



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

**2012 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

Contents

Foreword	2
1. Legal foundations and mandate	3
2. Opinions	4
3. Communication with the public	6
4. National and international cooperation	7
5. Plenary meetings	8
6. Working groups	8
7. Experts consulted	9
8. Secretariat	9
Annex	11

Foreword

The core responsibility of the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) is the provision of policy advice on ethical matters for the federal government. The Commission's task is to discuss ethical problems arising in medicine so as to support the democratic decision-making process. These problems emerge from the complex tensions existing between technological innovation and economic constraints, as well as normative social and institutional conditions, within a national and supranational framework. The Commission has to consider not only perceived changes in society's values but also new areas of action and options for intervention arising from technological developments. As an independent expert body, it seeks, in its Opinions, to explore the scope for action with regard to existing legislation in the public interest. It offers a forum for the discussion of contentious issues, such as whether homosexual couples – after appropriate amendments to legislation – should be granted access to new reproductive technologies. In discussing this question, consideration must also be given to existing relationships, in particular the mother-child relationship.

One of the challenges addressed by ethics is to assess whether, in view of changing circumstances, the moral norms underpinning society, medical practice and the legal system offer adequate guidance, or whether new regulations are required. There is a need to determine whether, from an ethical perspective, it is advisable to change or to maintain the norms prevailing within society in order to respond effectively to the risks associated with new technologies in particular.

In 2012 – the year reviewed in this report – the tensions between change and maintenance of the status quo were reflected in the Commission's activities and pronouncements. Thus, as regards the question whether it would be ethically justifiable, as a way of increasing the number of organ donors, to switch from an explicit to a presumed consent model, the Commission clearly endorsed the preservation of the existing system. The potential of presumed consent to deliver the expected benefits does not appear to the NEK-CNE to be empirically well-established; nor does the Commission consider this approach to be legitimate on fundamental ethical grounds. Accordingly, it recommends that, in this area, the current legal framework should be left unchanged. In contrast, as a result of its detailed consideration of the topic of "intersexuality", the Commission expressed its clear support for rapid change in a number of respects. Firstly, society should acknowledge the suffering which in the past has often been inflicted on individuals affected by this condition. At the same time, in the Commission's view, both the legal regulations and medical practice should be modified so as to ensure further improvements in the counselling, care and legal safeguards provided for people with DSD and their families.

The Commission was pleased to note the broad response generated by these Opinions among the public, healthcare professionals and those directly concerned, as well as in the media; it thus hopes to have helped to promote public debate on these issues, as this is another core responsibility of the NEK-CNE – and one which it will be happy to assume again in the current year.

Bern, June 2013

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 NEK-CNE Opinions issued in the period under review

In 2012, the Commission addressed the following topics:

NEK-CNE Opinions:

Opinion no. 19/2012	On presumed consent to organ donation: Ethical considerations (published on 25 October 2012)
Opinion no. 20/2012	On the management of differences of sex development: Ethical issues relating to “intersexuality” (published on 9 November 2012)

Opinions issued under the Federal Council's consultation procedures:

- NEK-CNE response to consultation on the Ordinances relating to the Human Research Act (issued on 26 October 2012) (only available in French/German)

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

2.2 Summary of NEK-CNE Opinions

Opinion no. 19/2012: On presumed consent to organ donation: Ethical considerations (published on 25 October 2012)

Under the presumed consent system, organs may be removed after death unless the person concerned has registered an objection to donation during his or her lifetime. In Switzerland, however, the “extended explicit consent” system applies: an organ donor must have explicitly consented to donation (e.g. via a donor card), or – if no wishes have been expressed by the deceased – consent to donation must be obtained from the relatives.

The Opinion requested by the Federal Council examines the question of whether a changeover to the presumed consent system – as currently advocated by certain groups within Switzerland – would be acceptable or even advisable from an ethical perspective. The Commission concludes, unanimously, that there is no case for changing the existing legal framework concerning consent to organ donation. In particular, it has yet to be empirically demonstrated that the presumed consent system leads to an increase in donor numbers. In the Commission's view, donation rates might even be adversely affected if public confidence were undermined by the introduction of presumed consent in Switzerland.

In addition, a clear majority of the Commission expresses its opposition to presumed consent on fundamental ethical grounds, since the removal of organs without the explicit consent of the person concerned (or the relatives) would represent a violation of individual rights.

Presumed consent would have to be accompanied by a mandatory declaration system so as to ensure that failure to opt out can actually be interpreted as consent to organ donation – rather than mere non-expression of wishes concerning organ donation. However, mandatory declaration would represent a significant restriction of the individual's decision-making autonomy and, at the federal level, involve a departure from the principle of neutrality with regard to organ donation.

Acknowledging the pressing nature of the problem of organ shortages, the Commission recommends that federal efforts and resources should be concentrated on measures to increase donor numbers which are demonstrably effective and ethically unobjectionable. As well as existing public information campaigns, such measures would include the optimization of processes within the transplantation system and in hospitals, improved identification of donors, training of health professionals, and professionalization of discussions with relatives.

The NEK-CNE Opinion was included as an Annex to the Federal Council's report published on 8 March 2013 (Examination of measures to increase the number of organs available for transplantation purposes in Switzerland) in response to the postulates submitted by Gutzwiller (10.3703), Amherd (10.3701) and Favre (10.3711).

Opinion no. 20/2012: On the management of differences of sex development: Ethical issues relating to “intersexuality” (published on 9 November 2012)

Having considered in depth the medical, psychological, ethical, legal and social issues arising in connection with the management of individuals born with ambiguous sexual characteristics, the NEK-CNE published its Opinion “On the management of differences of sex development: Ethical issues relating to ‘intersexuality’” as part of a public presentation held on 9 November 2012. In this Opinion, questions of legal and medical ethics are addressed, and 14 recommendations are formulated.

In its first recommendation, the Commission emphasizes that the suffering experienced by some people with differences of sex development (DSD) as a result of past medical practice should be acknowledged by society. It then calls for the provision of comprehensive, individually tailored counselling and support for all affected children and their parents, continuing from birth to young adulthood. In the Commission's view, multidisciplinary counselling and support services should be concentrated at a small number of specialized centres in Switzerland.

Until quite recently, sex assignment surgery was carried out on “child welfare” grounds in essentially healthy infants and children. Such procedures are irreversible and may have serious effects on the life of the person concerned. As a basic principle for the management of DSD, the Commission recommends that all (non-trivial) sex assignment treatment decisions which have irreversible consequences but can be deferred should not be taken until the person to be treated can decide for him/herself. In the Commission's view, a psychosocial indication is not in itself sufficient to justify such interventions. In order to prevent any pressure arising for premature surgical sex assignment procedures, the Commission suggests that restrictions on treatments covered by disability (IV) and health insurance schemes should be reconsidered, and that the age limit for IV coverage of somatic and psychological/psychiatric treatments for people with DSD should be raised.

In Switzerland, an indication of sex is required for the official registration of births, with only two sexes being recognized under the Swiss legal system. Individuals whose sex is not clearly identifiable as male or female are therefore assigned to one of these two categories.

Subsequent amendment of the officially recorded sex is extremely difficult. To avoid discrimination, the Commission argues that it should be possible for the recorded sex to be amended without undue bureaucracy; however, it is opposed to the introduction of a third category of sex at the present time. Lastly, the Commission recommends the adoption of clearer terminology: in order to avoid any negative or misleading connotations associated with the term “intersexuality”, DSD should only be referred to as “differences of sex development” or “sex variations” in non-specialist language.

The work of the NEK-CNE was undertaken partly at the request of the Federal Council, which – in its responses to the interpellations submitted in the National Council by Kiener Nellen (11.3265) and Glanzmann (11.3286) – had announced its intention to charge the Commission with the development of recommendations on the management of “intersexuality”.

3. Communication with the public

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

- On 5 July 2012, the fourth in a series of public symposiums jointly organized by the NEK-CNE and the Swiss Academy of Medical Sciences (SAMS) on the “Economization of Medicine” took place in Bern. At this symposium, entitled “Medicine for all? Ethical requirements for cost/benefit evaluations in medicine”, the principles and methods applied in the evaluation of costs and benefits in medicine were considered from an ethical perspective. The questions addressed included: What possibilities and limits are associated with the definition of quality of life as a key criterion in this area? What other criteria are of relevance? What has been the experience to date, and how is it to be assessed? And what specific requirements should be placed on such evaluation procedures from an ethical, legal, economic and political viewpoint? 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. Participating in the closing panel discussion were Dr Ignazio Cassis (National Councillor, FDP), Dr Ruth Baumann-Hölzle (co-director of Swiss Medical Board, member of NEK-CNE), Dr Reto Guetg (independent medical examiner, *santésuisse*), Professor Samia Hurst (Geneva University) and Professor Daniel Scheidegger (Basel University Hospital). The symposium presentations (in French/German) are available online at www.nek-cne.ch (under “Veranstaltungen”); some of the papers are also to be published in issue 2/2013 of the scientific journal *Bioethica Forum*, which is devoted to the NEK-CNE/SAMS symposium.
- As is customary, to accompany its annual two-day meeting (which in the year under review took place in Fribourg), the NEK-CNE organized an evening event for the public, including a panel discussion, on 25 October 2012. In line with the priorities defined for the Commission’s activities in 2012, this event also dealt with “Cost/benefit evaluations in medicine”, with one of the aims being to promote debate on this topic in French-speaking Switzerland. The event, held at Fribourg University, was attended by around 50 people, who discussed various aspects of this topic. Among the speakers was Anne-Claude Demierre, a member of the cantonal government and head of the Health and Social Affairs Directorate of Canton Fribourg. The participants in the closing panel discussion were Professor Daniel Betticher (Chief Physician, HFR Fribourg), Professor André Busato

(Bern University), Professor Samia Hurst (Geneva University) and Dr Bertrand Kiefer (member of NEK-CNE).

- On 9 November 2012, the NEK-CNE unveiled its Opinion no. 20/2012 (On the management of differences of sex development: Ethical issues relating to “intersexuality”) at a public presentation in Bern. At this well-attended event, which attracted wide media coverage, members of the Commission presented the Opinion and recommendations. Comments on the content from a personal perspective were then offered by human rights activist Daniela Truffer (Zwischengeschlecht.org), Dr Kathrin Zehnder (Zurich University) and PD Dr Michael Groneberg (Fribourg University).

In 2012, once again, the Commission’s public events attracted the attention of the media. For example, the “Economization of Medicine” symposium was covered by the *NZZ*, and a detailed report on the Fribourg event appeared in the newspaper *La Liberté*. The public presentation of the Commission’s Opinion on “Intersexuality” also prompted a long series of print media, radio and TV reports. In addition, the NEK-CNE and its Chair and members were also present in the media in various contexts throughout 2012. Particular mention should be made of contributions and interviews on the topics of enhancement, “intersexuality”, prenatal diagnosis (in connection with the introduction of the PraenaTest®) and the presumed consent system in the area of transplantation medicine.

4. National and international cooperation

At the national level, the Commission once again organized a public symposium on the “Economization of medicine” in cooperation with the SAMS (see above, Section 3). In addition, it is one of the sponsors of the TA-SWISS study on “Personalised Medicine”, with members of the NEK-CNE also actively participating in the Supervisory Group. 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.

As regards cooperation at the international level, the Chair of the Commission, Otfried Höffe, gave a presentation on 19 June 2012 in Copenhagen at the European Commission’s International Dialogue on Bioethics, an annual event organized by the European Group on Ethics in Science and New Technologies for representatives of national ethics councils from EU members and non-member countries. Jean Martin, a member of the NEK-CNE, and Jean-Daniel Strub, the Commission’s General Secretary, participated in the Global Summit of National Bioethics Advisory Bodies, which was held in Carthage (Tunisia) from 25 to 28 September 2012. Judit Pók, a member of the NEK-CNE, represented the Commission at a meeting of the NEC Forum in Nicosia (Cyprus) on 4/5 October. This event brings together national ethics councils from EU member countries and, for the first time, the two Swiss Commissions were also invited to attend. The Commission’s scientific collaborator, Susanne Brauer, took part in the World Congress on Bioethics, held in Rotterdam (Netherlands) from 26 to 29 June 2012. Finally, both members of the NEK-CNE Secretariat attended the annual meeting of the German National Ethics Council in Berlin on 24 May 2012, which focused on personalized medicine. They also engaged in in-depth discussions with their counterparts in the General Secretariat.

Jean Martin, a member of the NEK-CNE, has served on the International Bioethics Committee of UNESCO since 2006 (the IBC is composed of 36 individuals from around the world, nominated by member countries and appointed by the Director-General of UNESCO). The 19th session of the IBC was held in Paris in September 2012. The two reports finalized by the IBC in 2012 dealt with respect for human vulnerability and personal integrity, and with the ethical implications of traditional medicine systems.

6. Plenary meetings

In 2012, the Commission held six ordinary plenary meetings (on a total of seven meeting days). With the exception of the two-day meeting, which was hosted by Fribourg University, all the meetings took place in Bern.

7. Working groups

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

7.1 Reproductive medicine

This working group continued with the elaboration of a fundamental opinion on current ethical issues in the area of reproductive medicine. It is focusing in particular on existing reproductive medicine legislation in Switzerland and on the possible need for revision of current regulations on ethical grounds.

7.2 “Intersexuality”

This working group was responsible for preparing the draft version – subsequently discussed by the Commission as a whole – of Opinion no. 20/2012, which was presented to the public on 9 November 2012. In addition, during the period under review, it held a number of hearings to clarify key points with regard to the Commission’s Opinion. The working group was also involved in developing, preparing and conducting the public presentation of the Opinion.

7.3 Cost/benefit evaluations

This working group was 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. The predecessor of this working group was involved in developing and preparing the public events on this topic which were jointly organized by the Commission (as a thematic priority) and the SAMS. In its efforts to establish the terms of reference, the working group raised the issues of Health Technology Assessment and geriatric patients with multimorbidity.

8. Experts consulted

In the period under review, the following experts were consulted for the ongoing work of the NEK-CNE:

- On the topic of “intersexuality”:
 - Assistant Professor Michelle Cottier, Basel University, in cooperation with Professor Andrea Büchler, Zurich University
 - Professor Christa Flück, Paediatric Endocrinology, Inselspital Bern
 - PD Dr. phil. Michael Groneberg, Fribourg University
 - Professor Ulrich Meyer, President of the Second Social Law Division of the Federal Supreme Court
 - Daniela Truffer and Markus Bauer, human rights advocacy group “Zwischengeschlecht.org”
 - Mirjam Werlen, lic.iur./LL.M., Bern
 - Knut Werner-Rosen, psychologist/psychotherapist, Berlin
 - Dr Kathrin Zehnder, Zurich University

- On the topic of cost/benefit evaluations – Health Technology Assessment:
 - Dr Christian Affolter, santésuisse
 - Dr Andreas Faller, Federal Office of Public Health
 - Dr Daniel Herren, FMH & Swiss Medical Board
 - Dr Heiner Sandmeier, interpharma

9. Secretariat

The end of October 2012 saw the departure of both of the existing employees of the NEK-CNE Secretariat: Susanne Brauer PhD, who worked as a scientific collaborator (60% position), was succeeded on 1 November 2012 by Dr Simone Romagnoli (also a 60% position). The outgoing head of the Secretariat, Dr Jean-Daniel Strub, was replaced by Dr Elisabeth Ehrensperger, who took up her new role (an 80% position, as before) on 1 February 2013. The Secretariat thus continues to have a total of 1.4 full-time equivalents.

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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
- Maya Shaha, PhD, RN, Senior Lecturer (MER 1) at the University of Lausanne Institute of Nursing Sciences and scientific associate at Bern University Hospital, Nursing Care/MTT Directorate, Professional Development and Research
- Brigitte Tag, Prof. Dr. iur. utr., Professor of Criminal Law, Criminal Proceedings and Medical Law, University of Zurich