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Swiss National Advisory Commission on Biomedical Ethics

On presumed consent to organ donation

Ethical considerations

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Summary

In a letter dated 14 December 2011, the then-Head of the Federal Department of Home Affairs, Federal Councillor Didier Burkhalter, requested the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) to express its views on the following questions:

1. Are there any ethical concerns regarding the presumed consent system, and thus regarding a changeover to this system in Switzerland?
2. From an ethical perspective, what points would need to be considered if the presumed consent system were to be implemented – for example, public information, means of opting out (register), the role of relatives, the situation of health professionals, preparatory medical measures?

Fundamental decisions adopted by the Commission

1. As it is not clear whether donor numbers would be increased, remain unchanged or even decline if presumed consent were introduced in Switzerland, the Commission sees no reason to alter the legal framework in this respect. The Commission unanimously opposes recommending a changeover to the presumed consent system.
2. A clear majority of the Commission is opposed to presumed consent on fundamental ethical grounds, as this system affects individual rights. In order to ensure that organs are not removed without consent, presumed consent would have to be accompanied by a mandatory declaration system. 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.
3. A minority of the Commission takes the view that presumed consent would be ethically acceptable in principle but is opposed to a change in the legal position under the existing conditions: as it cannot be demonstrated that presumed consent leads to an increase in donor rates, there is no reason to change the relevant legislation.
4. **The Commission recommends that federal efforts and resources should be concentrated on measures to increase donor numbers which are demonstrably effective and ethically unobjectionable.** These include the optimization of processes within the transplantation system and in hospitals, improved identification of donors, training of health professionals, professionalization of discussions with relatives and, not least, information campaigns.

1. Is there a case for switching to presumed consent?

Under the presumed consent system, the removal of cadaveric organs is permissible unless an objection to donation has been registered by the person concerned during his or her lifetime. Underlying the renewed political debate on the legal authorization of organ removal is the expectation that, with presumed consent, the number of organ donors would increase. In the view of the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE), a change in the legal regulations should only be contemplated if it would in fact, demonstrably, lead to an increase in donor numbers or other improvements in the transplantation system.

However, this expectation is not confirmed by evidence from other countries. While donor rates increased after the introduction of a presumed consent system in some countries (e.g. Belgium¹), rates were unchanged in other countries (e.g. Sweden² and Singapore) or even declined (e.g. Brazil³, Denmark⁴, Latvia⁵). At the same time, in certain countries (Australia, the US), the introduction of an explicit consent system has been associated with an increase in donor rates.

It should also be borne in mind that, as legal practice often fails to coincide with legal theory, the differences between practices in countries with or without presumed consent are limited.⁶ A case in point is Spain: while, under the presumed consent regime, Spain is the country with the highest donor rates, organs are still only removed with the consent of relatives.⁷

It is true that, statistically, the majority of countries with some form of presumed consent show higher donor rates⁸ and higher levels of willingness to donate than are observed under explicit consent systems.⁹ However, given the complex interaction of multiple factors, it is not possible to demonstrate an unequivocal causal relationship between presumed consent and an increase in donor rates in any individual country;¹⁰ often, the introduction of this system has been accompanied by other measures which have a demonstrable positive impact on donor rates.¹¹ These include, in particular, public education¹², optimization of hospital processes and logistics¹³, transparency and promotion of confidence in donation systems¹⁴, effective identification of donors¹⁵ and training of health professionals.

The importance of a wide range of accompanying measures is also demonstrated by the history of transplantation in Switzerland. In Cantons Geneva and Zurich, donor numbers were not adversely affected by the changeover from presumed consent to an extended explicit consent system, which became mandatory nationwide when the Transplantation Act came into force on 1 July 2007. In Canton Ticino, which until recently had the country's highest donor rate, explicit consent was already applicable before the introduction of the Transplantation Act. Organ donation rates in Switzerland thus depend on a variety of factors.

There is also evidence that donation rates in Switzerland are influenced in particular by whether or not consent can be obtained from relatives.¹⁶ Donation rates in this country could therefore be adversely affected if presu-

¹ a et al. 2005

² Coppen et al. 2008..

³ Zink et al. 2005.

⁴ Zink et al. 2005

⁵ Robson 2005.

⁶ Boyarsky et al. 2011; Jannsen/ Gevers 2005.

⁷ Manatschal/Thomann 2011.

⁸ Da Silva et al. 2007; Horvat et al. 2010.

⁹ Mossialos et al. 2008.

¹⁰ Coppen et al. 2010; Healy 2005; Simillis 2010; a different conclusion is reached by Abadie/Gay 2006.

¹¹ Neades 2009, pp. 274f.

¹² Siminoff et al. 2012.

¹³ Seiler et al. 2006

¹⁴ European Commission/DG 2011.

¹⁵ Cf. *Programme Latin de Don d'Organes* (PLDO) – Swisstransplant 2010, p. 19, Manatschal/Thomann 2011, p. 35; Roels/Rahmel 2011, p. 362.

¹⁶ Dunkel 2011; Volz Wenger/Szucs 2010.

med consent undermined confidence and led to opposition among relatives. In addition, willingness to donate is significantly influenced by cultural attitudes to organ donation¹⁷, which show marked regional variation in Switzerland.¹⁸

Conclusions (1)

As donor rates in Switzerland would not necessarily be increased – and could even be reduced – by a presumed consent system, the NEK-CNE concludes that there is no case for introducing a system of this kind. For the Commission, this represents a sufficient reason not to recommend a change to the current explicit consent model.

2 Question 1: Ethical concerns regarding presumed consent

Organ removal is legally and ethically permissible as long as human dignity, individual rights and health are not adversely affected. The Transplantation Act (TxG) is designed to protect these basic goods.¹⁹ Also of legal and ethical relevance are the neutral stance adopted by the federal authorities towards transplantation medicine, and the conception of organ donation as an altruistic decision on the part of the donor. **Against this background, the Commission has considered the question of whether there are any fundamental ethical concerns which would rule out a presumed consent system even if the empirical situation** (as outlined in the previous section) **were to change.**

2.1 Human dignity

The Federal Council's Dispatch on the Transplantation Act specifies three aspects of human dignity which are relevant to transplantation. Human dignity is to be respected firstly when organs, tissues or cells are removed, and secondly in relation to the determination of death. Thirdly, the right to death with dignity is to be respected.²⁰

Whether there is a conflict between presumed consent and human dignity depends on one's notion of human dignity, the content of which is a matter of controversy. Explicit consent does, however, seem to accord more closely with human dignity than presumed consent.

¹⁷ Wright 2007.

¹⁸ Schulz et al. 2006; Balthasar/Müller 2009.

¹⁹ Dispatch of the Federal Council on the TxG, pp. 132f.

²⁰ Dispatch of the Federal Council on the TxG, p. 132.

2.2 Protection of individual rights

According to the Federal Council's Dispatch on the Transplantation Act, people are endowed with individual rights by virtue of their humanity and existence.²¹ In the context of transplantation, respect for individual rights involves in particular the protection of life, physical and mental integrity, and autonomy. In certain respects, individual rights also extend beyond death, even though from a legal perspective a cadaver is not a person. Thus, parts of a cadaver may not be removed against the wishes of the person entitled thereto (Art. 262, Para. 2, Swiss Criminal Code/StGB). The cadaver's right to protection is based on the need to respect the relatives' (and society's) remembrance and reverence for the deceased. However, such respect does not necessarily require that the cadaver should remain intact. For the Commission, the question arises whether individual rights – especially with regard to autonomy – would be affected by the introduction of presumed consent.

In support of presumed consent it is argued that, under the current explicit consent system, insufficient consideration is given to the unexpressed wishes of people who are willing to donate. Surveys of the population are said to show that the stated willingness to donate exceeds by far the actual number of donor cards.²² By failing to remove people's organs, one is thus acting contrary to their (unexpressed) wishes. In the Commission's view, however, this argument is not sound, since people who are willing to donate are responsible for ensuring that their wishes are known and can thus be put into effect. This responsibility represents a core element of their personality and their individual freedom of choice. **The claim that, statistically, people are highly likely to have been willing, during their lifetime, to donate an organ, cannot either override the individual right to *decide for oneself* about the removal of organs, or absolve other people of their duty to respect this individual right.**

Proponents of presumed consent would also have to accept this line of argument, as long as they intend organ removal to be based on some form of consent. In their view, silence, i.e. failure to register opposition to organ removal, is a sufficient form of consent. The Commission has reservations about this: silence can only – if ever – be construed as a form of consent if it is identifiable as such. Consent to organ donation should thus not merely be assumed – it must actually exist.

In essence, this line of argument is supported by a ruling of the Federal Supreme Court. The ruling states that silence can only be deemed to constitute consent to organ removal under certain conditions – namely, if all sections of the population regularly receive the relevant information on the regulations concerning organ removal, and it is additionally ensured that the people concerned have understood these regulations.²³ It must also be possible for them to express and document their opposition, and to revise this at any time. The Federal Supreme Court thus makes presumed consent subject to a duty to provide information. A requirement to inform organ donors and recipients, health professionals and the public is also specified in the Additional Protocol to the Convention on Human Rights and Biome-

²¹ Dispatch of the Federal Council on the TxG, p. 132.

²² Balthasar/Müller 2009.

²³ BGE 123 I 112.

dicine concerning Transplantation of Organs and Tissues of Human Origin, which came into force in Switzerland on 1 March 2010.²⁴

In the Commission's view, however, a mere duty to provide information is not sufficient. For if no declaration has been made concerning organ donation, this could also mean that a person's wishes are simply not known. Under the presumed consent system, silence may indicate either consent to organ removal or failure to express one's wishes. **The ambiguous nature of silence and the associated uncertainty as to whether a person is in agreement with organ donation would need to be eliminated so as to ensure that organs are not removed without people's consent and that individual rights are protected.** The only conceivable option would be a mandatory declaration system, under which people would be obliged to express their wishes concerning organ donation.

But the implications of a **mandatory declaration** system, in the Commission's view, are **ethically problematic**. (1) With mandatory declaration, it is no longer possible for people *not* to address the topic of organ donation – they are compelled to do so. For the Commission, however, the decision to consider organ donation is a personal one; here, the state should maintain its neutrality (see below, Section 2.4). (2) It would be necessary to determine what should happen in the event of non-compliance. The idea of imposing penalties for failure to make a declaration appears bizarre to the Commission, while organ removal in the absence of a declaration would represent a violation of individual rights. (3) With regard to organ donation, the Commission believes that people are free to abstain from making a declaration. (4) People could well have good reasons for choosing not to make a declaration – for example, the individuals concerned might be afraid of suffering discriminatory medical treatment, as their behaviour might be regarded as immoral and lacking in solidarity. (5) The implementation of mandatory declarations in practice would be costly and tie up resources which could otherwise be deployed for effective measures to increase donor rates. (6) It is not clear how the Swiss population would react to a *mandatory* declaration system; public confidence in transplantation medicine could possibly be undermined. (7) The combination of presumed consent with mandatory declarations could mean that the views of relatives would become legally irrelevant, as the wishes of the person concerned would always be known. This could only be prevented by granting relatives a veto, as was the case under the presumed consent system in Canton Geneva. **But in the Commission's view a veto for relatives is to be rejected** as it would negate the subsidiarity of relatives' wishes vis-à-vis those of the deceased. Under a presumed consent system, consideration for relatives' sense of reverence would be limited, for example, to efforts to minimize the period during which the cadaver was absent or to ensure the dignity of its physical appearance.

²⁴ Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Preamble, Articles 5 and 8.

Conclusions (2)

The Commission takes the view that organs should not be removed without the consent of the donor or – on a subsidiary basis, with due consideration of the donor’s presumed wishes – the next of kin. But presumed consent jeopardizes individual rights, as it may lead to organs being removed without the requisite consent. Silence can only be construed as an implicit form of consent under a mandatory declaration system. However, the Commission is opposed to mandatory declarations on the grounds of individual freedom. The Commission emphasizes that individual rights are not violated either as a result of the current explicit consent system or if organ removal is not undertaken because there are doubts or it is not known whether the person concerned would have consented.

2.3 Protection of health

The “protection of health”²⁵ mentioned in the Dispatch on the Transplantation Act relates primarily to organ recipients. They are not to be exposed to health risks (e.g. infection) as a result of transplantation, which should rather serve to extend life and improve the quality of life. The protection of human dignity, individual rights and health in a broader sense is also applicable to health professionals and relatives. It would therefore need to be considered whether the basic rights of these groups are affected by the uncertainties attaching to presumed consent. **For relatives in particular, but also for health professionals, it could be highly distressing if organ removal were carried out in spite of doubts as to its legitimacy.**

2.4 Requirement for neutrality of the state vis-à-vis transplantation medicine

The federal authorities have traditionally adhered to a principle of neutrality with regard to organ donation, under which such procedures are to be regulated and information is to be provided, but they are not to be promoted and individual decisions are to be respected. However, with the entry into force of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, the federal authorities are now obliged to take measures to increase donor numbers.²⁶ Irrespective of its actual impact on donor numbers, presumed consent can be regarded as a measure for the promotion of organ donation, as under this system organ removal becomes the “norm”, which one can only resist by opting out. Presumed consent would thus represent a departure from the traditional federal neutrality principle.

This change of position would certainly be welcomed by those in Switzerland who regard the shortage of organs as a public health problem which should be addressed by federal efforts to promote organ donation.

²⁵ Dispatch of the Federal Council on the TxG, p. 133.

²⁶ Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin, Preamble and Art. 19.

On this view, the federal authorities should in future pay greater attention to the interests of those patients who need an organ to extend their lives or enhance their quality of life, thus more effectively fulfilling the constitutional duty to protect human life.²⁷ However, the Commission takes the view that the public-health interest in transplantation is outweighed by the individual right to exercise control over one's body, even beyond death. No-one can claim an entitlement to "lost" organs belonging to another person. **The Commission recommends that the federal authorities should continue to adhere to the neutrality principle wherever individual rights would otherwise be violated.**

2.5 Organ donation as an altruistic decision on the part of the donor

Organ donation can be viewed as an expression of human solidarity, which deserves the support of the state. However, for reasons of individual freedom, people cannot be *obliged* to donate their organs. Unlike some advocates of presumed consent, the Commission does not believe that people have a moral obligation to donate organs, even if they would wish to receive an organ themselves. The logic of organ *donation* should not be superseded by a logic of organ *exchange*.

Accordingly, the Commission recommends that federal activities should be restricted to promoting a "**culture of giving**", thus strengthening solidarity and altruism as important motives for organ donation.²⁸ Under presumed consent, a "culture of giving" would be more difficult to foster.

3 Question 2: Ethical considerations relating to the implementation of presumed consent

3.1 Public information

In the Commission's view, to protect individual rights, organs should never be removed without the consent of the person concerned. Protection of these rights must also be assured under a presumed consent system. This requires that all potential organ donors in Switzerland should be informed of and comprehend the legal arrangements, and that they should have the option of expressing and recording their opposition, and of subsequently revising their wishes. It must be ensured that – as a result of poor language or reading skills, educational level, or socioeconomic/health status – no-one's understanding is limited to such an extent that their silence is construed as consent to organ donation. Elaborate efforts would thus be required to inform the public about presumed consent. The Commission emphasizes that only a mandatory declaration system could eliminate uncertainties as to whether silence is to be taken to indicate consent to organ donation. However, on the grounds of individual freedom, the Commission advises against the introduction of mandatory declarations (see above, Section 2.2).

²⁷ Art. 10 of the Federal Constitution.

²⁸ Rithalia et al. 2009, p. 3.

3.2 Means of opting out (register)

Under a presumed consent system, hospitals would need to have reliable and continuous access to the *latest* recorded wishes of potential organ donors. It would need to be defined who is responsible for the documentation of such wishes and how far this responsibility extends. Does the state merely have to provide a means of recording one's wishes, e.g. in the form of a register, or must it also ensure that everyone who is opposed to the removal of organs has actually opted out? Insofar as organ removal without consent represents a violation of individual rights, the Commission considers that the state would have a duty not only to provide a means of recording one's wishes but also to ensure that this option is utilized. In the absence of mandatory declarations, it would also have to be decided whether the information in the register is binding or whether it could be corrected in the light of the "presumed wishes" of the person concerned. This in turn would mean that relatives could exert an undue level of influence.

If a register were established, it would also need to be defined who is allowed to enter records (data control) and who would have access to the information recorded (data protection, data security). It would also need to be ensured that records are valid (data currency) and correctly assigned (identity security). Not least, the state would also have a responsibility to prevent social stigmatization of individuals who opt out and might thus be regarded as "lacking in solidarity". In this respect, access to the data would have to be carefully regulated.

3.3 Role of relatives

From a legal perspective, relatives would only play a role in an "extended" presumed consent system. They would have the task of making a decision on organ donation if the wishes of the person concerned were not known. If the Commission's recommendation to forgo mandatory declarations is followed, a particular problem arises under presumed consent: because each case where a person has failed to opt out can be interpreted not only as consent to organ donation, but also as an instance of unexpressed or unknown wishes, the relatives of the person concerned would have to be routinely consulted. This, however, would greatly increase the influence of the relatives. **Consequently, the priority of the wishes of the person concerned over the relatives' wishes – required by the principle of subsidiarity – would no longer be guaranteed. This would mean a restriction of individual autonomy.**

Evidence in the research literature suggests that the rate of refusal by relatives decreases under a presumed consent system²⁹, as it is easier to formulate a request to relatives if organ removal is the rule rather than the exception. However, relatives could also be uncertain as to whether the person concerned might have forgotten to opt out. There is also evidence that relatives could be distressed or even traumatized if organ removal were to become a standard procedure, whereas organ donation could alleviate the grieving process.³⁰ In addition, reference to legal regulations could provoke

²⁹ Delriviere/Boronovskis 2011.

³⁰ Rodriguez-Arias Vailhen 2009.

opposition among relatives, if presumed consent is not accepted by society. For relatives' consent, trust in the transplantation system is a decisive factor, which is promoted by transparent decisions and confidence that everything is being done for the patient's welfare. Here, there is a need for professional conduct of discussions by specially trained health professionals who are not involved in treatment, as well as sensitivity in the timing of an organ donation request (not to be made at the same time as the notification of death), the formulation of the request and the circumstances under which discussions are held. In view of the above-mentioned differences in mentality existing in Switzerland, a culturally sensitive approach to discussions is to be recommended.

3.4 Situation of health professionals

On this point, the Commission sees no need for any discussion beyond the concerns mentioned in Section 2.3.

3.5 Preparatory medical measures

The medical measures taken in preparation for a transplantation require the consent of the person concerned who, though still alive, is already incapacitated. In the view of a minority of the Commission, this consent can only be granted by the individual concerned – by means of an advance directive – and not by the relatives.³¹ The Commission is agreed that consent to preparatory medical measures should always be clear and unequivocal. The presumed consent system, which inherently involves ambiguity (silence may also indicate non-expression of wishes), is therefore not suitable as a form of consent in persons lacking capacity.

3.6 Parallel scientific research

If legislators decide to introduce a presumed consent system, the Commission recommends that scientific research should be conducted in parallel so that the consequences of the changeover can be analysed and, if necessary, control measures can be adopted in good time.

³¹ Cf. the Commission's submission (dated 15 September 2011) to the consultation on the partial revision of the Transplantation Act, available (in German) at www.nek-cne.ch.

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