NICE National Institute for Health and Care Excellence

NICE guideline

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

Clinical guideline

Published: 12 December 2011
www.nice.org.uk/guidance/cg135

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

Introduction

A significant proportion of people in England and Wales would wish to donate their organs after death for the purpose of transplantation. This guideline recognises the complexities that arise owing to the majority of potential organ donors lacking the capacity to be directly involved in decision making at the time of their death. This guideline seeks to promote the identification and fulfilment of these wishes through:

- more effective and expedient identification and referral of potential organ donors
- a more informed, considered and timely approach to consent for donation that is based primarily on identifying the wishes of the individual whenever known and however recorded.

The General Medical Council (GMC) guidance 'Treatment and care towards the end of life: good practice in decision making' requires that consultant staff who have clinical responsibility for patients who are potential donors exercise a duty to consider organ donation as part of end-of-life care.

Although donation occurs after death, there are steps that healthcare professionals may need to take before the death of the patient if donation is to take place. This guidance covers such steps, and in the case of clinical triggers for referral, refers to actions that might take place even before the inevitability of death has been recognised. These actions may result in challenges and tensions for the healthcare teams but they can and indeed should be incorporated into local hospital policies in order to better promote donation as part of end-of-life care.

Organ donation for transplantation is a complex area and one to which conventional clinical research methods cannot be easily applied. Consequently, much of the evidence included in this guideline is of a qualitative nature and does not lend itself to conventional use of GRADE assessment. A modified version of the GRADE assessment tool has been used to assess study limitations, indirectness and inconsistency.

Recognising the ethical and legal context in this area, legal advice was sought and incorporated during the development of the guideline.

Person-centred care

This guideline offers best practice advice on improving donor identification and consent rates.

Treatment and care should take into account people's needs and preferences. Where the person at the end of their life has the capacity to make decisions, they should have the opportunity to make informed decisions about their care, in partnership with their healthcare professionals. In many cases parents, families and guardians are an important part of the consent process and, unless the person has expressed otherwise, should be involved in decisions about consent. If potential donors do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

If the potential donor is under 16, healthcare professionals should follow the guidelines in 'Seeking consent: working with children'.

The Human Tissue Authority has produced codes of practice for consent and for donation of solid organs for transplantation, and the NHS has produced a code of practice on confidentiality[1].

Good communication between healthcare professionals and people is essential. It should be supported by evidence-based written information tailored to the person's needs. The information people are given about their care should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Parents, families and guardians should also be given the information and support they need.

[1] NHS UK Transplant has produced a policy on care of the donor family, and standards of practice for donor transplant coordinators.

1 Recommendations

Identifying patients who are potential donors

1.1.1 Organ donation should be considered as a usual part of 'end-of-life care' planning.

1.1.2 Identify all patients who are potentially suitable donors as early as possible, through a systematic approach. While recognising that clinical situations vary identification should be based on either of the following criteria:

- defined clinical trigger factors in patients[2] who have had a catastrophic brain injury, namely:
  - the absence of one or more cranial nerve reflexes **and**
  - a Glasgow Coma Scale (GCS) score of 4 or less that is not explained by sedation unless there is a clear reason why the above clinical triggers are not met (for example because of sedation) and/or a decision has been made to perform brainstem death[3] tests, whichever is the earlier
- the intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death.

1.1.3 The healthcare team caring for the patient should initiate discussions about potential organ donation with the specialist nurse for organ donation at the time the criteria in recommendation 1.1.2 are met.

Patients who have capacity

1.1.4 In circumstances where a patient has the capacity to make their own decisions, obtain their views on, and consent to, organ donation[4].

Assessing best interests

1.1.5 If a patient lacks capacity to make decisions about their end-of life-care, seek to establish whether taking steps, before death, to facilitate organ donation would be in the best interests of the patient.

1.1.6 While assessing the patient's best interests clinically stabilise the patient in an appropriate critical care setting while the assessment for donation is performed – for example, an adult intensive care unit or in discussion with a regional paediatric intensive care unit (see recommendation 1.1.8).

1.1.7 Provided that delay is in the patient's overall best interests, life-sustaining treatments should not be withdrawn or limited until the patient's wishes around organ donation have been explored and the clinical potential for the patient to donate has been assessed in accordance with legal and professional[5],[4] guidance.

1.1.8 In assessing a patient's best interests, consider:

- the patient's known wishes and feelings, in particular any advance statement or registration on the NHS organ donor register[7] but also any views expressed by the patient to those close to the patient
- the beliefs or values that would be likely to influence the patient's decision if they had the capacity to make it
- any other factors they would be likely to consider if they were able to do so
- the views of the patient's family, friends and anyone involved in their care as appropriate as to what would be in the patient's best interests; and
- anyone named by the patient to be consulted about such decisions.

Seeking consent to organ donation

1.1.9 If a patient lacks the capacity to consent to organ donation seek to establish the patient's prior consent by:

- referring to an advance statement if available
- establishing whether the patient has registered and recorded their consent to donate on the NHS organ donor register[6][8] and
- exploring with those close to the patient whether the patient had expressed any views about organ donation.

1.1.10 If the patient's prior consent has not already been ascertained, and in the absence of a person or persons having been appointed as nominated

representative(s), consent for organ donation should be sought from those in a qualifying relationship with the patient. Where a nominated representative has been appointed and the person had not already made a decision about donation prior to their death, then consent should be sought after death from the said nominated representative(s).

Approach to those close to the patient

The multidisciplinary team

1.1.11 A multidisciplinary team (MDT) should be responsible for planning the approach and discussing organ donation with those close to the patient.

1.1.12 The MDT should include:

- the medical and nursing staff involved in the care of the patient, led throughout the process by an identifiable consultant
- the specialist nurse for organ donation
- local faith representative(s) where relevant.

1.1.13 Whenever possible, continuity of care should be provided by team members who have been directly involved in caring for the patient.

1.1.14 The MDT involved in the initial approach should have the necessary skills and knowledge to provide to those close to the patient appropriate support and accurate information about organ donation (see recommendations 1.1.30 and 1.1.31).

Discussions in all cases

1.1.15 Before approaching those close to the patient:

- identify a patient's potential for donation in consultation with the specialist nurse for organ donation
- check the NHS organ donor register and any advance statements or Lasting Power of Attorney for health and welfare

- clarify coronial, legal and safeguarding issues.

1.1.16 Before approaching those close to the patient, try to seek information on all of the following:

- knowledge of the clinical history of the patient who is a potential donor
- identification of key family members
- assessment of whether family support is required – for example faith representative, family liaison officer, bereavement service, trained interpreter, advocate
- identification of other key family issues
- identification of cultural and religious issues that may have an impact on consent.

1.1.17 Approach those close to the patient in a setting suitable for private and compassionate discussion.

1.1.18 Every approach to those close to the patient should be planned with the MDT and at a time that suits the family's circumstances.

1.1.19 In all cases those close to the patient should be approached in a professional, compassionate and caring manner and given sufficient time to consider the information.

1.1.20 Discussions about organ donation with those close to the patient should only take place when it has been clearly established that they understand that death is inevitable or has occurred.

1.1.21 When approaching those close to the patient:

- discuss with them that donation is a usual part of the end-of-life care
- use open-ended questions – for example 'how do you think your relative would feel about organ donation?'
- use positive ways to describe organ donation, especially when patients are on the NHS organ donor register or they have expressed a wish to donate during their lifetime – for example 'by becoming a donor your relative has a chance to save and transform the lives of many others'

- avoid the use of apologetic or negative language (for example 'I am asking you because it is policy' or 'I am sorry to have to ask you').

1.1.22 The healthcare team providing care for the patient should provide those close to the patient who is a potential donor with the following, as appropriate:

- assurance that the primary focus is on the care and dignity of the patient (whether the donation occurs or not)
- explicit confirmation and reassurance that the standard of care received will be the same whether they consider giving consent for organ donation or not
- the rationale behind the decision to withdraw or withhold life-sustaining treatment and how the timing will be coordinated to support organ donation
- a clear explanation of, and information on:
  - the process of organ donation and retrieval, including post-retrieval arrangements
  - what interventions may be required between consent and organ retrieval
  - where and when organ retrieval is likely to occur
  - how current legislation applies to their situation[9], including the status of being on the NHS organ donor register or any advance statement
  - how the requirements for coronial referral apply to their situation
- consent documentation
- reasons why organ donation may not take place, even if consent is granted.

1.1.23 Allow sufficient time for those close to the patient to understand the inevitability of the death or anticipated death and to spend time with the patient.

1.1.24 Discuss withdrawal of life-sustaining treatment or neurological death before, and at a different time from, discussing organ donation unless those close to the patient initiate these discussions in the same conversation.

1.1.25 For discussions where circulatory death is anticipated, provide a clear explanation on:

- what end-of-life care involves and where it will take place – for example, theatre, critical care department
- how death is confirmed and what happens next
- what happens if death does not occur within a defined time period.

1.1.26 For discussions where neurological death is anticipated, provide a clear explanation on:

- how death is diagnosed using neurological criteria
- how this is confirmed and what happens next.

Organisation of the identification, referral and consent processes

1.1.27 Each hospital should have a policy and protocol that is consistent with these recommendations for identifying patients who are potential donors and managing the consent process.

1.1.28 Each hospital should identify a clinical team to ensure the development, implementation and regular review of their policies.

1.1.29 Adult and paediatric intensive care units should have a named lead consultant with responsibility for organ donation.

1.1.30 The MDT involved in the identification, referral to a specialist nurse for organ donation, and consent should have the specialist skills and competencies necessary to deliver the recommended process for organ donation outlined in this guideline.

1.1.31 The skills and competencies required of the individual members of the team will depend on their role in the process. However, all healthcare professionals involved in identification, referral to a specialist nurse for organ donation, and consent processes should:

- have knowledge of the basic principles and the relative benefits of, donation after circulatory death (DCD) versus donation after brainstem death (DBD)

- understand the principles of the diagnosis of death using neurological or cardiorespiratory criteria and how this relates to the organ donation process
- be able to explain neurological death clearly to families
- understand the use of clinical triggers to identify patients who may be potential organ donors
- understand the processes, policies and protocols relating to donor management
- adhere to relevant professional standards of practice regarding organ donation and end-of-life care.

1.1.32 Consultant staff should have specific knowledge and skills in:

- the law surrounding organ donation
- medical ethics as applied to organ donation
- the diagnosis and confirmation of death using neurological or cardiorespiratory criteria
- the greater potential for transplantation of organs retrieved from DBD donors compared with organs from DCD donors
- legally and ethically appropriate clinical techniques to secure physiological optimisation in patients who are potential organ donors
- communication skills and knowledge necessary to improve consent ratios for organ donation.

More information

You can also see this guideline in the NICE pathway on organ donation for transplantation.

To find out what NICE has said on topics related to this guideline, see our web page on organ and tissue transplantation.

See also the guideline committee's discussion and the evidence reviews (in the full guideline), and information about how the guideline was developed, including details of the committee.

[2] It is recognised that a proportion of the patients who are identified by these clinical triggers will

survive.

[3] See also Diagnosis of brain stem death in infants between 37 weeks and 2 months gestation published by the Royal College of Paediatrics and Child Health, 2015.

[4] If the potential donor is under 16, healthcare professionals should follow the guidelines in 'Seeking consent: working with children'.

[5] DCD consensus meeting report, available from www.odt.nhs.uk/pdf/DCD_Consensus_2010.pdf.

[6] GMC guidance on treatment and care towards the end of life.

[7] Available from www.uktransplant.org.uk or www.organdonation.nhs.uk.

[8] The NHS Organ Donor Register now allows anyone to register a decision to donate, not to donate or to nominate a representative to make a decision after their death.

[9] Mental Capacity Act (2005) and Human Tissue Act (2004).

2 Research recommendations

We have made the following recommendations for research, based on our review of evidence, to improve NICE guidance and patient care in the future.

2.1 Reasons for refusal for consent

Why do families refuse to give permission for organ donation?

Why this is important

High-quality research using mixed methodology is needed to identify the reasons behind family refusal to see if there are factors that are changeable (for example, poor understanding of the process, medical mistrust, 'knee-jerk' response that is later regretted). The study could be, for example, a multi-centre observational study where all family members (those that did and those that did not give permission for their deceased loved one's organ donation) are followed up 6 months later.

Such research could determine whether those participants who gave permission for donation have higher perceived benefits scores, lower prolonged grief scores and higher quality-of-life scores than those who did not.

2.2 Improving rates of identification and referral of potential donors

What are the key components of an intervention to improve identification and referral rates?

Why this is important

Currently, the evidence for improving identification and referral rates consists mainly of observational reports of complex interventions, with most studies being of limited follow-up. Further research is needed to identify the components, or combinations of components, of the interventions that are effective in increasing identification and referral rates. These studies should have an appropriate length of follow-up to ensure a sustained impact in the longer term.

2.3 Improving consent rates

What are the key components of an intervention to improve consent rates?

Why this is important

Currently, the evidence for improving consent rates consists mainly of observational reports of complex interventions, with most studies being of limited follow-up. Further research is needed to identify the components, or combinations of components, of the identified interventions that are effective in increasing consent rates. These studies should have an appropriate length of follow-up to ensure a sustained impact in the longer term.

2.4 The experience of consenting for organ donation

Does a positive experience of approach and process of consent for families increase consent rates?

Why this is important

It is generally accepted that if families have a more positive experience of the approach and process of consenting, then rates of consent will increase. However, no high-quality evidence was identified to support this perception. Further research is needed to confirm this assumption and, if true, to identify those components of the approach and process that are key to improving the experience, and hence the consent rate.

Update information

December 2016: A footnote on diagnosis of brain stem death in infants was added to recommendation 1.1.2. A footnote on the NHS Organ Donor Register was added to recommendation 1.1.9. An outdated research recommendation was removed.

ISBN: 978-1-4731-2250-5

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