

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation

1.1 Short title

Organ donation for transplantation

2 The remit

The Department of Health has asked NICE: 'To produce a clinical guideline on improving donor identification and consent rates for cadaveric organ donation'.

| Terms used in this scope | |
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| Brain-stem death | Death diagnosed after irreversible cessation of brain stem function and confirmed using neurological criteria. The diagnosis of death is made while the body of the person is attached to an artificial ventilator and the heart is still beating. |
| Cardiac death | Death diagnosed and confirmed by a doctor after cardiorespiratory arrest. |
| Potential donors | People for whom brain-stem death or cardiac death has been diagnosed and active treatment is planned to be withdrawn, and who have no medical contraindications to solid organ donation. |
| See Department of Health (2008) Organs for transplants: a report from the Organ Donation Taskforce. Available from www.dh.gov.uk/en/Publicationsandstatistics/Publications | |

3 Clinical need for the guideline

3.1 *Epidemiology*

- a) Organ transplantation has a major role in the management of patients with failure of a single organ system of either the kidneys, small bowel, liver, pancreas, heart, lung, or thymus, and of combined organ failure of the heart and lung, the kidney and pancreas, the liver and kidney, or liver and small bowel. Transplants may be needed because of primary organ disease, such as chronic inflammatory disease of the kidneys or cardiomyopathy, or because of secondary effects such as kidney, islet cell and pancreas transplants in people with diabetes, and lung transplants in people with cystic fibrosis.
- b) The distribution of the population on the transplant waiting list is 75% white, 25% non-white; 59% male, 41% female; 7% aged 0–17 years, 18% aged 18–34 years, 39% aged 35–49 years, 20% aged 50–59 years, 15% aged 60+ years.
- c) There is a shortage of organs for transplant resulting in long waits for transplantation and a significant number of deaths while awaiting transplantation.
- d) Approximately 8,000 people in the UK are waiting for an organ transplant. This figure is rising by about 5% per year because of a number of factors, such as: increasing prevalence of renal and liver disease; ethnic diversity of the UK population; lower thresholds for transplantation and better clinical management of serious illnesses. The true need is likely to be greater and is rising rapidly with changing demographics of the UK. Of particular note are an ageing population and an anticipated increase in the incidence of type 2 diabetes, a condition that can cause kidney failure and lead to the need for a kidney transplant.

- e) At any one time, a significant number of patients may be suspended from the active list. This is because their condition has temporarily deteriorated to the extent that a transplant is too risky. In 2008–09, 2552 transplants used organs from deceased donors; however, another 1178 patients were listed for transplant, of whom 448 died before receiving one and 730 were removed from the list.
- f) Data from NHS Blood and Transplant, on transplant activity in the UK 2008–09, showed that only 86% of potential donors after brain-stem death, and 42% of potential donors after cardiac death, were referred to donor coordinators. Of those families approached, permission was refused for donation to proceed for 38% of possible DBD (donation after brain-stem death) donors, and 42% of possible DCD (donation after cardiac death) donors

3.2 Current practice

- a) Europe has an average of 17.8 donors per million people. The UK has one of the lower rates at 15.5 donors per million people.
- b) Clinical practice, and whether families are asked to consider organ donation, varies significantly across the UK. The conversion rates for potential donors becoming actual donors in 2008/ 09 varied between 23.7% and 43%. In 2008–09, the mean conversion rate in UK intensive care units for potential donors becoming actual donors was about 51% for DBD to 15% for DCD.
- c) Kidney transplantation is more cost-effective than haemodialysis for treating stage 5 chronic kidney disease, but it is less commonly used than it should be due to shortage of transplantable kidneys. An increase in transplant rates will have a beneficial impact on resources and will increase quality of life for patients that are suitable for transplantation and are currently on dialysis.
- d) NHS Blood and Transplant data show that only 5% of deceased donors are of Asian or African–Caribbean descent, even though

these groups form 25% of the kidney transplant waiting list. People of Asian or African–Caribbean descent are three to four times more likely than white people to develop end-stage renal failure and to need a kidney transplant. People from these populations are also much less likely to give consent for organ donation when asked.

- e) A UK transplant¹ survey in 2003 showed that the public is very supportive of organ donation in principle, with 90% in favour. Nearly 17 million people are already on the NHS Organ Donor Register. However, the actual donation rate in the UK remains poor. This may be partly because of bereaved relatives not consenting to organ donation. Many reviews of organ donation have been done in the past, but all failed to resolve the problems that result from the lack of a structured and systematic approach to organ donation.
- f) The guideline will focus on identifying potential donors and obtaining consent for solid organ donation under current legislation. It will help to address the burden of disease by increasing the availability of organs for transplant. It will address current inequalities by helping to make organ donation a usual part of NHS practice, meaning that families of all potential organ donors are approached and supported, irrespective of factors such as ethnicity and religion.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

¹ In 2003, UK transplant subsequently changed to NHS Blood and Transplant.

The areas that will be addressed by the guideline are described in the following sections.

4.1 *Population*

4.1.1 Groups that will be covered

- a) Families, relatives and legal guardians of potential DBD donors (adults and children).
- b) Families, relatives and legal guardians of potential DCD donors (adults and children).
- c) Within this population, the following groups have been identified as needing special consideration:
 - people from black and minority ethnic groups.
 - people with differing religious beliefs.

4.1.2 Groups that will not be covered

- a) Groups involved in giving consent on organ donation other than those described in sections 4.1.1a and 4.1.1b.

4.2 *Healthcare setting*

- a) NHS hospitals.

4.3 *Clinical management*

4.3.1 Key clinical issues that will be covered

- a) Structures and processes for identifying potential DBD and DCD donors
 - timing of referral
 - criteria for consideration
- b) Structures and processes for obtaining consent for deceased organ donation for transplantation, including the optimum timing for approaching families about consent.

- c) Coordination of the care pathway from identification of potential donors to consent.
- d) Competencies of healthcare professionals involved in the activities described in sections 4.3.1 a, b and c.

4.3.2 Clinical issues that will not be covered

- a) Systems for declaring a willingness to donate before death.
- b) Tissue donation.
- c) The processes of organ retrieval.
- d) Living organ donation.
- e) Assessment of organs for transplantation.
- f) Organ donation for training and medical research.
- g) Prioritisation of organ allocation, including the structures and processes of organ transfers within or outside the UK.

4.4 Main outcomes

- a) Rates of identification of potential donors.
- b) Rates of consent for donation.
- c) Rates of organ donation for transplantation
- d) Rates of successful transplants.
- e) Rates of viable organs retrieved.
- f) Rates of family, relatives and legal guardians refusal.
- g) Families, relatives and legal guardians' experience of the structures and processes for organ donation.

4.5 *Economic aspects*

It is unlikely that standard HE modelling techniques will apply to this guideline. In the absence of these a cost impact analysis will be under taken that looks at how identification and consent impacts on current resources. The cost impact analysis will be included in the main text of the guideline.

4.6 *Status*

4.6.1 *Scope*

This is the final scope.

4.6.2 *Timing*

The development of the guideline recommendations will begin in September 2010.

5 *Related NICE guidance*

There is no related NICE guidance for this topic.

6 *Further information*

Information on the guideline development process is provided in:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).