



Nationale Ethikkommission im Bereich der Humanmedizin
Commission nationale d'éthique pour la médecine humaine
Commissione nazionale d'etica per la medicina
Swiss National Advisory Commission on Biomedical Ethics

2013 Report on the Activities
of the Swiss National Advisory Commission
on Biomedical Ethics (NEK-CNE)

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

Adopted by the Commission on 9 May 2014

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Foreword

Scientific and technological advances often, but not always, promote human welfare; this is particularly true of advances in human medicine. Here, the interests and needs of individual citizens seeking to shape their lives come up against economic challenges and social responsibilities. Progress in diagnostic and therapeutic techniques, for example, has opened up new possibilities for reproduction and life planning, which raise fundamental questions about life and death, the future of the community and the benefits of scientific research. In this context, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) sees itself as an instrument of the modern democratic, law-governed state. It helps to address ethical issues arising from contemporary, but also perennial, problems.

The Commission was established on the basis of Article 28 of the Reproductive Medicine Act, which came into force on 1 January 2001. Its task is to provide information on the current state of medical research, to explore the social possibilities and ethical problems associated with biotechnological methods in human medicine, and to contribute to the process of comprehensive ethical evaluation. Thanks to its independence, the Commission is able both to address topics proposed by the Federal Council and to select topics on its own initiative. In either case, it attempts to provide an in-depth analysis of ethical problems and – bearing in mind Switzerland’s democratic traditions, civil liberties and fundamental social rights – to develop recommendations, which are then (unless they are intended as a response to a specific request from the Federal Council) published for the attention of the government, Parliament and the public. Naturally, the Commission does not seek to pre-empt the decisions of the legislative authorities, but assumes the function of providing policy advice. The Commission cannot offer a definitive definition of what is ethically acceptable or morally justifiable, nor of what is ethically or morally desirable. However, with recourse to generally accepted moral – and especially legal-moral and medical-ethical – principles, it endeavours to work through the relevant problems, to formulate arguments illuminating the associated controversies and, as far as possible, to propose solutions capable of commanding a consensus.

Towards the end of 2013, the Commission approved its comprehensive Opinion entitled *Medically assisted reproduction: Ethical considerations and recommendations for the future*. This document covers a relatively broad spectrum of issues which are of public interest and arouse public concern. This wide-ranging approach was adopted for two reasons – one external, the other internal: firstly, a variety of normative questions have arisen within a relatively short period as a result of technological and social developments in the area of assisted reproduction; secondly, the membership of the Commission will change from 2014, since the tenure of seven members ended on 31 December 2013. As they had been following the controversies associated with assisted reproduction for more than a decade, this appeared to the Commission to be an opportune moment to review recent developments and offer its interpretation of the normative consequences. The Opinion is by no means intended to be the “last word” – especially since some of the positions adopted in this passionate debate are barely reconcilable – but the Commission hopes to contribute to a well-informed appreciation of the ethical issues involved. Such an appreciation is a prerequisite for a constructive public discussion and for the development of an appropriate legal framework.

Bern, May 2014

Otfried Höffe, 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 NEK-CNE is obliged to remain independent of political, industrial and scientific interests.

The legal basis for the NEK-CNE is provided by:

- Article 28 of the Reproductive Medicine Act of 18 December 1998 (see below) 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 NEK-CNE 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 recommendations, and on communication with the public. The NEK-CNE 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 2013, the Commission addressed the following topics:

Opinions:

Opinion no. 21 / 2013	<i>Ethical considerations concerning the financing of abortion</i> (published on 17 April 2013)
Opinion no. 22 / 2013	<i>Medically assisted reproduction: Ethical considerations and recommendations for the future</i> (published on 13 February 2014)

Opinions prepared as part of Federal Council consultation procedures:

- *NEK-CNE response to consultation on the Federal Act on the Registration of Cancer*, 21 March 2013
- *NEK-CNE response to consultation on the revision of the Federal Act on the Consultation Procedure*, 21 March 2013

⇒ All NEK-CNE publications (Opinions and consultation responses) are available for download at: www.nek-cne.ch

2.2 Summaries of NEK-CNE Opinions

Opinion no. 21/2013: *Ethical considerations concerning the financing of abortion* (published on 17 April 2013)

The aim of the popular initiative “Financing of abortion is a personal matter – relieving the burden on health insurance by removing the costs of pregnancy termination from basic health insurance” was to have termination of pregnancy removed from the list of services reimbursed under the mandatory health insurance system. The initiative was decisively rejected in the referendum held on 9 February 2014. Ahead of the vote, the Commission published its Opinion *Ethical considerations concerning the financing of abortion*, in which it concluded that the wording of the initiative was imprecise and contradictory, and unanimously recommended that the existing arrangements should be maintained – for the following reasons:

The heading and the text of the initiative do not match: The text refers to termination of pregnancy and selective reduction, while the heading only mentions termination. In addition, the intention and aims of the initiative are not clearly formulated in the text. It is not apparent whether the initiative is directed against reimbursement of the costs of terminations carried out under the first-trimester rule, or whether it also covers

terminations which are medically indicated in order to avoid the risk of severe damage to the health of the mother. The existing law emphasises that termination of pregnancy is neither a decision to be taken lightly nor a matter of arbitrary choice for the pregnant woman. This is true for terminations carried out during the first trimester and also later so as to prevent serious risks to the mother's physical health or severe mental distress. In both cases, the conditions for legal termination are clearly specified. These regulations protect both the unborn child and the mother. They are designed to prevent women from being forced by the state, either directly or indirectly, to carry a fetus to term. The attempt to weaken this protection and to exert indirect force – by excluding legal termination from reimbursement under basic health insurance – amounts to an insurance-based sanction which runs counter to the underlying purpose of the existing regulations on termination. It also disregards the state's duty not to cause harm to women. To protect personal integrity, there is a duty to ensure that a pregnancy can be terminated in accordance with medical standards and in compliance with the provisions of the Constitution and criminal law – irrespective of the pregnant woman's economic circumstances. In addition, making the decision whether or not to have a legal termination dependent on the pregnant woman's economic circumstances violates the elementary requirements of justice. Not least, the risk of terminations being carried out illegally or abroad would be considerably increased – with all the dangers this is known to pose to the life and health of the women concerned. Not only would the provision of high-quality counselling and medical treatment be called into question, but the protective function of the legislation would be undermined.

Opinion no. 22/2013: *Medically assisted reproduction: Ethical considerations and recommendations for the future* (published on 13 February 2014)

The Commission considers from an ethical viewpoint the medical, social and legal issues associated with assisted reproduction. Against the background of contemporary society, it critically reviews the normative values (human dignity, the family, the welfare of the child, personal freedom, and “nature” or “natural”) on which the existing legal provisions are based. Finally, it offers 13 recommendations.

In the first three recommendations, the Commission comments on the legal and ethical consequences of several types of preimplantation testing – for purposes of genetic diagnosis, aneuploidy detection and HLA typing to select a compatible tissue donor – which offer a means of preventing foreseeable suffering. A majority of the Commission recommends that these tests should be legalised for reasons of solidarity with the couples and families directly or indirectly affected by serious hereditary diseases. On this view, the aim should also be to ensure the consistency of legislation (as prenatal diagnosis, leading to terminations later in pregnancy, is already permissible).

The next three recommendations are concerned with the modalities and forms of gamete and embryo donation. In accordance with the principle of non-discrimination, the Commission unanimously recommends legalisation of sperm donation for unmarried heterosexual couples. In addition, a majority of the Commission recommends the legalisation of sperm donation for same-sex couples and single persons. The Commission also wishes to see an end to the prohibition on ovum and embryo donation.

Also discussed are the questions of surrogacy and the legal status of children born to surrogate mothers abroad: these children and their parents face major legal difficulties when entering Switzerland. The majority of the Commission believes that surrogacy may be accepted in principle but doubts that it is possible to establish an acceptable framework which would ensure appropriate protection for all parties, given the risks associated with

commercialisation of this practice.

Finally, the Commission emphasises that it is important for legal regulations to take account of good medical practice. In this connection, it advocates the removal of the specification of a maximum number of embryos that can be developed outside the woman's body, and it unanimously recommends the establishment of a registry of children born via assisted reproduction.

3. Communication with the public

In the period under review, the following public events were held by the NEK-CNE:

On 4 July 2013, the fifth in a series of public symposiums jointly organised by the NEK-CNE and the Swiss Academy of Medical Sciences (SAMS) on *Economisation of Medicine* took place in Bern. At this event, entitled *Medicine quo vadis? Ethical requirements for the management of the health system*, the ambivalent nature of incentives in medicine was discussed. Medicine is controlled, influenced and altered by economic or political incentives. Often they are deliberately employed to produce certain desired effects, but they also often operate at an unconscious level or produce unintended effects. The symposium first addressed the question of how and under what conditions incentives influence behaviour. Secondly, the ethical requirements for health system management models were discussed, bearing in mind that this topic has a systemic dimension, raising questions of social ethics, and also concerns the personal level, raising questions of individual ethics. These two dimensions were considered separately at the symposium. Once again, the event was attended by more than 150 people, with contributions from experts in fields such as medical practice, health economics, jurisprudence and ethics.

As is customary, to accompany its annual two-day meeting (held in Bellinzona on 24/25 October 2013), the NEK-CNE organised an evening event for the public, including a panel discussion. In line with the priorities defined for the Commission's activities in 2013, the topic of medically assisted reproduction was addressed, so as to promote debate on this issue in Italian-speaking Switzerland. Held at Bellinzona's Town Hall, the event was attended by about 40 people, who discussed various aspects of this topic. Among the speakers were Dr Jürg Stamm, a specialist in reproductive medicine and gynaecological endocrinology who is chief physician of the Cantonal Fertility Centre at the Ospedale Regionale di Locarno; the Cantonal Physician Dr Giorgio Merlani; and, representing the Commission, Professors Alberto Bondolfi and Olivier Guillod.

In 2013, once again, the Commission's public events attracted the attention of the media. Following the event in Bellinzona, the newspaper 'Corriere del Ticino' published a controversial debate featuring contributions from a commission member and a reproductive medicine specialist on the possible approval of pre-implantation diagnostics. The public presentation of the Commission's Opinion on medically assisted reproduction prompted a long series of print, radio and TV reports. The Opinion, which was prepared, written and adopted by the Commission in the year under review, was published in February 2014. Media coverage of the Opinion included around 20 articles in newspapers across Switzerland (*NZZ*, *Tages-Anzeiger*, *Schaffhauser Nachrichten*, *Aargauer Zeitung*, *WoZ*, *Le Temps*, *24 Heures*,

Tribune de Genève, L'Hebdo).

In addition, the NEK-CNE and its Chair and members were also present in the media in various contexts throughout 2013. Particular mention should be made of contributions and interviews on the topics of the presumed consent system in the area of transplantation medicine, intersexuality, reproductive medicine and the financing of abortion.

4. National and international cooperation

At the national level, the Commission once again organised a public symposium on the *Economisation of medicine* in cooperation with the SAMS (see above, Section 3). In addition, it was one of the sponsors of the TA-SWISS study on *Personalised Medicine*, with its representatives (Dr Bertrand Kiefer, Professor Brigitte Tag, Dr Elisabeth Ehrensperger) also actively participating in the Supervisory Group. Partly on the initiative of the Commission, the TA-SWISS Steering Committee decided to conduct a study on *Prenatal Genetic Diagnosis*, the sponsors of which will again include representatives of the Commission.

On 15 August, an NEK-CNE delegation (Dr Ruth Baumann-Hölzle and Professor Brigitte Tag) attended a hearing on the subject of *Preimplantation Genetic Diagnosis: Amendment of the Constitution and the Medically Assisted Reproduction Act* organised by the Council of States Committee for Science, Education and Culture (WBK-S).

Commission member Maya Shaha, PhD, and the General Secretary attended the "Health 2020" National Conference held in Bern on 9 September. The General Secretary also represented the Commission at the workshops on orphan diseases organised by the Health and Accident Insurance Directorate of the FOPH.

The Commission has regular exchanges with the Federal Ethics Committee on Non-Human Biotechnology (ECNH), the Expert Commission for Human Genetic Testing (GUMEK), the Federal Commission for Drug Issues (EKDF) and TA-SWISS, in whose Steering Committee the General Secretary of the NEK-CNE has the status of a guest without voting rights.

Trinational meeting of German-speaking ethics commissions in Vienna

At the inaugural meeting of the German-speaking ethics commissions, held on 4/5 March 2013, members of the German Ethics Council, the Austrian Bioethics Commission and the Swiss National Advisory Commission on Biomedical Ethics gathered to discuss current issues in transplantation medicine and genetic diagnosis. Specifically, the legal regulations on preimplantation genetic diagnosis in Germany and Switzerland were presented, and new methods of genetic diagnosis were discussed, as well as gene and genome tests available on the Internet. Representing the NEK-CNE at the meeting in Vienna was a delegation comprising the Chair, Professor Otfried Höffe; Dr Ruth Baumann-Hölzle, Professor Alberto Bondolfi, Dr Judith Pók, Professor Brigitte Tag and Maya Shaha, PhD; and the General Secretary, Dr Elisabeth Ehrensperger. Ruth Baumann-Hölzle gave a presentation in which she discussed the ethical implications of the presumed consent system and described the transplantation medicine situation in Switzerland. In another presentation, Brigitte Tag discussed the legal position in Switzerland with regard to current issues in genetic diagnosis. From now on, meetings will be held each year: in 2014, the event will be hosted by the German Ethics Council in Berlin, and the NEK-CNE will host the 2015 event in Bern.

Dr Jean Martin, a member of the NEK-CNE and also – until the end of 2013 – of the UNESCO International Bioethics Committee (IBC), attended the 20th (Ordinary) Session of the IBC which, at the invitation of the South Korean government, was held in Seoul from 19 to 21 June. The main topic of this session was the Draft Report of the IBC on the Principle of Non-Discrimination and Non-Stigmatization, as set forth in Article 11 of the UNESCO Universal Declaration on Bioethics and Human Rights.

The General Secretary, Dr Elisabeth Ehrensperger, and the scientific collaborator, Simone Romagnoli, PhD, represented the Commission at the conference on *Health research: Perspectives in social sciences* held on 14 June 2013 at the University of Fribourg and organised by the Swiss Academy of Humanities and Social Sciences (SAGW). The scientific collaborator also attended the conference on *Contesting Fertilities, Families and Sexualities: Social and Historical Perspectives on Assisted Reproductive Technologies* held on 5/6 September and organised by the Department of Social and Cultural Anthropology at the University of Zurich.

5. Plenary meetings

In 2013, the Commission held seven ordinary plenary meetings (on a total of eight meeting days); an additional meeting was held on 23 September. With the exception of the two-day meeting, which was held at Bellinzona Town Hall, all the meetings took place in Bern.

6. Working groups

In the period under review, NEK-CNE working groups met to discuss the following topics:

6.1. Reproductive medicine

In the year under review, this working group held six meetings to prepare an Opinion covering a wide variety of questions. Within the working group, the controversial topic of medically assisted reproduction generated intense and lively discussions. The Opinion was adopted at the plenary meeting held on 12 December 2013. Finalisation of the document – including translations into German, Italian and English – and preparations for printing took place at the beginning of 2014.

6.2. Cost/benefit evaluations

This working group had been set up in 2012 to carry out the necessary preliminary work (including definition of the issues to be covered) for the elaboration of an Opinion on ethical questions relating to cost/benefit evaluations in medicine. As preparations for the adoption of the Opinion on medically assisted reproduction were prioritised by the Commission, the activities of this working group were suspended during the second half of the year under review.

7. Experts consulted

In the period under review, the following experts were consulted for the ongoing work of the Commission:

- On the topic of *Medically assisted reproduction*:
 - Professor Andrea Büchler, Institute of Law, University of Zurich
 - Professor Dorothea Wunder, specialist in gynaecological endocrinology, Reproductive Medicine Unit, CHUV Lausanne
 - Professor Urs Scherrer, Swiss Cardiovascular Center Bern, University Hospital Bern
 - Dr Colette Rogivue, Biomedicine Division, Transplantation and Reproductive Medicine Section, Federal Office of Public Health
 - Dr Matthias Till Bürgin, Biomedicine Division, Transplantation and Reproductive Medicine Section, Federal Office of Public Health
 - Lic. iur. Peter Forster, Legal Affairs Division, Federal Office of Public Health

- On the topic of *Cost/benefit evaluations – Health Technology Assessment*:
 - Dr Daniel Grob, Medical Director, Chief Physician, Acute-Care Geriatric Department, Stadtspital Waid, Zurich
 - Professor Peter Breitschmid, Chair of Private Law (research focus: Swiss Civil Code), University of Zurich
 - Professor François Höpflinger, Institute of Sociology, University of Zurich
 - Professor Lorenz Imhof, Head of Research, Nursing, Zurich University of Applied Sciences
 - Dr Barbara Holzer, MPH, Center of Competence Multimorbidity, University of Zurich
 - Daniela Brunner, Head of Operational Management, Special Services, SPITEX Bern

8. Secretariat

The NEK-CNE Secretariat comprises two employees, representing a total of 1.4 full-time equivalents.

The General Secretary is Dr Elisabeth Ehrensperger (80% position); Simone Romagnoli, PhD (60% position) serves as a scientific collaborator.

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Members of the Commission

Chair:

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Ruth **Baumann-Hölzle**, Dr. theol., Director of the Interdisciplinary Institute of Healthcare Ethics, "Dialog Ethik", Zurich

Annette **Boehler**, Prof. Dr. med., Senior Physician in the Division of Pulmonology and Lung Transplant Programme, Zurich University Hospital

Alberto **Bondolfi**, Prof. Dr. theol., Emeritus Associate Professor of Ethics, University of Geneva

Kurt **Ebnetter-Fässler**, Dr. med., Specialist in General Medicine FMH, Appenzell

Carlo **Foppa**, PhD, clinical ethicist, "Communauté d'intérêts de La Côte", Morges Hospital

Olivier **Guillod**, Prof. Dr. iur., Professor of Civil Law and Director of the Institute of Health Law, University of Neuchâtel

Bertrand **Kiefer**, Dr. med., lic. theol., Editor-in-chief of Revue médicale suisse, Geneva

Jean **Martin**, PD Dr. med., former Cantonal Medical Officer and Privatdocent, University of Lausanne

Judit **Pók Lundquist**, Dr. med., Consultant Gynaecologist, Zurich University Hospital

Franziska **Probst**, lic. iur. and lic. phil., clinical psychologist, Zurich

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

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