

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Organ donation: improving donor identification and consent rates for cadaveric organ donation

1.1 Short title

Organ donation for transplants

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	
Brain stem death	Death diagnosed and certified following neurological tests of brain stem function. The diagnosis of death can be made while the body of the person is attached to the artificial ventilator and the heart is still beating.
Cardiac death	Death certified by a doctor after the heart has irreversibly ceased to beat.
Potential donors	People for whom brain death has been diagnosed, or cardiac death has been diagnosed and active treatment has been withdrawn, and who have no medical contraindications to solid organ donation.
Refer to the Department of Health document: Organ for transplants. A report from the organ donation taskforce (2008).	

3 Clinical need for the guideline

3.1 *Epidemiology*

- a) Organ donation plays a major role in the management of patients with single organ failure of the kidneys, cornea, liver, pancreas, heart or lung, and combined organ failure of the heart and lung, or of the kidney and pancreas. This applies to primary organ disease, such as chronic inflammatory disease of the kidneys or cardiomyopathy, and to secondary effects such as kidney, islet cell and pancreas transplants in diabetes, or heart and lung transplants in cystic fibrosis.
- b) Currently 79% of recipients are white and 21% of recipients are non-white. The distribution of the population on the transplant list is 75% white, 25% non-white; 59% male, 41% female; 7% aged 0–17, 18% aged 18–34, 39% aged 35–49, 20% aged 50–59, 15% aged 60+.
- 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) More than 10,000 people in the UK are waiting for an organ transplant. This figure is rising by about 8% per year as a result of a number of factors, such as: increasing prevalence of renal and liver disease; ethnic diversity of the UK population; lower thresholds and better clinical management of serious illnesses. This list does not reflect the true extent of need, because many clinicians are reluctant to list more patients than are realistically likely to receive organs. The true need is, at minimum, 50% more than currently available and is rising rapidly with changing demographics in the UK. Of particular note are an ageing population and an anticipated surge 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 becomes too risky. Each year more than 1000 people – 3 a day on average – die before an organ becomes available. In 2008/09 there were 2552 transplants using organs from deceased donors. In 2008/09 there were 1178 patients listed for transplant who died before receiving one.
- f) Data from UK Transplant on transplant activity in the UK 2008/09 showed that only 86% of potential donors after brain death and 42% of donors after cardiac death are referred to donor coordinators. Of these, the families refused permission for donation to proceed for 38% of possible donors after brain death, and 42% of possible donors after cardiac death.

3.2 Current practice

- a) Spain has the highest organ donation rate in Europe at 35 donors per million of population. The UK has one of the lowest rates at just 13 donors per million of population.
- b) There is significant variation in clinical practice, and the possibility of families being offered the choice of organ donation, across the UK. In 2008/09, the conversion rates in UK intensive care units for potential donors becoming actual donors ranged from 15 to 51%. .
- c) Kidney transplantation is a more cost effective treatment for stage 5 chronic kidney disease than haemodialysis, but it is currently less commonly used. If the transplant rates increase, it will have a beneficial impact on resources and enable patients currently on dialysis to enjoy increased quality of life.
- d) Current practice (UK Transplant data) shows that only 3% 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 need a kidney transplant. They are also much less likely to give consent for organ donation when asked.

- e) A UK Transplant survey in 2003 showed that the public is very supportive of organ donation in principle, with 90% in favour. Nearly 15 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. Although there have been many reviews of organ donation in the past, all have failed to resolve the problems that result from the lack of a structured and systematic approach to organ donation.
- f) The guideline will focus exclusively on identifying potential donors and obtaining consent for organ donation (solid and tissue) under current legislation. It will help 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 the families of all potential organ donors are approached and supported, regardless 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.

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 donors (adults and children) after brain stem death.
- b) Families, relatives and legal guardians of potential donors (adults and children) after cardiac death.
- c) Within this population, the following groups have been identified as needing special consideration:
 - People from black and minority ethnic groups.
 - Parents of children who are potential donors.

4.1.2 Groups that will not be covered

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

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 donors after brain or cardiac death.
- b) Structures and processes for obtaining consent for cadaveric organ donation for transplantation, including the optimum timing for approaching the families about consent.
- c) Coordination of the care pathway for conversion of potential donors to actual donors.
- 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 ante-mortem.
- b) The processes of organ retrieval.
- c) Living organ donation.
- d) Assessment of organs for transplantation.
- e) Organ donation for training and medical research.
- f) 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 transplantation.
- c) Rates of organ donation for transplantation.
- d) Rates of conversion for potential donors with consent to actual donors.
- e) Rates of successful transplants.
- f) Rates of viable organs retrieved.
- g) Families, relatives and legal guardians' experience of the structures and processes for organ donation.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further

detail on the methods can be found in 'The guidelines manual' (see 'Further information').

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 21 June to 19 July 2010.

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).