal for national bioethics committees to serve as overarching national ethics bodies in countries
John Ayotunde Isola Bewaji; National Bioethics Committee (Jamaica)

There are various issues relating to ethics in all aspects of life, and effective monitoring of these is important for the development of an ethically viable society. Those nations with acuity of perception and resources would set up national, regional or other research ethics committees. Recognizing the limitations of such committees and the need to broaden the scope of ethical coverage, the international community, through WHO and UNESCO (and international sporting organizations such as FIFA, WAAA, IOC are committed to fairness in the competitions they superintend) shall mandate that all countries should have independent and neutral national

bioethics committees (with volunteer renowned membership) as the overarching bodies superintending the observance and maintenance of the diverse ethical issues and codes which globally assist in sustaining humane cultures and societies around the world. It is recommended that the bioethics committees in countries serve as the body responsible for ethical issues in all countries.

Presentation 3: Introduction of 2017 WRPO/Asia NEC meeting in South Korea
Sangeun Park, National Bioethics Committee (South Korea)

At the 10th Global Summit of National Ethics/Bioethics Committees in Mexico city, WPRO members suggested to hold a regional forum on bioethics to enhance the regional network. I've discussed with the Ministry of Health and Welfare regarding this matter and we are pleased to host the 2017 WHO regional forum. I would like to communicate and discuss idea to prepare the meeting.

Presentation 4: Speeding up ethical review in multi-centre research: the case for collaboration in the Eastern Africa region
Simon K. Langat; National Bioethics Committee (Kenya)

The presentation argues about how it would be possible to cut down on the time taken to get all approvals in different countries that have different systems of review.

Presentation 5: Strengthening the institutional infrastructure in bioethics in Mexico. The endeavors and challenges of CONBIOÉTICA
Manuel H. Ruiz de Chávez; Comisión Nacional de Bioética (Mexico)

The following are some of the most relevant achievements of the National Bioethics Commission of Mexico (CONBIOÉTICA) since the last edition of the Global Summit in Mexico, which are proof of the innovative strength projected by CONBIOÉTICA.

Regarding training and capacity building, last year CONBIOÉTICA carried out academic activities and developed educational materials aimed at providing health professionals with knowledge and skills in bioethics to improve their performance.

A course/workshop on palliative care for specialized medical residents was conducted in collaboration with the National Cancer Institute (INCAN), which featured the participation of renowned experts who addressed the issue from different angles, and was made available in classroom and virtual modalities.

The course was a space for reflection that focused on the experiences of medical residents of the palliative care service to link them with conceptual, methodological and attitudinal elements used in the bioethical approach, to enable them to tackle the dilemmas that often arise in their daily practice. The focus of was to provide basic knowledge in bioethics and build capacities through case studies and deliberation.

With support from the National Council of Science and Technology (CONACYT), CONBIOÉTICA held regional training sessions aimed at members of hospital bioethics committees (CHB) and research ethics committees (CEI) in various states as a launching pad for the Network for Capacity Building on Bioethics for members of CEI and CHB; during these sessions, training was provided for 1,361 members of these committees and the building blocks for the Network were also established.

This Network represents a valuable tool for training specialized human resources in bioethics, which will allow providing core knowledge and skills, with unified criteria, to committee members nationwide, as well as contribute to identify and address the information needs of committee members on a regional level.

The new edition of videoconferences on bioethics was issued, which features the works of renowned specialists in various fields of bioethics. These conferences were broadcasted via live streaming as a means of training for health personnel, which is certified by the Professional Career Service of the Secretariat of Health.

One of the main lines of action of CONBIOÉTICA consists in providing guidance in public policymaking in order to strengthen the legal framework on bioethics. In this regard, it is important to consider the activities – academic fora and strategic meetings – carried out in May 2015 in coordination with the Institute of Legal Research of the National Autonomous University of Mexico (UNAM), the National Academy of Medicine of Mexico and the Secretariat of Foreign Affairs, to review the impact that the accession of Mexico to the *Convention on Human Rights and Biomedicine* would have for our country, as well as to establish a dialogue between biomedicine and law, which involved the participation of Dr. Laurence Lwoff, secretary of the Committee on Bioethics (DH-BIO) of the Council of Europe, and Dr. Javier Arias, a member of the Spanish delegation of the same council.

An important event that took place recently was the publication in the *Official Journal of the Federation* of the secretarial agreement that reforms the terms for registration and operation of the CEI, in accordance with the criteria set by CONBIOÉTICA. These agreements along with the amendments to the General Health Law in December 2011 – the addition of Article 41 bis and the reform to Article 98 – represent the modernization of the regulatory framework of the commission.

The Americas and Mexico have had a constant presence in the world field of bioethics. In 2011, a regional meeting of the Americas was held, in which Mexico declared its commitment to promote a regional bioethical culture. In preparation of the 9th edition

of the Summit, CONBIOETICA arranged a meeting with various countries of the region – i.e. Argentina, Brazil, Canada, Colombia, El Salvador, Jamaica, Mexico, Panama, Peru and the United States – to discuss issues related to research ethics, organ and tissue donation and transplantation, as well as Universal Health Coverage. The main objective of this meeting was the establishment of a collaborative network of consultative bodies of the region of the Americas. The considerations of the region and outcomes of this meeting were formally presented during the 9th Summit in Tunisia.

The commission has actively collaborated with Dr. Susana Vidal, executive coordinator of the UNESCO Latin American and Caribbean Bioethics Network (REDBIOETICA), conducting activities to ingrain bioethics among health professionals and the society in general. Last year, Mexico had an important participation in the second regional seminar of national bioethics committees in Latin America and the Caribbean, held in El Salvador; during this meeting the San Salvador Commitment was signed, a document that establishes the commitment to promote the establishment of national bioethics committees in the region and strengthen those that have already been established.

In order to comply with the agreements and endorse Mexico's leadership in Latin America and the Caribbean, CONBIOÉTICA will establish links with REDBIOETICA, helping to enrich its educational program by providing publications and educational resources, as well as support in academic activities, teaching, research and outreach in the region. The commission will also strengthen its ties with the commissions of Latin America in order to address common issues related to bioethics, not only in the field of research, but also in other areas such as education and development.

Regarding the editorial program of the commission, new offerings were developed in 2015. The results of world events on bioethics in 2014 were published: *Inspire the Future to Move the World* and *Finding Paths through the World*, which collect the views and perspectives of renowned experts in the international field.

In conjunction with the CONACYT, a new publishing was developed, as part of the strategy of the commission to create tools that serve for continuous training for committee members, as well as strengthening biomedical research in our country: *Ética de la Investigación, Integridad Científica* (Research ethics, scientific integrity), which offers a didactic approach to research ethics that seeks to raise awareness and develop the skills of researchers, through the analysis of the ethical principles involved in the pursuit of science and the revision of some of the most illustrative cases of malpractice in the history of science.

Convention, the commission co-published with the publishing house Fontamara a comparative study on the accession of Mexico, entitled: *Convención sobre los derechos humanos y la biomedicina. Análisis propositivo para la adhesión de México* (Convention on Human Rights and Biomedicine. Proactive Analysis for the Accession of Mexico).

An updated edition of the ruling documents concerning the work of the commission was published, which incorporated the opinions and suggestions of renowned experts and professionals: the national guidelines for the integration and operation of the hospital bioethics committees and research ethics committees, as well as the state commissions of bioethics (CEB).

Also worth mentioning is the publication of three new issues of our Gazette CONBIOÉTICA, which address key issues for our country, such as the social determinants of health, experimentation with non-human animals and palliative care.

Presentation 6: (un)natural – ideas about naturalness in bioethics debates
Hugh Whittall; Nuffield Council on Bioethics (United Kingdom)

The concept of naturalness – and the terms 'natural' and 'unnatural' – is widely used in everyday conversation as well as in public debate to express values, beliefs, hopes and fears. It runs through many key bioethics debates – from genetically modified food, assisted reproduction, cloning and stem cell research to alternative medicine and death and dying. In 2015, the Nuffield Council on Bioethics published a short report exploring how ideas about naturalness feature in and affect public discussions about the ethics of science, technology and medicine. The work was informed by in depth reviews and analysis of how the terms have been used in the media, Parliamentary debates, and by interest organisations, and how they are used and perceived by the public. The project also involved creative exploration of language and ideas around naturalness, in collaboration with the poet Kayo Chingonyi and through a national poetry competition. This presentation will set out the findings of this project, and showcase the poetry produced by Kayo Chingonyi and the winners of the poetry competition to stimulate further discussion and reflection on the concept of naturalness and its use in our societies.

Presentation 7: The legacy and body of work of the US Presidential Commission for the Study of Bioethical Issues
Elizabeth Pike, Nicolle Strand; Presidential Commission for the Study of Bioethical Issues (United States)

Two staff members of the US Presidential Commission for the Study of Bioethical Issues will present on the legacy and the body of work of the commission as it enters its final year. Additionally, they will discuss the commission's current project that focuses on the virtuous circle of democratic deliberation and bioethics education.

>> ANNEX

Travel Grants

Steering Committee

Speakers, Authors and Discussants

Participants

Group picture of the participants of the Global Summit 2016

Travel Grants

The generous funding of the German Ministry of Education and Research enabled the local organizers of the 11th Global Summit to offer financial assistance to a limited number of representatives of national ethics/bioethics committees in order to attend the event in Berlin.

Certain criteria which were established in close cooperation with the steering chad to be fulfilled if an application for the travel grant was to be considered. The according documents and information were forwarded together with the official invitation to all national ethics/bioethics committees as well as to competent ministries of all countries and published on the website of the 11th Global Summit.

In order to make a broader participation possible, only one representative per country was eligible for funding towards the costs of travel and accommodation. The Global Summit steering committee reviewed all applications and made recommendations to the German organizing committee based on the following criteria:

1. National of a low- or middle-income country according to World Bank classification (mandatory).
2. Chair or member of a current national ethics/bioethics committee, commission or advisory body.
3. One-page written expression of interest which included a statement of why the grant was needed, their own role in the area of bioethics, what attending the Summit will hopefully do to enhance the national ethics/bioethics committee's work, and which use will be made of the experience in the future.
4. If previous funding was provided, how did that funding contribute towards the work and/or functioning of the committee? Concrete examples should be provided.
5. Attempts to find co-funding.
6. Contribution to the Summit marketplace by a poster or other form of presentation.

7. Consideration of distribution between regions.

In total, the steering committee reviewed 24 applications for financial assistance. Ultimately, 18 countries received a travel grant, including two representatives who, unfortunately, were not able to attend the Global Summit due to bad weather conditions on departure day or due to other urgent and unpredictable short-term liabilities.

The following table provides an overview of the representatives that received financial assistance for attending the Global Summit in Berlin.

Travel Grant Recipients Global Summit 2016		
Country	**Region**	**Representative**
Congo, D.R.	AFRO	Evariste Likinda
Cuba	PAHO	Daniel Piedra Herrera
Ecuador	PAHO	Lissette Duque
Gambia	AFRO	Malamin Sonko
Jamaica	PAHO	John Ayotunde Isola Bewaji
Jordan	EMRO	Mohammad Ahmed Hamdan
Kazakhstan	EURO	Bakhyt Sarymsakova
Kenya	AFRO	Simon Kipngeno Langat
Lebanon	EMRO	Michel Daher
Libya	EMRO	Ali Bourawi
Malawi	AFRO	Joseph Mfutso-Bengo
Malaysia	WPRO	Azizan Baharuddin
Mongolia	WPRO	Damdindorj Lkhagvasuren
Nepal	SEARO	Khem Karki
Sudan	AFRO	Mohamed Ahmed A. El-Sheikh
Tajikistan	EURO	Abdulmanon Saidov
Tanzania	AFRO	Joyce Kemilembe Ikingura
Uzbekistan	EURO	Nozimkhon Makhmudov

Steering Committee

The organization of the Global Summit 2016 was supported by a steering committee composed of representatives of national ethics councils and international experts from WHO and UNESCO. The following short profiles provide a brief summary of the chair and the members of the steering committee of the 11th Global Summit.

Christiane Woopen
Chair of the steering committee and steering committee member for the WHO European region, studied human medicine at the University of Cologne and philosophy at the University of Bonn and Hagen. In 1993 she obtained her PhD in medicine at the University Bonn, Germany.

Mohamed Salah Ben Ammar
Steering committee member for the WHO Eastern Mediterranean region, studied medicine at the Medical Faculty Paris VI, specialized in anesthesia and reanimation at the Medical Faculty of Tunis and holds an Executive Master of Business Administration from the Mediterranean School of Business in Tunis. In 1985 he obtained his PhD in medicine at the Medical Faculty Paris VI.

John Ayotunde Isola Bewaji
Steering committee member for the WHO region of the Americas, studied philosophy at the University of Ife and at the University of Ibadan as well as distance education at the Mico University College. In 1991 he obtained his PhD in philosophy at the University Ibadan, Nigeria.

Dafna Feinholz Klip
Steering committee member from UNESCO, studied psychology at Universidad Iberoamericana Mexico and bioethics at Universidad Complutense Madrid. In 1999 she obtained her PhD in research psychology at Universidad Iberoamericana.

Anoja Fernando
Steering committee member for the WHO South-East Asia region, studied medicine at the University of Ceylon and humanities at the Open University (UK). In 1979 she obtained her membership of the Royal College of Physicians (UK), and in 1994 she was elected a fellow of the Royal College of Physicians, London (UK).

Aamir Mustafa Jafarey
Advisor to the steering committee, trained and qualified in general surgery in Pakistan and Edinburgh, ethics at the Harvard School of Public Health and bioethics at the Sindh Institute of Medical Sciences in Karachi. In 1988 he obtained his MBBS in medicine at the Karachi University of Pakistan.

Simon K. Langat
Steering committee member for the WHO African region, studied veterinary medicine at the Kharkov Institute Ukraine, international research ethics at the University of Cape Town and philosophy and ethics at the Strathmore University, Nairobi. In 2004 he obtained his PGD in international research ethics at University of Cape Town.

Bagher Larijani
Steering committee member for the WHO Eastern Mediterranean region, studied medicine at the Tehran University of Medical Sciences, where he specialized in internal medicine and subsequently passed his fellowship in endocrinology and metabolism. He has obtained F.A.C.E. distinction at the American College of Endocrinology and attended several medical training courses in Denmark, France, Italy and the United Kingdom since his graduation.

Laura Palazzani
Steering committee member for the WHO European region, studied philosophy at the Catholic University of Milan and biomedical ethics at the Georgetown University, Washington, D.C. She obtained her PhD in bioethics at the Catholic University of Rome.

Sangeun Park
Steering committee member for the WHO Western Pacific region, studied medicine at the Korea University Medical College and at the Kosin University Medical College. He completed his postdoctoral researches at the Saint Louis University and at the University of Missouri. In 1992 he obtained his PhD in medicine at the Kosin University Medical College, Korea.

Manuel H. Ruiz de Chávez
Steering committee member for the WHO region of the Americas, studied medicine at the National Autonomous University of Mexico (UNAM) and social medicine at the London School of Hygiene and Tropical Medicine, and holds board certifications in family medicine and public health. Prof. Dr. Ruiz de Chávez presided the organizing committee of the 10th Global Summit of National Ethics/Bioethics Committees held in Mexico in 2014.

Aissatou Touré
Steering committee member for the WHO African region, studied pharmacy at the University of Dakar and immunology at the University of Lille followed by diplomas in immunology, clinical trials and infectious diseases from Institut Pasteur Paris.

Hugh Whittall
Advisor to the steering committee, studied philosophy and politics at the University of Warwick.

Nikolajs Zeps
Steering committee member for the WHO Western Pacific region, studied medicine and biology at the King's College, the University of London, graduating BSc (Hons 1st class) in 1992. In 2000 he obtained his PhD in surgery and pathology at the University of Western Australia.

Speakers, Authors and Discussants

Anita L. Allen
Anita Allen, PhD, serves as a member of the US Presidential Commission for the Study of Bioethical Issues. Allen is the vice-provost for Faculty at the University of Pennsylvania and Henry R. Silverman professor of law and professor of philosophy. A distinguished scholar of privacy law and practical ethics, Allen is recognized for her work on confidentiality in medicine, genetics and research, racial justice, and women's health. She has lectured widely and published numerous articles, several books and a textbook about contemporary privacy and data protection practices.

Jean Claude Ameisen
Jean Claude Ameisen, MD, PhD, is president of the French National Consultative Ethics Committee (CCNE), professor of immunology and director of the Centre d'Etudes du Vivant at Université Paris Diderot. His main scientific contributions concern the role of programmed cell death in disease. He is the author of books and a national radio program on the relations between science, culture and society.

Chin Jing Jih
- Member, Singapore Bioethics Advisory Committee
- Member, Singapore Medical Council
- Chairperson, Research Ethics Committee, National Healthcare Group
- Adjunct associate professor, Centre for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore
- Associate professor and lead for ethics and professionalism, Lee Kong Chian School of Medicine
- Chairperson, Clinical Ethics Committee, Tan Tock Seng Hospital

Michel Daher
Michel Daher, MD, FACS, is a professor of surgery and professor of medical ethics and bioethics at the University of Balamand. He is the secretary general of the Lebanese National Consultative Committee on Ethics. He has more than 95 scientific publications mainly published in indexed journals. He presented more than 90 international lectures as invited speaker in international congresses. He is mainly interested in cancer control, palliative care, and medical ethics education.

Dafna Feinholz Klip
Dafna Feinholz has a PhD in research psychology (Ibero-American University, Mexico) and a Master in bioethics (Complutense University of Madrid, Spain). She was the head of the Department of Reproductive Epidemiology at the Mexican National Institute of Perinatology; as well as the research and planning director of the Women and Health Program, at the Ministry of Health (Mexico). She successively occupied the posts of academic coordinator of the National Commission of Human Genome at the Ministry of Health; and the executive director of the National Bioethics Commission of Mexico (CONBIOÉTICA), achieving a more independent legal status for the national bioethics committees, drafting the first national guidelines for research ethics committees and clinical bioethics committees, training their members, and promoting the law at the parliament that is currently in vigour, to legally establish and differentiate both types of committees. She is the founder of the Latin American Forum of Ethics Committees in Health Research (FLACEIS) and was the chairperson from 2000 to 2006. Invited member of the international expert group, TDR-WHO: drafting and translating *Operational Guidelines for Ethics Committees*. She was Mexico's representative at the meetings of the Intergovernmental Bioethics Committee to discuss the UNESCO *Universal Declaration on Bioethics and Human Rights*. Since September 2009, Feinholz is the chief of the bioethics section, within UNESCO Social and Human Sciences sector. In this capacity, she leads different activities aiming at reinforcing capacities of member states to manage bioethical challenges and to identify the ethical, legal and social implications of cutting-edge science, emerging technologies and their application for sustainable development.

Ehsan Shamsi Gooshki
Ehsan Shamsi Gooshki, Born in 1979 and graduated as a physician in 2005. After some years of administrative and NGO activities at a national level, he was enrolled in the first PhD program of medical ethics in Iran since 2009, when he elaborated his international experience in the Department of Ethics, Trade and Equity of WHO, the Institute of Biomedical Ethics at University of Zurich and the Kennedy Institute of Ethics at Georgetown University. After being graduated as the first Iranian who

completed his PhD program in medical ethics inside the country in 2013, Gooshki started his position as assistant professor of medical ethics at the Medical Ethics and History of Medicine Research Center of the Tehran University of Medical Sciences", where he is involved in several research projects and teaching activities. Since 2014, he is the director of National Committee for Ethics in Biomedical Research at the Ministry of Health and Medical Education and director of the Medical Ethics Department at the Iran Medical Council. Membership in a Supreme Council of Medical Ethics, Medical Ethics Group of Iran Academy of Medical Sciences and some research ethics committees is part of his other related activities.

Ritva Halila
General secretary, National Advisory Board on Social Welfare and Health Care Ethics, MD, PhD, docent in medical ethics, specialist in paediatrics. Publications in medical research ethics, especially in the field of research on children and the work of research ethics committees.

Joyce K. Ikingura
Joyce Ikingura works with the National Institute for Medical Research, an institution hosting the National Ethics Review Committee (NatHREC) in Tanzania. She is a member and assistant secretary of the committee. Ikingura was involved in establishing the national ethics committee in 2002. A South African Research Ethics Training Initiative (SARETI) scholar from 2003 to 2005 at the University Of Pretoria. She is also member of 3 other institutional ethics committees that she assisted to be established and developed. She works with other collaborators to facilitate health research ethics workshops to research ethics committees across Africa. Ikingura has accomplished to write a chapter in an e-book of health research ethics in Africa, and country health research ethics modules. Writing standard operating procedures for the national as well as the institutional using the national model.

Aamir Mustafa Jafarey
Aamir Jafarey is a general surgeon and a bioethicist. He is currently associate professor at the Centre of Biomedical Ethics and Culture, Sindh Institute of Urology and Transplantation (SIUT), Karachi, Pakistan. Jafarey is a member of National Bioethics Committee and the Research Ethics Committee at the federal level. He has extensive experience in bioethics education, from teaching school children to students enrolled in Masters of Bioethics programs. He has also conducted several research projects in bioethics.

Isidoros Karatzas
Isidoros Karatzas is a biochemist by training. He has been a Marie-Curie Science fellow. After joining the European Commission, he was responsible for the evaluation of the framework programmes where he participated in setting up the European RTD Evaluation Network. Consequently he managed the risk governance research file and was the scientific secretary of the European Research Advisory Board, a high level advisory body to the European Commission dealing with research policy and priorities. Currently, he is the head of the Ethics and Research Integrity Sector in Directorate-General for Research and Innovation. As head of the sector he established advanced training courses on research ethics and research integrity for commission staff and the ethics research community and has set up the first European system on ethics follow-up and audit.

Jorge E. Linares
- Associate professor at School of Philosophy and Literature and director of the University Program on Bioethics at National Autonomous University of Mexico
- Researcher level II of the National System of Researchers (National Council for Science and Technology of Mexico)
- Member of the Mexican Academy of Sciences
- Member of the International Association of Bioethics

Laurence Lwoff
Laurence Lwoff joined the Council of Europe in 1991. She was the secretary of the *International Conference of the Council of Europe on Ethical Issues Arising from the Application of Biotechnology* in Oviedo (Spain) in 1999. In 2002, she joined the bioethics department where she has been responsible in particular for the activities on human genetics and on the protection of the human embryo and the foetus. She was the secretary of the group in charge of the elaboration of the additional protocol to the *Convention on Human Rights and Biomedicine*, concerning genetic testing for health purposes. She is currently the head of the bioethics unit at the Human Rights Directorate and secretary of the Committee on Bioethics (DH-BIO), intergovernmental committee in charge of the activities on the protection of human rights in the biomedical field, at the Council of Europe.

Joseph Mfutso-Bengo
Chair of the National Advisory Committee on Bioethics in Malawi, head of the Department of Health Systems and Policy and director of the Centre for Bioethics in Eastern and Southern Africa (CEBESA) at the University of Malawi.

Meral Özgüç
Meral Özgüç is director of the Center for Genomics and Biobanking at Hacettepe University Ankara Turkey. Her work is in the area of rare diseases; genetic testing, biobanking and policy issues. She is the chair of the Bioethics Committee of Turkish National Commission for UNESCO. Life sciences related technologies and bioethical concerns, gaps between academia and public policy, developing bioethics curricula and awareness raising are among the main agenda of the Committee.

Laura Palazzani
- Professor of philosophy of law, Faculty of Law, LUMSA University, Rome, Italy
- Vice-chair, Italian Committee for Bioethics
- Member, European Group on Ethics in Science and New Technologies (EGE), European Commission (2010–2015)
- Italian representative, Committee on Bioethics (DH-BIO), Council of Europe
- Member, Ethics Committee of the Bambino Gesù Children's Hospital of Rome

Sangeun Park
- Chairperson, National Bioethics Committee, Korea
- Chairman, Korea National Institute for Bioethics Policy
- President, Sam Hospitals Group
- Former vice-president, Korean Society of Bioethics
- Former researcher, Center for Health Care Ethics, St. Louis University, United States

Andreas Reis
Andreas Reis (MD, MSc) is a technical officer in the Global Health Ethics Unit of the Department of Innovation, Evidence and Research at WHO in Geneva, Switzerland. After medical studies and practice in internal medicine in Germany, France and Chile he pursued studies in health economics and ethics. His main area of work is public health ethics, with a focus on ethical aspects of infectious diseases such as HIV, pandemic influenza, and tuberculosis. He has published widely, lectured and organized trainings for WHO in more than 40 countries, and is serving on the editorial boards of *Public Health Ethics* and *Monash Bioethics Review*.

Abha Saxena
An anaesthesiologist and a specialist in pain and palliative care by training, Abha Saxena relocated from New-Delhi, India, in 2001 to join the WHO where, in 2002, she re-established the Research Ethics Review Committee (ERC), led the development of norms and standards for research ethics committees, and developed research

ethics training tools. Saxena currently leads the work of the Global Health Ethics team. Under her leadership, the Organization is developing global ethics guidance for epidemics, public health surveillance, data sharing, implementation research and tuberculosis. Networking with other international organizations and national counterparts is an equally important part of her work. As the WHO lead for the Global Summit she manages the secretariat of the Global Summit and provides support to the steering committee.

Barry Smith
Barry Smith is chair of the Health Research Council of New Zealand Ethics Committee and a member of the Advisory Committee on Assisted Reproductive Technology amongst other entities. He has just completed a funded study of ethics review processes in New Zealand culminating in a book with Martin Tolich entitled *The Politicisation of Ethics Review in New Zealand* (2015). Smith is also a member of a research team that is finalising a report and a set of guidelines for the Health Research Council of New Zealand about the views of indigenous populations on tissue banking and genomic research.

Aissatou Touré
Aissatou Touré is a researcher at the Pasteur Institute in Dakar where she heads the Unit of Immunology. In parallel to her scientific activities as researcher in malaria, Touré has different activities in the field of ethics as member of the Senegalese National Ethics Committee for Health Research since 2003, member of the Working Group on the revision of CIOMS guidelines since 2012 and a member of the UNESCO International Bioethics Committee from 2006 to 2013 and as such participated to reports on various bioethics topics.

Johannes J.M. van Delden
Johannes van Delden (1960) is full professor of medical ethics at the Julius Center for Health Sciences of the medical school of Utrecht University. Ever since working as a house officer at an intensive care ward he is highly interested in medical ethics. He wrote a thesis on the medical and ethical aspects of do not resuscitate orders. Also, he was one of the principal researchers of the study of medical decisions concerning the end of life for the Remmelink committee. After his education as a nursing home physician he has worked in several nursing homes for 15 years (until May 2011). His special fields of interest are: research ethics, moral problems at the end of life and moral problems in the care for the elderly. He is currently president of the Council for International Organizations of Medical Sciences and chairman of the International Bioethics Committee of UNESCO.

Rinie van Est
Rinie van Est works at the Rathenau Instituut, where he is primarily concerned with emerging technologies such as nanotechnology, cognitive sciences, persuasive technology, robotics, and synthetic biology. He also lectures at the School of Innovation Sciences of the Eindhoven University of Technology. Some relevant publications: *Just Ordinary Robots. Automation from Love to War* (2016), *Working on the Robot Society* (2015), *Intimate Technology. The Battle for Our Body and Behaviour* (2014), *From Bio to NBIC Convergence – From Medical Practice to Daily Life* (2014).

Hugh Whittall
Hugh Whittall is director of the Nuffield Council on Bioethics, which reports on ethical questions raised by new developments in biological and medical research. The Council has recently published reports on biodata, children and clinical research, and naturalness. Hugh previously held positions at the Department of Health, working on human tissue and transplantation policy; the European Commission, funding bioethics research; and at the Human Fertilisation and Embryology Authority.

Nikolajs Zeps
Nikolajs Zeps is director of research for St John of God Health Care, the largest not-for-profit hospital network in Australia. He was a member of the Australian Health Ethics Committee from 2006 to 2012 and has been the Australian representative on the steering committee of the Global Summit since 2011. He is a member of the Ethics and Policy Committee of the International Cancer Genome Consortium. He has expertise in the ethical regulation and practice of clinical trials, biobanks and genomics.

Participants

Nearly 200 participants from 79 countries as well as from international organizations and other institutions attended the Global Summit 2016 in Berlin.

The following five tables indicate different groups of participants of the Global Summit. Table 1 is arranged in alphabetical order of the participating countries. The numbers of the first table neither include participants from international organizations and foreign institutions nor participants from Germany and the local organizing committee. Table 2 shows participation in relation to the WHO regions without indicating the number of participants from Germany. Table 3 includes all participants from international organizations and foreign institutions. Table 4 and 5 are related to members and staff of the German Ethics Council. Contacts to individual participants may be established via the office of the German Ethics Council.

Table 1: Participants by Country

Country	WHO region	Name
Andorra	EURO	Antoni Badia Trilla
Australia	WPRO	Nikolajs Zeps
Austria	EURO	Matthias Beck
Austria	EURO	Christiane Druml
Austria	EURO	Doris Wolfslehner
Bangladesh	SEARO	Biman Kumar Saha
Belgium	EURO	Paul Cosyns
Burkina Faso	AFRO	Seni Kouanda
Canada	PAHO	Mireille Lacroix

Canada	PAHO	Lina Al-Karkhi
Chile	PAHO	Ximena Luengo
China	WPRO	Yang Huanming
China	WPRO	Shen Yubiao
Congo, D.R.	AFRO	Evariste Likinda
Congo, D.R.	AFRO	Yvonne Pweto Mushama
Costa Rica	PAHO	Esteban Cerdas Quirós
Costa Rica	PAHO	Erna Meléndez
Cuba	PAHO	Daniel Piedra Herrera
Cyprus	EURO	Constantinos N. Phellas
Czech Republic	EURO	Petr Dvořák
Djibouti	EMRO	Abdoulkader Guelleh Miguil
Ecuador	PAHO	Lissette Duque
El Salvador	PAHO	Edgar Lobos Lazzeri
Estonia	EURO	Hele Everaus
Ethiopia	AFRO	Ato Workneh Aklilu Jembere
Fiji	WPRO	Vimlesh Chand
Fiji	WPRO	Devina Nand
Fiji	WPRO	Elina Veitamana
Finland	EURO	Ritva Halila
Finland	EURO	Tapani Keränen
Finland	EURO	Katja Kuuppelomäki
France	EURO	Jean Claude Ameisen
France	EURO	Patrick Gaudray
France	EURO	Marie-Hélène Mouneyrat
Gambia	AFRO	Malamin Sonko
Germany	EURO	(see Tables 3 to 5)
Greece	EURO	Ioannis Karakostas
Guinea	AFRO	Oumou Younoussa Bah-Sow
Guinea	AFRO	Alpha Ahmadou Diallo
Guinea	AFRO	Ousmane Souaré
Hungary	EURO	Jozsef Mandl
Iceland	EURO	Eiríkur Baldursson
Iceland	EURO	Kristin Benediktsdóttir
India	SEARO	Roli Mathur

Indonesia	SEARO	Siswanto
Iran	EMRO	Ehsan Shamsi Gooshki
Italy	EURO	Laura Palazzani
Ivory Coast	AFRO	Louis Penali
Jamaica	PAHO	John Ayotunde Isola Bewaji
Japan	WPRO	Hidenori Akutsu
Jordan	EMRO	Mohammad Ahmed Hamdan
Kazakhstan	EURO	Maksut Kulzhanov
Kazakhstan	EURO	Bakhyt Sarymsakova
Kenya	AFRO	Simon K. Langat
Korea (Rep.)	WPRO	Myunghee Kim
Korea (Rep.)	WPRO	Yeongho Lee
Korea (Rep.)	WPRO	Sangeun Park
Kuwait	EMRO	Manal Bouhaimed
Lebanon	EMRO	Michel Daher
Libya	EMRO	Ali Bourawi
Madagascar	AFRO	Juvet Razanameharizaka
Malawi	AFRO	Joseph Mfutso-Bengo
Malaysia	WPRO	Azizan Baharuddin
Mexico	PAHO	Manuel H. Ruiz de Chávez
Mexico	PAHO	Olaiz Gustavo
Mongolia	WPRO	Damdindorj Lkhagvasuren
Mozambique	AFRO	Rassul Nalá
Mozambique	AFRO	Esperanca Sevene
Myanmar	SEARO	Kyaw Zin Thant
Myanmar	SEARO	Kyaw Khaing
Namibia	AFRO	Ester Shaama
Namibia	AFRO	Immolatrix Linda Oneugbu
Netherlands	EURO	Alies Struijs
Netherlands	EURO	Dick Willems
New Zealand	WPRO	Barry Smith
Norway	EURO	Jacob C. Hølen
Oman	EMRO	Ahmed Binsumeit Badawy
Oman	EMRO	Ahmed Al-Shukaily
Pakistan	EMRO	Aamir M. Jafarey

Palestine	EMRO	Salwa Massad
Poland	EURO	A. Gorski
Poland	EURO	R. Krajewski
Portugal	EURO	Lucília Nunes
Portugal	EURO	Cintia Pereira
Qatar	EMRO	Elham Abdullatif M. Sharif
Romania	EURO	Constantin Mircioiu
Russia	EURO	Anastasia Koylyu
Rwanda	AFRO	Lisine Tuyisenge
Rwanda	AFRO	Jean-Baptiste Mazarati
Saudi Arabia	EMRO	Abdulaziz Alswailem
Saudi Arabia	EMRO	Emad Ali Aljadhaly
Senegal	AFRO	Samba Cor Sarr
Senegal	AFRO	Aissatou Touré
Singapore	WPRO	Charmaine Chan
Singapore	WPRO	Chin Jing Jih
Slovakia	EURO	Jozef Glasa
Slovakia	EURO	Marta Kollarova
Slovenia	EURO	Božidar Voljč
Spain	EURO	Federico de Montalvo
Spain	EURO	Victoria Ureña
Sri Lanka	SEARO	A.K. Sunil de Alwis
Sri Lanka	SEARO	Vindya Kumarapeli
Sweden	EURO	Kjell Asplund
Sweden	EURO	Lotta Eriksson
Switzerland	EURO	Andrea Büchler
Switzerland	EURO	Klaus Peter Rippe
Tajikistan	EURO	Abdulmanon Saidov
Tanzania	AFRO	Joyce K. Ikingura
Thailand	SEARO	Punkae Mahaisavariya
Thailand	SEARO	Yongyuth Yuthavong
Tunisia	EMRO	Hend Bouacha
Tunisia	EMRO	Mohamed Salah Ben Ammar
Turkey	EURO	Hilal İlbars
Turkey	EURO	Meral Özgüç

United Kingdom	EURO	Jonathan Montgomery
United Kingdom	EURO	Hugh Whittall
USA	PAHO	Anita L. Allen
USA	PAHO	Elisabeth Pike
USA	PAHO	Nicolle Strand
Uzbekistan	EURO	Nozimkhon Makhmudov
Uzbekistan	EURO	Madina Alikhodjaeva

Table 2: Participating countries and persons by WHO region

Region	Countries	No. of Participants
AFRO	14	21
EMRO	12	16
EURO	29	46*
PAHO	9	14
SEARO	6	9
WPRO	9	15
Total	**79**	**120**

* excluding participants from international organizations, German Ministries, the German Ethics Council and the local Organizing Committee (for further references, see Tables 3 to 5)

Table 3: Participants from international and German institutions

Institution	Name
Council for International Organizations of Medical Sciences	Johannes J.M. van Delden
Council of Europe	Laurence Lwoff
Council of Europe	Mark Bale
European Commission	Isidoros Karatzas
European Commission	Jim Dratwa
Federal Ministry of Education and Research	Marina Schindel
Federal Ministry of Education and Research	Philipp Hanske
Federal Ministry of Education and Research	Dietmar Walter
Federal Ministry of Education and Research	Stephan Roesler
Federal Ministry of Health	Birgit Schnieders
Federal Ministry of Health	Ingo Härtel

Federal Ministry of Health	Frank Niggemeier
Federal Ministry of Health	Raphaela Wagner
German Bundestag, Research Service	Christine Steinhoff
Office of the Parliamentary State Secretary Thomas Rachel	Kathrin Rau
Rathenau Instituut	Rinie van Est
UNESCO	Dafna Feinholz Klip
UNESCO	Irakli Khodeli
UNESCO	Seiko Sugita
UNESCO	Abdul Lamin
Universidad Nacional Autónoma de México	Jorge E. Linares Salgado
WHO - Regional Office AFRO	Martin Matthew Okechukwu Ota
WHO - Regional Office EURO	Tim Nguyen
WHO - Headquarter	Abha Saxena
WHO - Headquarter	Reva Gutnick
WHO - Headquarter	Andreas Reis

Table 4: Participating members of the German Ethics Council

Institution	**Name**
German Ethics Council	Katrin Amunts
German Ethics Council	Constanze Angerer
German Ethics Council	Wolf-Michael Catenhusen
German Ethics Council	Peter Dabrock
German Ethics Council	Frank Emmrich
German Ethics Council	Christiane Fischer
German Ethics Council	Carl Friedrich Gethmann
German Ethics Council	Thomas Heinemann
German Ethics Council	Martin Hein
German Ethics Council	Ilhan Ilkiliç
German Ethics Council	Leo Latasch
German Ethics Council	Anton Losinger
German Ethics Council	Reinhard Merkel
German Ethics Council	Eckhard Nagel
German Ethics Council	Edzard Schmidt-Jortzig

German Ethics Council	Eberhard Schockenhoff
German Ethics Council	Elisabeth Steinhagen-Thiessen
German Ethics Council	Jochen Taupitz
German Ethics Council	Claudia Wiesemann
German Ethics Council	Christiane Woopen
German Ethics Council	Michael Wunder

Table 5: Staff of the German Ethics Council's office and volunteers

Institution	**Name**
German Ethics Council - Office	Katrin Bentele
German Ethics Council - Office	Carola Böhm
German Ethics Council - Office	Ulrike Florian
German Ethics Council - Office	Steffen Hering
German Ethics Council - Office	Christian Hinke
German Ethics Council - Office	Petra Hohmann
German Ethics Council - Office	Christian M. Jolibois
German Ethics Council - Office	Torsten Kulick
German Ethics Council - Office	Nora Schultz
German Ethics Council - Office	Joachim Vetter
German Ethics Council - Volunteer	Antonia Fitzek
German Ethics Council - Volunteer	Lukas Griessl
German Ethics Council - Volunteer	Anna Maria Połeć
German Ethics Council - Volunteer	Wera Pustlauk
German Ethics Council - Volunteer	Hannah Schickl