

Swiss National Advisory Commission
on Biomedical Ethics NCE

2016 Report on the Activities

**for the attention of the Federal Council,
Parliament and the general public**

Contents

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Foreword

The extra-parliamentary commissions have been reconstituted. At the beginning of 2016, I was appointed as Chair of the NCE – a challenge I was happy to take on. At the same time, three new members – Drs Hélène Beutler, Karen Nestor and Dorothea Wunder – joined the Commission.

For the Commission, 2016 was an eventful year: having been reconstituted, it defined its priorities and reviewed its organisation and working methods. The diversity of disciplines and positions represented within the NCE is an asset that we wish to utilise and highlight as such. In addition, because we wish to further strengthen the Commission's public presence, new formats are under consideration.

In June, the Commission published an Opinion on "Gene editing in human embryos". From the beginning of the year, the CRISPR/Cas9 technique, which allows targeted modification of the genome in living cells, had been widely covered in the press. The possibility of deliberately modifying the human germline raises some familiar, but also new, ethical questions: not only do germline interventions affect the development of the unborn child, but the changes are also passed on to future generations. In its Opinion, the NCE underlines the urgent need for our society to engage closely, critically, openly and transparently with the ethical implications of ongoing technological developments.

Considerable media interest was also generated by the second NCE Opinion published in 2016 – "On the ethical assessment of non-invasive prenatal testing (NIPT)". Among the issues discussed in this Opinion are the prohibition on the disclosure of the embryo's sex to the mother or couple during the first twelve

weeks of pregnancy and the risks of routine application of NIPT.

One of the year's highlights was the start of a series of lectures on the subject of the beginning of life, which are available as podcasts on the NCE website and are thus widely accessible. The beginning of life raises questions which are of relevance in many areas of biomedical ethics – for example, the question of the embryo's status, women's self determination and human dignity. This acclaimed NCE lecture series includes contributions from representatives of various disciplines and schools of thought.

Biomedical developments are proceeding apace. More options also mean greater individual and social responsibility. This makes it all the more important to take the time to discuss ethical issues in detail. I am grateful for the confidence placed in me – and for the numerous stimulating discussions that have taken place both within and outside of the Commission.

Zurich, June 2017
Andrea Büchler, Chair

1. Legal foundations and mandate

The Swiss National Advisory Commission on Biomedical Ethics is an extra-parliamentary body, which was established by the Federal Council on 3 July 2001.

In carrying out its tasks, and especially in formulating its opinions, the Commission is obliged to remain independent of political, industrial and scientific interests.

The legal basis for the Commission is provided by:

- ✓ Article 28 of the Reproductive Medicine Act of 18 December 1998 (see beside) and
- ✓ the Ordinance on the National Advisory Commission on Biomedical Ethics of 4 December 2000 (SR 810.113).
- ✓ In addition, the Commission's deliberations are governed by the NCE Rules of Procedure of 29 October 2009.

The Commission's mandate is to conduct a careful and comprehensive assessment of ethical issues arising in the areas of medicine and healthcare, focusing in particular on new scientific knowledge and technological developments. It thus contributes to a process of opinion forming, at all levels of society, which is evidence-based and guided by arguments.

The emphasis is placed on the preparation of opinions and on communication with the public. The NCE does not, however, review individual research projects; this remains the responsibility of Switzerland's cantonal ethics committees.

Federal Act on Medically Assisted Reproduction ([Reproductive Medicine Act, RMA](#)) of 18 December 1998 (status as of 1 January 2013)

Chapter 3: National Ethics Commission

Art. 28

1. The Federal Council shall establish a national ethics commission.
2. The commission shall monitor developments in assisted reproductive techniques and gene technology in the area of human medicine and comment from an ethical perspective, in an advisory capacity, on associated social, scientific and legal issues.
3. In particular, the commission shall have the following tasks:
 - a. *to draw up additional guidelines relating to this Act;*
 - b. *to identify gaps in the legislation;*
 - c. *to advise the Federal Assembly, the Federal Council and the cantons on request;*
 - d. *to inform the public about important findings and to promote debate on ethical matters within society.*
4. The Federal Council shall determine the other tasks to be carried out by the commission in the area of human medicine. It shall enact implementing provisions.

2. Opinions

2.1 Overview of Opinions prepared by the Commission in the period under review

In 2016, the Commission addressed the following topics:

[Opinion no. 25/2016](#)

Gene editing in human embryos

(adopted on 3 June 2016)

[Opinion no. 26/2016](#)

On the ethical assessment of non-invasive prenatal testing

(adopted on 9 December 2016)

[Commission's response of 9 December 2016 to the consultation on the amendment of the Reproductive Medicine Ordinance \(RMO, SR 810.112.2\)](#)

2.2 Summary of NCE Opinions

Opinion no. 25/2016:

Gene editing in human embryos

In 2016, a gene editing technology known, somewhat cryptically, as CRISPR/Cas9 was widely covered in the press. This is a “new” genetic engineering tool for targeted genome modification in living cells. Compared to the methods used to date, CRISPR/Cas9 is much more straightforward and less costly. In a single operation, a number of different segments of DNA can be identified, cut out and replaced by other segments. From an ethical perspective, intervention in the germline of embryos is the most controversial aspect of this new technology. The possibility of using CRISPR/Cas9 for deliberate modification of the human germline raises some familiar ethical issues – already discussed in previous NCE Opinions – but also some new questions. Significantly, not only do germline interventions affect the development of the unborn child, but the changes are also passed on to future generations – they are irrevocable. There is agreement that the efficacy, risks, dangers and incidental effects of germline modification in embryos remain largely unknown. With regard to applications in humans, the technology is still far from mature. But what about potential gains in knowledge? And what does the future hold?

In its review of gene editing, the NCE notes that interventions in the genome of human germ cells and embryos are prohibited under current legislation (Art. 119 para. 2 let. a Federal Constitution; Art. 35 Reproductive Medicine Act). Some members of the Commission believe that this prohibition should be maintained at all costs. Others acknowledge the need for a moratorium on germline modifications at the present time, in particular to allow further assessment of medical risks and ethical questions. Lastly, part of the Commission wishes to exempt basic research on the embryonic germline from a moratorium and to permit such research. The NCE considers it essential that society should engage closely, critically, openly and transparently with the ethical implications of ongoing technological developments. The fundamental question needs to be asked, to what extent interventions in human genetic evolution can be legitimised – or perhaps even made to appear essential – by the prospect of curing diseases, avoiding disabilities or enhancing human capabilities.



All NCE publications (opinions and consultation responses) are available for download at www.nek-cne.ch

The NCE contributed to the public debate by holding a panel discussion on "Gene editing in human embryos" at Lucerne University on 20 October 2016 (see Section 3).

Opinion no. 26/2016:

On the ethical assessment of non-invasive prenatal testing (NIPT)

Prenatal testing options are being continuously improved and expanded, and a non invasive prenatal test (NIPT) was recently introduced. In its Opinion, the NCE comments on three controversial questions: (1) disclosure of the embryo's sex during the first twelve weeks of pregnancy, (2) the definition of a "significant health impairment" as a criterion for carrying out a test, and (3) the risks of routine application of NIPT. In its responses, the NCE emphasises the importance of individual responsibility on the part of those concerned.

NIPT expands the existing options for prenatal genetic testing. The test, which involves collecting a blood sample from a pregnant woman, provides information on certain genetic characteristics of the embryo. It can be carried out at an early stage of pregnancy, leading to a reduction in invasive diagnostic tests and associated miscarriages. From an ethical perspective, views differ as to whether the additional knowledge yielded by NIPT is to be regarded as an advantage or a disadvantage for the couple concerned, for the unborn child and for society.

In the first instance, NIPT raises similar ethical questions to those familiar from other prenatal tests. Mention should be made in particular of the practice of selective abortion, routine application, the availability of appropriate non-directive counselling, the expansion of screening to include more minor disorders or non-disease-related traits (e.g. the embryo's sex), equitable financing, appropriate handling of genetic information, undesirable social consequences such as further medicalisation of pregnancy, and possibly increasing pressure on couples to use existing and established test options.

In its Opinion, the NCE concludes that there are no compelling arguments justifying the prohibition on disclosing the embryo's sex to the mother during the first twelve weeks of pregnancy. However, it supports the

proposal to restrict screening to traits in the embryo associated with a significant health impairment, particularly as this involves an appeal to implicit normative assumptions about the dignity of human life. Lastly, the risks of routine application are not to be dismissed: therefore, the NCE takes the view that measures to counteract these risks – for example, ensuring the availability of appropriate genetic counselling – are now of particular importance.

3. Communication with the public

To mark the publication of Opinion no.°24/2015 on [Biobanks for research](#), the NCE organised a symposium – held in Bern on 2 May – for experts directly involved in the collection of biological materials linked to personal data. Dr Christine Currat (Executive Director of the [Swiss Biobanking Platform](#)), Professor Bernice Elger (Director of the Institute for Biomedical Ethics, Basel University), Michael Gerber (Head of Legal Area 3, FOPH), Dr Georges Imbert (Biobanking Project Leader, Novartis) and Dr Peter Grolimund (Senior Industry Consultant Life Sciences, Teradata) were thus able to discuss the recommendations formulated in the Opinion with Professors Andrea Büchler (NCE Chair) and Bernhard Rütsche (Working Group Chair) and other members of the Commission. As well as offering opportunities, biobanks involve risks to privacy and risks of discrimination; there is thus a need for appropriate regulation at the national and international level. The symposium was successful in terms of both the quality of the exchanges and public participation.

As part of its annual two-day regional meeting – held in Lucerne on 20/21 October – the Commission once again organised an [evening event for the public](#), including a panel discussion, on the subject of new gene editing techniques. The attendees were welcomed by Professor Bruno Staffelbach (Rector of Lucerne University), and an introduction to the topic was given by Professor Andrea Büchler (NCE Chair). Dr Benno Röthlisberger (NCE member; Head of Medical Genetics Division, Aarau Cantonal Hospital) spoke on “CRISPR/Cas9: heading towards designer babies?” and Professor Bernhard Rütsche (NCE member; Professor of Public Law and Philosophy of Law, Lucerne University) on “Eugenics from a legal/ethical standpoint”. The perspectives of the geneticist and the lawyer made it possible to compare different conceptions of interventions in the human genome. For the panel discussion, the two speakers were joined by PD Dr Hans Peter Bernhard (developmental biologist, Basel University), Professor Monika Bobbert (Chair of Moral Theology, Münster University), Professor Verena Briner (until 2016, Head of the Medical Department at Lucerne Cantonal Hospital and Visiting Professor at Lucerne University) and Professor Martin Hartmann (Chair of Philosophy, Lucerne University). The discussion was moderated by Professor Brigitte Tag (NCE member).

The Commission and its Chair and members were also present in the media in various contexts throughout 2016. Particular mention should be made of contributions and interviews on the topics of gene editing, reproductive medicine, the culture of death and dying, assisted suicide, biobanks, intersexuality and the economicisation of healthcare.

4. In-depth explorations

Lecture series: The beginning of life

In December 2016, the NCE launched a series of lectures on the subject of the beginning of life.

The beginning of life raises questions which are of relevance in many areas of biomedical ethics – for example, the question of the embryo's status, women's self-determination and human dignity. Discussions of these matters typically involve the expression of a wide variety of ethical perspectives. This lecture series includes contributions from representatives of various disciplines and schools of thought.

The series is addressed to members of the public interested in bioethical issues; to ensure that the lectures are widely accessible, they are available as [podcasts on the NCE website](#) (in German).

The series began on 9 December with presentations by two NCE members – Professor **Bernhard Rütsche** (a legal examination of the question "**Beginning of life – Are human embryos bearers of rights?**" and Professor **Frank Mathwig** (a philosophico-theological discussion entitled "**Beginning of life – between biology and biography**").

This series of lectures will continue at irregular intervals in 2017.

5. National and international cooperation

At the national level, the Commission – in cooperation with the [Central Ethics Committee](#) (CEC) of the Swiss Academy of Medical Sciences (SAMS) – is organising a series of public symposiums (2015–2018) on the subject of *Autonomy in medicine*. The second symposium, entitled [Autonomy and relationships](#), was held at the Inselspital in Bern on 7 July 2016. For ethical reasons, patients facing important health-related decisions should be able to exercise the greatest possible degree of autonomy. However, because autonomous decision-making requires interpersonal dialogue, this event focused on concepts of "relational autonomy". An introduction to the topic was given by NCE Chair Professor Andrea Büchler. In his presentation on "Contexts of decisional autonomy: their significance in the clinical setting", NCE Vice-Chair Professor Markus Zimmermann discussed how the capacity for autonomous decision-making develops and how patients in various life phases make decisions on recommended treatments. This was followed by in-depth reflection on how autonomy can be promoted, especially in cases where individual decision-making or mental capacity is reduced or not (yet) present. Clinical situations and areas of medicine were discussed where particular attention needs to be given to the promotion of autonomy – e.g. in psychiatry, in prison medicine, or in the intercultural context.

The [symposium proceedings](#) (in German, with a French summary) have been jointly published by the NCE and the SAMS.

NCE Chair Professor Andrea Büchler gave presentations at various events, including the following: "The relationship between (bio)ethics and law in the context of pluralism" (Zurich Cantonal Ethics Committee meeting, 31 October); "To be or to have? On the rights to own and use (one's) body parts" (International Conference "Human: Non-Human – Bodies, Things and Matter across Asia and Europe", Zurich University, 6–8 October); "Why is oocyte donation so problematic for Switzerland?" (OVA IVF Clinic Zurich training event, 6 October); "Reproductive rights" (42nd Feminist Lawyers' Conference, Vienna University, 7 May); "Tell me who the parents are... The construction of parenthood between tradition and medical advances" (ETH Zurich/UZH Collegium Helveticum, 13 April); "Surro-

gacy and ordre public" (MERH lunchtime event, Zurich University, 8 March); and "Genetic testing in children, designer human beings", Olten, 25 February).

At the *Colloque Alpin de soins palliatifs* on 8 April, NCE member Professor Samia Hurst spoke on "Requests for death – the context in Switzerland".

At the 17th Zurich Gerontology Symposium, NCE member Professor Katja Rost gave a presentation on "Health and ageing in the era of big data".

In the year under review, NCE member Professor Brigitte Tag gave the following presentations: "To what extent does medicine have a social responsibility?" (Zurich Geriatrics Forum, Stadtspital Waid, 23 September); "Ethical conflicts in organ transplantation" (Bioethics Committee of the Swiss Bishops' Conference meeting on *Organ transplantation – an ethical challenge*, 31 October); "Financing of preimplantation diagnosis" (MERH lunchtime event, Zurich University, 8 November); and "E-Health – Implementation in Canton Zurich" (MERH lunchtime event, Zurich University, 15 December).

The Commission has regular exchanges with the [Federal Ethics Committee on Non-Human Biotechnology \(ECNH\)](#), the [Expert Commission for Human Genetic Testing \(GUMEK\)](#) and the [Centre for Technology Assessment \(TA-SWISS\)](#), in whose Steering Committee the NCE's Executive Secretary, Dr Elisabeth Ehrenspäger, has the status of a guest without voting rights. In August, the Executive Secretary attended the annual meeting of the extra parliamentary social policy commissions, where the main topic was the different organisation models adopted by the various commissions.

Trinational meeting of German-speaking ethics commissions

Since 2013, the national ethics commissions of the German-speaking countries (Germany, Austria, Switzerland/DACH) have met once a year, taking turns to host the event. In 2013 in Vienna, the topics of transplantation medicine and genetic diagnosis were discussed. In 2014 in Berlin, discussions focused on questions relating to the welfare of the child in a medical context, arguments for and against compulsory vaccination, and the opportunities and risks of personalised

medicine. In 2015, the NCE invited the German Ethics Council and the Austrian Bioethics Commission to Bern for a meeting devoted to the topic of *Culture of death and dying*.

The venue for the [2016 DACH meeting](#) was once again Vienna: at this event, held in November and hosted by the Austrian Federal Chancellery, representatives of the three commissions discussed the topic of *Gene editing*. Three of the presentations were given by NCE members: Dr Benno Röthlisberger spoke on “CRISPR/Cas9: current state of science and applications”, Dr Karen Nestor on “Advances in genetic research and social utopias – what can we learn from history?”, and Professor Bernhard Rütsche on “Eugenics and the Constitution”. Presentations were also given by Professor Elisabeth Steinhagen-Thiessen (member of the German Ethics Council) on “Experience with lipoprotein lipase gene therapy in familial hyperchylomicronemia – a case report”, by Professor Markus Hengstschläger (member of the Austrian Bioethics Commission) on “Germline therapy – a critical look into the future”, by Professor Peter Kampits (member of the Austrian Bioethics Commission) on “Gene technology and conceptions of humanity”, and by Professor Peter Dabrock (Chair of the German Ethics Council) on “Ethical challenges posed by genome editing”.

On the second day, Professor Christiane Druml (Chair of the Austrian Bioethics Commission) opened the public part of the trilateral meeting, which included a presentation by Professor Andrea Büchler (Chair of the NCE) providing an overview of statements issued to date by international ethics bodies, including those of the Council of Europe, UNESCO, the US National Academies’ International Summit on Human Gene Editing, the German National Academy of Sciences (Leopoldina), the Union of the German Academies of Sciences and Humanities, and the Nuffield Council. While these statements agreed that further research should be conducted, they also called urgently for global standards on emerging applications. In many cases, there have been calls for a moratorium on germline editing, i.e. applications affecting future generations; in addition, the technology is still a long way from maturity. Participating in the subsequent panel discussion alongside Peter Dabrock were Rainer Riedl (DEBRA Austria patient organisation), Professor Johannes Gobertus Meran

(oncologist and Austrian Bioethics Commission member) and Karen Nestor (NCE member).

Global Summit

The theme of the [11th Global Summit](#) of National Ethics/Bioethics Committees – held in Berlin from 16 to 18 March – was “Global Health, Global Ethics, Global Justice”. The NCE was represented by its Chair, Professor Andrea Büchler. The event was attended by delegates from 100 countries, members of international organisations (e.g. WHO, UNESCO and CIOMS) and government officials. The opening address was given by the German Federal President, Joachim Gauck. The 2016 Global Summit was jointly organised by the German Ethics Council and WHO in close cooperation with UNESCO. The programme included four main topics: (1) Emerging and converging technologies, (2) Epidemics and global solidarity, (3) Bioethical policies and bioethical law, and (4) Raising social awareness of bioethical issues. The lively discussions demonstrated not only that there is a global dimension to many pressing issues but also that needs, priorities and available resources differ. The numerous contacts established with individuals and institutions will enhance the work of the NCE.

NEC Forum

The latest [meeting of the National Ethics Councils \(NEC\) Forum](#) was held in The Hague on 10 and 11 May; the NCE was represented by its Chair, Professor Andrea Büchler. The Forum enables the exchange of information on topics addressed by European NECs, and of best practices for their activities. The meeting focused on “*The ethics of e-health*”, “*Dementia*” and “*The future: new technologies and values*”. Of particular interest were the contributions on CRISPR/Cas9, highlighting the wide variety of fundamental approaches and ways of thinking which characterise different countries/regions and different actors.

UNESCO

The [UNESCO International Bioethics Committee \(IBC\)](#) focused on two topics – (1) big data and the complex issues raised by information-sharing across borders and (2) the urgent question of refugee health worldwide. Professor François-Xavier Putallaz of the NCE is a member of the IBC working group responsible for developing an initial reflection on the latter topic; excellent progress has been made.

6. Plenary meetings

In 2016, the Commission held five ordinary plenary meetings (on a total of six meeting days).

With the exception of the two-day meeting, which was hosted by Lucerne University, all the meetings took place in Bern.

7. Working groups

In the period under review, NCE working groups met to discuss the following topics:

7.1. Non-invasive prenatal testing

The working group held three meetings during the period under review in order, firstly, to define the aspects of NIPT to be considered in more detail and, secondly, to discuss the ethical implications with regard to the various perspectives in question. This provided the basis for the preparation of an Opinion.

7.2. The culture of death and dying

In the year under review, the working group met on one occasion to develop a first draft for an Opinion. The Opinion, in accordance with the Commission's mandate, will seek to draw attention to a number of questions and aspects which the NCE believes to be unjustly neglected in current end-of-life debates in Switzerland. The aim is, firstly, to address underlying societal changes with regard to the perception, experience and shaping of the final phase of life and, secondly, to identify associated ethical challenges for discussion.

7.3. Migration and health

The working group met twice during the period under review. Thanks to the hearings conducted, it was possible to appreciate the various dimensions of the topic and to begin the preparation of an Opinion.

7.4. Economisation of medicine

The working group met on two occasions during the period under review. Discussions focused on the definition of the questions to be studied.

8. Experts consulted

On the topic of migration and health, the following experts were consulted at the plenary meeting held on 8 July 2016:

- ✓ Michèle Baehler, Intercultural Interpreting Project Manager, National Programme on Migration and Health, FOPH
- ✓ Dr Melissa Dominicé Dao, staff physician, Primary Care & Transcultural Consultation, Geneva University Hospitals (HUG)
- ✓ Alexander Bischoff, PhD, Dean of Research and Development, School of Health Sciences, HES-SO, Fribourg
- ✓ Dr Christian J. Jäggi, Inter-Active Association, Meggen
- ✓ Dr Patrick Bodenmann, Medical Director, Migrant Care Unit (USMi), Head of the Centre for Vulnerable Populations (CPV), PMU, Lausanne.

9. Secretariat

The [Commission's Secretariat](#) comprises two employees, representing 1.3 full-time equivalents until the end of 2016, and 1.2 FTEs from 2017.

The Executive Secretary is Dr Elisabeth Ehrenspurger (80% position); Simone Romagnoli, PhD (50% position) works as a researcher.

Members of the Commission

Chair

Andrea Büchler, Prof. Dr. iur., Professor of Private Law and Comparative Law, Zurich University

Vice-Chair

Markus Zimmermann Prof. Dr. theol., Titular Professor of Christian Social Ethics, Department of Moral Theology and Ethics, Fribourg University

Hélène Beutler, Dr. med., Head of Department of Child and Adolescent Psychiatry, Neuchâtel Psychiatry Centre (CNP)

Samia Hurst, Prof. Dr. med. Associate Professor of Bioethics, Geneva University Medical School

Valérie Junod, Prof. Dr. iur., Adjunct Professor, Geneva University; Associate Professor, Lausanne University

Frank Mathwig, Prof. Dr. theol., Adjunct Professor of Ethics, Bern University; Theology and Ethics Officer, Federation of Swiss Protestant Churches (SEK)

Paolo Merlani, Prof. Dr. med., Head of Intensive Care Unit, Lugano Regional Hospital

Karen Nestor, Dr. med., Consultant, Palliative Care/Pain Management Centre, St Gallen Cantonal Hospital

François-Xavier Putallaz, Prof. Dr. phil., Adjunct Professor of Philosophy, Faculty of Theology, Fribourg University

Katja Rost, Prof. Dr. rer. oec., Professor of Sociology and Adjunct Professor of Economics, Institute of Sociology, Zurich University

Benno Röthlisberger, Dr. med., Head of Medical Genetics Division, Aarau Cantonal Hospital

Bernhard Rütsche, Prof. Dr. iur., Professor of Public Law and Philosophy of Law, Lucerne University

Maya Zumstein-Shaha, PD, PhD in Nursing, Senior Lecturer at University of Lausanne Institute of Nursing Sciences, CHUV Lausanne

Brigitte Tag, Prof. Dr. iur. utr., Professor of Criminal Law, Criminal Proceedings and Medical Law, Zurich University

Dorothea Wunder, PD Dr. med., Gynaecologist, Centre for Reproductive Medicine and Gynaecological Endocrinology (CPMA), Lausanne



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