

The National Advisory Board on
Social Welfare and Health Care Ethics ETENE

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**STATEMENT ON THE PARTICIPATION OF AN ANAESTHESIOLOGIST WHO HAS
PERFORMED THE APNEA TEST IN THE CARE OF A DECEASED PERSON'S ORGANS
FOR ORGAN REMOVAL**

On 17 April 2014, the Ministry of Social Affairs and Health requested a statement from ETENE on whether an anaesthesiologist having declared a person brain dead may care for the deceased person in an organ transplant operation. Attached to the request for a statement was a letter from Professor Helena Isoniemi, Chief Physician of the Transplantation and Liver Surgery Ward at Helsinki University Hospital, and Adjunct Professor Anna-Maria Koivusalo, Chief Physician of Helsinki University Hospital's Intensive Care Unit 20 at Meilahti, dated 25 March 2014, and a statement issued on this letter by Valvira on 14 April 2014. In addition, ETENE had access to legislation on this matter, as well as the relevant texts of the Council of Europe Convention on Human Rights and Biomedicine, its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin, and the Explanatory Report to the Additional Protocol.

ETENE discussed the matter at its meeting on 8 May 2014. The advisory board consulted Leena Soininen, Chief Physician from Helsinki University Hospital's Meilahti Hospital. Professor, Chief Physician Helena Isoniemi, Chief Physician Olli Kirvelä, and Chief Physician Tarja Randell from Helsinki University Hospital also provided background information on organ transplantation to ETENE.

Finnish legislation

Finland has ratified the Council of Europe Convention on Human Rights and Biomedicine (ETS 164, later referred to as the Biomedicine Convention) and the associated Additional Protocols to the Convention on the Prohibition of Cloning Human Beings (ETS 168) and on Transplantation of Organs and Tissues of Human Origin (ETS 186, later referred to as the Protocol on transplantation) by treaty 24/2010, which entered into force in Finland on 1 March 2010. Under Finnish health care legislation, organ transplantations are regulated by the Act on the Medical Use of Human Organs, Tissues and Cells (101/2001, later referred to as the Tissues Act). By virtue of this act, the Ministry of Social Affairs and Health has issued a decree on the certifying of death (asetus kuoleman toteamisesta, 27/2004).

The Biomedicine Convention's Protocol on transplantations contains provisions on organ and tissue removal from deceased persons (Chapter IV) and, in this context, on certification of death. In the Additional Protocol, the term "transplantation" covers the entire process from removing an organ until it is implanted in a recipient, including all procedures related to preparation, storage and retrieval. Article 16 of the Additional Protocol states that "the doctors certifying the death of a person shall not be the same doctors who participate directly in removal of organs or tissues from the deceased person, or subsequent transplantation procedures, or having responsibilities for the care of potential organ or tissue recipients."

A similar provision is included in the Tissues Act. The Act (Section 8(3)) notes that physicians who certify death may not be involved in transplantation of organs, tissues and cells. Subsection 2 of this Section prescribes that death must be certified as laid down in a Decree of the Ministry of Social Affairs and Health. The Tissues Act specifies that a person is considered to be dead when brain function has totally ceased. Decree 27/2004 specifies the procedure for establishing brain death. In addition, a guide issued by the Ministry of Social Affairs and Health 2004:5 (Kuoleman toteaminen: Opas terveydenhuollon henkilöstölle) contains



more detailed instructions on certifying death. The guide states that "doctors having certified the death, or having performed medical examinations preceding the certification, may not take part in caring for an organ transplant patient. Regardless of this, a doctor who has certified the death may provide care that maintains essential functions and carry out other requisite medical procedures until the removal of organs begins." In addition, the instructions state that doctors taking part in organ transplantation may not participate in certifying the death, or in discussions about organ donation with the family members of the brain dead patient.

In Finland, organ transplantations have been centralised to Helsinki Region University Hospital under a Government decree on the provision and centralisation of highly specialised medical care (valtioneuvoston asetus erityistason sairaanhoidon järjestämisestä ja keskittämisestä, 336/2011).

Organ transplantations in Finland

Organ transplantations have been carried out in Finland since 1964. A definition of brain death was provided in a National Board of Medicine's circular in 1971, after which organ transplantations developed rapidly. Today, an average of one hundred organ donations from deceased persons take place every year. Of these, nearly 30% are carried out at a central or a regional hospital (277 donations out of 955 in 2004 - 2013). The organs obtained from a single donor are on average used to treat three people, and at best, seven patients may receive an organ from the same donor. In 2013, organ transplants were received from 95 donors, of whom 63% donated multiple organs.

In 2013, the number of organ transplantations completed was 265. Over 350 people are on a waiting list for various organ transplants in Finland. Every year, approx. 6% of patients on this list die because no suitable transplant can be sourced for them. Organ transplantations can save the lives of patients with serious liver, heart and lung conditions. When the kidneys cease to function, the patient can be treated by dialyses even for extended periods. In severe heart failure, a mechanical pump can be used for a short period, and when the liver ceases to function, short-term albumin dialysis treatment is helpful.

In Finland, organ transplantations have been concentrated to Helsinki University Central Hospital (HUCH), and they are thus more centralised than in many other European countries. All organ transplantation operations in Finland are coordinated by the HUCH Transplantation Services. Organ donations come from all central hospitals and certain regional hospitals. All hospitals also treat patients who are on a waiting list for an organ, and patients having received a transplant.

The number of organ transplantations carried out is limited by the lack of donor organs. In 2013, there were on average 17.5 brain dead donors per one million inhabitants in Finland, whereas in Croatia and Spain, for example, this figure was over 30 donors per a million inhabitants. There also are significant regional differences in Finland in the number of organ donations in proportion to the population. An international study indicates that in 2007–2009, functional organs could only be retrieved from slightly over one half of potential donors in Finland. The greatest individual problem was identifying potential organ donors among seriously ill patients, which was relevant to over one fifth of the cases.

Organ transplantation and organ donation activities are quite clearly separated in Finland. The persons responsible for organ donations do not participate in transplantations, and those responsible for organ transplantations do not make decisions about organ donations. The objective of donations is ensuring that the organs are in as good a condition as possible for the transplantation. The results of organ transplantations in Finland are good: within one year of the transplantation, 85–95%, and after ten years, 60–80%, of the organs are functioning.



Organ transplantation process

Brain death in an organ donor is most typically caused by a severe brain haemorrhage or serious brain damage. The status of the brain is examined by such means as imaging, ultrasound examinations, measurements of electrical activity in the brain and similar. The purpose of neurological tests is to establish if the patient's brain or brain stem are still active. If not, an apnea test is carried out. If all these tests indicate that the patient's brain activity has ceased, the person may be declared dead. Brain death is usually certified by two doctors, one of whom is a neurologist or a neurosurgeon, and the other an anaesthesiologist or a critical care physician.

If the person is certified dead, the objective of his or her care will be optimal maintenance of the vitality and condition of the organs to be donated until they can be removed. The decision on whether or not these procedures will be initiated is usually made by a surgeon working at the hospital, who contacts HUCH Transplantation Services; the neurologist or anaesthesiologist having examined the patient does not take part in making these decisions. Based on the information provided, the transplantation team will decide whether or not the transplantation will go ahead and which organs could be used for treating patients in need of transplants.

If a transplantation is possible, the persons taking part in retrieving the organs prepare to travel from HUCH to the donor's hospital. At best, the team responsible for removing the organs can be ready for departure a couple of hours after the patient has been certified dead, but the required examinations may result in delays. The journey to the donor hospital may take no longer than two hours. Collecting the organs takes nine hours on average. Today, the number of staff members involved in retrieving multiple organs is rather large: dedicated teams are needed for removing a kidney, the heart and lungs, and the liver, intestine and pancreas, and in addition to surgeons, these groups include perioperative nurses and coordinators. If the distance to the donor hospital is short, the teams may depart at different times, but to such destinations as central hospitals in Northern Finland, the teams travel together by air.

In 2011, Helsinki University Hospital District gave up emergency duties for organ donations. This meant that one emergency unit was shut down, and also that the anaesthesiologist's duties were reallocated to other day-time functions at the hospital. This was justified by the fact that anaesthesiologists are needed during the day in many other tasks at the HUCH, and anaesthesiologists' on-call workload already was significant. The HUCH currently has 27 on-call anaesthesiology units, of which six at Meilahti Hospital, where the organ transplantations take place. The hospitals also work in the evenings to shorten waiting lists for operations, which adds to the anaesthesiologists' workload. The need to detach an anaesthesiologist from their normal duties may delay departure when collecting organs, and this delay may affect the functioning of the removed organs before the transplantation. The free time allowed as compensation for on-call duties may also disrupt normal surgery activities that require the specialist skills of anaesthesiologists. The number of anaesthesiologists competent in transplantations outside the HUCH is not sufficient to maintain emergency preparedness. Ethical questions related to organ transplantations

Organ transplantations represent modern patient care that requires top class expertise. A donated organ may save the recipient, or significantly improve his or her quality of life. The results of organ transplantations in Finland are excellent by international comparison: some nine out of ten organs function one year after the transplantation, and three out four are still functioning after five years. It has been estimated that a kidney transplantation brings savings amounting to some half a million euros in dialysis costs, and a transplanted kidney has already paid itself back within two years of its implantation. A heart transplant is also cost-effective compared to treatment with a mechanical support system. The cost effects are not, however, the only significant point of view: kidney transplantations allow patients to give up dialysis, which ties them to regular treatment, exposes them to risks and, according to patient experiences, is physically demanding. A mechanical pump device to support heart function also mainly ties the patient to hospital care. Studies conducted in Finland and elsewhere have found that in most cases, the quality of liver transplant patients improves after the transplantation.



Organ transplantations are mainly carried out as emergency operations. Almost all organ retrievals take place during on-call hours, and so do organ transplantations, which are carried out immediately after the organ retrieval team returns to the HUCH. Organs and tissues start decaying immediately after brain death, and the longer the time interval, the greater the risk of losing the donated organ.

Stringent ethical criteria and principles, as well as strict national and international regulations, apply to organ donations. The stringent regulations were put in place with the purpose of ensuring trust and preventing unethical activities. The regulations prohibit doctors who certify death from participating in any part of the organ transplantation process from the retrieval of organs to treating a transplant patient. The purpose of this is to separate the treatment of the donor and the recipient to ensure that the criteria for declaring a patient dead do not become lax, and that family members are not put under pressure to consent to an organ donation where a donation is inconsistent with the donor's will or beliefs. In the international context, trust in organ transplantations is undermined by the trade in organs in some countries. In Finland, organ transplantations have been centralised to a single university hospital maintained by the public health care system, which has the information of all patients on the waiting list and their health status on record. The results of organ transplantations are world class, and the level of trust in the activities is high. Organ donations and organ transplantations are administratively separated in Finland. These activities are also kept separate in the Helsinki and Uusimaa Hospital District, both operatively and administratively.

In Finland, a brain dead patient is examined by a neurologist or a neurosurgeon and an anaesthesiologist. Several other persons with specialist skills also take part in declaring a person dead, including radiologists, neurophysiologists and the nursing staff. The situation is often also monitored by the patient's family members, to whom the patient's status and test results must be explained carefully. Additional examinations listed in Ministry of Social Affairs and Health instruction 2004:5 are often also carried out. Chief Physician Leena Soininen, who was consulted at ETENE meeting, stated that the criteria and the examinations are watertight: a person whose brain function may recover cannot pass the tests.

The anaesthesiologist plays a key role in successful organ transplantations, as the cells in the body of a brain dead patient start decaying immediately. Maintaining organ function until the organs are removed is crucial to ensure that they will also function after implantation. In the Finnish circumstances, it is difficult to follow a procedure where the anaesthesiologist of the organ transplantation team could be responsible for the organ functions once the person has been certified dead; even in favourable conditions, the anaesthesiologist may be hours away from the hospital. If we wish to ensure that a doctor who participates in certifying death does not take part in activities leading up to the removal of organs, the doctor who certifies death would need to be an anaesthesiologist or a doctor competent in carrying out an apnea test who does not otherwise take part in caring for the patient. In normal circumstances, this can be arranged at central hospitals, where the apnea test can in the daytime be performed by an anaesthesiologist who does not have any other involvement in the care of the patient, and during on-call hours, another anaesthesiologist can be called in to assist. Problems arise during holiday times, when calling in another specialist from his or her free time merely to carry out and interpret an apnea test is difficult.

In ETENE's view, the care of the patient and his or her organs that can be donated after the patient has been declared dead is a specific entity that can be examined as a series of procedures separate from the organ transplantation. Maintaining the patient's organ function can be seen as an extension of the good care of the patient until the tissues have been removed. The patient's own will is always investigated before initiating the transplantation process, and if the patient has not been opposed to organ transplantations during his or her lifetime, the care can be considered to be in line with the patient's wishes also at this stage. According to this interpretation, the anaesthesiologist does not have a direct involvement in organ transplantation, but he or she ensures that the process required to prepare for the transplantation is completed. This interpretation is supported by the administrative separation of organ transplantations from donations in Finland, and the fact that the anaesthesiologist on call is an employee of the donor hospital throughout the process.



A different type of problem arises if both the donation and the transplantation take place in the same hospital. In this case it is possible that an anaesthesiologist who was involved in certifying death could later end up caring for a patient in intensive care who has received an organ transplant. At a university hospital, this can be avoided by sufficiently clear instructions and internal arrangements, as long as the hospital is aware of the issue. If organ donations are being planned, death can for example be certified by a doctor from another unit who is not on call at the intensive care unit where organ transplant patients are cared for after the operation.

ETENE's position

ETENE finds that organ transplantations are activities requiring top medical expertise which produce significant benefits not only by saving costs to society but also, and in particular, by improving the quality of life of patients and their families. Organ transplantation activities are restricted by the number of donated organs, and it is thus an important task for all parties to ensure as good an availability of donated organs as possible. Almost all donated organs in Finland come from deceased donors, of whom one out of three are cared for at a central or a regional hospital in various parts of Finland.

ETENE takes safeguarding the citizens' trust in organ transplantations seriously; an effort to do so underpins both national and international provisions on the matter. Keeping organ donations and organ transplantations separate is crucial. In Finland, these functions have been rather well separated, both administratively and operatively. The staff at the donor hospital work to care for a brain dead patient, whereas the organ transplantation teams make decisions about organs to be transplanted without interfering in local treatment decisions.

The anaesthesiologist plays a key role in organ donations by maintaining the viability of organs. An anaesthesiologist is responsible for the intensive care of a seriously ill patient, and if the patient cannot be saved, the anaesthesiologist's specialist skills are needed to run tests that allow certification of death. If it is possible to use the patient's organs for organ transplantations, the task continues as intensive care until the organs can be removed, often hours after the patient has been certified dead.

This task is emotionally stressful for the anaesthesiologist on call. At university hospitals, these tasks can be divided between several persons, and the anaesthesiologist thus need not continue caring for the patient's organs once he or she has certified death. At a central hospital, there often only is a single anaesthesiologist on duty during on-call hours who is responsible for the anaesthesia and pain relief of patients in intensive care and surgery. In establishing whether or not the patient is brain dead, the anaesthesiologist's duties include carrying out and interpreting an apnea test. During on-call hours, it is not always possible to make special arrangements to ensure that two different anaesthesiologists would declare the patient dead and maintain the function of the deceased person's organs.

After consulting with specialists and considering the issue, ETENE proposes that the actions of the anaesthesiologist can, during the entire treatment process, be interpreted as organ donation activities, which in Finland are clearly separated from organ transplantations, or the removal and transplantation of organs, both administratively and operatively. The role and duties of the anaesthesiologist do not change once the patient declared dead is moved from intensive care into the theatre. ETENE finds that under current legislation, this is a continuum of good care in line with the patient's wishes. The care also continues after the removal of organs, as the patient is detached from the lung ventilator and all procedures maintaining vital functions may be discontinued. A good death and communication with the patient's family members is part of good care. This view is also supported by the fact that persons involved in an organ donation, including the anaesthesiologist caring for the patient, are in the service of the donor hospital district throughout the process. Administratively, the members of the organ transplantation team are office holders in the organisation responsible for transplantations, or Helsinki and Uusimaa Hospital District.



However, ETENE considers that due to the emotional stress to which the anaesthesiologist is exposed, it is recommended that death is not certified by the physician who is in charge of caring for the patient and maintaining the vital functions of the deceased person. This should also be taken into account when both the organ donation and transplantation take place at the HUCH, where an anaesthesiologist may otherwise end up caring for both a donor and a transplant patient.

ETENE also looked at the financial perspectives of the issue. Organ transplantations are extremely useful in terms of the patient's quality of life, but they also reduce the costs to society. If a precondition for preserving trust in society is that a HUCH anaesthesiologist who is involved in organ transplantations takes part in removing the organs, a 24/7 on-call system is needed. In the current arrangements, anaesthesiologists working at the HUCH cannot be detached from their other duties, and the making of the arrangements could unnecessarily delay organ transplantation operations and thus have a negative impact on their outcome. In order to operate a 24/7 on-call system, at least five new posts would have to be created. If about one hundred operations to remove organs are performed a year, and approximately 30% of these are carried out at central hospitals, it is questionable if maintaining these activities would be cost-effective for society.

Valvira notes in its statement that including a dedicated anaesthesiologist in the organ retrieval team of the Transplantation Services would be one way of safeguarding the availability of best expertise in organ removal. According to ETENE's investigations, this would not reduce the workload of local anaesthesiologists, as the retrieval team's anaesthesiologist could only arrive on scene for the removal surgery hours after the patient has been declared dead, and during this interval, the care of the deceased person would be in the hands of the anaesthesiologist at the donor hospital. Responsibility for caring for the patient after the operation to remove the organs also rests with local physicians.

ETENE does not express an opinion on whether Finnish legislation should be amended if we wish to maintain and reinforce organ donation activities at central hospitals. ETENE notes that the wording of Section 8 of the Tissues Act to a great extent corresponds with wording of Article 16 in the Biomedicine Convention's Additional Protocol. The advisory board also notes that the current separation of organ donations and organ transplantations can be interpreted as being consistent with this Article and the principles and goals expressed in its Explanatory Report. This builds up society's trust in organ transplantation operations in our current public health care system. In the event that our health care system changes in this respect in the future, the issue must be re-examined.

On behalf of the Advisory Board

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