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The ethics of non-heart-beating donation: how new technology can change the ethical landscape

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ABSTRACT

The global shortage of organs for transplantation and the development of new and better medical technologies for organ preservation have resulted in a renewed interest in non-heart-beating donation (NHBD). This article discusses ethical questions related to controlled and uncontrolled NHBD. It argues that certain preparative measures, such as giving anticoagulants, should be acceptable before patients are dead, but when they have passed a point where further curative treatment is futile, they are in the process of dying and they are unconscious. Furthermore, the article discusses consequences of technological developments based on improvement of a chest compression apparatus used today to make mechanical heart resuscitation. Such technological development can be used to transform cases of non-controlled NHBD to controlled NHBD. In our view, this is a step forward since the ethical difficulties related to controlled NHBD are easier to solve than those related to non-controlled NHBD. However, such technological developments also evoke other ethical questions.

Non-heart-beating donation (hereafter referred to as NHBD) was common in the 1970s. At that time, NHBD was the only way that the donation of vital organs could be performed according to “the dead donor rule” since organ donation was only acceptable after irreversible cardiac arrest. The acceptance of the whole-brain-death definition, that is, death defined as “the irreversible cessation of all functions of the entire brain, including the brain stem”,¹ changed this and it made transplantation of vital organs from brain-dead donors possible.

During the 1980s and 1990s, the number of heart-beating, brain-dead donors increased and NHBD gradually became less common. The development of new and better medical technologies for organ preservation and the global shortage of organs for transplantation have resulted, however, in a renewed interest in NHBD.

At present, there are protocols for both non-controlled and controlled NHBD.^{2–7} Non-controlled NHBD protocols are applied when resuscitation efforts fail after cardiac arrest. This situation usually occurs in the hospital, and most often in the emergency room. Controlled NHBD typically involves a patient who is on a ventilator. There is no hope of recovery, but the patient has brain activity. Furthermore, the heart as well as other organs still function. If further treatment is deemed futile, the medical team stops the artificial ventilation. After cardiac arrest has occurred and death has been declared, organs can be removed if the patient wanted to donate and if there are no

medical contraindications against NHBD. The required time span between cardiac arrest and the declaration of death varies between countries and NHBD/transplantation programmes (compare for example^{2–7}).

We consider NHBD to be an interesting way to increase the number of organs available for transplantation. However, it evokes a number of ethically difficult questions, some of which we will discuss in this paper.

- ▶ How long should one wait after cardiac arrest before declaring death and removing organs, if the donor wanted to donate when alive?
- ▶ For whose sake are preparations made? Donation, we will argue, is done for the benefit of recipients *and* out of respect for the donor’s autonomy.

One well-known controversy concerns whether preparative measures, such as giving anticoagulants, are acceptable before the patient is dead, in the interest of the recipients-to-be as well as for the donor-to-be. We will argue that such treatment is acceptable when a still living patient has reached a point where further curative treatment is futile, the patient is in the process of dying and she or he is deeply unconscious. We will call this point the *point of no return* and we will argue that this is the ethically important point. When the patient has passed beyond this point, nothing can be done to stop the process of dying and restore health. In practice, the existence of such a point has been accepted in all countries where it is deemed acceptable to abort treatment because it is futile.

- ▶ Another ethical question concerns how and when informed consent should be obtained.

Obtaining informed consent before one starts organ donation preparatory treatment is more complicated in the non-controlled NHBD case than in the controlled case. Below, we will argue that whereas explicit consent should be obtained before one starts organ donation preparatory treatments in controlled NHBD, and whereas it is an advantage to get an explicit consent for these treatments also in the early phase of the non-controlled NHBD, it should *not* be necessary when the person has passed the point of no return. Our reasons for holding this view are both practical and ethical.

Finally, even if these ethical questions were to be resolved, there are still problems—particularly in the case of non-controlled NHBD—related to the change from life-saving efforts to preparatory measures for organ donation. This paper discusses how NHBD can be done in an ethically acceptable way. It discusses the three ethical questions presented above. We will also discuss the

consequences of a possible technological development based on improvement of a chest compression apparatus used today to perform mechanical heart resuscitation. Such technological development can be used to transform cases of non-controlled NHBD into cases of controlled NHBD. In our view, this is a step forward since the ethical difficulties related to controlled NHBD are easier to solve than those related to non-controlled NHBD. Most of the ethical and psychological difficulties with NHBD are associated with the non-controlled case, where one starts with a life-saving treatment and then changes to preparatory measures for organ donation.

ON THE RELATION BETWEEN ETHICS AND LAW

In most countries, transplantation laws regulate the medical practice of organ donation. In our view, the ideal situation is that the relevant laws harmonise with ethics. However, it is not difficult to imagine scenarios in which laws and ethics do not harmonise. In such cases we suggest that the law should be changed. However, medical professionals should follow the existing laws—but they may argue and work for a change of the law.

THE ETHICS OF PRESENT-DAY NHBD

First ethical question: time span between cardiac arrest and declaration of death

When the British Transplant Society refers to brain-related death criteria, it states that it is a key requirement that a certain interval has elapsed without circulation, long enough to ensure that profound hypoxic injury to the brain has occurred—so that the capacity for consciousness and the capacity to breathe are irreversibly lost.⁸ An interval of five minutes “hands-off” is recommended,ⁱ provided that the patient has normal core body temperature.ⁱⁱ

This time span is disputed and NHBD protocols differ on what time is required without circulation. According to the Maastricht protocol, a ten-minute hands-off period is required to ensure that irreversible brain death has occurred.²⁻⁴ Other protocols state that it is mandatory to observe a no-touch interval of five minutes.⁵⁻⁹ Still others, such as the University of Pittsburg Medical Center policy, argue that death could be declared only two minutes after loss of cardiopulmonary function.^{7 10-12}

How long the waiting time needs to be should depend on what exact death criteria is being used.ⁱⁱⁱ However, for the present discussion, the important issue is not the exact minutes for the hands-off time. It is more important to consider when someone has passed the point of no return. For this reason, we will allow ourselves not to enter the discussion of exactly how long this hands-off time should be.^{iv}

ⁱ It should also be noted that a brain-stem concept of death is used in the United Kingdom.

ⁱⁱ During hypothermia, the human brain is able to withstand much longer periods of circulation arrest. See for example Litasova *et al.*²⁰

ⁱⁱⁱ Since most (but not all) countries have accepted the whole-brain death definition as the legally valid definition, we will allow ourselves not to discuss death definitions in this article. Furthermore, we will argue as if the whole-brain death definition was the legally accepted version. See²¹ for a death declaration law that accepts not only the whole-brain death definition as legal, but also the traditional heart-lung death

^{iv} If one holds the view that all the functions of the entire brain, including the brain stem, should be irreversibly lost, this may result in a longer necessary time-span than if one holds the view that it is the irreversible loss of higher brain functions that matters. A higher-brain-death definition implies that death is defined as the irreversible loss of higher cognitive functions.

Second ethical question: for whose sake is treatment done?

In order to discuss patients' medical treatment a distinction can be made between:

- ▶ treatment *before the point of no return*, ie, the point when (a) there is no curative treatment nor hope of spontaneous improvement, (b) the patient is in the process of dying and life cannot be prolonged more than marginally even with intensive care, and (c) the patient is deeply unconscious,
- ▶ treatment when the patient has passed this point, which we will call *treatment after the point of no return*,
- ▶ measures undertaken *after the patient is dead*.

We need also to distinguish between treatment for the health of the person and treatment for the sake of respecting the will of the person.

Clearly, *after death* nothing can be done for the sake of the patient's health. After the declaration of death, organ donation can take place if the patient has given her or his consent during life. If interventions are performed on the deceased after the declaration of death these are performed in the interest of the recipients-to-be. They are *also*, in our view, performed for the sake of respecting the will of the person *if* she or he wanted to become a donor.

What, then, about treatment *before the point of no return*? Before this point, the patient should *only* be treated for her/his own sake. This general rule, which obviously applies to the whole health care system, is important in order to maintain people's trust that medical treatment is given to patients in order to improve their situation and that no efforts are spared as long as the patient has not passed the point of no return.^v

After the point of no return, we will argue, it is ethically acceptable to start preparatory measures aiming at organ donation—for example, to give a large amount of heparin. In this stage, the patient is in the process of dying and is deeply unconscious. By definition, nothing curative can be done for the patient at this time though the patient is still alive. Since nothing curative can be done for the patient, s/he is in the process of dying and is deeply unconscious, we suggest that treatment may be initiated whose primary goal is good consequences for a future organ recipient.

Let us give an example from the Swedish situation. According to the Swedish transplantation act,¹³ the known will of the deceased person should always be respected. However, if the will of the deceased person is *not* known, which is often the case, presumed consent applies (and relatives have the right to say no to donation).

Organ donation is allowed when the patient has been declared dead and up to 24 hours after the declaration of death. Furthermore, when death has been declared, medical treatment for the sake of enabling a later organ donation *is* allowed even if the will of the deceased person is not yet known.¹⁴ It should be noted that in Sweden, the medical staff are advised not to discuss the patient's organ donation wishes, with her or his family members, before the declaration of death. Whereas it is possible to register one's view on donation in a national Donation Registry, medical professionals are *not allowed* to look into this Register for Organ Donation Advance Directives before the patient has been declared dead.

Consider now the following case: a patient is declared dead, and no preparatory treatment is initiated prior to death in order to make organ donation possible. The patient has not registered in the Donation Registry, but relatives (after death has been declared) say that the patient wanted to donate organs.

^v Obviously, if the patient is conscious, the rules of informed consent apply.

However, due to the time-factor, and since donation preparatory measures were not performed earlier on, donation is no longer possible.

In cases of this sort, the will of the deceased who did want to donate cannot be respected. We believe that those who want to donate should be given this possibility, since donation is a beneficent and possibly life-saving act. In accordance with the Swedish law, we hold that it is important that steps can be taken to enable donation when death is declared even if the will of the patient is yet unknown. However, in accordance with our ethical view—but in contrast to the Swedish law—we suggest that donation preparatory measures should be allowed *also* before death but after the point of no return, provided that it is not known that the patient did not want to donate organs and, in the case of controlled NHBD, provided that relations have given their informed consent.

It should be noted that this implies not that a human being is treated as a means only; she or he is treated as a means but also as an end. She or he is given heparin in the interest of others, *and* in order to ensure the possibility of respecting her/his will.^{vi}

We suggest that the will of those who did not want to donate is not harmed, even if they are given heparin *while information is being sought about what they wanted*: if they did not want to donate organs, such donation will not take place. If it is known beforehand that the patient did not want to donate organs, no preparatory measures aiming at organ donation should take place.^{vii}

Third ethical question: how and when should informed consent be obtained?

Informed consent for donation needs to be distinguished from informed consent for preparatory treatments in order to enable a possible organ donation. The third ethical question in need of being addressed is whether, and if so what kind of, informed consent for preparatory treatment is necessary in cases of NHBD.

It is commonly assumed that medical treatment should require informed consent in some form. There are also exceptions to be noted, such as when the patient is unconscious and in need of emergency treatment. In these cases, medical professionals act paternalistically, on the basis of what is assumed to be for the best of the patient, and consent is presumed. (However, also in these circumstances, relatives should be contacted expeditiously.)

It should be noted that many ethicists argue that one must put emphasis on the *informed* part of the informed consent. Although there are various ideas about how this part of the informed consent should be understood, many ethicists agree that the person who makes the decision (if not the patient, then perhaps some relative) needs to go through some process of deliberation.¹⁵ In the case of controlled NHBD, informed consent for preparatory treatments can in principle always be obtained (at least from the patients relatives) since there is more

^{vi} In a recent EU opinion poll, a majority of the Swedish population (74%) stated that they would like to donate their own organs after death.²²

^{vii} One more ethical argument can support our view of the acceptability of organ-preserving treatment after the point of no return. The doctrine of double effect can be applied to this specific scenario. Even though giving a large amount of heparin could cause further haemorrhage in patients with brain injuries and thereby hasten death, this act meets the requirements of the double effect principle. The act is performed for the sake of something good: to ensure fulfilment of the patients' wishes. The intention is *not* to hasten the patient's death. Furthermore, the risk of death due to heparin is not a means to achieve organ viability. And, the patient is already in the process of dying.

time. One may simply wait to stop ventilation and other treatment that is not palliative until informed consent from relatives has been obtained, or from the consent registrar, if such exist in the particular country. However, in most cases of non-controlled NHBD there is no time for such a deliberative process, provided that there is no answer to be found in a registry or in a written advance directive. The need for a very hasty decision, and the lack of time needed to make an informed one, therefore renders it problematic to *require* informed consent for preparatory treatments in the acute phase of non-controlled NHBD when the person has reached the point of no return. It is practically complicated, as well as ethically questionable, to urge relatives to make such a hasty decision.

We conclude that whereas informed consent for preparatory treatments should be required in cases of controlled NHBD, it should not be required in the acute phase of non-controlled NHBD when the person has reached the point of no return. Obviously, regarding valid informed consent, it would be advantageous if non-controlled NHBD could be transformed into controlled NHBD—as this would ease the problem of obtaining informed consent.

Controlled NHBD is less problematic than non-controlled NHBD since decisions do not need to be made in such haste. We believe that a change from a non-controlled to controlled NHBD situation would be positive and that it will be possible—given some technological development.

A FUTURE SCENARIO

Consider the following future scenario in which a pneumatic chest compression/decompression apparatus will be used. Such apparatuses, for example LUCAS (Joliffe AB, Lund, Sweden), are already approved for use in mobile emergency units.¹⁶ Our scenario is based on the possibility of further improving the present technology. Assume that a person outside the hospital suffers a myocardial infarction that leads to cardiac arrest. The ambulance arrives within a few minutes and resuscitation efforts by means of a highly effective pneumatic chest compression/decompression apparatus start immediately. This is aimed at saving the patient's life. Assume also that the patient can be intubated and ventilated immediately.

Even if resuscitation fails (the heart does not regain its function), pneumatic chest compression/decompression and ventilation may be continued until arrival to the emergency room. After arrival, the blood is still flowing to the brain and the patient is still alive. (We assume that the patient has not developed a total brain infarction though there has been severe brain damage.) When the patient is still attached to a heart compressor in the hospital (she or he has no spontaneous heart activity), relatives can be contacted in order to find out the patients' will. If the patient is *beyond the point of no return*, the compressor is withdrawn and, after relevant medical examination, death is declared. Organ donation may proceed, if the patient so wanted when alive. If the wish of the patient is not known, the relatives' consent should be sought.

This is a future controlled NHBD scenario, different from the controlled NHBD scenarios of today. Still, it resembles the present-day NHBD scenario in important ways. Resuscitation efforts start as soon as the ambulance arrives, the highly effective pneumatic chest compression/decompression apparatus making sure that heart as well as other organs function when the ambulance arrives at the hospital, and (we assume) during the next couple of hours. Relatives are contacted. If the patient wanted to donate, and if there are no medical contraindications against NHBD, the medical staff stops the

artificial ventilation, after consent from the relatives, and waits until cardiac arrest occurs.

In discussions of future scenarios, it is difficult to access how many organs can be retrieved. It is also difficult, for obvious reasons, to access the quality of these organs. However, non-controlled NHBD that result in transplantations of kidneys, livers and pancreas do occur today.^{16 17} Furthermore, there are reasons to believe that the future scenario can become reality. The pneumatic chest compression/decompression apparatus LUCAS has been used in cases of non-controlled NHBD. Steen and colleagues in Lund, Sweden, transplanted a lung in such a case, where the lung was reconditioned *ex vivo*.^{18 19} The transplantation was possible thanks to the usage of LUCAS.^{viii}

We may expect better results, the more similar to the present day controlled donation after cardiac death that the future scenario will become.^{ix}

The future scenario would do away with the special ethical and psychological problems surrounding non-controlled NHBD, such as the problem of informed consent in a very urgent situation and the change from life-saving efforts to organ donation preparation. It is an example of a scenario where some feasible technical advance may solve some ethical problems. However, the use of such future technology may also result in a new category of patients who survive a cardiac arrest and who live supported by the artificial heart compressor until their hearts either regain their activity or are replaced or supported by a medical device.

Ethical issues raised in the future scenario

Suppose the new chest compression technology is so effective that the scenario may occur. However, the use of chest compression technologies and artificial ventilation may not always restore the patient's health, nor may the patient die. In some cases the heart may regain its activity but only after there has been severe brain damage and the patient may end up in a vegetative state needing continuous life-supporting treatment. Here, the personal suffering of the patients and relatives, and the will of the patients need to be taken into account.

Another issue raised by new methods in transplantation and in particular the use of non-optimal organs (which may be the case at least in the early stages of our future scenario) is who should receive these "marginal" organs and what kind of informed consent is needed. However, this is a general problem in any expansion of what counts as acceptable organs for transplantation and not special to our scenario.

CONCLUDING REMARKS

Although some of the ethical problems outlined in this paper remain, this transformation of uncontrolled NHBD candidates into controlled NHBD candidates would give the medical staff the time needed to find out if consent for organ donation can be obtained, either through an advance directive of some sort or by giving the proxy enough time for reflection and a truly *informed* decision. The possible development of chest compression technologies may help to ease the ethical problems surrounding present-day NHBD.

^{viii} However, it should also be noted that this lung was first rejected as non-acceptable by the Scandinavian transplant centres; later it was accepted for transplantation.

^{ix} Of course, it could be argued that this is an expensive way of obtaining organs for donation and that living organ donation, as one example, is much less expensive. This, however, presumes that there are living organ donors that want to donate organs. This is not always the case.

However, the new advances in technology suggest that there will be a grey area between resuscitation efforts and measures that are undertaken in the interest of future transplant recipients. It is hard to define when resuscitation efforts including a heart compressor, such as LUCAS, stop being a tool for rescuing the patient's life and turn into a means for maintaining function, at least partly, of the organs in a possible organ donor.

Usually, attempts at resuscitation are made in the case of patients with cardiac arrest. We suggest that these attempts continue either until the patient recovers or reaches the point of no return. This may seem problematic, since the longer cardio-pulmonary resuscitation continues, the more severe mechanical damage to myocardium and lungs occurs. However, the actual Swedish scenario described above, which resembles our future scenario, did result in a lung transplant.

In the best possible scenario, the patient will survive with minimal or no brain damage. In another scenario, the patient would be a candidate for controlled NHBD, if she or he so wanted when alive.

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