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

NICE clinical guideline

Draft guideline for PPC

This guideline was developed following the NICE short clinical guideline process. This document includes all the recommendations, details of how they were developed and summaries of the evidence they were based on.

Contents

Disclaimer

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement.

However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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 which 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 health care 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.

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. People at the end of their life 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 (available from www.dh.gov.uk/consent) and the code of practice that accompanies the Mental Capacity Act (summary available from www.publicguardian.gov.uk). In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government (available from www.wales.nhs.uk/consent).

If the potential donor is under 16, healthcare professionals should follow the guidelines in 'Seeking consent: working with children' (available from www.dh.gov.uk/consent).

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 Summary

1.1 List of all recommendations

Identification of patients who are potential donors

1.1.1 Consideration of organ donation should be 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[1] 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 tests, whichever is the earlier

- the intention to withdraw life-sustaining treatment in patients with

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

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.

1.1.4 So long as any delay is in the patient's best interests, life-sustaining treatments should not be withdrawn or limited until the potential for the patient to donate has been assessed, in accordance with legal[2] and professional[3,4] guidance. Clinically stabilise the patient in an appropriate critical care setting while such an assessment is performed – for example, in an adult critical care unit or in discussion with a regional paediatric intensive care unit.

Seeking consent

1.1.5 If a patient has the capacity to make their own decisions, obtain their views on organ donation, and their consent if appropriate.

1.1.6 If a patient lacks the capacity to consent to organ donation seek to find out the patient's views by:

- referring to an advance care directive if available
- establishing whether the patient has registered and recorded their consent to donate on the NHS organ donor register[5,6] and
- exploring with those close to the patient whether the patient had expressed any views about organ donation.

1.1.7 Where the patient lacks the capacity and their wishes are not known, explore the person's values and preferences with close

[2] www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825
[3] www.ics.ac.uk/intensive_care_professional/standards_and_guidelines/dcd
[4] www.gmc-uk.org/guidance/ethical_guidance/6858.asp
[5] www.uktransplant.org.uk
[6] www.organdonation.nhs.uk

family in order to establish whether taking steps, before death, to facilitate organ donation would be in the best interests of the patient.

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

1.1.9 Discuss the 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.

1.1.10 The multidisciplinary team (MDT) responsible for planning the approach for consent and seeking the consent for organ donation 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.

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

1.1.12 The MDT involved in the initial approach should have the necessary skills and knowledge to provide appropriate support and accurate information about organ donation to those close to the patient.

1.1.13 Before approaching those close to the patients for consent:

- 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 care directives or Lasting Power of Attorney for health and welfare
- clarify coronial, legal and safeguarding issues.

1.1.14 Before approaching those close to the patient about consent, 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 needed – for example local 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.

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

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

1.1.17 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 they are offered.

1.1.18 Only approach those close to the patient for consent when it is clearly established that they understand the inevitability of the death.

1.1.19 When approaching those close to the patient about consent:

- discuss with them that donation is a usual part of the end-of-life care that the patient will receive
- use open-ended questions – for example 'how do you think your relative would feel about organ donation?'

1.1.20 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'). The healthcare team providing care for the patient should provide those close to the patient who are potential donors 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[7], including the status of being on the NHS organ donor register or any advance care directive
  - 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.

1.1.21 For potential donors where death has been confirmed using neurological criteria, provide those close to the patient with a clear explanation of how death is diagnosed using neurological criteria,

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

and how this is confirmed.

1.1.22 For potential donors where circulatory death is anticipated, provide those close to the patient with a clear explanation on all of the following:

- 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.

Organisation of the identification, referral and consent processes

1.1.23 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.

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

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

1.1.26 The MDT involved in the identification, referral to 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.

1.1.27 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 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, polices and protocols relating to donor management
- adhere to relevant professional standards of practice regarding organ donation and end-of-life care.

1.1.28 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.

1.2 Overview

1.2.1 Consent for organ donation

Organ transplantation has a major role in the management of organ failure – that is, of a single organ system of the kidneys, small bowel, liver, pancreas, heart, or lung, 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 of a disease – for example, people with diabetes needing kidney, islet cell and/or

pancreas transplants, and people with cystic fibrosis needing lung transplants.

There is a shortage of organs for transplant resulting in long waits for transplantation and a significant number of deaths among those awaiting transplantation, and among those not considered for transplantation because of organ scarcity.

UK Transplant commissioned a survey in 2003 that showed a large majority of the public is supportive of organ donation in principle, with 90% of those responding in favour. Nearly 17 million people (28% of the population) 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, but all failed to resolve the problems that result from the lack of a structured and systematic approach to organ donation.

This guideline focuses on identifying potential donors and obtaining consent for solid organ donation under current legislation. It aims to help address the burden of disease by increasing the availability of organs for transplant. It also addresses current inequalities in approach 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.

This short clinical guideline aims to improve consent rates by making recommendations based on evidence where it is available, on the structures and processes of identifying potential donors and the approach for consent.

How this guideline was developed

‘Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation’ (NICE clinical guideline [XX]) is a NICE short clinical guideline.

For a full explanation of how this type of guideline is developed, see 'The guidelines manual' (2009) at www.nice.org.uk/GuidelinesManual.

Who this guideline is for

This document sets out NICE guidelines for health professionals involved in the process of organ donation, including their interactions with potential donors, and parents, partner, family, carers or guardians.

2 Care pathway

2.1 Increasing donation rates through identification, referral and consent

2.1.1 Evidence review

The five review questions were:

- Review question 1:
  - What structures and processes including timing for referral and criteria for consideration are appropriate and effective for identifying potential DBD and DCD donors?
- Review question 2:
  - What structures and processes are appropriate and effective for obtaining consent from families, relatives and legal guardians of potential DBD and DCD donors?
- Review question 3:
  - When is the optimal time for approaching the families, relatives and legal guardians of potential DBD and DCD donors for consent?
- Review question 4:
  - How should the care pathway of deceased organ donation be coordinated to improve potential donors giving consent?
- Review question 5:
  - What key skills and competencies are important for healthcare professionals to improve the structures and processes for identifying potential DBD and DCD, to improve structures and processes for obtaining consent, and to effectively coordinate the care pathway from identification to obtaining consent?

A total of 3465 articles were found by systematic searches for review questions 1 to 4. Full text article was ordered for 311 articles based on the title and abstract. Sixty-one papers met the eligibility criteria (for review protocol and inclusion and exclusion criteria, see appendix C). Although searches were undertaken for review question 5, the technical team and the GDG considered

that evidence already reviewed and included for review questions 1 to 4 would adequately inform evidence-based recommendations on the skills and competencies needed by healthcare professionals. For example, where a lack of knowledge or skills was identified for healthcare professionals as part of review question 2, a recommendation was made that healthcare professionals should have those skills and knowledge in order to implement the other recommendations made in the guideline.

Although systematic reviews were undertaken for each of the review questions (except review question 5 as noted above), this evidence review provides a summary of the whole evidence base used for this guideline. The reviews for each question can be seen separately in appendix G. However, when drafting the evidence statements and recommendations, it became clear that the evidence reviewed often covered more than one area of interest (that is, the search strategies used were not able to be specific enough to separate out the detailed components of the process that were of interest); therefore the process of identifying the evidence and drafting recommendations was iterative and reflective.

GRADE assessment was adapted, and the following variables were considered: limitations, inconsistency, and indirectness. Imprecision was rated as not relevant for some areas because it did not apply to the type of evidence considered (for example, qualitative studies).

Summary GRADE tables are presented below. For full GRADE profiles, see appendix E.

Review question 1

What structures and processes including timing for referral and criteria for consideration are appropriate and effective for identifying potential DBD and DCD donors?

GRADE profile 1: Summary of structures and processes for identifying potential DBD and DCD donors

Summary of findings		
Number of studies	Analysis	Quality

Summary of findings		
Number of studies	Analysis	Quality
9 studies 3 x Audit retrospective studies - [A], [P], [Ma] 1 x Audit report - [G&E] 1 x Medical records retrospective review - [G] 3 x Survey questionnaires - [O], [W], [M] 1 x Audit prospective study - [T]	Studies showed that one of the factors for low identification rates was healthcare professionals missing identifying potential donors.	Very low
1 study 1 x Audit study - [Pu]	A study showed that there was an improvement in identification of potential donors in hospitals with a donor action programme (an international initiative providing tools and guidelines to assist hospitals in assessing and improving donor potential) implemented.	Very low
2 studies 1 x Audit retrospective study - [A] 1 x Survey using a questionnaire - [Mo]	Studies showed that a lack of organ donation protocol or knowledge of the referral process in emergency departments may be a cause for non-identification of potential donors.	Very low
2 studies 1 x Medical records retrospective reviews - [G] 1 x Survey questionnaire - [O]	Studies showed that healthcare professionals did not approach family members to make a decision about donation.	Very low
1 study 1 x Survey questionnaire - [Pe]	A study showed that healthcare staff felt that families were too distressed to be approached for organ donation.	Very low
1 study 1 x Audit retrospective study - [A]	A study showed the lack of available contact details of the donor transplant coordinator in emergency departments as a factor for lack of identification of potential donors.	Very low
1 study 1 x Audit retrospective study - [A]	A study showed the following personnel should be part of the identification process in the emergency department: hospital consultants - A&E, anaesthetists and neuro-surgeons emergency trauma team A&E nursing and medical staff.	Very low
1 study 1 x Audit retrospective study -	A study showed that HM coroner's involvement was seen as too complex, acting as a barrier cited by healthcare staff as to why patients may not be recognised as potential donors in the A&E department.	Very low

Summary of findings		
Number of studies	Analysis	Quality
[A]		
1 study 1 x Audit retrospective study - [A]	A study showed that lack of confidence and experience of A&E staff in offering the option of donation to acutely bereaved families acted as a barrier cited by healthcare staff as to why patients may not be recognised as potential donors in the A&E department.	Very low
2 studies 1 x Audit retrospective study - [A] 1 x Survey questionnaire - [Pe]	Studies showed that healthcare professionals perceived that a lack of resources and shortage of intensive care beds in the hospital may have contributed to non-identification and referral.	Very low
1 study 1 x Structured questionnaire - [Pl]	A study showed that the following factors influenced the decision to discuss with families regarding organ donation: number of potential organs in a particular donor knowledge of contraindications by physician cause of death with natural causes of death sex of the physician – female physicians are more likely to ask than male colleagues.	Very low
2 studies 1 x Medical records retrospective review - [G] 1 x Survey questionnaire - [Pe]	Studies showed that people of African-American origin and people with perceived cultural differences were less likely to donate and also healthcare professionals were less likely to approach them.	Very low
1 study 1 x Medical records retrospective review - [G]	A study showed that rates of organ donation were higher when the cause of death was a motor vehicle accident, a gunshot wound or stabbing, or other head trauma compared with cerebrovascular, asphyxiation, or cardiovascular events	Very low
1 study 1 x Survey questionnaire - [Pe]	A study showed that threats to staff from family members acted as a barrier to identification of potential donors.	Very low
1 study 1 x Survey questionnaire - [Pe]	A study showed that healthcare staff experienced language difficulties in explaining to families about organ donation which acted as a barrier to identification of potential donors.	Very low
1 study 1 x Survey using a questionnaire - [Mo]	A study showed that healthcare staff felt that approaching families for organ donation was too emotionally demanding and acted as a barrier to identification of potential donors.	Very low
1 study 1 x Survey using a questionnaire - [Mo]	A study showed that healthcare professionals' fear of potential litigation was a factor for non-identification and donation.	Very low
1 study 1 x Structured	A study showed that healthcare professionals identified the following factors that acted as barriers for non-identification of potential donors: lack of time	Very low

Summary of findings		
Number of studies	Analysis	Quality
questionnaire - [Pl]	did not think difficult situation.	

Abbreviations
[A] = Aubrey et.al (2008)
[G&E] = Gabel and Edstrom (1993)
[P] = Petersen et al. (2009)
[G] = Gortmaker et al. (1996)
[O] = Opdham et al. (2004)
[T] = Thompson et al. (1995)
[W] = Wood et al. (2003)
[M] = Moller et al. (2009)
[Ma] = Madsen et al. (2006)
[Pu] = Pugliese et al. (2003)
[Mo] = Molzahn et al. (1997)
[Pe] = Pearson et al. (1995)
[Pl] = Ploeg et al. (2003)

GRADE profile 2: Summary of use of clinical triggers

Study characteristics	Summary of findings	
Number of studies	Analysis	Quality
Conversion rate		
1 study 1 x observational study - [B]	<table><tr><td>Outcome</td><td>2004</td><td>2005</td></tr><tr><td>Conversion rate</td><td>50%</td><td>80%</td></tr></table> A study showed that the conversion rate statistically significantly increased when clinical triggers were used to screen all intensive care unit (ICU) patients.	Very low
Number of organ donors		
1 study 1 x observational study - [S]	A study showed that the number of organ donors in collaborative hospitals increased by 14.1% in the first year, a 70% greater increase than the 8.3% increase experienced by non-collaborative hospitals. Moreover, the increased organ recovery continued into the post-collaborative periods.	Very low
Number of potential and effective donors		
2 studies 2 x observational studies - [Sh] and [V]	The number of potential donors increased between 4% and 27.46%. The number of effective donors increased by 22% to 30.86%.	Very low
Total number of referrals		

Study characteristics	Summary of findings	
Number of studies	Analysis	Quality
1 study 1 x observational study - [Sh]	Total referrals increased by 26% in the project IHC LITCs vs. 14% in the comparison hospitals.	Very low
Abbreviations [B] = Bair et al. (2006) [S] = Shafer et al. (2008) [Sh] = Shafer et al. (2004) [V] = Van gelder et al. (2006) IHC = in-house cordinators LITC = Level I trauma centres		

GRADE profile 3: Summary of use of required referral

<table>
<tr><th>Study characteristics</th><th colspan="2">Summary of findings</th></tr>
<tr><td>Number of studies</td><td>Analysis</td><td>Quality</td></tr>
<tr><td colspan="3">Referral rate and number of potential donors</td></tr>
<tr><td>1 study

1 x observational study - [M]</td><td>
<table>
<tr><td></td><td colspan="2">2006-7</td><td colspan="2">2007-8</td></tr>
<tr><td>Number</td><td>Heart beating donors</td><td>Non-heart beating donors</td><td>Heart beating donors</td><td>Non-heart beating donors</td></tr>
<tr><td>Referred</td><td>2</td><td>1</td><td>7</td><td>31</td></tr>
<tr><td>Accepted</td><td>1</td><td>1</td><td>6</td><td>7</td></tr>
</table>
There was an increase in referral rate.
There was an increase in the number of potential donors referred to the organ procurement organisation (OPO) representative.
</td><td>Low</td></tr>
<tr><td colspan="3">Referral rate and number of potential donors</td></tr>
<tr><td>5 studies

4 x observational studies - [H], [Hi], [R], and [S]

1 x retrospective study - [B]</td><td>There was an increase in referral rate of between 56% and 450%.

There was an increase in the number of potential donors referred to the OPO representative of between 3% and 80%.</td><td>Very low</td></tr>
<tr><td colspan="3">Number of donors</td></tr>
<tr><td>6 studies

3 x observational studies - [S], [R], and [Sh]

3 x retrospective studies - [B], [D], and [G]</td><td>Studies showed that there was an increase in the number of donors of between 24% and 275% from potential donors.</td><td>Very low</td></tr>
<tr><td colspan="3">Number of organs retrieved per donor</td></tr>
<tr><td>1 study

1 x observational study - [S]</td><td>A study showed that there was an increase of 312% for the number of organs retrieved per donor.</td><td>Very low</td></tr>
<tr><td colspan="3">Number of organs retrieved per donor</td></tr>
<tr><td>1 study

1 x retrospective study -[G]</td><td>But one study showed that the overall number of organs per donor was essentially unchanged from the baseline year.</td><td>Very low</td></tr>
<tr><td colspan="3">Abbreviations
[M] = Murphy et al. (2009)
[H] = Higashiwaga et al. (2001)
[Hi] = Higashiwaga et al. (2002)
[R] = Robertson et al. (1998)
[S] = Shafer et al. (1998)
[B] = Burris et al. (1996)
[Sh] = Shafer et al. (2008)</td></tr>
</table>

Study characteristics	Summary of findings	
Number of studies	Analysis	Quality
[D] = Dickerson et al. (2002) [G] = Graham et al. (2009)		

Review question 2

What structures and processes are appropriate and effective for obtaining consent from families, relatives and legal guardians of potential DBD and DCD donors?

GRADE profile 4: Summary of effect of 'collaborative requesting' on consent rate for organ donation					
Study characteristics		**Summary of findings**			
		No of patients		**Effect**	
Number of studies	Design	Collaborative	Routine	Results (95% CI)	**Quality**
Consent to organ donation (ITT)					
1 [Y]	RCT	57/100 (57.0%)	62/101 (61.4%)	OR 0.83 (95% CI 0.47 to 1.46)	Low
Consent to organ donation (Adjusted for ethnicity, gender, and age)					
1 [Y]	RCT	57/100 (57%)	62/101 (61.4%)	OR 0.80 (95% CI 0.43 to 1.53, p = 0.49)	Low
Any solid organ retrieved from all patients (ITT)					
1 [Y]	RCT	45/100 (45.0%)	57/101 (56.4%)	OR 0.63 (95% CI 0.36 to 1.10)	Low
Any solid organ retrieved from patients who consented (ITT)					
1 [Y]	RCT	45/79 (57.0%)	57/92 (62.0%)	OR 0.81 (95% CI 0.44 to 1.50)	Low
Abbreviations [Y] = Young et. al (2009). Collaborative request (Relatives approached by clinical team and a donor transplant coordinator) vs. routine request (Relatives approached by the clinical team alone)					

GRADE profile 5: Summary of views of families of potential adult donors

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
Influence of staff involved in organ donation		
1 study 1 x Qualitative Study - [J]	A study showed that family members felt that presence of and interaction with nursing staff were strongly valued by both donor and non-donor family members. Satisfaction with nurses' behaviour and care was expressed by all, and nurses were seen as a s source of emotional support.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that family members felt that treating physicians are not readily available to families, do not provide continuity of care and information, do not use simple language, and do not verify whether the families have understood everything being explained to them by the physicians.	Very low
1 study 1 x Qualitative retrospective study - [H]	A study showed that donor families found it easier to talk to donor coordinators because they did not wear any uniform.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that there were variations in the family experiences while being approached for consent on organ donation.	Very low
Continuity of care		
1 study 1 x Qualitative Study - [J]	A study showed that families preferred continuity of care for their loved ones. Continuity of care was sometimes considered inadequate to increase consent for organ donation.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families of potential donors preferred to interact with a single physician.	Very low
Quality of approach		
2 studies 1 x Qualitative retrospective study - [H] 1 x Qualitative Study - [J]	Studies showed that families of donors and non-donors wanted compassionate care of their loved one (potential donor) and wanted them to be treated with dignity and respect.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families wanted to be listened to by the staff and wanted the staff to be there for them when needed.	Very low
Provision of information		

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
2 studies 2 x Qualitative Studies - [J] and [S]	Studies showed that families of donors and non-donors wanted understandable, prompt, accurate, in-depth and consistent information.	Very low
2 studies 1 x Qualitative retrospective study - [H] 1 x Qualitative Study - [J]	Studies showed that the different kinds of information required by families included the meaning of brainstem death, the confirmation of death, the reasons for brainstem testing, other medical information related to the condition of the potential donor, and the whole process of organ donation. Also, it should be made sure that families have understood clearly what they were told and what they asked for.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families of donors and non-donors considered the tone and pace of information giving to be crucial. Families considered that they were rushed and pressured, and information was conveyed insensitively. They wanted the information to be conveyed with empathy, concern, and consideration.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families of donors and non-donors considered privacy for the discussion to gain consent for organ donation as being critically important.	Very low
Sources of support		
1 study 1 x Qualitative Study - [J]	A study showed that families viewed nurses as a source of support during the discussion to gain consent for organ donation.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families of donors believed that that faith and spiritual support was important to them during the discussion to gain consent for organ donation but non-donor families believed this support to be of less importance.	Very low
1 study 1 x Qualitative retrospective study - [H]	A study showed that some donor families found follow-up care to be useful. It enabled them to ask further questions and to make the process of donation feel more personal and sincere following discussion to gain consent for organ donation. But, not all donor families thought that follow-up care was useful.	Very low
Views of physicians involved in organ donation		
1 study 1 x Qualitative Study - [S]	A study showed that physicians involved in the organ donation process considered the need to be certain of their decisions and of the process to be important. They also found the entire process very stressful.	Very low
Factors associated with decision stability or satisfaction		
1 study 1 x Retrospective study - [B]	A study showed that one factor associated with consent in potential adult donors was an understanding of the term brain death.	Very low
Factors associated with decision instability or dissatisfaction		

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
1 study 1 x Retrospective study- [R]	A study showed that the factors associated with denial of consent in potential adult donors were: a lack of discussion of donation with the deceased poor timing of donation discussion not being told of the death before the first mention of donation not being given enough time to discuss the donation decision with others.	Very low
Factors associated with the decision to grant consent		
12 studies 7 x Retrospective studies- [B], [Br], [M], [F], [D], [N], [Si & L] 1 x Retrospective study (chart review and interviews) - [Si-b] 2 x Retrospective studies (survey) - [Si], [P] 1 x Cross sectional survey- [C] 1 x Retrospective cross sectional qualitative study- [Sq]	Studies showed that the following factors were associated with families of potential donors granting consent to organ donation: understanding that transplantation was a proven procedure with a high success rate, and knowledge of the benefits or organ donation an understanding of the term brain death acceptance of death, and confidence in the 'diagnosis of death' consideration and knowledge of the deceased's wishes (through carrying a donor card or discussion) earlier timing of request involving more family members with the decision the level of comfort with which the healthcare professional requested consent good relationships between the family and the healthcare professionals satisfaction with treatment (either of the family or the deceased) congruence between the views of healthcare professionals and the families at initial approach request for donation being initiated by a healthcare professional (not a physician) with further discussion with an organ donation professional request by different healthcare professionals more time spent with an organ donation professional knowledge of the impact of donation on other processes, such as funeral arrangements knowledge of the costs of donation choice of organs for donation families being able to discuss both specific and wider issues and getting answers to questions.	Very low
Factors associated with the decision to refuse consent		

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
18 studies 11 x Retrospective studies- [B], [Br], [M], [D], [Si & L], [La S], [No], [So], [Do], [Sh] and [Ch] 1 x Cross sectional survey - [C] 1 x Retrospective cross sectional qualitative study - [Sq] 1 x Retrospective study (chart review and interviews) - [Si-b] 2 x Retrospective studies (survey)- [Si], [P] 1 x Prospective study - [Si-a]	Studies showed that the following factors were associated with families of potential donors refusing consent to organ donation: feelings of pressure to consent feeling emotionally overwhelmed feeling of surprise on being asked about consent fear of causing more 'suffering' or disfigurement, and not wanting the deceased to have more medical intervention concern that donation may cause more distress to family members uncertainty about the deceased's wishes reluctance to accept the death social resentment lack of understanding and confidence in the concept of brainstem death lack of family consensus and the family being 'upset' family reticence making the decision before information was provided by a healthcare or organ donation professional an absence of key decision makers the length of the process not liking the hospital or healthcare professionals feeling that the medical care was not optimal initial approach by a healthcare professional perception that the healthcare professional did not care or was not concerned, or the healthcare professional showing a lack of respect healthcare professionals stating that the request was required lack of knowledge of the impact of donation on other processes, such as funeral arrangements lack of detailed information on the process of organ donation, including the timing of retrieval and information on recipients initial perception of healthcare professionals that the family were likely to refuse consent.	Very low
Other factors influencing consent for organ donation		
12 studies 7 x Retrospective studies- [B], [Br], [M], [Si & L], [La S], [F] and [No] 1 x Retrospective study (chart review and interviews) - [Si-b] 2 x Retrospective studies (survey) - [Si], [P] 1 x Prospective study (survey) - [Yo] 1 x Retrospective study (audit) - [Pi]	Studies showed that other factors that influenced the families of potential donors in obtaining consent were: donor ethnicity donor age donor sex type of death (trauma or not) familial (or consentor) level of education socioeconomic status marital status, previous examples of belief in or support for organ donation (such as carrying a donor card or donating to relevant charities) religious, cultural or spiritual beliefs personal experience or knowledge of transplantation setting of donation or death. However, some associations were not consistent across studies.	Very low
Abbreviations [J] = Jacoby et al. (2005)		

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
[H] = Haddow (2004) [S] = Sanner et al. (2007) [B] = Burroughs et Al. (1998) [R] = Rodrigue et al. (2008) [Si-b] = Siminoff et al. (2001b) [Br] = Brown et al. (2010) [Si] = Siminoff et al. (2002) [P] = Pearson et al. (1995) [M] = Martinez et al. (2001) [F] = Frutos et al. (2002) [D] = Douglas (1994) [C] = Cleiren and Van Zoelen (2002) [Sq] = Sque et al. (2007) [N] = Niles et al. (1996) [Si & L] = Siminoff and Lawrence (2002) [La S] = La Spina et al. (1993) [No] = Noury et al. (1996) [So] = Sotillo et al. (2009) [Ch] = Chapman et al. (1995) [Yo] = Yong et al. (2000) [Pi] = Pike et al. (1990) [Do] = Douglass et al. (1995) [Si-a] = Siminoff et al. (2001a) [Sh] = Shaheen et al. (1996)		

GRADE profile 6: Summary of views of families of potential paediatric donors

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
Influence of staff involved in organ donation		
1 study 1 x qualitative study - [B], [Be-a], [Be-b]	A study showed that parents of potential paediatric donors were more likely to give consent if they had a good relationship with the ICU personnel; they were then more likely accept the irreversibility of their child's death. Conversely, where this relationship was poor or when staff did not allow parents to be at the child's bedside, parents of potential paediatric donors were less likely to give consent.	Very low
Influence of family members		
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors tended to make the final decision about consent with their spouse but extended family members played a significant role in the decision-making process. In cases where parents of potential paediatric donors lacked spousal or mate support, consent for donation was less likely.	Very low
Factors related to consent		
1 study 1 x qualitative study - [B], [Be-a], [Be-b]	A study showed that parents of potential paediatric donors gave consent when they were able to accept their child's death, attribute meaning to the donation (for example, the benefits to the recipient) and when they believed that consent was consistent with their child's wishes.	Very low
1 study 1 x qualitative study - [B], [Be-a], [Be-b]	A study showed that parents of potential paediatric donors were more likely to decline consent when they had no previous knowledge about organ donation, wanted to know the recipient, considered that their child had been inappropriately cared for, or were unaware of their church's position on organ donation.	Very low
1 study 1 x qualitative study - [B], [Be-a], [Be-b]	A study showed that other factors related to obtaining consent from parents of potential paediatric donors included: fear of mutilation or disfigurement subjecting the child to further 'ordeal' a reluctance to assume responsibility for another's organs.	Very low
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors who gave consent reported feeling that their grief was eased, through helping others to live or feeling that their child was living on through others.	Very low
Method of approach		
1 study 1 x qualitative study - [B]	A study showed that parents of potential paediatric donors were more likely to give consent when family members or friends were approached by healthcare professionals, and they then approached the parents (indirect approach).	Very low
Quality of approach		
1 study 1 x qualitative study - [B], [Be-a], [Be-b]	A study showed that parents of potential paediatric donors were more likely to decline consent when the parents were informed in an inappropriate manner and pressured to make a decision.	Very low
Provision of information		

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors requested the following information before giving consent for organ donation: the process of organ retrieval the outcomes of transplantation the identity of the recipient the possibility of making contact with the recipient.	Very low
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors experienced more distress and were less likely to give consent if they were not given information on: the child's condition the chance of survival of the child the concept of brain death.	Very low
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors who had given consent for organ donation wanted more information on what happened next, including the process of burial. Some parents of potential paediatric donors expressed resentment and anger at healthcare professionals who never expressed concern about their wellbeing during the period following the child's death. They also felt that their act was not socially recognised and that they were quickly forgotten. A few even believed that they had been exploited.	Very low
Factors associated with the decision to grant consent		
2 studies 1 x Retrospective study - [V] 1 x Retrospective study (survey) - [W]	Studies showed that the following factors were associated with families of potential paediatric donors granting consent to organ donation: belief in the process of donation, and feeling that it was 'the right thing to do' perception that the child would go on living in others good interaction with healthcare professionals involved in organ donation type of healthcare professional who asked for consent.	Very low
Factors associated with the decision to refuse consent		
2 studies 2 x Retrospective studies (survey) - [W] and [F]	Studies showed that the following factors were associated with families of potential paediatric donors refusing consent to organ donation: a perception that the doctors who determined death were not part of the organ donation process lack of information fear or lack of belief in organ donation perception that timing of approach was not optimal feeling that the child had been through enough and fear of further trauma concern that donation would have an impact on survival consideration of donation was too upsetting poor interaction with healthcare professionals involved in organ donation, including a perception of insensitivity.	Very low
Other factors influencing consent for organ donation		

Study characteristics	**Summary of findings**	
No. of studies	Analysis	Quality
2 studies 1 x Retrospective study (survey) - [F] 1 x Retrospective study - [P]	Studies showed that other factors that influenced the families of potential paediatric donors in obtaining consent were: donor ethnicity familial (or consentor) ethnicity religious beliefs previous examples of belief in or knowledge of transplantation.	Very low
Abbreviations [B] = Bellali et al. (2006) [Be-a] = Bellali et al. (2007-a) [Be-b] = Bellali et al. (2007-b) [V] = Vane et al. (2001) [W] = Weiss et al. (1997) [F] = Frauman et al. (1987) [P] = Pietz et al. (2004)		

Review question 3

When is the optimal time for approaching the families, relatives and legal guardians of potential DBD and DCD donors for consent?

GRADE profile 7: Summary of the optimal time for approaching the families, relatives and legal guardians of potential DBD and DCD donors to gain consent

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
Approach before death		
2 studies 2 x retrospective studies - [N] and [S]	Studies showed that when families of potential donors were asked about donation before death of their loved one, they tended to have a higher chance of giving consent than those asked at the time of death or after death.	Very low
Approach after death		
1 study 1 x retrospective study - [C]	A study also showed that when families of potential donors were asked about donation following notification of death of their loved one, as opposed to before or simultaneously with notification of death, they tended to have a higher chance of giving consent.	Very low
Time difference between approaches		
1 study 1 x retrospective study - [V]	A study showed that when time to initiation of brain death protocol was examined, success was obtained when a mean delay of 15.5 hours was respected compared with a mean delay of 7.0 hours, when donation was requested but denied.	Very low
Factors associated with optimal time to approach families of adult potential donors		
1 study 1 x Qualitative Study - [J]	A study showed that families who had denied consent had not been given enough time to prepare for organ donation and had not been clearly informed that their loved one (potential donor) was brain dead.	Very low
3 studies 2 x Qualitative Studies -[J] and [S] 1 x Qualitative retrospective study - [H]	Studies showed that families of potential adult donors thought that time was needed to allow families to recover from shock, to consider the benefits of donation, allow them sufficient time to discuss the decision with other family members, and to understand the concept of brainstem death.	Very low
1 study 1 x Qualitative Study - [J]	A study showed that families of potential adult donors who gave consent thought that the timing of the approach was ‘as good as could have been’ and had time to spend with the family member and to say goodbye.	Very low
Factors associated with optimal time to approach families of paediatric potential donors		

Study characteristics	**Summary of findings**	
No. of studies	Analysis	Quality
1 study 1 x qualitative study - [B]	A study showed that parents of potential paediatric donors felt that the indirect approach for consent gave them time to consider the request for donation before the discussion with the physician.	Very low
1 study 1 x qualitative study - [Be-a], [Be-b]	A study showed that parents of potential paediatric donors felt distressed and tended to refuse consent if they were not given the chance to see their child and say goodbye.	Very low
Abbreviations [N] = Niles et al. (1996) [S] = Siminoff et al. (2002) [C] = Cutler et al. (1993) [V] = Vane et al. (2001) [J] = Jacoby et al. (2005) [H] = Haddow (2004) [S] = Sanner et al. (2007) [B] = Bellali et al. (2006) [Be-a] = Bellali et al. (2007-a) [Be-b] = Bellali et al. (2007-b)		

Review question 4

How the care pathway of deceased organ donation should be coordinated to improve potential donors giving consent?

GRADE profile 8: Summary of co-ordination of the pathway for organ donation and consent from families

Study characteristics	Summary of findings	
No. of studies	Analysis	Quality
Donor referrals		
2 studies 1 x Observational study- [S] 1 x Retrospective study - [R]	Studies showed that there was an increase in the number of donor referrals of between 46% and 450% when hospitals had in-house coordinators coordinating the process in hospitals.	Very low
Consent rates		
1 study 1 x Observational study - [Sh]	A study showed that despite demographic differences, the 8 centres with in-house coordinators had higher consent rates (60% vs 53%) than hospitals without in-house coordinators.	Very low
Conversion rates and number of donors		
4 studies 2 x Observational studies - [S] and [Sh] 2 x Retrospective studies - [R] and [A]	Studies showed that there was an increase in the conversion rates of potential donors of between 32% and 67% when hospitals had in-house coordinators coordinating the process in hospitals compared with hospitals without in-house coordinators. Also there was an increase of about 275% in the number of donors when hospitals had in-house coordinators coordinating the process in hospitals compared with hospitals without in-house coordinators.	Very low
Number of organs recovered		
1 study 1 x Observational study - [S] 1 x Retrospective study - [R]	Studies showed that there was an increase of between 70% and 312% in the number of organs recovered from donors when hospitals had in-house coordinators coordinating the process in hospitals compared with hospitals without in-house coordinators.	Very low
Abbreviations [S] = Shafer et al. (1998) [R] = Roth et Al. (2003) [Sh] = Shafer et al. (2004) [A] = Al-Sebayel et al. (2004)		

Review question 5

What key skills and competencies are important for healthcare professionals to improve the structures and processes for identifying potential DBD and DCD, to improve structures and processes for obtaining consent, and to

effectively coordinate the care pathway from identification to obtaining consent?

As noted above, evidence from other questions was used to inform recommendations on skills and competencies needed. Therefore there is not a separate GRADE profile provided for this question.

2.1.2 Evidence statements

Identification and referral of patients who are potential donors

2.1.2.1 Nine studies (Aubrey et al. 2008; Gabel and Edstrom 1993; Gortmaker et al. 1996; Madsen and Bogh 2005; Moller et al. 2009; Opdam and Silvester 2006; Petersen et al. 2009; Thompson et al. 1995; Wood et al. 2003) showed that healthcare professionals do not recognise potential donors (very low quality evidence).

2.1.2.2 There was a belief that protocols/structures would lead to improved rates; however, no high quality evidence to support this was found (very low quality evidence).

2.1.2.3 One study (Pugliese 2003) showed improvement in identification after implementation of a donor action programme (very low quality evidence).

2.1.2.4 Two studies (Aubrey et al. 2008; Molzahn 1997) recognised that a lack of organ donation protocol or knowledge of the referral process in emergency departments was a cause for non-identification (very low quality evidence).

2.1.2.5 Two studies (Gortmaker et al. 1996; Opdam and Silvester 2006) showed that healthcare professionals did not consistently approach the families about organ donation (very low quality evidence).

2.1.2.6 One study (Pearson et al. 1995) identified that healthcare staff perceived that families were too distressed to be approached for consent (very low quality evidence).

2.1.2.7 One study (Aubrey et al. 2008) showed that no contact details of

the donor transplant coordinator were available in the emergency department (very low quality evidence).

2.1.2.8 *One study (Aubrey et al. 2008) identified the following key personnel that should be involved in the identification process in the emergency department (very low quality evidence):*

- *hospital consultants – A&E, anaesthetists and neurosurgeons*
- *emergency trauma team*
- *A&E nursing and medical staff.*

2.1.2.9 *One study (Aubrey et al. 2008) showed that lack of identification of potential donors in the emergency department was associated with HM coroner's involvement being seen as too complex (very low quality evidence).*

2.1.2.10 *One study (Aubrey et al. 2008) showed that emergency department staff lacked confidence and experience in offering the option of donation to bereaved families (very low quality evidence).*

2.1.2.11 *Two studies (Aubrey et al. 2008; Pearson et al. 1995) suggested that a perception among healthcare staff of a lack of resources and shortage of intensive care beds in the hospital may have contributed to non-identification and referral of potential donors (very low quality evidence).*

2.1.2.12 *One study (Molzahn 1997) identified that healthcare professionals found it difficult to explain brain death to families (very low quality evidence).*

2.1.2.13 *One study (Ploeg et al. 2003) identified the following factors that influenced whether discussions with families regarding donation occur (very low quality evidence):*

- *number of potential organs in a potential donor*
- *physician's knowledge of contraindications to organ donation*
- *cause of death (with physicians more likely to ask when there*

was a natural cause of death)

- *sex of the physician (female physicians are more likely to ask than male physicians).*

2.1.2.14 *Two studies (Gortmaker et al. 1996; Pearson and Zurynsky 1995) identified that African-Americans and people with perceived cultural differences were less likely to donate and the healthcare professionals were less likely to approach them (very low quality evidence).*

2.1.2.15 *One study (Gortmaker et al. 1996) identified that rates of organ donation were higher when the cause of death was a motor vehicle accident, a gunshot wound or stabbing or head trauma compared with cerebrovascular, asphyxiation and cardiovascular events (very low quality evidence).*

2.1.2.16 *One study (Pearson and Zurynsky 1995) identified threats to staff as a barrier to organ donation (very low quality evidence).*

2.1.2.17 *One study (Pearson and Zurynsky 1995) identified language difficulties in explaining about organ donation to families as a barrier to organ donation (very low quality evidence).*

2.1.2.18 *One study (Molzahn 1997) identified that healthcare professionals feel that organ donation is emotionally demanding (very low quality evidence).*

2.1.2.19 *One study (Molzahn 1997) identified that fear of potential litigation to healthcare professionals is a factor for non-identification and non-donation (very low quality evidence).*

2.1.2.20 *One study (Ploeg et al. 2003) identified the following factors for non-identification (very low quality evidence):*

- *lack of time*
- *did not think*
- *difficult situation.*

Use of clinical triggers

2.1.2.21 One study (Bair et al. 2006) showed that the conversion rate statistically significantly increased when clinical triggers were used to screen all ICU patients (very low quality evidence).

2.1.2.22 One study (Shafer et al. 2008) showed that the number of organ donors increased when centres introduced clinical triggers (GCS 5) compared with centres that did not (very low quality evidence).

2.1.2.23 Two studies (Shafer et al. 2004; Van et al. 2006) showed that there was an increase in potential donors and effective donors when some form of donation criteria was used to identify patients (very low quality evidence).

2.1.2.24 One study (Shafer et al. 2004) showed that the total number of referrals increased when clinical triggers were used (very low quality evidence).

Use of required referral

2.1.2.25 Five studies (Burris and Jacobs 1996; Higashigawa et al. 2002; Higashigawa et al. 2001; Robertson et al. 1998; Shafer et al. 1998) showed that there was an increase in referral rate and the number of potential donors referred to the OPO representative when required referral was used in hospitals (very low quality evidence).

2.1.2.26 One study (Murphy et al. 2009) showed that there was an increase in referral rate and the number of potential donors referred to the OPO representative when required referral was used in hospitals (low quality evidence).

2.1.2.27 Six studies (Burris and Jacobs 1996; Dickerson et al. 2002; Graham et al. 2009; Robertson et al. 1998; Shafer et al. 1998; Shafer et al. 2008) showed that there was an increase in the number of organ donors from potential donors when required referral was used in hospitals (very low quality evidence).

2.1.2.28 One study (Shafer et al. 1998) showed that the number of organs retrieved per donor increased when required referral was used in hospitals (very low quality evidence).

2.1.2.29 One study (Graham et al. 2009) showed that there was no change in the number of organs retrieved per donor when required referral was used in hospitals. (very low quality evidence).

Process of obtaining consent

Method of approach

2.1.2.30 One RCT (Young et al. 2009) showed that approaching families of potential donors using 'collaborative requests' did not result in any increased rates of consent for donation, or increased rates of organ retrieval when compared with routine requests (low quality evidence).

2.1.2.31 One study (Bellali and Papadatou 2006) found that if family members or friends were approached by healthcare professionals, and they then approached the parents of potential paediatric donors (indirect approach), parental consent was more likely (very low quality evidence).

Family experience and factors related to consent

2.1.2.32 One study (Jacoby et al. 2005) found that the presence of the nursing staff was valued by both donor and non-donor families and families expressed satisfaction with the nurses' behaviour and care. Nurses were also a valued source of emotional support (very low quality evidence).

2.1.2.33 However, one study (Jacoby et al. 2005) showed that families considered that treating physicians tended not to be available to families, provided inadequate continuity of care and information, did not use simple language and did not verify whether the families had understood everything being explained to them (very low quality evidence).

2.1.2.34 One study (Haddow 2004) showed that donor families reported that because donor coordinators did not wear uniforms, they found it easier to talk to them (very low quality evidence).

2.1.2.35 One study (Jacoby et al. 2005) showed that there was, however, considerable variation in the experience of all families (very low quality evidence).

2.1.2.36 One study (Bellali and Papadatou 2007; Bellali and Papadatou 2006; Bellali et al. 2007) showed that parents of potential paediatric donors tended to give consent for donation when they were able to accept their child's death, to attribute meaning to the donation (for example, the benefits to the recipient) and to believe that consent was consistent with the child's wishes (very low quality evidence).

2.1.2.37 One study (Bellali and Papadatou 2007; Bellali and Papadatou 2006; Bellali et al. 2007) showed that parents of potential paediatric donors were more likely to decline consent if they had no previous knowledge about organ donation, wanted to know the recipient, considered that their child had been inappropriately cared for, or were unaware of their church's position on organ donation (very low quality evidence).

2.1.2.38 One study (Bellali and Papadatou 2007; Bellali and Papadatou 2006; Bellali et al. 2007) showed that other factors related to the decision for consent of potential paediatric donors were fear of mutilation or disfigurement, subjecting the child to further 'ordeal', and a reluctance to assume responsibility for another's organs (very low quality evidence).

2.1.2.39 One study (Bellali and Papadatou 2007; Bellali et al. 2007) showed that where consent was granted, some parents of potential paediatric donors reported feeling that their grief was eased through helping others to live or feeling that their child was living on through others (very low quality evidence).

2.1.2.40 One study (Sanner 2007) showed that physicians reported that clear and consistent use of terminology was related to the families' decision to consent (very low quality evidence).

2.1.2.41 One study (Sanner 2007) showed that physicians considered certainty in their decisions and the process important. They also reported finding the process of consent very stressful (very low quality evidence).

2.1.2.42 A factor associated with decision stability or satisfaction was an understanding of the term brain death (Burroughs et al. 1998) (very low quality evidence).

2.1.2.43 Factors associated with decision instability or dissatisfaction were:

- *a lack of discussion of donation with the deceased*
- *poor timing of donation discussion*
- *not being told of the death before the first mention of donation*
- *not being given enough time to discuss the donation decision with others (Rodrigue et al. 2008) (very low quality evidence).*

2.1.2.44 Factors associated with the decision to grant consent were:

- *understanding that transplantation was a proven procedure had a high success rate, and knowledge of the benefits or organ donation*
- *an understanding of the term brain death*
- *acceptance of death, and confidence in the 'diagnosis of death'*
- *consideration and knowledge of the deceased's wishes (through carrying a donor card or discussion)*
- *earlier timing of request*
- *involving more family members with the decision*
- *the level of comfort with which the healthcare professional requested consent*
- *good relationships between the family and the healthcare professionals*

- *satisfaction with treatment (either of the family or the deceased)*
- *congruence between the views of healthcare professionals and the families at initial approach*
- *request for donation being initiated by a healthcare professional (not a physician) with further discussion with an organ donation professional*
- *request by different healthcare professionals*
- *more time spent with an organ donation professional*
- *knowledge of the impact of donation on other processes, such as funeral arrangements*
- *knowledge of the costs of donation*
- *choice of organs for donation*
- *families being able to discuss both specific and wider issues and getting answers to questions*

  (Brown et al. 2010; Burroughs et al. 1998; Cleiren and Van Zoelen 2002; Douglas 1994; Frutos et al. 2002; Martinez et al. 2001; Niles and Mattice 1996; Pearson et al. 1995; Siminoff and Lawrence 2002; Siminoff et al. 2001; Siminoff et al. 2002) (very low quality evidence).

2.1.2.45 Factors associated with the decision to refuse consent were:

- *feelings of pressure to consent*
- *feeling emotionally overwhelmed*
- *feeling of surprise on being asked about consent*
- *fear of causing more 'suffering' or disfigurement, and not wanting the deceased to have more medical intervention*
- *concern that donation may cause more distress to family members*
- *uncertainty about the deceased's wishes*
- *reluctance to accept the death*
- *social resentment*
- *lack of understanding and confidence in the concept of brainstem death*

- *lack of family consensus and the family being 'upset'*
- *family reticence*
- *making the decision before information was provided by a healthcare or organ donation professional*
- *an absence of key decision makers*
- *the length of the process*
- *not liking the hospital or healthcare professionals*
- *feeling that the medical care was not optimal*
- *initial approach by a healthcare professional*
- *perception that the healthcare professional did not care or was not concerned, or the healthcare professional showing a lack of respect*
- *healthcare professionals stating that the request was required*
- *lack of knowledge of the impact of donation on other processes, such as funeral arrangements*
- *lack of detailed information on the process of organ donation, including the timing of retrieval and information on recipients*
- *initial perception of healthcare professionals that the family were likely to refuse(Brown et al. 2010; Burroughs et al. 1998; Chapman et al. 1995; Cleiren and Van Zoelen 2002; Douglas 1994; La et al. 1993; Martinez et al. 2001; Noury et al. 1996; Pearson et al. 1995; Siminoff et al. 2001; Siminoff et al. 2002; Siminoff et al. 2001 ; Sotillo et al. 2009; Sque et al. 2008) (very low quality evidence).*

2.1.2.46 Other influences on consent were donor ethnicity, age, sex, type of death (trauma or not). However, some associations were not consistent across studies (Brown et al. 2010; Martinez et al. 2001; Noury et al. 1996; Pike et al. 1991; Siminoff and Lawrence 2002; Siminoff et al. 2001; Siminoff et al. 2002) (very low quality evidence).

2.1.2.47 Other influences on consent were familial (or consentor) age; ethnicity; level of education; socioeconomic status; marital status;

previous examples of belief in or support for organ donation (such as carrying a donor card or donating to relevant charities); religious, cultural or spiritual beliefs; personal experience or knowledge of transplantation; setting of donation or death. However, some associations were not consistent across studies (Brown et al. 2010; Burroughs et al. 1998; Frutos et al. 2002; La et al. 1993; Martinez et al. 2001; Pearson et al. 1995; Siminoff and Lawrence 2002; Siminoff et al. 2002; Siminoff et al. 2001; Yong et al. 2000) (very low quality evidence).

2.1.2.48 Factors associated with the decision to grant consent of potential paediatric donors were:

- *belief in the process of donation, and feeling that it was 'the right thing to do'*
- *perception that the child would go on living in others*
- *good interaction with healthcare professionals involved in organ donation*
- *type of healthcare professional who asked for consent (Vane et al. 2001; Weiss et al. 1997) (very low quality evidence).*

2.1.2.49 Factors associated with the decision to refuse consent of potential paediatric donors were:

- *perception that the doctors who determined death were not part of the organ donation process*
- *lack of information*
- *fear or lack of belief in organ donation*
- *perception that timing of approach was not optimal*
- *feeling that the child had been through enough and fear of further trauma*
- *concern that donation would impact on survival*
- *consideration of donation was too upsetting*
- *poor interaction with healthcare professionals involved in organ donation, including a perception of insensitivity*

(Frauman and Miles 1987; Weiss et al. 1997) (very low quality evidence).

2.1.2.50 *Another influence on consent of potential paediatric donors was donor ethnicity (Frauman and Miles 1987; Pietz et al. 2004) (very low quality evidence).*

2.1.2.51 *Other influences on consent of potential paediatric donors were familial (or consentor) ethnicity, religious beliefs, previous examples of belief in or knowledge of transplantation (Frauman and Miles 1987; Pietz et al. 2004) (very low quality evidence).*

Continuity of care

2.1.2.52 *One study (Jacoby et al. 2005) showed that continuity of care was considered important by families, but this was sometimes considered inadequate (very low quality evidence).*

2.1.2.53 *One study (Jacoby et al. 2005) showed that families of potential donors preferred to interact with a single physician (very low quality evidence).*

Quality of approach

2.1.2.54 *Two studies (Haddow 2004; Jacoby et al. 2005) found that compassionate care of the potential donor and their being treated with dignity and respect was important to both donor and non-donor families (very low quality evidence).*

2.1.2.55 *One study (Jacoby et al. 2005) showed that families wanted to be listened to and have staff 'be there' for them (very low quality evidence).*

2.1.2.56 *One study (Bellali and Papadatou 2007; Bellali and Papadatou 2006; Bellali et al. 2007) found that parents of potential paediatric donors were informed in an inappropriate manner and pressured to make a decision; this tended to result in a refusal for donation (very low quality evidence).*

Provision of information

2.1.2.57 Two studies (Jacoby et al. 2005; Sanner 2007) found that both donor and non-donor families wanted information that was understandable, prompt, accurate, in-depth and consistent (very low quality evidence).

2.1.2.58 Two studies (Haddow 2004; Jacoby et al. 2005) showed that types of information requested included the meaning of brainstem death, the confirmation of death, the reasons for brainstem testing, other medical information related to the condition of the potential donor, and the whole process of organ donation. The understanding of such information should be verified with the family (Jacoby 2005) (very low quality evidence).

2.1.2.59 One study (Jacoby et al. 2005) showed that tone and pace of information giving was considered critical. Both donor and non-donor families reported feeling rushed and pressured, and considered that information had been conveyed insensitively. Families wanted information to be conveyed with empathy, concern, and consideration (very low quality evidence).

2.1.2.60 Two studies (Haddow 2004; Jacoby et al. 2005) showed that families considered privacy for the discussion of donation as being critically important (very low quality evidence).

2.1.2.61 One study (Bellali and Papadatou 2007; Bellali et al. 2007) showed that parents of potential paediatric donors requested information on the process of organ retrieval, the outcomes of transplantation, the identity of the recipient, and the possibility of making contact with him or her (very low quality evidence).

2.1.2.62 One study (Bellali and Papadatou 2007; Bellali et al. 2007) showed that parents of potential paediatric donors experienced more distress when they were not given information on the child's condition, the chance of survival, and the concept of brain death

(very low quality evidence).

2.1.2.63 *One study (Bellali and Papadatou 2007; Bellali et al. 2007) showed that after consenting to donation, parents of potential paediatric donors wanted information on what happened next, including the process of burial. Some parents expressed resentment and anger at healthcare professionals who never expressed concern about their wellbeing during the period following the child's death. They also felt that their act was not socially recognised and that they were quickly forgotten. A few even believed that they had been exploited (very low quality evidence).*

Sources of support

2.1.2.64 *One study (Jacoby et al. 2005) showed that nurses were a valued source of emotional support (very low quality evidence).*

2.1.2.65 *One study (Jacoby et al. 2005) showed that donor families reported that faith and spiritual support was important to them. This was reported as being less important to non-donor families (very low quality evidence).*

2.1.2.66 *One study (Haddow 2004) found that some donor families found follow-up care allowed them to ask further questions and to make the donation feel more personal and sincere; however, not all donor families thought this would be of any value (very low quality evidence).*

Influence of staff involved in organ donation

2.1.2.67 *One study (Bellali and Papadatou 2007; Bellali and Papadatou 2006; Bellali et al. 2007) found that if parents of potential paediatric donors had a good relationship with the ICU personnel, they were more likely to accept the irreversibility of their child's death and give consent to donation. Where this relationship was poor or when staff did not allow parents to be at the child's bedside, parents were less likely to consent (very low quality evidence).*

Influence of family members

2.1.2.68 One study (Bellali and Papadatou 2006) showed that although parents of potential paediatric donors tended to make the final decision about consent with their spouse, extended family members played a significant role in the decision making process. Where spousal or mate support was not available or possible, consent for donation was less likely (Bellali and Papadatou 2007; Bellali et al. 2007) (very low quality evidence).

Timing of approach for consent

2.1.2.69 Two studies (Niles and Mattice 1996; Siminoff and Lawrence 2002) showed that families who were asked about organ donation before death (decoupling approach) tended to have a higher percentage of consent rate for donation than those asked at the time of death, or after death (very low quality evidence).

2.1.2.70 One study (Cutler et al. 1993) showed that if the request for donation was made following notification of death as opposed to before or simultaneously with notification of death, the family was more likely to grant consent for donation (very low quality evidence).

2.1.2.71 One study (Vane et al. 2001) showed parental consent of potential paediatric donors was obtained when a mean delay of 15.5 hours from admission to time to initiation of brain death protocol was respected vs. a mean delay of 7.0 hours when consent was sought but denied (very low quality evidence).

2.1.2.72 One study (Jacoby et al. 2005) found that families in the non-donor group had not been given enough time to prepare them for organ donation and had not been clearly informed that the potential donor was brain dead (very low quality evidence).

2.1.2.73 Three studies (Haddow 2004; Jacoby et al. 2005; Sanner 2007) showed that time was needed to allow families to recover from

shock, to consider the benefits of donation, to allow people to discuss the decision with other family members, and to understand the meaning of brainstem death as this was considered to be a difficult concept (very low quality evidence).

2.1.2.74 *Conversely, one study (Jacoby et al. 2005) identified that donor families described the timing of the approach as 'as good as could have been' and had time to spend with the family member and to say goodbye (very low quality evidence).*

2.1.2.75 *One study (Bellali and Papadatou 2006) reported that where the approach to consent was indirect, parents of potential paediatric donors felt they had had more time to consider the request before discussion with the physician (very low quality evidence).*

2.1.2.76 *One study (Bellali and Papadatou 2007; Bellali et al. 2007) reported that parents of potential paediatric donors experienced more distress when they were not given the chance to see their child and to say goodbye (very low quality evidence).*

Co-ordination of the care pathway

2.1.2.77 *Two studies (Roth et al. 2003; Shafer et al. 1998) showed that there was an increase in the number of organ donor referrals when hospitals had in-house coordinators coordinating the process in hospitals (very low quality evidence).*

2.1.2.78 *One study (Shafer et al. 2004) showed that hospitals with in-house coordinators had a higher consent rate than hospitals without in-house coordinators (very low quality evidence).*

2.1.2.79 *Four studies (Al-Sebayel et al. 2004; Roth et al. 2003; Shafer et al. 2004; Shafer et al. 1998) showed that there was an increase in conversion rates and number of organ donors when hospitals had in-house coordinators coordinating the process in hospitals (very low quality evidence).*

2.1.2.80 Two studies (Roth et al. 2003; Shafer et al. 1998) showed there was an increase in the organs recovered when hospitals had in-house coordinators coordinating the process in hospitals (very low quality evidence).

2.1.3 Health economic modelling

The decision problem for this guideline is to examine the value of increasing consent and conversion rates. It is not to examine the value of transplantation. A search for literature did not find any relevant papers that addressed this particular economic issue. Papers were identified that examined the cost effectiveness of different allocation processes and the cost effectiveness of certain transplantations.

The approach taken therefore is based on the assumption that increases in conversion and consent rates would lead to a reduction in waiting lists for organs and, therefore, increased transplantation rates.

The analysis will therefore examine the effect of reducing the waiting time for organ transplantation. It is not possible to conduct an analysis that includes all transplantations because of the lack of readily available data on all solid organ transplants. However, analysis can be done examining the effect of reduced waiting times on kidney transplantation. This is made possible because of the significant amount of data available on kidney transplantation including graft and overall survival estimates, costs of alternatives to transplantations (dialysis), waiting times and the ability to use a model developed for another short clinical guideline on peritoneal dialysis.

The appendix on health economics for peritoneal dialysis[8] contains data on the clinical and cost effectiveness for other renal replacement therapies. Data on transplantation came from the NHS Blood and Transplant (NHSBT) report 2009, the health technology assessment on kidney perfusion machines and NHS reference costs. A sensitivity analysis was conducted where the waiting time for kidney transplantation was varied from the current waiting time of 3.04 years to 6 months, which was achieved in Spain and is often considered to

[8] www.nice.org.uk/CGXX Health economic appendices

represent a optimum situation. Table 1 outlines the results of various waiting times for kidney transplants and the corresponding cost effectiveness results.

Table 1 Health economics – cost effectiveness results associated with average waiting times for kidney transplantation

Waiting time (years)	Costs (£)	Life years gained	QALYs	Incremental		ICER (£)[b]	Net monetary benefit (£) £20,000 threshold
				Costs (£)	QALYs[a]		
3.04[c]	130212	5.78	3.77	-	-	-	-
2.74	128236	5.82	3.83	-1976	0.059	Dominates	3162
2.43	125840	5.87	3.90	-4372	0.132	Dominates	7004
2.13	123086	5.92	3.98	-7126	0.215	Dominates	11432
1.82	119656	5.99	4.09	-10556	0.321	Dominates	16969
1.52	115590	6.07	4.21	-14622	0.447	Dominates	23565
0.5	91904	6.62	5.00	-38308	1.234	Dominates	62983

[a] Quality-adjusted life year.

[b] Incremental cost-effectiveness ratio.

[c] Derived from NHSBT please see the peritoneal dialysis guideline for more detail.

The analysis indicates that reducing the waiting time for kidney transplant is cost effective. As waiting times fall, this reduction in waiting time becomes even more cost effective. This is the case even when factoring in the cost of more transplantations.

A limitation of this analysis is that it only considers kidney transplantations. However, kidney transplants are the most common transplant undertaken by the NHS and approximately 2% of NHS resources are spent on renal replacement therapies. In addition, the recommendations in this guideline are not limited to only one type of organ and therefore, the benefits realised for kidneys could be applied more widely. Improving transplant rates and organ availability for transplant would not be associated with significant costs and therefore their implementation would present a cost-effective use of NHS resources. A costing template and report which estimates the national cost impact of implementing the guideline, including the potential cost impact of increasing the number of organs available for transplantation, has been

produced (see www.nice.org.uk/guidance/CGXXX).

2.1.4 Evidence to recommendations

Overall, the GDG considered the quality of evidence to be low to very low. There are two main reasons for this. First, most studies were observational (rather than experimental), and second, many studies were from countries other than the UK that have different legislative systems relating to organ donation and different healthcare systems. However, the evidence and recommendations are consistent with the considerable experience that the NHSBT and patient groups have in using interventions and strategies to increase rates of consent for organ donation.

No direct evidence on how to increase rates of consent in black and minority ethnic groups or in people with religious beliefs was identified and no recommendations specific to these groups have been made. However, the guideline includes recommendations on the need to understand the beliefs and needs of the families, and to tailor practice appropriately.

The tables below outline the five criteria that the GDG considered when translating the evidence into recommendations.

Identification and referral of patients who are potential donors

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors by exploring an individual's wish to donate. A recommendation was therefore made on the inclusion of organ donation as a standard part of end-of-life planning.
Trade-off between benefits and harms	Allowing a patient to discuss their beliefs or values about organ donation is part of best practice at the end of life and should be part of all planned care (as specified by the GMC). Evidence also shows that if the family is aware of the patient's wishes to donate, they are more likely to consent to organ donation.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the patient's views on organ donation influence the family's consent rate. However, the evidence reviewed showed consistently that where patients' views on donation were known, families were more likely to make a decision conforming with that view.
Other considerations	The GDG highlighted the responsibility of the physician providing care under the GMC guidance 'Treatment and care towards the end of life: good practice in decision making'[9].

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

[9] Available at www.gmc-uk.org/guidance/ethical_guidance/6858.asp

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising identification of potential donors as soon as possible. A recommendation was therefore made on the early identification of both DBD and DCD potential donors.
Trade-off between benefits and harms	Although early identification is key and is expected to result in more donations (as procedures to preserve the viability of organs can be planned and made more timely), the GDG was aware of the concerns of families and healthcare professionals that this may be perceived as denying the potential donor appropriate care. This is not the intention of the recommendation and therefore the use of clinical triggers and the decision to perform brainstem testing or withdraw life-sustaining treatments are used to define when potential donors should be identified.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of considerable value to the NHS. The size of this reduction therefore supports the use of potentially expensive interventions or increased training requirements. So, increasing the identification of potential organ donors would be cost effective.
Quality of evidence	There was a lack of high quality evidence identified that specified how potential donors could be identified earlier. However, many services reported that the number of potential donors was not being maximised. Identification was therefore considered to be an area where practice could be optimised with early and consistent identification criteria. The clinical triggers were based on the clinical experience of the GDG.
Other considerations	None.

2.1.6 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[10] who have had a catastrophic brain injury, namely:

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

  - 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 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising referral of potential donors as soon as possible. A recommendation was therefore made on the timely referral of all potential donors to the specialist nurse for organ donation team.
Trade-off between benefits and harms	Early referral of all potential donors to the specialist nurse for organ donation team would have an impact on several factors of the process. First, early referral is key and is expected to result in more donations (as procedures to preserve the viability of organs can be planned and made more timely). In addition, the specialist nurse for organ donation team has the expertise to quickly determine whether a potential donor is suitable for further assessment for donation. This will result in fewer inappropriate approaches to families. Conversely, the specialist nurse for organ donation team will have the expertise to determine whether potential donors in whom donation may previously have not been considered possible (for example, older people, people with learning disabilities, or people with hepatitis).
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified specifying the most effective method and timing of referral. However, one study was identified that showed some association between the introduction of a required referral policy and increased referrals and accepted donors. Many services reported that the number of potential donors was not being maximised. Referral was therefore considered to be an area where practice could be optimised with early and consistent referral criteria.
Other considerations	None.

2.1.7 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the organ donation rate of potential donors, through appropriate management when the decision to withdraw life-sustaining treatment has been made. A recommendation was therefore made on the clinical stabilisation of patients in whom the decision to withdraw treatment has been made.
Trade-off between benefits and harms	Clinical stabilisation of patients in whom life-sustaining treatment is to be withdrawn would be expected to result in more donations (as procedures to preserve the viability of organs can be planned and made more timely). In addition, the specialist nurse for organ donation team has the expertise to quickly determine whether a potential donor is unsuitable for further assessment for donation. This will result in fewer inappropriate approaches to families. Conversely, the specialist nurse for organ donation team will have the expertise to determine whether potential donors in whom donation may previously have not been considered possible should be considered for organ donation (for example, older people, or people with hepatitis).
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements. Therefore, increasing the identification of potential organ donors would be cost effective.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the organ donation rate of potential donors could be optimised through the use of clinical stabilisation. However, many services reported that the number of potential donors was not being maximised. Appropriate management before withdrawal of life-sustaining treatment was therefore considered to be an area where practice could be optimised to allow time for the assessment of organ donation potential. Based on GDG expertise, this should be conducted in an appropriate setting, with access to the required skills for withdrawal of life-sustaining treatment.
Other considerations	None.

2.1.8 So long as any delay is in the patient's best interests, life-sustaining treatments should not be withdrawn or limited until the potential for the patient to donate has been assessed, in accordance with the

legal[11] and professional[1213] guidance. Clinically stabilise the patient in an appropriate critical care setting while such an assessment is performed, for example an adult critical care unit or in discussion with a regional paediatric intensive care unit.

Seeking consent

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through exploring an individual's wish to donate, where possible. A recommendation was therefore made on obtaining a patient's view on donating organs after death.
Trade-off between benefits and harms	Allowing a patient to discuss their beliefs or values about organ donation is part of best practice at the end of life and should be part of all planned care (as specified by the GMC). Evidence also shows that if the family are aware of the patient's wishes to donate, they are more likely to consent to organ donation.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the patient's views on organ donation influence the family's consent rate. However, the evidence reviewed consistently showed that where patients' view on donation were known, families were more likely to make a decision conforming with that view.
Other considerations	The GDG highlighted the responsibility of the physician providing care under the GMC guidance 'Treatment and care towards the end of life: good practice in decision making'[14]. This states that "[d]epending on the patient's circumstances, it may also be appropriate to create opportunities for them to talk about what they want to happen after they die. Some patients will want to discuss their wishes in relation to the handling of their body, and their beliefs or values about organ or tissue donation."

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

[11] http://www.dh.gov.uk/en/Publicationsandstatistics/
[12] http://www.ics.ac.uk/intensive_care_professional/standards_and_guidelines/dcd
[13] http://www.gmc-uk.org/guidance/ethical_guidance/6858.asp
[14] Available at www.gmc-uk.org/guidance/ethical_guidance/6858.asp

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through exploring an individual's wish to donate as specified in advance care directives, registration on the NHS organ donor register, or through expressing these wishes to others. A recommendation was therefore made on obtaining a patient's view on donating organs after death.
Trade-off between benefits and harms	Allowing a patient to discuss their beliefs or values about organ donation is part of best practice at the end of life and should be part of all planned care (as specified by the GMC). Evidence shows that if the family are aware of the patient's wishes to donate, they are more likely to consent to organ donation.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the patient's views on organ donation influence the family's consent rate. However, the evidence reviewed consistently showed that where patients' view on donation were known, families were more likely to make a decision conforming with that view.
Other considerations	The GDG highlighted the responsibility of the physician providing care under the GMC guidance 'Treatment and care towards the end of life: good practice in decision making'[15]. This states that "[i]f a patient is close to death and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility."

2.1.10 If a patient lacks the capacity to consent to organ donation seek to find out the patient's views by:

- referring to an advance care directive if available
- establishing whether the individual has registered and recorded their consent to donate on the NHS organ donor register[16][17] and
- exploring with those close to the patient whether the patient had expressed any views about organ donation.

2.1.11 Where the patient lacks capacity and their wishes are not known,

[15] Available at www.gmc-uk.org/guidance/ethical_guidance/6858.asp
[16] www.uktransplant.org.uk/
[17] www.organdonation.nhs.uk

explore the person's values and preferences with close family in order to establish whether taking steps, before death, to facilitate organ donation would be in the best interests of the patient.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on when the approach for consent should be made.
Trade-off between benefits and harms	Evidence shows that the timing of approach for consent was considered more positively by families when the approach was made after the family had time to come to terms with the anticipated death and spend time with their loved one.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating when the approach to families should be made. However, evidence reviewed supported the timing of approach being made when families had time to consider the anticipated death and prepare for it.
Other considerations	None.

2.1.12 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on how the approach for consent should be made.
Trade-off between benefits and harms	Evidence shows that the timing of approach for consent was considered better by families when the approach was made before death ('decoupling' approach) than those asked at the time of death, or after death. This was also associated with higher rates of consent.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating when the approach to families should be made. However, evidence reviewed supported the 'decoupling' approach being made when families were approached before death.
Other considerations	None.

2.1.13 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on who should be involved when planning the approach and obtaining consent.
Trade-off between benefits and harms	Evidence shows that the experience of approach for consent was considered more positively by families where the approach was tailored, taking into account the history of the patient and the needs of the family. There was also some evidence that families valued the involvement of those healthcare professionals who cared for their family member. Evidence also supported the specialist input of a healthcare professional with expertise in organ donation.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements. Therefore, increased use of staff to facilitate consent is cost effective.
Quality of evidence	There was a lack of high quality evidence identified evaluating who should be involved in the approach to families and who should ask for consent and how this impacted on consent rates. However, based on the limited evidence available, evidence showed that families valued the input of all the recommended professionals. The needs of each family may differ, and so the different level of contribution will differ accordingly.
Other considerations	None.

2.1.14 The multidisciplinary team (MDT) responsible for planning the approach and seeking the consent for organ donation 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through providing optimal care to the potential donor. A recommendation was therefore made on who should be involved when planning the approach and obtaining consent.
Trade-off between benefits and harms	Evidence shows that the families valued the involvement of those healthcare professionals who cared for their family member. As recommended above, early identification is key and is expected to result in more donations (as procedures to preserve the viability of organs can be planned and made more timely). However, the GDG were aware of the concerns of families – that is, that this may be perceived as denying the potential donor appropriate care. The GDG therefore considered that those healthcare professionals who have been involved in the care of patient should continue to provide care throughout the process of consenting where possible.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating who should be involved in the continuing care of the patient. However, based on the limited evidence available, evidence showed that families valued continuity of care.
Other considerations	None.

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

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through providing accurate information and appropriate support to families throughout the process of consent. A recommendation was therefore made on the provision of skills and knowledge needed to provide accurate information and support to families.
Trade-off between benefits and harms	Evidence shows that the healthcare professionals lacked information and training for approaching for consent. In addition, families wanted accurate information and appropriate support. Although there was no direct link between information and support with consent rate, the GDG considered that by providing accurate information and support appropriate to the family that the experience of consent may be improved, and hence consent rates may increase.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements. So training for the MDT to improve consent will be cost effective.
Quality of evidence	There was a lack of high quality evidence identified showing that providing accurate information and appropriate support increased consent rates. However, based on the limited evidence available, evidence showed that healthcare professionals lacked information and training for approaching for consent. In addition, families wanted accurate information and appropriate support.
Other considerations	None.

2.1.16 The MDT involved in the initial approach should have the necessary skills and knowledge to provide appropriate support and accurate information about organ donation to those close to the patient.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through exploring an individual's wish to donate. A recommendation was therefore made to ensure that the wishes of the patient are explored when planning the approach for consent. In addition, the recommendation includes other factors that may impact on the potential to donate.
Trade-off between benefits and harms	Evidence shows that if the family are aware of the patient's wishes to donate, they are more likely to consent to organ donation. The GDG therefore considered that before planning the approach to the family for consent, the healthcare team should explore various sources for information on the wishes of the patient.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the patient's views on organ donation influence the family's consent rate. However, the evidence reviewed consistently showed that where patients' view on donation were known, families were more likely to make a decision conforming with that view.
Other considerations	The GDG highlighted the responsibility of the physician providing care under the GMC guidance 'Treatment and care towards the end of life: good practice in decision making'[18]. This states that as part of the process of determining the wishes of patients "[p]atients may have recorded their wishes about organ or tissue donation in the NHS Organ Donor Register held by NHS Blood and Transplant (www.nhsbt.nhs.uk)." The GDG also wished to specify the need to clarify coronial, judicial and safeguarding issues as these may be legal requirements that have implications for the potential to donate.

2.1.17 Before approaching those close to the patients for consent :

- 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 care directives or Lasting Power of Attorney for health and welfare
- clarify coronial, legal and safeguarding issues.

[18] Available at www.gmc-uk.org/guidance/ethical_guidance/6858.asp

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on what should be considered in the planning of approach.
Trade-off between benefits and harms	Evidence shows that the experience of approach for consent was considered more positively by families where the approach was tailored, taking into account the history of the patient and the needs of the family.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the approach to families should be planned. The GDG considered that the approach should be planned and individualised irrespective of the outcome on consent rates. And although there was no evidence suggesting that a more positive experience results in increased consent, the GDG theorised that if the process of approach could be optimised by avoiding negative and apologetic language for example this may result in increased rates of consent.
Other considerations	None.

2.1.18 Before approaching those close to the patient about consent, 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on where the approach for consent should be made.
Trade-off between benefits and harms	Evidence shows that the experience of approach for consent was considered more positively by families where the approach was made in a suitable setting.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating where the approach to families should be made. Evidence reviewed supported the need for a suitable setting for the approach. Although there was no evidence suggesting that a more positive experience results in increased consent, the GDG theorised that if the process of approach could be optimised, this may result in increased rates of consent.
Other considerations	None.

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

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on how timing should be considered in the planning of approach.
Trade-off between benefits and harms	Evidence shows that the experience of approach for consent was considered more positively by families where the approach was tailored, taking account of the timing of the approach and the needs of the family.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the approach to families should be planned. The GDG considered that the approach should be planned and individualised irrespective of the outcome on consent rates. And although there was no evidence suggesting that a more positive experience results in increased consent, the GDG theorised that if the timing of approach could be optimised, this may result in increased rates of consent.
Other considerations	None.

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

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on how and when the approach for consent should be made.
Trade-off between benefits and harms	See recommendations 2.1.18 and 2.1.22 above on how and when to approach for consent.
Economic considerations	None.
Quality of evidence	See recommendations 2.1.18 and 2.1.22 above on how and when to approach for consent.
Other considerations	None.

2.1.21 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on when the approach for consent should be made.
Trade-off between benefits and harms	Evidence shows that the timing of approach for consent was considered more positively by families when the approach was made after the family had time to understand the process of death, and specifically the concept of brainstem death.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating when the approach to families should be made. However, evidence reviewed supported the timing of approach being made when families had understood the process of death.
Other considerations	If families did not understand or accept the inevitability of death, the specialist nurse for organ donation would spend time explaining the process of death and supporting families before an approach for consent is made.

2.1.22 Only approach those close to the patient for consent when it is clearly established that they understand the inevitability of the death.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through planning a considered approach to the family. A recommendation was therefore made on how the approach for consent should be made.
Trade-off between benefits and harms	Evidence shows that the experience of approach for consent was considered more positively by families where the approach was made using appropriate language, including framing organ donation as being a usual part of the end-of-life care.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the approach to families should be made. However, evidence reviewed consistently supported the avoidance of apologetic and negative language and this was associated with increased rates of consent.
Other considerations	None.

2.1.23 When approaching those close to the patient about consent:

- discuss with them that donation is a usual part of the end-of-life care that the patient will receive
- 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’)

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through providing accurate information to families throughout the process of consent. A recommendation was therefore made on what information should be provided to families.
Trade-off between benefits and harms	Evidence shows that healthcare professionals who were not specialists in organ donation lacked knowledge (and therefore were unable to provide accurate information), yet families wanted information on the whole process of consenting and organ donation. The level and type of information needed will differ by family and circumstance.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements.
Quality of evidence	There was a lack of high quality evidence identified showing that providing accurate information increased consent rates. However, based on the limited evidence available, evidence showed that families wanted accurate information on the whole process of organ donation.
Other considerations	None.

2.1.24 The healthcare team providing care for the patient should provide those close to the patient who are potential donors 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[19], including the status of being on the NHS organ donor register or any advance care directive
  - 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.

2.1.25 For potential donors where death has been confirmed using neurological criteria:

- a clear explanation of how death is diagnosed using neurological criteria, and how this is confirmed.

2.1.26 For potential donors where circulatory death is anticipated:

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

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

Organisation of the identification, referral and consent processes

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through locally developed policies and procedures. A recommendation was therefore made on the need for a policy and protocol for the identification and referral of potential donors and the process of consent.
Trade-off between benefits and harms	None.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how policies and procedures increase consent rates for donation. However, the evidence reviewed consistently showed that the potential donors were being missed, and those healthcare professionals who were not organ donation specialists were not aware of their own organisational policies and procedures in this area.
Other considerations	None.

2.1.27 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.

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

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through good team working and coordination of processes. A recommendation was therefore made on the process of co-ordination, including the collaborative working with the specialist nurse in organ donation.
Trade-off between benefits and harms	None.
Economic considerations	None.
Quality of evidence	There was a lack of high quality evidence identified evaluating how the coordination of organ donation increased consent rates for donation. However, the evidence reviewed consistently showed that where the process was coordinated and managed (often by the SN-OD or similar), that rates of identification, referral and consent were improved.
Other considerations	None.

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

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through good team working and having the required skills and competencies. A recommendation was therefore made on the skills and competencies needed by the wider healthcare team involved in the process of organ donation.
Trade-off between benefits and harms	None.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements.
Quality of evidence	Evidence from other areas consistently showed that healthcare professionals often lacked the skills and knowledge for organ donation. Although no evidence showing that if these gaps were filled, then consent rates were increased, the GDG considered that teams should have the skills and competencies to deliver the recommendations outlined in this guideline.
Other considerations	None.

2.1.30 The MDT involved in the identification, referral to 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.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through good team working and having the required skills and competencies. A recommendation was therefore made on the skills and competencies needed by the healthcare team involved in the process of organ donation.
Trade-off between benefits and harms	None.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements.
Quality of evidence	Evidence from other areas consistently showed that healthcare professionals who were not specialists in organ donation often lacked the skills and knowledge for organ donation. Although no evidence showing that if these gaps were filled, then consent rates were increased, the GDG considered that teams should have the skills and competencies to deliver the recommendations outlined in this guideline.
Other considerations	None.

2.1.31 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 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, polices and protocols relating to donor management
- adhere to relevant professional standards of practice regarding organ donation and end-of-life care.

Relative value of different outcomes	The GDG considered that the aim of this guideline was to improve rates of consent for organ donation through optimising all stages of the process. This would include maximising the number of potential donors, through good team working and having the required skills and competencies. A recommendation was therefore made on the skills and competencies needed by the healthcare team involved in the process of organ donation.
Trade-off between benefits and harms	None.
Economic considerations	Health economic analysis indicates that reducing the waiting list for organ donation is of value to the NHS. The value of this reduction to the NHS is considerable and therefore, supports the use of potentially expensive interventions or increased training requirements.
Quality of evidence	Evidence from other areas consistently showed that healthcare professionals often lacked the skills and knowledge for organ donation. Although no evidence showing that if these gaps were filled, then consent rates were increased, the GDG considered that teams should have the skills and competencies to deliver the recommendations outlined in this guideline.
Other considerations	The GDG highlighted the responsibility of the physician providing care under the GMC guidance 'Treatment and care towards the end of life: good practice in decision making'[20].

2.1.32 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

[20] Available at www.gmc-uk.org/guidance/ethical_guidance/6858.asp

- 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.

3 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.

3.1 Joining the NHS organ donation register

What are the factors and processes that would encourage the general public to sign up on the UK NHS organ donor register (ODR)?

Why this is important

Ninety percent of the UK general public approve of organ donation, but only 28% have registered on the ODR. Research is urgently needed to find out what factors would encourage people to register, and what processes could increase registration. If these factors could be identified and processes implemented, the number of people on the ODR could be significantly increased. Therefore the supply of donor organs should be improved given that evidence shows that families are more likely to consent if the potential donor is known to be on the ODR.

3.2 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.

3.3 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.

3.4 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.

3.5 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.

4 Implementation

NICE has developed tools to help organisations implement this guidance (see www.nice.org.uk/guidance/CG[xxx])'. Note: these details will apply when the guideline is published.

5 Other versions of this guideline

This is the full guideline. It contains details of the methods and evidence used to develop the guideline. It is available from our website (www.nice.org.uk/guidance/CG[XX]Guidance). **[Note: these details will apply to the published full guideline.]**

Quick reference guide

A quick reference guide for healthcare professionals is available from www.nice.org.uk/guidance/CG[XX]QuickRefGuide

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1[XXX]). **[Note: these details will apply when the guideline is published.]**

'Understanding NICE guidance'

A summary for patients and carers ('Understanding NICE guidance') is available from www.nice.org.uk/guidance/CG[XX]PublicInfo

For printed copies, phone NICE publications on 0845 003 7783 or email publications@nice.org.uk (quote reference number N1[XXX]). **[Note: these details will apply when the guideline is published.]**

We encourage NHS and voluntary sector organisations to use text from this booklet in their own information.

6 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into

account important new information. New evidence is checked 3 years after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations.

7 References, glossary and abbreviations

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7.2 Glossary

Advance care directive

A set of instructions given in advance by individuals specifying what actions should be taken for their health in the event that they are no longer able to make decisions due to illness or incapacity. It does not always have to be written down, although most are.

Brainstem

The lower part of the brain, which adjoins and is structurally continuous with the spinal cord.

Brainstem death

Death diagnosed after irreversible cessation of brainstem 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.

Circulatory death
Death diagnosed and confirmed by a doctor following cardiorespiratory arrest.

Clinical triggers
A set of clinical criteria used to indicate a high probability of death, which is used to define a standard point in care when the hospital is expected to initiate referral.

Close to the patient (those)
Family, friends, partners and anyone who knows the patient who can be, but is not necessarily, in a qualifying relationship.

Consent ratio
Consent ratio refers to the number of people for whom consent was sought and who actually consented

Conversion rate
Depending on the stage of the process for organ donation, this can mean the percentage of potential donors for whom consent is obtained, the percentage of potential donors with consent who then become actual (DBD or DCD) donors, or the percentage of potential donors (before consent) who become actual donors.

GRADE (Grading of Recommendations Assessment, Development and Evaluation)
A systematic and explicit approach to grading the quality of evidence and the strength of recommendations.

Lasting Power of Attorney
A Lasting Power of Attorney (LPA) is a legal document that enables a person who has capacity and is over 18 to choose another person or people (Attorney[s]) to make decisions on their behalf. A health and welfare LPA is for decisions about both health and personal welfare, such as where to live, day-

to-day care or having medical treatment.

Potential donor

People for whom brainstem death or circulatory death has been diagnosed and active treatment is planned to be withdrawn, and who have no medical contraindications to solid organ donation

Qualifying relationship

A person who can give consent on behalf of a patient who has not indicated their consent or refusal to postmortem removal or storage of their organs. Consent should be obtained from the person ranked highest in the Human Tissue Authority hierarchy:

- spouse or partner (including civil or same sex partner)
- parent or child (in this context a 'child' can be any age)
- brother or sister
- grandparent or grandchild
- niece or nephew
- stepfather or stepmother
- half-brother or half-sister
- friend of long standing.

Required referral

A system where all deaths (including anticipated death) are referred to the healthcare professional(s) responsible for organ donation.

Specialist nurse for organ donation

A healthcare professional with specific expertise in the promotion and facilitation of the entire donation process through working with all staff in critical care areas to support and maximise organ/tissue donation and providing support and information to families of potential donors.

7.3 Abbreviations

Abbreviation	Meaning
A&E	Accident and Emergency
BSD	Brainstem death
CI	Confidence interval
CQI	Continuous quality improvement
DA	Donor Action Programme
DBD	Donation after brainstem death
DCD	Donation after circulatory death
D-form	Donation form
DTC	Donor transplant coordinator
EEG	Electroencephalogram
GCS	Glasgow Coma Scale
GDG	Guideline Development Group
GMC	General Medical Council
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HIV	Human immunodeficiency virus
HM	Her Majesty
ICU	Intensive care unit
IHC	In-house coordinators
ITT	Intention to treat
LITC	Level I trauma centres
MDT	Multidisciplinary team
NA	Not assessable or applicable
NATCO	North American Transplant Coordinators Organizations
NDR	No donation request
NICU	Neuro-intensive care unit
NS	Not serious
NSW	New South Wales
NYPHS	New York-Presbyterian Healthcare system
OD	Organ donation
ODC	Organ donation consent
ODR	Organ donation refusal
OPC	Organ procurement coordinators
OPO	Organ procurement organisation
OR	Odds ratio
PICU	Paediatric intensive care unit
RCT	Randomised control trial
SD	Standard deviation
SN-OD	Specialist nurse for organ donation
TOSA	Texas Organ Sharing Alliance

8 Contributors

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The following person was not a full member of the Guideline Development Group but was co-opted onto the group as an expert adviser:

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8.2 The short clinical guidelines technical team

A short clinical guidelines technical team was responsible for this guideline throughout its development. It prepared information for the Guideline Development Group, drafted the guideline and responded to consultation comments. The following NICE employees made up the technical team for this guideline.

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8.4 The Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring adherence to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to. The panel includes members from the following perspectives: primary care, secondary care, lay, public health and industry.

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8.6 Declarations of interest

GDG Member	Interest Declared	Type of Interest	Decisions Taken
Simon Bramhall	None		
Tim Collins	None		
James Fraser	None		
Karen Morgan	None		

Paul Murphy	None		
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Angus Vincent	None		
Gurch Randhawa	• Director, Institute for Health Research, University of Bedfordshire • Chairman, NHS Luton • Member, UK Donation Ethics Committee • Member, Human Tissue Authority • Previously served as a Member of the UK Organ Donation Taskforce	Non-personal pecuniary interest	Declare and can participate in discussions on all topics.
Huw Twamley	None		
Barry Williams	None		

8.7 Authorship and citation

Authorship of this document is attributed to the NICE Short Clinical Guidelines Technical Team and members of the Guideline Development Group under group authorship.

The guideline should be cited as:

National Institute for Health and Clinical Excellence ([Year]) [Title]. London: National Institute for Health and Clinical Excellence. Available from: www.nice.org.uk/guidance/CG[XX]