

*Presidenza del Consiglio dei Ministri*



**ITALIAN COMMITTEE FOR BIOETHICS**

***International Meeting***

**EMERGING TECHNOLOGIES AND BIG DATA**

28 October 2016

## Introduction

### LORENZO d'AVACK - Deputy Chair of the ICB



In the name of the Italian Committee for Bioethics and on my own behalf, I would like to welcome everyone, and express my heartfelt thanks to all our illustrious rapporteurs: Prof. Jean Claude Ameisen, Chair of France's Advisory Ethics Committee for Life and Health Sciences; Prof. Peter Dabrock, Chair of the German Ethics Council; Prof. Jonathan Montgomery, Chair of the Nuffield Council on Bioethics, and to the authorities, represented by Dr. Paolo Bonaretti for the Prime Minister's Office, and Prof. Andrea Lenzi, Chair of the National Committee for Biosecurity, Biotechnologies, and Life Science.

We are honoured by their presence at this Conference, held by the Italian Committee for Bioethics, thanks to the initiative of our Deputy Chair, Prof. Laura Palazzani.

The Italian Committee for Bioethics, especially in this past decade, has always given special emphasis to the need to deal with the new bioethical problems, arising from the continuous evolution of science, in the awareness that these issues have no national boundaries, but require transnational debate. It is on these premises that the Committee has established relations with leading institutions, UNESCO, the Council of Europe and the European Commission, as well as with the most important international Committees. I recall the meetings in 2012, on *Sustainability and perfection in the relationship between science, technology, and society* and *The role and function of the Committees for Bioethics* and, in 2014, the meeting, organized with the European Commission, of all the European Ethics Councils (*Nec Forum*).

Today's meeting proposes the discussion of an issue of great interest: emerging technologies, and among these in particular the new technologies of information and communications, and the most recent technique of gene editing. These issues were and are currently the focus of attention by the Italian Committee for Bioethics. The objective now is to point out the strengths and criticality related to the latest developments in techno-sciences, in this "new technological wave", through the insights provided by our distinguished rapporteurs and the ensuing debate. These developments are characterized by their velocity, continuous dynamic evolution, technological complexity, breadth of possible applications, the uncertainty and unpredictability of future scenarios, the invasiveness of techniques on the body and mind, and the pervasiveness of technology in society. We are dealing with so-called "*intimate technologies*", that is, technologies "close" to us, "among" us, "like" us "about" us and "in" us. During this Conference, our illustrious guests will be examining the ongoing "bioethical challenge" to founding values in the intertwining of prospective plans, both on a social and juridical level.

The era of Big Data compels us to outline new scenarios. Not an easy task, given that the requests made to the digital user are by nature absolutely heterogeneous: information regarding social/civil registry data, religion, political-ideological affiliation, attitudes, aptitudes, and personal preferences. There is a consequent difference between the potential uses of the data and connected risks: use for commercial purposes (advertising and marketing purposes) differs from scientific use (care services/record, information for the purpose of clinical and epidemiological research). Of course, these distinctions are not easily drawn, and in most cases the boundary between market research and scientific research becomes blurred and indistinguishable; this makes *privacy* protection complex, to the detriment of the digital user.

Numerous ethical reflections arise from gene *editing* and the CRISPR CAS9 technique, which once again revive the debate on genetic engineering and the problems raised by the possibility of modifying the DNA of living organisms, both human and non-human. The debate dates back to the 1970s, when a group of scientists called for a moratorium on research on recombinant DNA. The alarm prompted scientists to develop a self-regulatory code to address the safety problems underlying the request for the moratorium (Asilomar, 1975). It is within this context and in the face of new highly innovative techniques, capable of modifying the DNA sequences of living organisms with a high degree of precision, relative ease, and low costs, that the ongoing discussion, in various scientific journals (*Science*, *Nature*, *Cell*) and the less-technical (*The Economist* and *National Geographic*) and regional and international scientific organizations, is to be placed.



## BEATRICE LORENZIN, Minister of Health



Personalized medicine, Prevention, Clinical Research and Experimentation: these are just some of the aspects of care which are being thoroughly and radically transformed, at an increasingly rapid pace, thanks precisely to the emergence and convergence of new technologies and the enormous amount of data that can be gathered.

The Italian Committee for Bioethics has already dealt with some particular aspects of this change, inherent to the health sector: I am thinking, for example, of the so-called sector of *`Mobile Health`*, and the *`Managing of "incidental findings" in genomic investigations with new technology platforms`*.

There are a great number of areas to be explored. Emerging technologies and Big Data mean new paths of therapy and prevention that forge a new relationship between citizens and the National Health Service, and this means physicians and healthcare workers, as well as administrators and system operators.

In this landscape of new technologies we all must ask ourselves what is meant by freedom of care, informed consent, the doctor/patient relationship, and privacy. Above all, however, emerging technologies and Big Data require a major effort for transformations that are already on the horizon. Current endeavours should live up to the task of handling the transformations that are already taking place, in addition to taking great care to protect citizens from market dynamics: one needs merely to consider the problem of accessing the new opportunities and approaches to care that are being made available.

Therefore, we as politicians must ask ourselves what stance, the various modes of *governance* used until now – and I am referring, for example, to the possibility of legislating on various levels, to the codes of ethics in healthcare professions, to the work of institutional committees such as this one, and that of national and international regulatory agencies and institutions – should be taken in the face of this new technological scenario. We must ask ourselves whether and how these “instruments” have to change to keep pace with the evolution of technologies, in order to be able to judge, monitor and manage their impact on society with awareness, while not giving in to commercial and market logic. Moreover, we must be aware that the velocity of the transformations leads us to modes of governing that are increasingly flexible and above all dynamic, while at all times respecting and protecting the dignity of every single human being.

I am certain that this day will provide important contributions to the reflections of all – scholars like yourselves, but also politicians, administrators, and ordinary citizens – regarding these issues, enriching the cultural heritage which the Italian Committee for Bioethics has built and offered to the country in its 26 years of history.

**PAOLO BONARETTI, Legal-economic counsellor to the under-secretary of the Presidency of the Council of Ministers**



The Italian Government pays very close attention to the developments of what is effectively a “new technological paradigm”. We are in a situation in which the convergence of three important cross-cutting technologies – digital technology, the genome, and materials technologies – are truly leading to a paradigm shift which can not be addressed using old and exclusively defensive tools. At this time, we need to understand what is taking place from the technological standpoint, and to address problems for the long-term.

We are aware that digital technologies, and Big Data in particular, are changing the very concept of privacy we were accustomed to; we are aware that they are limiting the concept of privacy; we are aware that we should find a way to make all citizens, of all classes, aware of the changes that are taking place. We are at the dawn of these technologies.

There is also the problem of having an overall vision of these new technologies. We are dealing today with gene therapies to treat full-blown diseases. If, in future we will be using *gene editing* for prevention or on cells that can transmit mutations, what will we be faced with? Therefore, the problem is no longer for individual persons. It is a problem that concerns society as a whole and has profound implications.

Let us keep in mind that we Europeans, each in our own country, have found the way to guarantee the right to health for our own citizens, in ways that vary greatly among countries. This paradigm shift, and in particular precision medicine, poses a problem that is necessarily the guarantee of the right to health for all European citizens. We cannot only guarantee free circulation of persons or finance within our Union. We, as Government, believe that the right to health must also be a right aligned with new paradigms; and it must be a right for all European citizens and as such enshrined within Treaties. Therefore, we believe that this is a point which the Union, in order to remain so, must necessarily address.

We are extremely attentive and aware of this paradigm shift, and we are also investing; the Italian Government is trying to invest in particular in initiatives related to healthcare technologies and the convergence of data and the development of technologies applicable to the genome. We will be very happy to pursue this dialogue, because we think that the policies, choices, and legislative capacity of our countries must be based upon this paradigm, which requires sharing and also common ethics.

**ANDREA LENZI, Chair of the Italian Committee for Biosafety, Biotechnology and Life Sciences**



The Scientific Committee for Risks Deriving from the Use of Biological Agents, as it was originally called, was founded in 1992. Back then, these risks may have been only presumed or feared. However, as we know all too well, they have now progressed from a newspaper topic to an all-too-real problem for many populations.

The committee's evolution included a change of name, to the Italian Committee for Biosafety, Biotechnology and Life Sciences (also known as the Biosafety Committee). Its provision of direct support on these themes to the Presidency of the Council of Ministers remains unchanged. The Biosafety Committee embraces the technical and scientific aspects of the themes which the Italian Bioethics Committee addresses from a bioethical perspective.

Our responsibility and expertise relates to biosafety, biological and chemical agents and genetically modified microorganisms. When the term "biotechnology" was originally added it might have seemed a piece of jargon; however, it is now in common use even by the general public.

The Biosafety Committee works closely with the Italian Bioethics Committee. Traditionally, a mixed group has produced common documents and given life to common debated themes. These are two worlds necessarily in constant communication: the scientific world, although self-regulating, must in any case interact with the ethical world, which in turn must keep pace with the advances of science. The interaction between science and ethics must not modify their respective epistemological paradigms, but undoubtedly can and must change the way issues are handled, with an interdisciplinary approach.

It has been said that we are now facing challenges that were once confined to the realms of authors such as Asimov, the master of science fiction. These challenges are now encountered by doctors and researchers every day: just consider the use of gene therapies and other advanced therapies. Each day we must ask ourselves how far we can go when "playing" with an individual's genome: to what point does it help their treatment and to what extent does it violate their privacy? We are faced with an issue which has "boundless borders".

On the other hand, we certainly cannot hold back from the opportunity to combine big data with emerging technologies. The new possibilities opened up by ICT enable us to build a better world for future generations. We cannot stop it, but we must undoubtedly regulate the system.

The Biosafety Committee consists of various working groups which interact with external stakeholders - namely manufacturers, workers, academics and researchers, as well as those producing information - given that both scientific and ethical concepts are fundamental to the training of biotechnologists. The goal is to train Italian biotechnologists who are capable of meeting both current and future needs, by applying our European culture to the processing of the ever-changing and ever-increasing technological data at our fingertips.

## LAURA PALAZZANI, Deputy Chair of the Italian Committee for Bioethics



*“Emerging technologies”* is now a recurring expression in debates used to indicate the most recent developments in technoscience. The term “emerging” refers to the continuous dynamicity of the development we have been experiencing in the present, and outlines the scenarios which we can imagine and anticipate in the near and distant future. Alongside the expression “emerging” technologies there is often another adjective: “converging,” taken to mean “moving from different directions towards the same point”.

The novelty of these new technologies lies in the unprecedented acceleration of the development and the unification of various, previously separate, scientific sectors. Today, when reference is made to emerging/converging technologies, the abbreviation NBIC is also used, which includes: nanotechnology/nanoscience, biotechnology (that includes biology and genetics/genomics), information technology, and cognitive sciences.

This convergence of various scientific sectors is not just something that happens occasionally, on a “de facto” basis, which we merely take note of. The “emergence/convergence” of technologies is proposed as a project “of principle”, with the objective of altering, modifying and transforming society and humanity itself (in a moderate or more radical way). The “new technological wave” or “technological revolution” marks a break with what might be called the “traditional” themes of bioethics (e.g. reproductive technologies, end-of-life issues). The novelty lies in the *raison d’être* and in the purpose of these technologies: they are designed for a “dual use”, both medical and non-medical. Medical to prevent, diagnose, cure certain pathologies or improve the quality of life; but also non-medical, by intervening “beyond” therapy in order to enhance, which means to alter, modify and transform the human body and mind, through the quantitative increase and qualitative improvement of capacity (physical, cognitive, and emotional enhancement).

“Big Data” is an increasingly widespread expression within the context of the extremely rapid development of the technologies of information and communication (ICT), it indicates the enormous quantity of information that can be gathered at an ever-increasing speed. It is considered a “ubiquitous and pervasive” phenomenon, with unlimited expansion in the global network, since it is built on the traces released everywhere by individuals/communities in this environment with growing rapidity.

Consciously or unconsciously, our life is being increasingly ‘digitized’ every day. Nowadays, we can no longer live or move without a smartphone or Internet connection. However, whenever we are connected (to make purchases, search for a location, or communicate) we are asked for information of all kinds (name and surname, sex, age, profession, place of birth, but also habits, preferences, behaviour), even only as a condition for accessing a service. The collection, use, and application of “data” (computer, biometric, and genomic) for the monitoring, surveillance, and quantification of one’s identity and that of others (“quantified self”) is now exponential.

Enormous opportunities are opening: greater interaction between people, better potential control, at an individual and collective level, of one’s own life and lifestyle, and security. The extremely rapid and enormous development of ICT in the health sphere

makes it possible to store and stratify a huge quantity of data for each individual or groups of individuals, in an infinitesimal space (a microchip). This allows physicians to have available, in real time, the personal health histories and lifestyles of each individual, as well as quickly providing researchers with stratified epidemiological information for their studies. This opens future scenarios for improvement in terms of precision and efficiency in the prevention, diagnosis and treatment of individual and collective diseases, and also regards scientific research.

One relevant application is the so-called “*Data-driven precision medicine*”, that is the possibility (still under study, but already being developed and tested) of constructing, based on the collected data, the predictions and the virtual simulation of diagnoses and treatments for individual patients in accordance with specific characteristics and specific contexts. This is the so-called “personalized/stratified” medicine, or “precision medicine”. A further application, based on Big Data, is the determination of public health policies, particularly those regarding prevention, in addition to the project to increase the efficiency of healthcare services. The frontiers of telemedicine and *cybermedicine* are opening and easing communication between institutions, physicians, and patients.

However, there are also certain risks and critical areas emerging: the difficulty or impossibility of controlling and governing the enormous mass of data, in order to guarantee confidentiality and secrecy; there is talk of the “end” of privacy, privacy being considered an “evaporating” concept. At times, citizens resign themselves to the constant and insistent demand for data and information, which extends to all areas of our lives, including health but they are also beginning to perceive the dangers that lurk behind this insistence.

The main ethical question regards the treatment and protection of private life and personal data: the need emerges for digital users to be able to control the management of healthcare data, starting from “informed consent” to the collecting and use of data. Operators should specify who is collecting and who will be using the data, as well as what data, how these are gathered, and the explicit possibility of their revocation, rectification, and erasure. These specifications appear increasingly utopian, given the enormous quantity and heterogeneous nature of the collected information, and the lack of transparency by providers. Users, increasingly enthusiastic about information technology, do not stop to carefully read the contracts/consents which they subscribe to (these are often long, complicated, and in fine print) in order to be able to access the service they are interested in, and forgetting the traces they leave behind in the digital environment. They frequently feel “forced” to give their consent (perhaps “in exchange” for a service) or often have no alternative (sometimes there is no possibility to disagree: the only alternative is to renounce the service).

A second ethical problem is the transparency of the algorithms, or rather the selection of data and the construction of correlational relationships between the information and predictions, or the configuration of likely future scenarios (of health, behaviour, or other). It is profiling, which identifies the greater and lesser likelihood of acting, or the propensity to act, in certain ways, by certain stratified groups of individuals. This results in the consequent and possible marginalization and even discrimination of certain categories of individuals or, conversely, citizens’ conforming to the more frequent behaviours, subject of the profiling. The intent is to avoid marginalization, but with the consequence of reducing spaces for freedom.

Another problem is the “digital divide” due to age, socioeconomic condition and geographical area: the elderly, the less educated, and inhabitants of developing countries are the most vulnerable parties in the digital era, because they do not possess the technologies, and/or lack the education and motivation to use them. Although raising some critical areas, connection presents many positive elements: therefore, equal access should be guaranteed, allowing everyone to acquire the tools, knowledge, and skills to take democratic part in the global society and not be excluded from the web. At the same time, at least on a temporary basis, pending the implementation of technologies, alternative access to services (in particular in the healthcare sector) ought to be guaranteed for persons or groups that do not possess the technologies or the skills to use them. The objective should be to allow everyone to take part in accordance with the principle of equality, equal opportunity, and non-discrimination.

This issue was the topic of discussion also in the context of the European Group on Ethics in Science in New Technologies at the European Commission, as part of the Opinion entitled *New Health Technologies and Citizen participation* (2015); at the Council of Europe’s Bioethics Committee (DH-BIO), a “strategic group” was set up on the theme of emerging technologies, also including Big Data; at UNESCO, in the international Bioethics Committee, a document on ‘Big Data and health’ is being debated.

In the face of emerging/converging technologies and Big Data, scenarios of complexity, uncertainty and unpredictability are taking shape. The radical transformation of new technologies is highlighted in the confusion/breaking of traditional boundaries: broken is the boundary between biology and technology, natural and artificial, therapy and enhancement, real and digital/virtual. Ethics is urged to reflect and call into question traditional categories; to rethink the boundaries between health and illness, normal and pathological, the very purposes of medicine and technology; to rethink human identity/dignity, freedom, justice in the context of the convergence of natural/artificial, within the context of the digitization of life.



## **RICCARDO DI SEGNI, Deputy Chair of the Italian Committee for Bioethics**



The rapid and dynamic progress both in scientific knowledge and in technological applications makes it difficult to provide an updated description of emerging technologies: each attempt to update is inevitably incomplete.

The conditions to use emerging technologies in an appropriate way is – first of all - the right to be correctly informed on possible risks and benefits: information is necessary in order to protect the right to safety (both physical and mental) and to privacy (in the sense of confidentiality and private life). Another ethical challenge is the so called “technological divide”, which outlines a possible scenario of inequalities.

The risk is the one of discrimination, stigmatization and marginalization of those having no access to technologies, that live under disadvantaged conditions and emerging technological vulnerabilities.

The complexity of techno-scientific knowledge necessarily entails an informed, inclusive and active democratic participation of citizens: this will be made possible by fostering a public debate during the regulatory process. Regulations should be focused on elaborating instruments needed to protect human health to the specificity of different technologies, in order to safeguard personal freedom and justice.



**JEAN CLAUDE AMEISEN, President of the Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé**



***The Will to let the Freedom of the Other be***

The question about emerging technologies is whether they will open up our possibilities and our freedom or paradoxically restrict them. I think that the question of whether they will open our individual and collective freedom is also a question of whether they may harm us or harm others, whether they might delude us regarding our powers, and whether they might impoverish humanity by reducing us to biological or virtual constituents.

I think that the way we intend to use new technologies (all technologies, since they all can be used in new ways) depends on the way we envisage them, ourselves and others. The sociologist says that our inventions change the world and we invented the world that changes us. Therefore, it is not only the way we use technology that changes us, but it is the way we dream about the new technologies or the way we fear the new technologies that changes us. So, even before we use them, they change us and it is interesting to realize this when we think about them. We always think that the main ethical problems arise from the potential use of technologies. In physics, a modern ethical problem has arisen from the use of the technical application of the atom bomb. In modern bioethics the biggest ethical problem has not been the use of an authentic technique, but a change in worldview, the way we look at ourselves and others which lead to eugenism, to forced sterilization, to what was called social Darwinism or racial Darwinism and which had a tragic outcome during the Second World War.

The birth of new modern bioethics or biomedical ethics may be identified with the Nuremberg Code during the trial of Nazi physicians in 1947 in Nuremberg. One of the pillars of modern bioethics emerging from the Nuremberg Code is what has been called “free and informed consent” and which is more frequently called “informed choice”. We often speak about consent, this involves a degree of paternalism as the designation “consent” dates back the middle of the 20<sup>th</sup> century; in fact, it is the right, given to anyone, to refuse. It could have been called “informed and free refusal”, so everybody would then say “why do you think people would refuse?”, therefore, why do we think people would consent?

It is a free and informed choice which is not only the possibility to say ‘yes’ or ‘no’, but the possibility to deliberate and be helped by others to deliberate, an individual choice based on collective deliberation, an individual freedom embedded in solidarity. I think it builds a hierarchy between knowledge and freedom, since the knowledge for an informed and free choice is given to a person in order to build freedom; it is not the freedom of the individual which is constrained by the knowledge that we have about a person’s will. Therefore, it is knowledge in the service of freedom. When we think about technologies maybe the first question is epistemological: it regards their meaning and what they can do. Knowledge is important as a preliminary for ethical reflection simply in order to understand what we are looking for.

There are numerous very close interactions between techniques and knowledge and these are evolving interactions. One example is a new technique called gene editing. In the last four years, we have come closer to being able to change the sequence of DNA, and therefore to be able to correct, repair and treat the genetic sequence associated with disease. At the same time, in August 2016, two papers were published, one on *Nature* and one on *New England Journal of Medicine* stating that quite a few of the genetic disorders that were thought to be related to the genetic sequence were, in fact, not related to disorders. *Nature's* paper which sequenced the DNA from 60,000 people found that everyone has just over 50 sequences in their DNA which have been associated with genetically driven disease. Plus, they found that more than 40 of these 50 sequences did not induce disease, they were just present in a large number of people. The understanding of the link between genetic sequences and disease was partial and inexact, and the paper, in the *New England Journal of Medicine*, which was looking for the association between the DNA sequence and cardiac disease found the same.

It is interesting to see that when we begin to be able to change the sequence very precisely, we also discover that we do not really know the relationship between DNA sequences and disease. The relationship between technical possibilities and knowledge is an ever evolving process and maybe it is the first ethical requirement when we think that the use of new technologies is for knowledge, information, and research. Informed choice is not possible without information. Information is knowledge, and research creates knowledge.

There are numerous relationships between knowledge and technical use, but it is obvious that gene editing requires knowledge about DNA. Modifying DNA requires knowledge about the consequences of modification.

Another relationship, almost the opposite of knowledge and techniques, is exemplified by 'Big Data'. It is a technique that involves the collection of data in order to treat them and to enhance knowledge.

When we think about technique and we ask the epistemological or ethical question, we should first of all think about the relationship between techniques and knowledge. The French Ethical Committee is working as is the Italian Committee, the British Committee and the German one, on both Big Data and gene editing. We are in the process of working and have not finished yet.

As many of you know, just on the biological level there is, what is called "connected health": how many steps you take every day, what you eat, where you go. Just on the biological level, we collect data on the genome, about epigenome, proteome, metabolome, and tomorrow it will be about the microbiome, the bacteria in our diegetic tract. This is a huge amount of data. It has been wrongly called "personalized medicine" and it is increasingly being called "precision medicine", however, what is often forgotten is, that it is statistical medicine. Evidence-based medicine is based on statistics (evidence).

Firstly, the precision and adaptation of medicine to the person is not an adaptation to this particular person, but to the closest statistical group that can be correlated to the person. It does not speak about the person, rather, it speaks about statistics and probabilities. A treatment that is working for you is a treatment that works for 80% of people in the same case, which means that it does not work in 20% of cases because of side-effects. We live in the illusion that the approach of new technologies will change this

aspect and make medicine adaptable to the individual. Instead, it is just statistical closeness and does not speak about the person.

Secondly, it speaks about the biological makeup of the person, but not about the actual person. The French philosopher Paul Ricoeur said that a person's identity is a narrative identity; a story you tell about yourself, it is what defines you. It is not the same as a sophisticated analysis of your biological makeup and by calling this precision medicine "personalized medicine" has given the illusion that to address the biological constants of the person is to address the actual person while, in fact, it does not. If we want medicine to take the person into consideration, we need to do something in addition to Big Data and precision medicine. If we only practice precision medicine, the actual person will disappear.

This is one of the questions. The other is that this technique makes everything faster. What will be done with this time that is gained? Will it be used to develop another technique or dedicated to the person? What we see, at least in French hospitals, is that when time is gained thanks to a technique, that time is not used for the person, but for another technique.

There is another question that is related to knowledge and raised by Big Data. Big Data gives correlation that does not allow you to intervene because knowing that two events are statistically associated does not mean that there is a causal relationship between them. It means that the more correlation is detected, the more research has to be done in order to understand the causal relation if you want to intervene.

However, if there is a great amount of data analysis, who is going to do the research? The more data there is to analyze, the more research is required in order to make use of them. This means that, as a country or as the European Union, we need to train the actual researcher to interpret the growing quantity of data.

Big Data makes us more and more transparent because it needs more data about us and this goes far beyond health and medicine: e.g. where we walk, what we do and so on. There is, therefore, the huge issue of confidentiality; our wanting to protect our private life and how we can actually do so, are two separate questions. Big Data increasingly prevents anonymity. It is no longer possible for us to be anonymous: therefore, it is no longer possible for us to protect our personal data. Big Data is only useful in health and medicine if it can be crossed by analyzing a lot of data from many people. Crossing data means that the data must circulate. The more they circulate, the more difficult it becomes to protect confidentiality. We want circulation because we want knowledge, but we want the protection of these data because we want to protect our private life. How these two aspects should be reconciled is a very relevant issue.

We are becoming increasingly more transparent, but the algorithm that analyzes the complex data is a computer-based program which, conversely, is becoming increasingly less so. So, we are transparent to processes that are not transparent. There have been copious studies related to the use of American justice in some states, using algorithms to predict whether a released prisoner would recommit a crime or not. Retrospective analysis has shown that the algorithm did not predict accurately. With great surprise, it over-predicted new crimes for Afro-American and Latino people, while it under-predicted new crimes for white people. When the researcher and judges taking the results of the algorithm wanted to know what its bias was, they could not find out because it was the

intellectual and industrial property of a private company, therefore, a complete lack of transparency.

Is the researcher able to understand how the algorithm that he uses works? Who will do the research on how the algorithm works? If we are giving our diagnostic or therapy procedure to an algorithm, it is important to know how this algorithm comes up with its decision. The interesting part of the algorithm is artificial intelligence which means that after collecting data, the algorithm invents new answers. You are not asking the algorithm to do what you want it to do, but to apply data in a way that is innovative. It is a new kind of engineering.

Usually, engineers build machines that do what they want them to do. Here, we are building machines in the hope that they will do what we cannot do or do not expect. If this Artificial Intelligence (AI) algorithm is working, how do we control that its innovation and invention correspond to what we want or not? One trivial example nowadays is the self-driving car. The problem arises when something unexpected happens: If there is a child on the road and a passenger in the car, what does the algorithm decide? Will it decide to protect the passenger and run over the child, or protect the child and kill the passenger, and who is going to decide the ethical implications of this choice? How do we coach these machines in order to have answers that, otherwise, we could not have?

The other aspect is that the giants that operate in this realm (Google, Apple, Facebook and Amazon) have no traditional relationship with the world of health and medicine. Industrial pharmacies have long-term relationships and regulations. Here, we have a new world and how can we build a common understanding of public interest in health and medicine, with industrial giants that have no past and prospective in those fields. For Google, health and medicine are just one of the fields in which it can intervene. This raises the question of how to train independent and expert researchers. We have to form researchers who have no conflict of interest when working in this field. There is an enthusiasm, a need, as with connected medicine, to differentiate between information and publicity. Information does not depend on publicity, it depends on innovation. There is a need for the capacity to build public information.

There are interesting ethical issues, regarding gene editing. There is gene editing for what is called somatic therapy: gene therapy to treat a disease and the new techniques of gene editing do not raise more problems than other gene therapy techniques. There is the issue of what is called germ line therapy, hereditary therapy that will transmit modifications to future generations.

The first remark to make is that germ line therapy has already happened, it is a mitochondrial replacement. Therefore, a child has already been born. Why do we think that this is not the same kind of problem as gene editing in the germ line? It might be because mitochondrial replacement, would constitute germ line therapy, changing the heredity of the child, however, the consequences of this are unknown because we are replacing something with something else without knowing what has changed. When gene editing is carried out, the DNA sequence is intentionally changed and it seems that we are more worried about the intention of changing something, rather than the change itself. Therefore, it is the intention and misuse that worries us. There have been European conventions on germ line gene editing and also the Oviedo Convention which states that we must not change the genetic makeup of a child.

When we thought about it collectively 10-15 years ago we did not really consider whether it would be possible. It was difficult and unlikely to happen, therefore we post-scribed it. Now that it is possible, maybe we should think again. When we think of innovation, are we thinking of new real situations or are we thinking about something remote? There is another example which is very similar and it has to do with embryonic research which has begun in some countries.

The question was: "When you are conducting research on an embryo in vitro, how long are you allowed to let the embryo develop before it can be destroyed?": seven days was the limit ten years ago, because it is the time in which the embryo can be implanted in the uterus. After seven days, there was a possibility of life in the mother. The British say that a person is dead when the brain is dead. The body is not dead, but the person is. An embryo is not a person until the first set that builds the brain appears, in 14 days.

A few weeks ago, researchers were able for the first time to develop an embryo for 14 days. Can we go further? When we think about the future, can we take into consideration the possibility that it could be possible tomorrow and not in 10 days? Therefore, whatever is decided, by ethical entities or legislation, can be revised. In fact, in France, the law that pertains to bioethical questions should be revised every seven years. Similarly, they too can change when things change. As ethical committees, we should consider what we would do if something were really possible from tomorrow, and not in 10 years time.

I would like to say a few words about gene drive, regarding gene editing in the wild. It is changing the makeup of wild animals and plants, all within a few generations, it is something new, that has not been sought as an implication. It can be considered domestication of the wild. We have domesticated animals, but not engineered animals. The issue that it raises is about ecosystems: if we change something in mosquitos or other wild animals, how do we know what the ecological consequences will be? Knowledge is required. It is typically a trans-national issue, since if we change mosquitoes in Brazil; you may change the equilibrium in the whole world. The biologist Edward Wilson who wrote the book "Half-Earth" said that if we want nature to continue to evolve and renew itself, we should give nature half of the Earth and half of the oceans. We want more and more sustainable development which means letting nature evolve itself.

The other question is that we cannot trace gene editing, therefore, how can that kind of technique be identified? It is possible to identify the traces of GMO, but not those of gene editing. Is the idea of regulation merely an illusion, or another kind of "upstream" regulation which will involve more responsibilities? We need to think again about the concept of regulation.

If knowledge is important to choose freely, research results should be shared and with open access to the public, because the majority of public research in the biomedical world, carried out thanks to public money, are sold as private goods, by private journals. Only those that can pay or work in the field have access to these publications. The result of public research should be public knowledge, therefore technology should be shared. Then, there is the huge question of whether technologies prevent or reduce inequalities, or actually increase them. People without the internet or a computer, are lost, compared to those who can enjoy their benefits. Therefore, we need to manage developing technologies in order to reduce inequalities rather than increase them.

There are a lot of new technologies: gene editing, engineering of the embryo, embryonic culture, neural modification which give rise to the enormous question of the self and freedom. Neuroscience raises questions about freedom, ethics raises questions about neuroscience and the modification of our brain function raises many deep questions.

On the subject of health and medicine, there is also a collective dimension. Therefore, one of the problems with these technologies which allow us to look deeply into the body and life of every individual, is that, perhaps, they make us blind to aspects of health and medicine which are not written in the body and life of the individual, but in his/her environment; which can be just physical. The World Health Organization (WHO) stated in a recent publication that three and a half million people are dying prematurely each year from air pollution alone. In France, 48,000 people die each year from air pollution and environmental disasters. This, however, does not happen or affect people equally: a study, carried out last year and published in PLOS Biology, by two French groups asked when the peak of air pollution in France was and focused on those who died in the 3 days that followed. The mode of analysis was crude; they simply looked at specific quarters of Paris. In some of these quarters, the average income is higher and in others lower: poor and rich quarters. When there is a peak in pollution in Paris, the probability of dying in the 3 days following it is significantly higher in the poor quarters.

The reason for this is not because the air is more polluted over there, but because those who are poorer are more vulnerable to changes in the environment. Therefore, health does not depend only on environmental factors. The more someone is vulnerable due to economic and physical reasons, the more he/she is likely to be affected by changes in the environment. There is a physical, living environment (with bacteria for example) and a human environment. When Darwin reflected on the evolution of the species, he stated that for this evolution the most important part of the environment were the other members of the same species, they are more important than the members of other species and physical conditions, like climate or other factors. We underestimate our own impact as a community on the well-being, health, and diseases or premature deaths of others. This is what the WHO has called the socio-economic determinants of health, similar to the name of the department (department of public health and social determinants of health).

In England, Michael Marmot and other workers have shown that longevity is correlated to social environment and work. All the technologies aimed at analyzing the individual for his benefit may lead to underestimating the actual role played by these different levels in the environment. It is easier to use techniques than to change society. It is easier to use techniques than to prevent poverty. In our country, three and a half million children live in poverty, and consequently health problems occur. The question is: how should technology advances be integrated into societal changes in order to guarantee everyone's well-being, rather than go in a direction where technological innovation will substitute social changes, and where people will be responsible for their own health, without taking into account environmental factors?

There are new techniques that can be used with naïve enthusiasm or panic. In addition to looking at these techniques and what they do, we should reason about them. In what framework should they be used in order to change the current situation? It should be done by crossing different perspectives. It should not be about medicine or health, but about how far away we can see.

The title of my talk is taken from a statement by the French philosopher Paul Ricoeur: “The Will to let the Freedom of the Other Be”. It means that one truly enters ethics when alongside the affirmation of one’s own freedom, there is added the statement “I want your freedom to be”. In France, there is the view that a person’s freedom ends where the freedom of the other person begins.

Ricoeur also states what is at the very basis of the French Republic, which is freedom, equality and fraternity because freedom is set as essential. The freedom of the other is as essential as mine, which represents equality; and it wants the freedom of the other which represents fraternity. A view that embodies freedom in solidarity: this means that my freedom depends on your freedom and vice versa. It is both a statement and a question.

Freedom is not predetermined, but a co-evolving and emerging process. Freedom is what emerges when people build something that might not pre-exist, which is a form of collective freedom coming from individual freedoms. It is one way of trying to translate this pillar of modern bioethics which is a free and informed choice, centered on the individual. The contribution of society is to provide the objective knowledge that allows this choice. It means that we can build freedom together and, maybe, the more diverse we are the more interesting, original and inclusive this freedom will be.

This is the way we build our ethical committees: by crossing perspectives, coming from dialogue with other committees which allows us not only to cross different perspectives in one country but also different cultures and concerns in Europe and all the world. This is the only way to be sure that, by talking about new technologies, we will include different perspectives from everyone, and this is what democracy should be; not just choosing for a collective response among pre-existing responses, but building together the most respectful answer for everyone.



## PETER DABROCK, President of the German Ethics Council

### *The new novel Big-Data-driven health domain*



The topic is at the very forefront not only of scientific progress but also of our daily life. Because when we talk about and when we face what I call "the novel Big-Data-driven health domain", it may influence and have an enormous impact on our entire life as individuals, as researchers - as was already mentioned when several speakers before addressed the topic of precision medicine - but also when it comes to using wearables and applications, doing life-logging and self-tracking. It is a daily life experience which might shape - in the way Jean-Claude has addressed - our identity, our concept of personhood and also our idea of solidarity.

I would now like to make you familiar with three arguments in order to analyze this new trend of Big Data in what I called the "novel health domain" and I will explain why I call it "novel health domain" later. But what I would like to share, to comment on or to discuss, to criticize, are these three arguments, and I will summarize and wrap them up in advance to allow you to follow my train of thought later.

Firstly, Big Data connects what under certain conditions does not belong together. Secondly - and paradoxically under the guise of self-determination and the gain of freedom - a threat is developing for self-determined freedom. Thirdly, in order to approach these new trends with responsible governance, it is not sufficient to encourage individuals to proceed with caution - what we traditionally call the notice and consent approach. Instead there is a need for developing regulations with regards to social rights and in particular with a focus on sensitive data in the old traditional healthcare sector. These are my three ideas which I would like to explain now in more detail.

So first of all, Big Data connects what under certain conditions does not belong together. Therefore, of course, my considerations start with a brief introduction of how I understand the term Big Data. Many of you who are familiar with that field are also aware that normally three or four characteristics are associated with the term Big Data: first, the enormous volume or the scale of the given data; second, the velocity of the analysis and streaming of data; third, the variety of covering and analyzing a broad range of different forms of structured or unstructured data which can be combined; and fourth, veracity, how certain we can be about the analysis.

But where it gets more interesting - especially when it comes to the field of ethics and responsible governance - is when you try to analyze and evaluate these technical features of Big Data. I think that especially when you want to assess something critically - critically in the sense of careful differentiation - you face interesting ambiguities. Some of these were mentioned already by Jean-Claude, and I want to pick up his ideas, so that we have an overlapping consensus in the analysis with our Ethics Councils. Often, the results of an analysis seem to describe "reality" but in fact they just give "probabilities". The same applies to causality where results that seem to describe a causal relationship between two factors in fact merely describe their correlation, but not if one causes the other. The increasingly fine stratification permitted by Big Data analyses that permits precise

classification of ever smaller groups can also create the mistaken impression that you were addressed as an individual person. But I remind you of the interpretation of Jean-Claude, that I entirely share, that what is mentioned as personalization in such a context is not really personalization.

What strikes me profoundly is that the claim of increasing freedom and self-determination via the technological advancement of Big Data-driven technology might in fact only be a technologization of the self - but we will tackle that in the next steps. Nevertheless, we have ethicists that are always under the impression of having to address solely the risks and threats of technology when instead we should also be careful not to forget about the sometimes tremendous potential of a given technology. We have to take responsibility not only for using technology but also for failing to use it, for refraining from technologies which offer enormous potential in the field of healthcare. We should not forget about the opportunities, for example in the fields of epidemiology and systems medicine. We might become more precise at diagnosing, treating and preventing disease especially if we do not focus only on genomics but include a broader range of biomarker-based data, also lifestyle data, of social media communications that you might analyze (Facebook and Google are able to do this).

You might come to the conclusion that someone has certain health conditions (namely depression, schizophrenia), just from their social media data and it might be interesting to ask yourself if social media companies like Facebook, Apple or Google are allowed to send messages to individuals to exhort them to go to the doctor for example. This, in terms of health output, is not simply a crazy idea - many of us I guess share this impression - in terms of a utilitarian/preference idea this could be discussed. So, this is just to give you a feeling of how many opportunities these developments offer.

What is a relatively new trend of what I called the "novel health domain" - which includes more data than that from only the traditional healthcare sector - is that the data from the medical and lifestyle area get mixed up. So for example, as far as I know, the technology company Philips is working on medical applications or wearables (comparable to the Apple Watch) that measure health-relevant variables such as blood pressure so accurately that they meet the standards of medical products, so they are so precise that they could be used for medical diagnostics. So if they, someday, meet these standards, what could happen? For example, the doctor, your general practitioner or whoever, if you have e-health records with him, might ask you for access to the data in the records from your personal apps and wearable - let's say the last six months - as they might contain more information than just having a clinic-based monitoring of the last 24 hours. Of course, other consequences may pop up. For example, Generali (a big insurance company from Italy), is keen to collect such data from wearable and apps and then offer you for example a better insurance premium if you give them access to these data. But of course the budget the insurance company gets from the payments of the insured persons stays the same. So, those who do not want to share the data with the company may soon face not only worse premiums but also an increased burden of proof, not only when it comes to getting the insurance company to pay out but perhaps also in terms of behavior and moral values. So, just the possibility of such a practice can change our attitudes and understanding of ourselves.

Practice and the organizational framework will transform our understanding and practice of ourselves - this is also a point Jean-Claude addressed earlier. Remember that

no more than 4 weeks ago the “Economist” compared the world’s business giants from 2006 with the giants of 2016. There was only one company from the sector of the digital industry back in 2006, nowadays there is only one that is not in the digital sector from the seven world-leading companies. Six of them are unsurprisingly based in Silicon Valley. That is our realistic future and there comes a challenge for politics not only at a national but also at an international level as these companies act like sovereign States. Also, if they were addressed or sued they have so much power and money that they could relax with regards to such state-based threats directed at their policy. The challenge emerging with regards to Google, Apple, Amazon and Facebook might be that they combine different sectors which we, for very good reasons (especially in modern times), have kept separate. They can put together information from medical apps, fitness apps, research apps, social media and health-insurance data. Google is pressing to offer healthcare products. They have an enormous amount of data and Big Data-analyzed information, information from search engines that they can use in a new and deeper way to trace the history of individuals’ search entries. On Apple’s Facetime, you have all the information of the communication processes put forward by the same individuals.

All this is coming together and we should be aware of this and we shouldn't say: “Well, I do not care about it”. This is the major challenge for what we formerly approached under the umbrella term of “privacy”. I mentioned why I am convinced that this term does not work anymore in the old-fashioned way. The main problem perhaps with privacy is that usually we associate privacy with some data protection principles that do not work anymore. Within the frame of Big Data, which most of us do appreciate, who is willing to abolish or abandon the use of his mobile device? Many of us do not want that, we are happy to get information sitting in the car, having real-time information about traffic and using that to get to the meeting on time. We do appreciate it all the time, but it would not function if we did not accept the terms and conditions in a very uncritical manner. Of course, true informed consent to all uses in the field of Big Data cannot be given. Similarly, the principles of proportionality and data economy cannot be met when it comes to the broad use of Big Data. Currently, if we do not have a real transformation in the framework, you are giving away your data without proper consent.

So that is one of the main challenges of Big Data and its impact might be wrapped up in this way: especially in the field of the novel-health domain you face a risk of de-anonymization of sensitive data. Several studies have demonstrated that it is possible by combining just the right kind of data to de-anonymize a person. So be very careful if someone claims to be able to offer complete anonymization, having in mind that we have an enormous pace in technological development that might make it easier to de-anonymize persons from Big Data sets.

On to my second argument: the erosion of data protection principles is also accused of endangering self-determination and freedom. Self-determination can be understood in the sense of freedom - understood as the realistic possibility for each person to be accountable for his or her actions. Whether you follow Immanuel Kant in describing freedom as agency and the ability to give reasons for decisions and actions, or John Stuart Mill who understands freedom as individuality, authenticity, originality and well-being, it becomes more and more difficult to meet the expectations of freedom, liberty, and self-determination. Because if you remember the characteristics of Big Data, it is not so

much about individuality, freedom and causality but more about stratification, correlation and self-technologization, driven by big IT-companies.

You might draw the conclusion that what seems at first glance to be free is in fact the algorithm-based offer of a corridor of self-technologization. It may create the feeling that this is your own decision, when you are in fact nudged by big companies that narrow the range of opportunities you have. This does not pop up just by coincidence in our times, but in a new way of quantity that transforms to a qualitative level. I think that this is the point. For those of you who are perhaps familiar with the theory of the individual and society put forward by the French philosopher and sociologist Michel Foucault, we might run for the first time into an era of what he calls "self-Governmentalization". This means we feel that we are acting freely when in fact our self-esteem and our self-image are heavily influenced by the expectations of others - in this case not Foucault's State based institutions but rather big companies and their visions of our own self-esteem and self-image.

What concerns me - and you can argue that this is not brand new - is that we are all at risk. We are at risk of losing sensitivity for extraordinary elements in life, for the value of strangeness, or for the fact that not everything fits into the frame of predictions, or for the value of secrecy, fragmentarity, and forgetting. Big Data-driven agencies do not forget anything and it is easy for the algorithms to go through the unforgettable. Remember that forgiveness is a human behavior that connects people to each other. Think about the close relationship between the creativity and sickness and disease of many great inventors, philosophers and artists, people with - let's say - pathogenic effects in their lives, all these might be at risk when we just follow a line of self-adopted streamlining.

Now I will deal with the consequences of argument three. It is not enough to follow ethical recommendations in a way that we should build up digital literacy. Of course, it is necessary that we should strengthen the capabilities of individuals to cope with life in a digital age, but it is not sufficient. Of course, we should also refrain from the extreme alternatives of uncritically approving this trend by accepting claims that there are technological solutions to fix any societal problems - a strategy that Eugenij Morozov, interpreter of the digital age, calls "solutionism". I am very much in line with the Nuffield Council's idea that we should strengthen the principle of participation and accounting for decisions. They understand this as ensuring not only that a decision can be accounted for in a community but also that there is an opportunity to challenge and re-evaluate decisions. But I think we also have to go further in a way that - to my understanding - first of all, calls for the ethics of Big Data as a form of social ethics.

The current challenges in dealing with Big Data are global issues, accordingly suitable and sustainable solutions have to be developed on a transnational or even global level. Nevertheless, this doesn't mandatorily mean that it would not be necessary to call on as well as to enable openness for individual responsibilities in dealing with Big Data, but - and this is important - we need Governmental framing which enables and re-opens spaces for such digital self-determination. Big Data will transform the established modes of governance. It remains an open question if Big Data with its processes such as data mining, self-tracking and granulation will offer new modes of participation or will rather significantly challenge the foundations of democracy.

Caused by these transformations, it is really unclear if the frequently discussed concept of data sovereignty could deal with these complex challenges. Let us work on privacy by default and by design when offering Big Data based devices, processes and

industries. Even if one normally prizes democratization, transparency and participation, we really need the big approach here, we need top-down approaches, we need some kind of regulation on a global level. I also think we should create incentives within this framework, to give the industry incentives to change the devices or programs in order to meet standards of responsible governance.

One could go into far more detail with this but that is what we at the German Ethics Council are currently still working on, we are still drafting our opinion Big Data and health. I have to make a disclaimer that at the moment we have not finalized our opinion but I am part of the working group and maybe my opinions will be integrated. I am very pleased that you from the Bioethics Committee in Italy, we in Germany and previously the Nuffield Council and the French Committee, we are or were all working on these challenging topics that may transform our society in an enormous way. We should be at the forefront of trying to responsibly cope with these issues, and not only react after the big IT giants have decided about how to run our future. It is really about our future and not just about the ideas of some ethicists, philosophers or lawyers.

**JONATHAN MONTGOMERY, President of the Nuffield Council on Bioethics**  
*Emerging technologies, bioethical challenges, the case of genome editing*<sup>1</sup>



I'm going to draw on three Nuffield Council reports, which amounts to more than five hundred pages, so I will endeavour to be reasonably concise. It's great to be here in this wonderful room again. We were here for the NEC forum in 2014 and I had the privilege of presenting there on research transparency in my role at the Health Research Authority. The issues we've been discussing this morning and which the Italian Committee is grappling with, are all questions which have been on the Nuffield's agenda and are still central at the moment in discussing genome editing.

We are part-way through our process on that, and the title you see on the slide - the "review" - is the first phase of what we are doing about genome editing. I want to put it in the context of the work we did in 2012 about the proper way of approaching emerging biotechnologies and how we picked that up in terms of grappling with questions of biodata. I'm going to work my way through some things that we learned in our previous work before I get to details on gene-editing.

The first point is that we have not to think about the challenges simply in terms of techniques. When we think about an emerging biotechnology or converging technologies that come together, what actually interests us is the way in which different sets of knowledges, different practices, different things that we can make or achieve, different ways in which we can use them, come together. What makes something a technology rather than just a technique is in large part a cultural artifact. We are not sure in Nuffield yet that it is right to talk about genome editing as a technology in this sense. There are a number of techniques that are being used, that are used to alter the genome and not just the human genome. But it is not yet clear whether they have solidified into a particular way to do something that we can effectively analyze in terms of the significant moral frameworks. It may be too early to tell.

A second precursor for our genome editing work, Jean Claude has already mentioned it, is the line between somatic and germline therapies. At one point our government in the UK was arguing that mitochondrial replacement therapies should not be understood as being gene-editing because you didn't change any of the genetic frameworks you simply brought two other-pre-existing genetic contributions together, much like natural reproduction does. It was also reluctant to think about it as a germline therapy, principally because of the international consensus that we should be rather cautious about interfering with the germ line. We do, of course, interfere with heritable characteristics all the time; when we select our partners and our mates. One of the things we recognized in the mitochondrial report that we did, was that we were moving in this territory of germline therapies, but it wasn't the main focus of our work and we anticipated

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<sup>1</sup> I should acknowledge particularly Dr. Peter Mills who has driven the work from the Secretariat of the Nuffield and Dr. Andy Greenfield who chaired the working group that I have just been summarizing.

to come back to that. We have done so with the genome editing report. However, I want to start with the work we did about emerging biotechnologies.

### **Challenges of emerging biotechnologies**

We considered the nature of the challenges that presented us when we begin to think about emerging biotechnologies of all sorts. We need to think about moral frameworks, and governance challenges, in circumstances where it is not very clear what could happen if we take advantage of the technologies. Often the things that might happen are ambiguous. They are not simply going to be either attractive or unattractive. They bring questions we might feel require tradeoffs between things that we value. Most importantly, the challenge of the emerging biotechnologies that seems so pressing come in relation to those technologies that are described as of "transformative potential". That is to say, the issues are not just about the decision whether to adopt the technologies, but the fact that they will change the way we think about other things not just the particular techniques themselves

We also identified a number of tendencies in the way in which the UK, but not just the UK, was likely to approach questions about emerging biotechnologies. The first one we picked up then is that there was a tendency to hypothecation, that's to say to holding out the technology as the way of solving a particular problem. This focus on technology might blind us to other ways of solving those problems. We also noted that any identified concerns were often approached in terms of what we described as the "biotechnology wager." That is, we acknowledge that difficulties are ahead, but it believe that all will be okay because we will find technological ways of getting over them. In addition, we drew attention to the tendency to limit the scope of both our predictions and also the factors relevant to our decisions to questions of economics. This suppresses questions about social impact and tends to exclude questions about moral reasoning. There is a massive tendency in the UK to hype, to overpromise the possibility of what we are able to achieve. One of the scary things about emerging biotechnologies is that despite the fact that they might not work you will never see people talking about the fact that new techniques might fail. You are always encouraged to invest in the promise that this is going to go well, changing the world for the better.

Next, we identified that there was a tendency in the way we thought about emerging biotechnologies, to see them as highly controlled by experts. It was the people who understood the techniques, including expert funding bodies, who were involved in taking decisions about whether to move forward or not. That was very remote from our usual democratic politics. These only came into play after the key decisions had been taken. We talk at a number of points about the challenges of path dependency. You take a step on the path at an early stage in decision-making where the people who have influence also have particular interest in pursuing those technologies. The people who think about alternatives don't have voice in that stage of the process. But then you realize you are too far down the track to recover it in terms of democratic accountability.

Finally, we identified a set of issues that arose out of the way in which the challenges were usually framed in terms of benefit for individuals and opportunities for individuals, but that suppressed the extent to which they had an impact in the form of wider social implications. A line of thinking, in terms of responding to that, was to think in terms of the importance of creating opportunities for public deliberation- We talk about the idea of

creating a sphere of public ethics. This aims to reinvent social responsibility and pull that into decision making about the choice of biotechnologies in which to invest. We want to bring the concept of social value into that process. We should not talk solely about scientific possibilities and economic value when we select technologies to adopt.

We thought that such public ethics should recognize social values, which we thought were generally absent from the decisions that were currently being taken. Our report identifies some of virtues that should be pursued in public ethics -in particular, equity, solidarity, and sustainability – that we thought were often suppressed in the decision making processes that we saw going on. In order to ensure that those values come into play, we suggested that public ethics needed to be open and inclusive, making sure that the various voices who are at stake actually have the chance to influence the discussions.

We also raised a set of questions around making people accountable for the choices they made. Typically, accountability comes much too late in the process to enable it to have influence. There is a need for public and not just private issues to be addressed. There is also a requirement for openness and honesty to counteract the overpromising. Recognition of public ethics requires a considerable amount of facilitation and support, if those voices are actually going to be part of the process. We have resisted a formal 'precautionary principle', but rather promote a virtue of caution. By this, we mean that we should not refrain from doing things that seems to be promising, but we should proceed carefully in a way that recognizes that we might be mistaken. For example, we should proceed with robust regulatory powers, with good follow up, and with careful recording of what goes on. The idea is that we need to ensure that if we were to discover that the choices that we made about emerging biotechnology look less attractive as we began to step down the path, then we would have built in the possibilities of revisiting our thinking and possibly changing our direction.

So we had some very particular recommendations we built in into that in terms of how we should make choices about emerging biotechnologies. One was about trying to see them in context, in terms of the other solutions that might emerge from the problems that they claim to be addressing. Typically, evaluation focuses on whether or not they would work and if it works what will it achieve. In addition, you need an opportunity to consider whether or not you could have achieved something as equivalent and as good through alternative routes. We tend to hear the voices of the proponents of the technologies more easily than those of the competitors. We identified the need for public engagement, to secure the wider range of voices and the discussion that you get when you debate things with a public. There is a difference between a quantitative assessment (,51% of the population supported this and therefore you have public support for it), and seeking to understand the reasons that lay behind their concerns or their support. We need to be able to examine choices and understand the range of views. Given that the future of emerging technologies is uncertain, it may turn out that the promises are not realized. It doesn't necessarily follow that just because the public was supportive initially, that their support will be retained as the applications develop. We can make better judgments on that if we have a clear and rich understanding of their rationale.

We need to recognize the tendency to technological reductionism. We tend to think that doing things in clever ways solves problems. However, the majority of the problems that we are interested in solving are very complex and have wider social dimensions. If we are not careful, we avoid addressing the key social questions. We identified a whole range

of ways in which this happens. We followed some of them up in our work on research culture. This noted that lots of incentives exist that encourage researchers to claim a lot more for the effectiveness or the success of the impact of their work than they are qualified to do or comfortable in doing. I don't know what the position is in Italy, but if you seek grants from UK funding bodies, you usually need to explain what the impact of your work is going to be. You really don't know that, you're just speculating, but we build such speculation into our decision-making.

We also need to try to avoid the capture of decision making on emerging biotechnologies by small range of like-minded people. We typically go back to the same range of established experts again and again asking about the reliability of the technologies, the probability of things coming to pass and the sense of the aspirations for the future. We need to defuse that power in order to make sure that we don't get in some form of group thinking and just say what we were expected to say. We need to try to make sure that policy decisions use the full breadth of evidence that is available to trying predict what might happen. We need to think about what we might learn from the choices we made for one technology rather than another in the past, and use this to inform our decision making better in the future.

Fundamentally, as we move forward - and this goes with our virtue of caution - we should try to make sure our steps into the use of the new emerging biotechnologies are properly assessed and researched. We should use a whole range of techniques and methods to try to understand what the actual impacts of emerging technologies are. We should not just listen to the people who have vested interests in the adoption of new technologies. So, in summary, that emerging biotechnologies report was aimed to create some morally responsible framework for decision making

### **Big data and health**

We then found ourselves beginning to work on Big Data. I am going to refer only to a few parts of the biodata report which runs up to two hundred pages - and obviously had many other things in it. However, one of the things that it required us to do was to think about how we could construct an ethical approach to decide which uses of biodata made sense, and which didn't. So, as many of our reports do, we picked up a range of the ethical principles we thought were at stake. We picked up some of the questions about the protection of individuality. We noted the paradox that you become more individual and more specified but you also become lost in the data. We identified issues around the implementation of human rights norms. -However, most importantly for today's discussions, we set out some principles around securing participation of people who were affected and how to make sure that there was an accountability framework when people took decisions that affected them.

Part of our report related to the idea that we should require those who establish what we described in our report as 'data initiatives' to take responsibility for moral reflection on what they are doing. One of the odd aspects of 'big data' is it fosters the myth that no one is in control. Yet you have to establish the collection mechanisms. Somebody at some point takes a decision to set up a data initiative to pull things together. We argue that the people who set that up should be able to give a public account of the reasons why they think it is an appropriate thing to do. They should be able to show that their purposes are morally reasonable in the eyes of the people whose interests are affected. So essentially

we set out the challenge of articulation of the moral case for moving forward in big data. Once articulated, it then becomes possible to deliberate on it.

Now we are working with the Department of Health in the UK in taking that forward in relation to the use of health data in health service records. In the UK, we have lost the social licence to collect information that could be extremely useful in terms of improving the quality of health services, understanding better the epidemiology of disease and (we hoped) enabling services more effectively tailored to the needs of their users. So we are using this ethical framework to work with our colleagues in government to talk about articulating the case for using the data in this way. This needs to identify, things are recognizably morally valuable on the part of the patients and community. Such a requirement for articulation of morally reasonable purposes seems to us important in the biodata context, but it is also an important part of good governance for emerging biotechnologies more generally.

The final aspect of the biodata report that I want to pick up has been touched on by my colleagues to some extent. This is the recognition that ethics is not enough and law is not enough. Law is not enough, particularly because the data protection paradigm we are working with is insufficient to deal with the challenges of big data. In particular, it relies on the idea that you can protect interests by anonymization. That makes little sense, given the re-identification opportunities that big data technologies provide. In addition, the traditional tool of informed consent is implausible when we really don't know the uses to which big data will be put. We cannot inform people of what we do not ourselves understand. What we need to do is to find a governance model which really enable us to get beyond the weaknesses of those two approaches.

The fact that is legally permissible to do things does not make it morally wise or desirable. So that governance design needs to identify who the affected communities and people are. It then needs to provide a process for them to not merely take into account their interests but to deliberate on what they believe is at stake. This will include challenging them, trying to identify what it is that they would regard as relevant to their consent, when their concerns are well founded and when not. In addition, we argue that if the governance of a data initiative is to be trustworthy, this accountability process cannot be limited to a single point of decision. It needs to be a continuing involvement and the accountability mechanisms need to reassure people that their interests will remain at the forefront of decisions that are made. This implies new types of governance structure in relation to big data.

So, in summary, what you have seen there is that we were seeking to apply some of our ideas about how we made good choices about emerging technologies to the particular context of big data.

### **Genome Editing**

We are now working on the same sort of questions in relation to genome editing. We have published on our website, but not in print, a review of the ethical issues that we see emerging around genome editing. This is not an opinion in the traditional sense, nor a full report of the sort I have described so far. This is, because we have got yet carried out the depth of reflection required to generate recommendations. The only thing we had printed is a short version of genome editing. Everything else is just on the website, available to

support debate but not regarded as final. The longer version on the website is likely to be revised as we move through the second phase of the work. The first phase of it was aimed to try in getting some handle on what the questions were. The next phase is to work on them in detail.

We have tried to define more precisely what it is we are dealing with. We talk about genome editing rather than gene-editing. The differences become important because every although we do 'edit' in a way it addresses particular genes, what seems to matter is where these genes sit in relation to other genes and therefore in the genome. There is a whole set of things to tease out in order be clearer about the metaphors that we are using. Editing is a metaphor. It is different from engineering. What significance do we give to those changes in the metaphors that we use?

We also tried to identify what it was that people thought was at stake and from that we identified the salient ethical questions. This is in accordance with our commitment to make sure that our process is inclusive, in the sense that all voices are heard. However, once we have heard them, we move into a process of trying to make sense of that we have heard. That is the second stage, which we are now beginning to address. This will begin to explore the normative questions that we have identified, with the we aim of formulating practical recommendations.

So I want to take you a little bit through what is in stage one and then going into stage two. First of all in terms of methods of working, we started this process with an academic literature review. We had a workshop in April last year, trying to work out whether there was a topic to be looked at here and then we charged an interdisciplinary working group to produce the framework review that I'm talking about here. This included an open-call for evidence but we also invited people to come and talk about what we thought were the most salient areas of interest. Finally, we interviewed a small number of people we thought had something to say about the things that were emerging. The details and process are set out in appendix 1 of the document on the website. This process is not systematic, nor comprehensive. It is more like a snowball recruitment, trying to find out what people seems to be interested in and trying to follow it up, so that we can understand it better, trying to make sure that we have not made any significant errors.

This gets us to a phase where we will be able to offer our take on what needs to be covered (the agenda, if you like) to our constituents and colleagues from other Committees. The stage 1 review report broadly tries to describe what seem to be the things that people say about genome editing, to place that scientific activity in the context in which it seems to be emerging, and to summarize different moral approaches that came through in our engagement. We can then to begin to think about addressing the applications where genome editing seem to be most controversial, focusing on where it is already going on or where we might anticipate that it is coming soon.

A key part of our assessment is that are various characteristics of genome editing that do suggest that it has the potential to be transformative in the sense that I described earlier. However, but they are not necessarily the ones that you would first identify. Quite lot of them are just around the practicalities that these new technologies offer compared to other alternatives. It seems to me a more flexible way of doing things with DNA than we were able to do previously. It seems to be more efficient and promises fewer off-target effects.

We already have one example in the UK of approval the CRISPR gene-editing technology in an embryo research project that demonstrates this. The applicant already had a license for researching the embryo. They were already using various ways to try to suppress or manipulate genes to stop them working. Taking these genes out by editing would give clearer picture and therefore offer more reliable answers to the research questions. There will be no more (and no fewer) embryos involved in research as a result of approving this use of CRISPR. We had already decided that it was ethical to manipulate the embryo DNA in this study. The approval was to permit the use of a tool that was a more efficient way to do something that was already approved. Put in those terms, it seems a relatively straightforward step. One perspective is that it is just an efficient way of doing something we've been trying to do for a while. We also to need to consider that because is more efficient it enables all research project to be carried out much more quickly.

In addition, it is not actually that difficult a technique to use and more people can therefore use it. It may also be cheaper than the ways we have been using previously to study gene function. Up until now, our thinking about genetic engineering has been partly based on the fact that we need a lot of background knowledge to decide when to deploy it, and whether it would make sense to deploy it. This means that the use of gene editing/engineering has been contained within communities of experts. What you begin to see now is that the transformative nature of genome editing might be found in the fact that things that we previously found to be difficult and limited to a small group of experts are becoming straightforward and more widely deployed. People might be tempted to try it and see what happens unconstrained by the caution of the current experts. This might be where the disruptive aspects of genome editing actually emerges.

One dimension of this is the possibility that the sense of 'proper' purpose that has been developed within the current expert community might be lost. Sir. Francis Bacon is associated with the view that science is a morally charged enterprise. It was, he said, to be undertaken "for the glory of the creator and the relief of man's estate". Such a sense of purpose was clear in much of what we heard from those interested in genome editing.. The rationale, the purposes, the incentives and the motivations for exploring this are not to be frowned upon or dismissed. There were many people who saw potential for improving human well being. For them, therefore, there was a sense in the key question to be answered was whether an account could be given of why we should hold back science in pursuing those aims. This contrasts with one of the challenges that we identified in relation to Big Data. There, we were concerned that no one seems to be in charge of it or to accept responsibility for the proper conduct of affairs. This gives an illusion of absence of morality because no one quite seems to be taking control and therefore no one can be held to account. This was not what we found in our exploration of the terms of genome editing. People were considering using it with a strong sense of purpose and felt that they were doing something which would lead to improvements.

A second thing we explored in the responses we had was whether or not there was something exceptional about intervening in the genome. What we heard in that process was there wasn't something about the genome which was particularly owed some special reverence. If you think about it, we interfere with the genome in natural reproduction. This process involves a new combined genome drawn from parts provided by two parents. You get a new genome from that. There isn't any static thing called the human genome.

The human genome reproduces itself in a way that makes sure it is varied. So we didn't pick up any sense that the issues about genome editing were best understood as being something specific to the genome. What we did pick up, of course, was a whole set of frameworks in which we might make sense of the choices we had to make on whether to move forward or not with these new techniques.

We have brought them together into broad categories. What we are trying to do here is to reflect fairly the range of views that we heard about ways of which we might approach the ethical challenges. The first group of views we described as forms of bio-conservatism. This approach manifest itself in a number of different ways, but I think that there are two or three things that are worth pulling out. One is that there is a sense in which those transformative aspects that I spoke about might threaten the ecological stability of the situations that we are dealing with. This is a sort of bioconservatism in the sense of conservation.

Jean Claude talked a little bit about gene drive. Gene drive technologies would aim to use genome editing in a way that they will have an impact on wild populations. Now, of course, we do things that have impact on wild populations without doing into anything greatly technical like gene editing. We introduced rabbits into Australia, and they have had a major impact. But if gene drive works (which it may not), for example trying to drive out malaria by modifying mosquitoes that carry it, this it might have wide reaching effects quickly. Ecologies will have little time in which to adapt. The problem might come not so much from the technique, but from deploying it in a way that makes it more difficult for the other parts of the world to react to and accommodate it.

But there is also a sense in which our ecology and associated morality may be challenged. This concern, is essentially consistent with the questions about enhancement and discussions about the ethics of genetic engineering that we have explored over some decades. These concern the design of babies and their life. These might already provide a suitable moral framework to make sense of the new challenges, although there is also the possibility that the concepts that have been developed may not be resilient enough to deal with the new context. There is a final element of bioconservatism which is about the tendencies to overpromise and to fail to recognize that things might not work out the way we intended. There is a group of arguments that we have clustered together which are not dissimilar to our earlier discussion about proceeding with caution.

The second broad group of responses concerned the application to genome editing of those widely established general moral norms and human rights which are brought into play. Here, the point is that we already know quite a lot about those things. We need to work through their implications, but we don't necessarily need to do new conceptual work.

There is a third group of responses that focus on what will happen if we adopt the technologies. What would they do to people? What benefits might they get? What harms might they cause? This type of approach frames the issues less in terms of fundamental norms that in analysis of the likely consequences.

Finally, we identified separately a group of concerns about social justice. A lot of the discussion on welfare and harm feels very individualistic. However, some of the significant questions about the broader impact of genome editing might arise from unequal access to these technologies rather than whether or not they are used at all. This looks very different when you think about plants rather than questions of human genome editing. The human element is not likely to be used very much, nor very quickly, even in rich countries.

However, in relation to other uses, particularly in relation to livestock and farming we may well find that developed countries show the most interest, but the risks are borne by developing countries. We already know that can happen from plant science.

So now we have begun to build on our model for emerging biotechnologies and to consider how we could address the governance challenges. All these moral frameworks will need to be explored further. However, we recognize that this won't be sufficient. Even if we engage with them and reach some conclusions, there will need to be a political component the governance of genome editing that holds together different challenges. The big challenge we identified in that related to where the communities and public interest might be incorporated. How should we specify the affected communities that we have argued should be included in decision-making? Should we understand them in terms of those directly affected; those in the industries that might use genome editing, the people who might consume food that has been produced using the techniques. Then we need to consider the extent to which the public interest should be considered in ways that are distinctively national, to what extent they are European or perhaps global. We don't have effective mechanisms for engaging the public at all the levels. So that will be a challenge in going forward.

Another set of challenges concerns where we might start in terms of defining the problem and this goes back to my question from early on about whether we can yet address technology of genome editing. We are still not quite sure where these techniques will go. We have identified a range of practices, techniques for doing the editing, that are emerging. These that are similar in the sense that they engage in genome editing, but they work slightly differently. It seems slightly odd to think that somehow the moral analysis is going to be dependent on particular techniques for changing things. However, we may find that we need to distinguish some of practice in order to specify the inquiries that are needed.

A second way we might organize the next phase of our enquiry would be to distinguish the genomes we might be editing. On this approach, we would consider examining the differences between deploying genome editing techniques to viruses, plants, non-human animals or to humans. It may well be that there are reasons for separating out some of the moral questions in relations to those. We are not yet clear on how much weight we should put on those distinctions.

A third way in which we might navigate the issues could begin from purposes for which the technologies are being contemplated. Is it about understanding better the basic biology? Public health questions? Agricultural uses? We can imagine clear opportunities for genome editing in biological weaponry, and in protection from them. We may need to be analyzing the purposes into which things are put, using those intentions to develop our set of questions – developing a framework that is focused on separating acceptable aims from those that should be rejected.

Finally we could begin by trying to understand better the context in which the technologies are being used. Such an approach might better address our anxieties about uses and help identify the disruptive impacts that genome editing might have on our current knowledge and culture. It might be also easier to draw out the questions of alternatives and opportunity/costs of the technologies if we adopt that way into the issues (as our work on emerging biotechnologies suggests that we should). The contextual social and economic conditions would acquire a higher profile in analysis of this sort.

All of those things are uncertain and the categorizations that I have outlined are tentative. We are not yet clear how useful they are in framing the questions. However, but they all came out of what we heard. We now need to move towards normative work. We have identified in that second phase that there will be at least three strands of the work. First, we will seek to explain what is at stake in terms of the values, including drawing out how the distinctions that governance arrangements make constitute expressions of specific values. Second, our work will need to identify where and how private or public interests are engaged. This will include how we can distinguish those that are powerful and important. If we have to make tradeoffs, we need to consider who is entitled to make those tradeoffs and how they should go about determining what should happen. Third, there is a need to explore how we should imagine the future, comparing different visions of desirable states of affairs. This will enable us to sharpen our sense of ways in which we could think through the possible outcomes, what the likely consequence of this technologies are. We can then use these different narratives of the possible future state of affairs to feed them back into our deliberation process.

So having identified that we should do those things in order to move into the normative stage, we then had to decide what our priorities were in terms of working. We have started two working parties to take this forward. For one, we have identified human reproductive applications and our working party has began to meet on that. If everything goes to plan, we will publish a normative report on that in 2017. We actually raised quite serious questions about whether we really needed to do this as a priority because we can't quite see why people will want to do it for reproductive purposes. At present is not clear what advantages gives genome editing over other areas. However, there was significant public interest and it therefore seemed appropriate to pick it up.

For the second, we have selected applications to livestock. We identified significant use in relation to livestock. This feels like a pressing issue because it is already something that people are looking at deploying. It also raises questions for the decision making processes that we need to deal with, not least questions about what counts as a GM product. Something already under examination in Germany. And it seems something where genome editing actually was being used. On one view it is not that different from selective breeding but just more effective. This d provides an opportunity to tease out some of the most important questions about genome editing that we have identified from our more general exploration, summarized above.

We have also identified a couple of areas where it seems likely that there is work to be done but it was not our immediate priority. The application of gene drive to mosquitoes in order to control disease is a good reason we might want to look at it more closely. In the UK, we already had a parliamentary committee inquiry on these genetically modified mosquitoes. We can also see the potential for use of gene editing to enabling Xeno-transplantations to become safer and more effective. These might be good topics for subsequent working parties if others have not picked them up first. There is a third group of possible applications we thought should be kept under review, but which we don't think that need immediate attention. These include cell-based therapies and plant science. We can see a substantial program of possible working parties, so we don't know how long our work program will be on genome editing but this seems consistent with the challenges of emerging biotechnologies.

## DISCUSSION



**d’AVACK:** In the report on Big Data by Peter Dabrock, among the many interesting observations made, he calls our attention to privacy and maintains that the term “privacy” – continuously mentioned in the context of these problems – ought to be given another meaning today. I agree that in the era of data and ICT, we are witnessing a digital transformation with social repercussions, which are so radical that a change in the ethical and legal approach is required, with the rewriting of traditional categories, and among these, specifically privacy.

But I ask: Is the right connected to this term disappearing? Many refer to the end of privacy, or at any rate, of it being a concept destined to “evaporate”.

However, starting from a multitude of historical events, I recall that there is a certain trend, also in democratic societies, for citizens to spontaneously waive rights (often fundamental rights) in exchange for useful benefits, for other conveniences, or when faced with states of need or situations of fear. We need merely quote Hobbes to recall that in the name of “fear”, even personal freedom is renounced, in exchange for guaranteeing one’s own existence. I think that in the world of biotechnologies, everything that is offered and guaranteed is highly interesting and appealing for citizens; certainly, so are the collection of data and the enormous field of information made available to us for any kind of use – personal, commercial, industrial, political. It is the citizens/users themselves that continuously leave their digital fingerprints around the web, on the basis of what B. Schneier defines as the “feudal model” of the Internet: users releasing personal information to IT colossuses in exchange for free and secure services.

I therefore see a strong thrust by society towards happily renouncing the idea of their

right to privacy. I do not find, however, the same willingness on the part of the State, or, better, of power. It cannot be denied that we are dealing with a “war for control over cyberspace”: on the one hand, there are the classic institutions of power – Governments and corporations – hunting for our personal data, and on the other the dissidents, hackers, and movements demanding the availability of data and information, even outside the confines of the law. It is a battlefield, whose victims – the citizens themselves – are often unaware of the conflict. The problem is how to free the debate from the confinement of technology and make it a “public concern”. For various scholars, the problem lies in the converging interests of Governments and companies: they want access to the users’ personal data, to record and store what they read, look at, eat, study, and think.

It is my impression that the ability for surveillance of States has reached a level incompatible with human rights. The risk is that “power” (if the form of Government is democratic, the risk is more contained) might keep all this information for itself and, to the contrary, have it censored, redacted, or withheld from the public depending on the case. The great advantage provided by data, then, which is to say, to inform and educate society at large - even those who are poor and uneducated – becomes a mirage, and “individual privacy” is replaced by “state privacy”, which becomes a powerful tool for Governments, and totalitarian ones in particular. To conclude, there is a frightening potential for the abuse of power.

**DABROCK:** This sophisticated question offers me the opportunity for some clarifications.

First of all, of course, who could be against some value of the concept of privacy if privacy is understood in the sense of a right to be let alone, in a way of informational self-determination as we call it in Germany? Anyone would say “yes, I am in favor of privacy”. I am not against this ideal of privacy, but the question is - for someone trying to cope with ethical questions in a concrete world - how are we able to translate this ideal concept of privacy and how are we able to manage it, when we also want to appreciate all the advantages of Big Data driven devices. That is the problem, to combine on the one hand our wish to use and appreciate all these technologies and on the other hand also to keep this concept of privacy. I mentioned the many paradoxes that we are confronted with if we follow that route of dealing with big data and technology devices. So, my idea is not to give up on the idea of privacy in general but to transform it to the era of Big Data and that means - since we cannot hold the idea of purpose limitation of data - we should look for different styles of keeping this idea.

This could for example be by looking for options for individuals to have some kind of control over their data, for example in the classical medical system, or for example when it comes to bio-banking activities. Here it might be useful to introduce technical and governance options for “dynamic consent”, where I am able to have on the one hand the opportunity to have an individual data box - where, if I wish, I can control which of my personal data are used, by whom and for which opportunities they are to be shared. To have an idea of privacy driven by negative freedom, with a more positive account of controllability, a new idea is the concept of data sovereignty. Everything depends on how you interpret it, but if you interpret this concept in a more comprehensive way (and in this way I understand your proposal about state-based privacy), one has to look at very different elements: in terms of governance, legal regulations, and incentives for industry,

the education of individuals. So, we need a comprehensive network of activities and structures to hold on to the idea that is behind the concept of privacy and Big Data. This is primarily the idea of human dignity – a concept which we should still defend also in an age of Big Data.

**AMEISEN<sup>2</sup>:** I think it is a very important question, which is also linked, not only to the concept of dignity but also to freedom.

Let us think about the difference between a modern democracy and a totalitarian regime when it involves voting. We have a secret vote, which we think is a guarantee of the expression of free will and of the lack of pressure exerted in the vote. There are cultures where you have a public vote and if you do or do not you are seen when you vote, so the question of privacy and protection of privacy is basically related to our conception of freedom and democracy, in the first place. Now it is often said that it is interesting as a technical advance; that because privacy is no longer possible as technology might infringe it, it should be abandoned. It is like saying that if freedom is no longer possible because we are observed, it should be abandoned.

I think we should not abandon a fundamental right or value because it is more difficult to protect, we should just change the way of protecting it. Last year the European Court of Justice suppressed the Safe Harbor Treaty between EU, Google, and Facebook because Facebook said: "we are collecting data in the States". So, it amounts to a State/Government problem, the ECJ said: "you are collecting data from European citizens so you should protect them with the same guarantees that we provide in Europe". I think that the fact of guaranteeing protection is one thing, the second one is from whom you should be protected (you spoke about the State); if the vote is protected, but States know who has voted, what is protection or privacy? Or should the State not know, not have access to this data? So, the question of who should have access to the data is a very important notion. Peter mentioned it: the risks of giving data are its result, and the results that are coming back are statistical means.

Whether it is to predict someone's behavior, or to edit the genome of a child, everything that is rare is hard to predict. So rarity, diversity, originality are dangerous to predict. If you want to predict when it is frequent, you can on the basis of statistical analysis, but not when it is rare and so if you rely too much of behavior on statistical results, you will want a world in which behavior, genomes, and consent become frequent, because it is not possible to handle what is rare and what is diverse. There is a risk of 'normativization' not only as protection of the data but in what you expect from receiving data, it is transformative in the sense that - Jonathan mentioned it - it changes expectations, if I know what will happen that is good, if I do not want to know that is bad.

I think, upstream and downstream, it asks questions about guaranteeing privacy also in the one sense, of secret, non disclosure, and in the other of guaranteeing that doing things which are original - creators, artists - will not be seen by communities as dangerous, simply because Big Data cannot provide an outcome. The last thing that you have not commented concerns the book by Dave Eggers titled "The Circle", which is about a woman working in a company in which data sharing is seen as a virtue: it is virtuous to

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<sup>2</sup> This answer is a recording of the discussion, without the review of the speaker.

share anything and so a person who does not want to share what he/she thinks, does and feels, is a person who is a bad citizen that should be shamed because this prevents others from using his/her data; that may be a pressure, even an insidious pressure to give everything because it may be useful to others. You know, when we are always under public scrutiny we do not behave in the same way as when we are not, so it is not only about recollecting and observing data, it is about changing behavior upstream and downstream because of the pressure of conformity. I think we do have ways not to say privacy is no longer useful, rather we can continue to use it and have the best of both worlds, having new technologies bring us good things and protect things which we think are fundamental values and refrain from saying that if it is difficult then we should abandon the value. We should keep both: the value and the technology.

**MONTGOMERY:** I wanted to make a couple of observations about privacy. We have a couple of pages in our report on Big Data, trying to tease out what it is that we value about privacy, and I think we should remember privacy is not really a single thing, is a cluster of things. So just picking up three that seem to me particularly important in relation to this area. One is that we value privacy because of the opportunity it gives us to share our lives and learn who we are. Of course, that isn't private in the secret sense because you can't do that except in relationships with other people. It doesn't mean you can be completely isolated but it means that we need a degree of control. So if what we see in the Big Data is a loss of control, then it will undermine that. Second, is the set of arguments about privacy which are about protection from State control. It seems to me in relation to Big Data, the question really is whether we are substituting other institutions for the State in that paradigm. At a simplistic level, the Google philosophy feels very like the type of state controls that we worry about. In simplistic contrast, Apple's philosophy tends not too because it does not hold data in itself but rather passes it through its applications. So the argument about whether or not this is destroying privacy will be different depending on those institutions. The third thing about privacy is that, this goes back to one of the points made by Peter, one of the big challenges is about re-purposing. This was a quite strong argument in our report on Big Data. We illustrated it with some fairly easy examples. If you publish private diaries, what you're doing is taking data that belongs to one sphere and moving it into another. If you hack someone's phone messages you are also doing that. So I think Peter's point about the challenge of Big Data arising from the way it brings together things that do not belong together is a really important insight. Finally, I want to pick up something that Jean Claude said about how we behave differently when we are under scrutiny, I wonder how new this set of problems really is. There is a very long theological tradition about thing about being under the divine gaze that addresses such issues. When we consider the predictive abilities that Big Data brings, we should perhaps relate it to older answers to ancient questions about free will and predetermination. We should not be seduced into thinking that just because something is done digitally or technically it is a completely new set of human problems.

**AMEISEN:** Under God's gaze, means, being observed but not shared. God does not tell us, usually, what He thinks. One of the big questions is when do we have new ethical problems and when do we have ancient ethical problems in new forms. Sometimes the fact that they have new forms has very big implications.

**DABROCK:** Of course, Jonathan, you provoked the theologian, I am called to give a comment on this analogy not only to grace but also to the idea of God's providence and I think there are really some analogies between God's providence and the Data collection analysis and also the prospect big companies gain from their mostly comprehensive analysis. But I think there is another really crucial difference, not only that God does not share - as a Christian theologian, I can say: well He shares with himself - but another point is that in terms of God's use of the data you have, if you take it in the Christian understanding of God, you have God's promise that it is for well-being, not for the single utility of a company or industry which exploits the data and is not primarily interested in the well-being of the other. I think this mixing-up between ultimate and penultimate elements of life, this helps to use this analogy of God's providence because it demonstrates clearly where the limits and threats of these given technologies are.

**AMEISEN:** you make me think of when in States where religions are not separated from temporal power, you get totalitarianism, so the fact that what God sees and how it is interpreted becomes a way of controlling people, leads very often to totalitarianism.

**d'AVACK:** I agree it is necessary to safeguard the right to privacy, necessarily by renouncing traditional schemes but I also see great difficulties in being able to safeguard it. This is also because informed consent in this sector acquires its own specific nature. This consent must be based on legible, synthetic information regarding the type of data, the modes of gathering them, their processing procedures, and their analysis and use. These requirements are not simple to ensure. It is thus indispensable for the user to be aware of the limits to privacy, just as he or she must be aware of the difficulty of obtaining the "right to be forgotten". I recall that as early as the 1990s, Spiros Simitis, who was at the vanguard in the theories on privacy, stated that no progress could be called such until it is reconciled with the individual right to decide what personal data can be disseminated, and when. After a number of decades, the question remains open, and data hunters are working in anarchy.

In any case, I think it cannot be the companies themselves to regulate the protection of privacy, but States. Today, the prevailing model is that of notification/consent. It was thought that the solution was to entrust companies with the options on the citizens' online navigation, leaving the choice to them. It is an unconvincing solution, as it does not ensure the nature of the consent process: to make transparent - within the limits of security and of free trade - the terms of the agreement between citizen and institutions, and to lay on the table the risks and benefits of the market for personal data. Now, I think the relationship between privacy and transparency is a political matter par excellence, and therefore it must be the State to safeguard privacy by legislation. The difficulty in regulating the matter shall not lead lawmakers to elude their duties, which are those of protecting not only personal data (confidentiality, secrecy, privacy), but also personal freedom, with appropriate anti-discrimination laws that allow the new technologies' "social risks" to be adequately supervised.

There is lastly the circular relationship pointed to by Dabrock when speaking of education, participation, and transparency. I agree that education in a new world should begin as soon as possible, right from the early schooling phases. Moreover, this new world

cannot be stopped, and I do not think we can imagine setting particular limits; it is also quite difficult to set these limits when doing so would actually bring no benefit at all.

At times, I am concerned, given past experiences, that these new technologies may also become the instrument for the exercise of a power that is not a democratic one, but a power that controls. Let us not forget that economy, politics, and biotechnologies are “strong” powers that increase but at the same time compress the terrain of freedom: fundamental rights are in general to be affirmed and defended against the powers. This should be done by biolaw in the age of the “new technological wave” of emerging technologies and big data.

