

COMMENTARY

UK guidance for non-heart-beating donation

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This guidance offers consensus opinion on the optimum management of non-heart-beating organ donation in adult critical care units. The guidance is not meant to dictate practice but rather to offer suggestions as to what might be considered reasonable practice. The following sections mainly relate to the medical aspects of non-heart-beating organ donation. Fuller guidance on other aspects of organ and tissue donation is available on the Society's website (www.ics.ac.uk). There are a number of parallel areas of work, such as the law on consent, the definition of death and revision of the original Code of Practice describing brainstem testing, which means that many aspects of organ donation are changing rapidly. This guidance is designed to help critical care practitioners while these issues are resolved.

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Organ and tissue transplantation is one of the major medical success stories of our time. Results of organ transplantation continue to improve, approximately 90% of transplant recipients being alive and well after 1 yr. Demand for organs (and in some cases tissues, particularly corneas and bone) outstrips supply throughout the developed world. At the end of December 2004 there were over 6000 people on the active UK waiting list for organ transplantation. Recent data suggest that over 400 of these people will die each year before a new organ becomes available.¹ The NHS can only meet the need for organs and tissues for transplantation if (i) the public is aware of the possibilities of donating organs and tissues, and are willing to do so; (ii) health-care staff, particularly critical care teams, identify all potential donors; and (iii) skilled transplant professionals retrieve high-quality organs and tissues and use them effectively.

Heart beating (HBD) and non-heart-beating donors (NHBD)

When transplantation started, all organs were retrieved from patients immediately after cardiorespiratory arrest, i.e. from 'non-heart-beating' donors. After the recognition that death resulted from irreversible damage to the brainstem by the Harvard Medical Committee in 1968² and the subsequent introduction in 1976³ of direct brainstem testing to determine when death has occurred, organ retrieval rapidly switched (except for a very few centres) to patients certified dead after brainstem testing. These 'heart-beating'

donors have become the principal source of organs for transplantation for the last 25–30 yr.

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The number of heart-beating donors is declining and this is likely to continue for two reasons: fewer younger people are dying as a result of severe injury or catastrophic cerebrovascular events,⁴ and improvements in diagnosis and management of severe brain injuries mean that fewer fulfil the brainstem testing criteria. At present, patients receiving intensive care are more likely to die after the withdrawal of active treatment. Although numbers of non-heart-beating donors are slowly increasing, they still accounted for only 85 of 750 (11.3%) UK cadaveric donors in 2004–2005. The fundamental problem with NHBD is warm ischaemia, which may lead to suboptimal transplanted organ function. Developments in organ protection will only lead to more successful outcomes from non-heart-beating donors if strategies can be devised to keep warm ischaemia times as short as possible.

Controlled non-heart-beating organ donation

Organs suitable for donation

Solid organs suitable for transplantation from non-heart-beating donors include kidneys, livers and lungs. The results of transplantation of kidneys from non-heart-beating donors have been reviewed⁵ and, although kidneys from non-heart-beating donors may be slow to function, the 5-year results from a successful transplant are the same as for kidneys from heart beating donors.⁶ Early results of liver transplants from non-heart-beating donors are encouraging, and there is growing evidence that lungs can also be transplanted successfully.^{7,8} Tissue donation (e.g. corneas etc) should also be considered in asystolic cadaveric donors.

Patients suitable for non-heart-beating donation

An international meeting on non-heart-beating donation held in Maastricht in 1995⁹ identified four categories of potential non-heart-beating organ donors, to which a fifth category has recently been added (Table 1). These may be described as either uncontrolled (Categories I/II and V) or controlled (Categories III/IV) donors.

Controlled non-heart-beating donation in the critical care unit involves mainly Category III patients, and may increasingly be appropriate for Category IV patients. Both allow organ retrieval to be planned, warm ischaemic time to be minimized and organ outcomes optimized. Category III patients will usually be in a critical care unit, but occasionally in the accident and emergency department, and usually represent patients in whom it has been decided that further active treatment is futile. In these patients, asystole and cardiac arrest are predicted and expected. A decision to

Table 1 The modified Maastricht classification of non-heart-beating donors⁹

Category I	Dead on arrival
Category II	Unsuccessful resuscitation
Category III	Awaiting cardiac arrest
Category IV	Cardiac arrest in a brainstem dead donor.
Category V	Unexpected cardiac arrest in a critically ill patient

withdraw or limit active treatment in critical care is common in UK practice, where such decisions are made in 9.9% of all intensive care unit admissions and 31.8% of all critical care unit deaths.¹⁰

In general, patients likely to be suitable for non-heart-beating donation are similar to those who become heart-beating organ donors. Typically, these are patients who have suffered catastrophic brain injuries (e.g. head injuries, intracranial haemorrhage, hypoxic brain insult) but do not fulfil the criteria for brainstem death, and in whom further active treatment is futile. However, critically ill patients with other diagnoses, who may be suitable for non-heart-beating donation, should be discussed with a transplant coordinator when a decision to withdraw treatment is made.

Withdrawal of active treatment

The decision to withdraw treatment should be made in accordance with current guidelines from the Intensive Care Society, British Medical Association and the General Medical Council.^{11–14} There must be consensus among the critical care consultant, the patient’s relatives, the referring consultant and nursing staff that the decision is made in the patient’s best interest. However, the ultimate responsibility for the decision and its timing rests with the responsible critical care consultant.

Intensivists should develop local protocols for treatment withdrawal based on national guidelines. It is important to emphasize that withdrawal of active treatment should be according to the local critical care unit protocol and should not differ when organ donation is being considered. It is mandatory that transplant teams should not be involved in any decision to withdraw treatment. This ensures that the interests of the dying patient remain paramount. The decision should be communicated clearly to the family by the clinician caring for the patient and should be documented in the patient’s notes.

The donation process

Communication. Discussion of a patient’s suitability for non-heart-beating donation with the donor transplant coordinator should take place before approaching the patient’s family to avoid the situation of establishing the family’s agreement to organ donation, only to find that the patient is not suitable for non-heart-beating donation. For the same reason, when necessary appropriate patients should be discussed with the coroner or procurator fiscal at this time. It is important to stress that the possibility of non-heart-beating donation should be discussed with the relatives only after they have understood and accepted the futility of the clinical situation, and the reasons for the withdrawal of treatment. The donor transplant coordinator should only become involved with the family after this discussion has taken place.

All the procedures involved in non-heart-beating donation need to be explained sensitively, but in detail, to the patient’s relatives. The logistics of non-heart-beating donation are

different from those of heart-beating donation. The process of cannulation and perfusion that will occur after death should be explained in detail. It is important to explain that:

death may occur quickly after treatment withdrawal, and the relatives may have little time with their loved one if organ donation is to be possible;

death may not occur quickly after treatment withdrawal.

Organ donation may not be possible if the dying process is prolonged and results in an unacceptable warm ischaemic time. However, tissue donation is still possible in this scenario;

organ donation may not be possible if the coroner or procurator fiscal refuses permission;

transplantation may not be possible after organ retrieval if perfusion has failed;

the family will have an opportunity to see their relative after organ retrieval;

the relatives can stop the donation process at any stage.

Process of treatment withdrawal. Once a decision to withdraw treatment has been reached by the critical care consultant, the current level of support should continue until the time to withdraw treatment is agreed with the relatives. It is inappropriate to escalate current treatment, add new therapies (e.g. inotropes, heparin, hormone replacement) or to undertake invasive interventions (e.g. vascular cannulation before death for cold perfusion) to improve organ viability. However, with the agreement of relatives, it is reasonable for blood samples to be taken from an indwelling line for tissue typing and serology purposes.

The appropriate time to withdraw treatment is influenced by many factors but the wishes and needs of the patient's relatives are the main determinants. Although the donor transplant coordinator may be present during withdrawal of treatment if the family find it helpful, it is inappropriate for the retrieval team to meet the family, except at the family's request. Communication with the family should remain the responsibility of the critical care team and/or the donor transplant coordinator.

Withdrawal of active treatment should proceed in accordance with the usual practice of the critical care unit. This may include stopping artificial ventilation, supplementary oxygen, inotropes and extubating the patient, but starting the infusion of opioids or sedatives to ensure that the patient is pain-free and not distressed. Withdrawal of active treatment should not vary from local practice because organ donation is being considered. Withdrawal of active treatment should usually take place within the critical care unit. In exceptional circumstances, treatment may be withdrawn within the theatre complex (e.g. an anaesthetic room or recovery area). This should be undertaken only as a way of meeting the patient's and relatives' wish to donate organs and not simply as a means of reducing warm ischaemic time. The same level of critical care nursing skill and expertise in the care of the dying patient should continue to be provided if treatment is withdrawn outside the critical care unit.

Confirmation of death in potential non-heart-beating donors. After withdrawal of active treatment, when non-heart-beating donation is being considered, a member of the critical care unit team should certify death by confirming the absence of cardiac output and respiration, the lack of response to supraorbital pressure and absence of the pupillary and corneal reflexes. This should be done at a minimum of 5 min after cardiorespiratory arrest, as currently recommended by the Institute of Medicine.¹¹ Any return of cardiac or respiratory activity during this period of observation should prompt a further 5 min of observation.

Management after death certification. After certification of death, a brief respectful period may be valuable for the relatives to have further time with the patient, before transferring the body to the operating theatre. This period of time is usually about 5 min; if at this point the relatives still need more time with their loved one, the donation process should be reviewed. Procedures that reduce the warm ischaemic time of organs to be transplanted, but that may inadvertently result in changes to cerebral and/or coronary blood flow, are not in the patient's interest and must not be instituted post-mortem. These include chest compressions and cardiopulmonary bypass. Drugs may not be administered to facilitate organ donation (e.g. heparin) until death has been certified, as this would not be in the patient's interest.

It is recommended that cannulation and organ perfusion should take place in the operating theatre. However, for logistic reasons some critical care units may prefer to cannulate the patient's femoral artery and vein and to infuse cold fluids in the critical care unit after death.

Failure to proceed with donation. Some patients continue to breathe spontaneously or with reduced ventilatory support for some time after treatment is withdrawn. They may become profoundly hypotensive and hypoxic during this time. In these situations, the organ donation process may have to be abandoned if organ function has deteriorated so that viable transplantation is not possible. The family should have previously been made aware of this possibility. This decision is usually taken after 2–3 h. The decision to abandon organ donation is determined by the need to limit the warm ischaemic time and by the availability of an operating theatre and retrieval team. This is a particular problem for hospitals based a long way from regional transplantation centres.

It is central to the principles of organ donation that donation is carried out to meet the wishes of the deceased and also to bring comfort to the relatives. The dignity, well-being and comfort of the dying patient are paramount in this process. The relatives can stop the process of non-heart-beating donor at any time without reason.

Implementing a non-heart-beating donation scheme in the critical care unit

Individual critical care units may choose to develop a protocol that takes into account any local factors influencing the practicalities of non-heart-beating donation. The critical

care medical and nursing staff, theatre staff, the retrieval team, and clinicians that refer patients to the critical care unit all need to be consulted and involved. Local audit of all deaths within the critical care unit provides data on the likely number of suitable non-heart-beating donors and allows planning and informed discussion with all interested parties. The protocol should be approved by the hospital ethics committee or Trust Board.

The British Transplant Society has published guidelines on other aspects of the transplantation of organs from non-heart-beating donors. These are available at www.bts.org.uk.

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