National Institute for Health and Care Excellence

Surveillance programme

Surveillance proposal consultation document

Organ donation for transplantation NICE guideline CG135 – 4-year surveillance review

Background information

Guideline issue date: December 2011

2-year Evidence Update: no update.

Surveillance proposal for consultation

We will not update the guideline at this time.

We also propose to remove the following NICE research recommendations from the NICE version of the guideline and the NICE research recommendations database:

- What are the factors and processes that would encourage the general public to sign up on the UK NHS organ donor register (ODR)?
- Why do families refuse to give permission for organ donation?
- What are the key components of an intervention to improve identification and referral rates?
- What are the key components of an intervention to improve consent rates?
- Does a positive experience of approach and process of consent for families increase consent rates?

Reason for the proposal

New evidence

We found 23 new studies in a search for all publication types published between 14 August 2013 and 19 July 2016. We also considered 4 additional studies identified by members of the guideline committee who originally worked on this guideline.

Evidence identified in previous Evidence Update 2 years after publication of the guideline was also considered. This included 11 studies identified by search.

From all sources, 38 studies were considered to be relevant to the guideline.

This included new evidence that is consistent with current recommendations:

- Identifying patients who are potential donors
- Patients who have capacity
- Assessing best interests
- Seeking consent to organ donation
- Approach to those close to the patient
- Discussions in all cases
- Organisation of the identification, referral and consent processes

We also identified new evidence in the following areas that was inconsistent with, or not covered by, current recommendations, but the evidence was not considered to impact on the guideline:

- Identifying patients who are potential donors
  - Neonatal organ donation

None of the new evidence considered in surveillance of this guideline was thought to have an effect on current recommendations. We asked topic experts whether this new evidence would affect current recommendations on Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation. Generally, the topic experts thought that

an update was not needed. We are aware of the updated guidance on diagnosis of brain stem death in infants between 37 weeks and 2 months gestation in 2015. However, we are not clear whether organ donation in neonates is common clinical practice and we would like to know the views of stakeholders on this.

Additionally, we did not identify any relevant ongoing research that is expected to publish results in the next 3–5 years.

No equalities issues were identified during the surveillance process.

Research recommendations

At 4-year and 8-year surveillance reviews of guidelines published after 2011, we assess progress made against prioritised research recommendations. See the research recommendations section for further information.

For this surveillance review we assessed 5 prioritised research recommendations, and proposed that 5 should be removed from the NICE version of the guideline and the NICE database.

Overall decision

After considering all the new evidence and views of topic experts, we decided not to update this guideline.

We also propose to remove 5 NICE research recommendations from the NICE version of the guideline and the NICE research recommendations database.

Further information

See appendix A: summary of new evidence from surveillance below for further information.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

Appendix A: summary of new evidence from surveillance

4-year surveillance (2016)

Organ donation for transplantation (2011) NICE guideline CG135

Appendix A: Summary of new evidence from surveillance

Identifying patients who are potential donors

Patients who have capacity

Assessing best interests

135 – 01	**What structures and processes including timing for referral and criteria for consideration are appropriate and effective for identifying potential donation after brainstem death (DBD) and circulatory death (DCD) donors?**

Recommendations derived from this question

Identifying patients who are potential donors

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

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

- defined clinical trigger factors in patients* 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 a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death.

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

Patients who have capacity

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

Assessing best interests

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

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

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

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

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

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

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

† DCD consensus meeting report, available from www.ics.ac.uk/intensive_care_professional/standards_and_guidelines/dcd

†† GMC guidance on treatment and care towards the end of life

‡ Available from http://www.uktransplant.org.uk/ or https://www.organdonation.nhs.uk/

Surveillance decision

This review question should not be updated.

Identifying potential DBD and DCD donors using clinical triggers

2-year evidence update summary

A retrospective study[1] tested 3 tools for identifying patients who could imminently become brainstem dead and who would be potential heart-beating organ donors (also known as donation after brainstem death [DBD] donors). The donor conversion rate (DCR) was also calculated. A total of 564 patients diagnosed with subarachnoid haemorrhage, traumatic brain injury or intracerebral haemorrhage were identified. There were 179 deaths of whom 36 became organ donors with 23 DBD donors and 13 after circulatory death (DCD) donors. The Full Outline of UnResponsiveness (FOUR) score was better than the Glasgow Coma Score (GCS) and the Organ Procurement Transplantation Network (OPTN) with DCR of 37%, 27%, and 26% respectively. The 3 tools did not identify 7 potential DBD donors.

4-year surveillance summary

A retrospective cohort study[2] (n=186 potential donors) reported that the success of the DCD program had minimal impact on the number of DBD donors.

A retrospective audit[3] (n=106 deceased people referred for DCD) reported rate of successful organ donation in people who sustained an out of hospital cardiac arrest. Consent was

obtained from the deceased's family with a good conversion rate of 64%.

A prospective observational study[4] (n=100 people with out of hospital cardiac arrest) reported that 14 participants were potential DCD donors after treatment withdrawal in the intensive care unit (ICU). Families consented to donate in 7 cases. However, only one of these was a successful donor because death time was within the acceptable warm ischaemia.

Seventeen studies[5-21] were identified related to the identification of potential donors using clinical triggers. However, these studies were done in other countries outside the UK including Australia, US, Spain, Belgium, Japan, Germany, Canada, and France.

Topic expert feedback

A topic expert highlighted that 'there is an emerging view that all patients with devastating brain injury should be admitted to the ICU for a period of physiological support and repeated neurological assessment rather than have early treatment withdrawal.' It was considered that the wording of recommendation 1.1.2 does not contradict this emerging view.

Impact statement

At the 2-year evidence update the evidence showed that tools to identify potential DBD donors had a low DCR. Although indicating potential future refinements to triggers, limitations of the evidence (for example being a retrospective observational study in a single centre and that the FOUR score is not in common use in England and Wales) meant that these data were unlikely to have an impact on guidance. During the 4-year review, there was new evidence about the success of the DCD program showing no impact on DBD, good DCR after family consent in people with out of hospital cardiac arrest who were potential DCD donors, and low rate of successful DCD after out of hospital cardiac arrest, and an emerging view about a monitoring period rather than early treatment withdrawal. It was considered that this evidence was in line with current recommendations 1.1.2 – 1.1.3. There were also 17 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Identifying potential DCD donors in the emergency department

2-year evidence update summary

A cross-sectional survey[22] sought people's opinions on uncontrolled DCD (uDCD) (n=200 participants aged over 15 years). Participants were patients and relatives attending the emergency department of a teaching hospital. The findings showed that participants were willing to discuss organ donation after confirmation of circulatory death in the emergency department and after confirmation of brainstem death in an intensive care unit (ICU); would be willing to discuss organ donation soon after the cardiac arrest of a relative in the emergency department; and would consider donating their relative's tissues. Few participants would not consider donation and others were undecided. People were mostly happy for the 3 organ preservation procedures (insertion of a small tube into the groin to deliver cold fluid, continuation of mechanical chest compressions, and continuation of mechanical ventilation) to be used after circulatory death of a relative. This evidence was considered to be consistent with the guideline recommendation that patients who will, or are expected to, reach circulatory death should be considered as potential organ donors.

4-year surveillance summary

A study[23] (n=564 people with cardiac arrest) reported that 4 out of 564 people were potential uDCD donors who arrived to the emergency department after cardiac arrest and were unsuccessfully resuscitated. It was concluded that the contribution of uDCD donors to the overall organ donation rate seems low but relevant.

Two studies[24,25] were identified related to the identification of potential DCD donors in the emergency department. However, these studies were done in France.

Topic expert feedback

No relevant evidence was identified.

Impact statement

At the 2-year evidence update, the evidence showed that patients and families were willing to discuss DCD soon after the cardiac arrest and accepted the organ preservation procedures. During the 4-year surveillance review, there was evidence of a low rate of donation after uDCD. uDCD at the UK is currently inactive. Therefore, it was considered that new evidence on uDCD does not have an impact on current recommendation 1.1.2 to identify potential donors which is based on DCD and DBD. There were also 2 studies in France. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Identifying potential neonatal organ donors

2-year evidence update summary

A retrospective study[26] examined the proportion of deaths in neonatal ICUs that would theoretically have been eligible for DCD (n=192 infants born at 23 weeks' gestation or later who subsequently died). Sixteen infants were potential liver and kidney DCD candidates and would have yielded 14 livers and 18 kidneys. Twelve of these 16 infants were also suitable candidates for cardiac DCD and would have yielded 10 hearts.

A retrospective study[27] estimated the proportion of neonates who might be potential candidates for cardiac DCD from a neonatal ICU (n=117 infants weighing more than 2.5 kg at the time of death). Sixteen infants would have been potential candidates for DCD and 5 of these infants would have been suitable for cardiac DCD.

This evidence was considered unlikely to have an impact on current recommendations because cardiac DCD was largely experimental and the evidence in neonates was at a preliminary stage.

4-year surveillance summary

A retrospective study[28] (n=84 deceased infants, 37 weeks gestation to 2 weeks of age) reported the potential neonatal organ donation in a tertiary's children hospital at the UK. Half of the infants who died in hospital were potential donors with most of them identified as DCD. It was concluded that there seems to be potential for neonatal donation in the UK which does not currently occurs.

One study[29] was identified related to potential and actual neonatal DCD donors in the US.

Topic expert feedback

A topic expert referred to the Royal College of Paediatrics and Child Health which updated their guidance regarding the diagnosis of brain stem death in infants between 37 weeks and 2 months gestation in 2015.

A topic expert highlighted that there is increasing interest in organ donation from infants and neonates as well as antenatally.

Impact statement

Through surveillance, there was new evidence on potential neonatal organ donors. During the 4-year surveillance review, new guidance was reported on the diagnosis of brain stem death in infants between 37 weeks and 2 months gestation and an increase interest in organ donation from infants and neonates. However, we did not find evidence on current clinical practice regarding organ donation in neonates. It seems that evidence in neonates is still at preliminary stages. Therefore, the potential of neonatal organ donation will be considered during the next surveillance review of NICE guideline CG135.

New evidence is unlikely to change guideline recommendations.

Paediatric organ donation

2-year evidence update summary

No relevant evidence was identified.

4-year surveillance summary

Two studies[30,31] reported rates of paediatric organ donation in the US.

Topic expert feedback

A topic expert referred to the 'Ethical issues in paediatric organ donation – a position paper by the UK Donation Ethics Committee (UKDEC)' published in 2015. In this position paper, UKDEC provides an ethical framework for making decisions on paediatric donation with 8 recommendations on particular ethical issues for example donation from neonates, organ donation from anencephalic infants, cases involving the Coroner or Procurator Fiscal, and sudden unexpected death in infancy (SUDI).

The topic expert also highlighted the development of a NICE guideline on the care of children with life-limiting conditions (End of life care for infants, children and young people [expected publication date: December 2016]). The draft version of this new guideline includes a review question and 5 recommendations about organ donation.

Impact statement

At the 4-year surveillance review, topic experts referred to a new NICE guideline on the care of children with life-limiting conditions which includes a review question and 5 recommendations about organ donation. Related recommendations have been consulted on in the End of life care for infants, children and young people guideline and this surveillance report will be updated once the End of life care for infants, children and young people guideline has been published, however we are not anticipating any conflicts in recommendations. There was also new evidence about ethical issues on organ donation from children. The new evidence was considered to be in line with current recommendation 1.1.4 which refers to the Department of Health guidance when seeking consent in children and recommendation 1.1.9 which covers seeking consent in people who lack capacity. There were also 2 studies in the US but none were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Legal determinants on organ donation

2-year evidence update summary

No relevant evidence was identified.

4-year surveillance summary

A study[32] (62 countries) investigated the impact of legal determinants of deceased and living organ transplantation rates. Deceased transplant rates are negatively affected by the legal requirement of family consent or the maintenance of written procurement standards.

Seven studies[33-39] were identified related to the legal determinants on organ donation. However, these studies were done in other countries outside the UK including US, Belgium, Italy, and Canada.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

During the 4-year surveillance review, there was new evidence about the negative impact on organ donation from the legal requirements of family consent and written procurement standards. It was considered that the new evidence is in line with recommendations 1.1.7 and 1.1.8 which address these issues. There were also 7 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Seeking consent to organ donation

135 – 02 What structures and processes are appropriate and effective for obtaining consent from families, relatives and legal guardians of potential DBD and DCD donors?

Recommendations derived from this question

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

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

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

* GMC guidance on treatment and care towards the end of life

Surveillance decision

This review question should not be updated.

A footnote should be added to recommendation 1.1.9.

Opt-in and opt-out organ donation consent

2-year evidence update summary

No relevant evidence was identified.

4-year surveillance summary

A panel study[40] (48 countries) reported that deceased donor rates were significantly higher in opt-out (donation by anyone who has not refused to be a donor) than opt-in (donation after explicit consent) consent countries.

Topic expert feedback

A topic expert highlighted that the legislative framework for consent for organ donation in Wales changed on 01 December 2015, and is now one of deemed consent also called 'soft opt-out system' which applies to people over 18 years who live and die in Wales (deemed consent means that people who do not register a clear decision about being an organ donor will be treated as having no objection to being a donor). The topic expert mentioned that this has required a change to the NHS Organ Donor Register, which now allows anyone in the UK to register a wish NOT to donate after death (as well as register a wish to be a donor). The topic expert considered that this legislative reform is not in any conflict with NICE guideline CG135 because the role of the specialist nurse in organ donation (SNOD) remains central to the family approach but the details may need to be amended in order to reflect the complicated legal landscape for consent.

Impact statement

During the 4-year review, new evidence was identified about the high rates of deceased donation in opt-out consent countries and the new legislation in Wales which changed to a 'soft opt-out system'. The NHS Organ Donor Register has been modified allowing anyone to register a decision to donate, not to donate or nominate other to make a decision after their death. Therefore, the guideline will be amended to include a footnote to the second bullet point of recommendation 1.1.9 which

refers to establishing whether the patient has registered and recorded their consent to donate on the NHS organ donor register when the patient lacks the capacity to consent to organ donation. This footnote is to make reference to the modification of the NHS Organ Donor Register which is now allowing anyone to register a decision to donate, not to donate or to nominate a representative to make a decision after their death. The footnote will also include a link to the NHS Organ Donor Register where these options can be seen.

New evidence is unlikely to change guideline recommendations.

Views on organ donation

2-year evidence update summary

A systematic review[41] analysed factors influencing the general public's attitudes towards organ donation (n=1019, 18 qualitative studies). There were 8 emerging themes: relational ties; religious beliefs; cultural beliefs; family influence; body integrity; knowledge and information about donation; previous interaction with the healthcare system; and major reservations about donation (even among those supporting donation). This evidence was considered to strengthen the guideline recommendation that healthcare professionals should take account of the patient's beliefs or values and any other factors the patient would be likely to consider when assessing whether to take steps to facilitate organ donation.

4-year surveillance summary

The Faith and Organ Donation Summit was held with faith leaders and the National Health Service Blood and Transplant (NHSBT)[42]. It was reported that a commitment is necessary regarding organ donation, diagnosis and definition of death at both national and local levels.

A systematic review of qualitative studies[43] (34 studies, n=1,035 participants) reported seven themes about donor families' views on organ donation: comprehension of sudden death; finding meaning in donation; fear and suspicion; decisional conflict; vulnerability; respecting the donor; and needing closure.

One study[44] was identified related to the family views on organ donation in the US.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

At the 2-year evidence update, new evidence was found about factors influencing attitudes towards organ donation. During the 4-year surveillance review, the views of donor families and faith leaders were reported. This evidence was considered to be in line with current recommendations 1.1.9 and 1.1.10 that healthcare professionals should take account of the patient and family beliefs or values when assessing whether to take steps to facilitate organ donation.

New evidence is unlikely to change guideline recommendations.

Approach to those close to the patient

Discussions in all cases

135 – 03 When is the optimal time for approaching the families, relatives and legal guardians of potential DBD and DCD donors for consent?

Recommendations derived from this question

Approach to those close to the patient

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

1.1.12 The MDT should include:

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

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

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

Discussions in all cases

1.1.15 Before approaching those close to the patient:

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

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

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

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

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

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

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

1.1.21 When approaching those close to the patient:

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

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

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

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

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

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

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

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

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

* Mental Capacity Act (2005) and Human Tissue Act (2004).

Surveillance decision

This review question should not be updated.

Factors influencing decision-making by those close to the patient

2-year evidence update summary

An integrative review[45] explored decision-making by relatives of neurologically dead potential donors. The study employed an 'integrative review' process that allowed for the inclusion and combination of diverse methodologies, such as experimental and non-experimental research (70 empirical, theoretical and practical articles). Results and conclusions were extracted from these articles and grouped under 3 themes: factors affecting families' decision to consent; evaluation of the decision to consent or not; and need for information and support to make a decision about organ donation. The evidence was considered to be consistent with the guideline recommendation that discussions about organ donation with those close to the patient should only take place after they understand that death is inevitable or has occurred. The guidance also

recommends that families should be provided with a clear explanation of and information on the process of organ donation and retrieval and should be offered support.

4-year surveillance summary

A study reported[46] (n=4,703 family approached for organ donation) that consent for DBD was significantly higher than consent for DCD at the UK ICUs and emergency departments. There were factors significantly associated with consent such as patient ethnicity, knowledge of a patient's wishes and involvement of a specialist nurse in organ donation in the approach. There was a stronger association between the involvement of the specialist nurse and DCD compared to DBD.

Ten studies[47-56] were identified related to factors influencing decision-making by those close to the patient. However, these studies were done in other countries outside the UK including Netherlands, India, US, Korea, China, Denmark, and Switzerland.

Topic expert feedback

A topic expert mentioned that NHS Blood and Transplant (NHSBT) 'is moving towards a more specialised service for families, separating the tasks of family approach (request for consent for donation) from the donor coordination that follows.' However, NICE guideline CG135 covers identification, referral and consent of organ donation and it does not cover donor coordination that follows afterwards.

The topic expert also highlighted the increased involvement of 'designated requesters'. However, the involvement of designated requesters has not been included yet as part of the process of Approaching the Family regarding Organ and Tissue Donation by the NHSBT.

Impact statement

At the 2-year evidence update, new evidence was found on the decision-making process that relatives of potential DBD donors go through. During the 4-year surveillance review, new evidence showed a higher consent to DBD compared to DCD at UK ICUs, factors associated to donation consent, and SNOD involvement. There was also evidence about the separation of the family approach for donation and coordination that follows as well as the increase involvement of 'designated requesters' during the family approach for donation consent. It was considered that the evidence on discussions about organ donation with the patient's family is in line with current recommendations 1.1.17 – 1.1.26. It was also considered that the separation of family approach for donation and coordination that follows is not relevant to current recommendations because NICE guideline CG135 does not cover donor coordination that follows afterwards. The NHSBT has not included the involvement of designated requesters as part of the process of organ donation discussion with the family. Therefore, this issue will be addressed during the next surveillance review of NICE guideline CG135. There were also 10 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Cultural and religious factors

2-year evidence update summary

A retrospective study[57] analysed national data to identify variation in consent rates between different age and ethnic groups (n=31,408 deaths). Data included patients aged up to 70 years declared neurologically dead and with no medical conditions precluding donation where consent had not been provided before death through a registry or legal documentation. Consent for donation had been obtained from family or other decision makers in 21,601 deaths. Compared with consent rates for white patients, likelihood of consent was lower for Asian patients, patients of 'other' ethnicity, such as Native American and multiracial patients, black patients, and Hispanic patients. Consent rates were higher when the request process satisfied the organisation's criteria for being an 'effective request', for example, using skilled staff and ensuring that relatives understand neurological death. Compared with relatives of white patients, relatives of patients from other ethnic groups were no more or less likely to receive an effective request. The exception was relatives of Asian patients, where an effective request was significantly less likely. Analysis of age data showed that compared with patients aged 18–39 years, consent to

donation was lower for patients aged 40 or older. Relatives of patients aged 40 years and older were less likely to experience an effective request than relatives of those aged 18–39 years.

A retrospective analysis[58] sought to identify factors that might predict whether family members would donate a relative's organs (n=995 first-degree relatives [father, mother, brother, sister, son, daughter or spouse]). Religion was the biggest predictor of whether relatives agreed to organ donation: two thirds of Christians consented, compared with half of Jews and just under a quarter of Muslims. Female relatives were more likely to consent than male relatives, and willingness to donate decreased with increasing education level achieved. Family relationship was the biggest predictor of donation in Christians and Muslims.

4-year surveillance summary

Eleven studies[59-69] were identified about cultural and religious factors related to consent of organ donation. However, these studies were done in other countries outside the UK including Islamic countries, Muslim countries, Canada, Australia, Islamic traditions, US, Istanbul, and Turkey.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

At the 2-year evidence update, new evidence was found about rates of consent in different age and ethnic groups as well as family factors related to organ donation such as religion and family relationship. The evidence was considered to be consistent with recommendation 1.1.16 that cultural and religious issues that may affect consent, and the use of local faith representatives, should be considered when approaching those close to the patient. There were also 11 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Understanding of neurological death

2-year evidence update summary

A prospective trial[70] investigated the effect on consent rate of relatives' presence during determination of neurological death (n=8 relatives). Determination of neurological death was with GCS scoring, testing of brainstem reflexes, and the apnoea test. Seven of the 8 relatives consented to organ donation. Relatives' views on being present during the process were mixed regarding the understanding of the concept of neurological death and had varying views on the value of being present during the determination process. The authors also noted that medical and technical staff were uneasy about having relatives present during neurological testing. The possibility of being present during neurological testing is not covered explicitly by current recommendations, but limitations of the evidence mean that this evidence was considered to be unlikely to have an impact on the guidance.

4-year surveillance summary

A systematic review[71] (15 studies, n=2,100 participants) reported that family's decision for organ donation is affected by the knowledge about brain death and what happens during organ donation and transplantation.

Two studies[72,73] were identified related to the understanding of neurological death in Japan and the US.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

At the 2-year evidence update, new evidence showed that relatives' presence during determination of neurological death does not seem to affect donation consent. During the 4-year surveillance review, new evidence showed that family's decision for organ donation is affected by the knowledge about brain death and what happens during organ donation and transplantation. It was considered that family's presence during neurological testing is not covered explicitly by current recommendations, but limitations of the evidence mean that this evidence was considered to be unlikely to have an impact on the guidance. There were also 2 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Support for those close to the patient

2-year evidence update summary

A retrospective cross-sectional survey[74] evaluated the support family members received when considering whether to donate the organs of a neurologically dead relative (n=199 family members whose relative had died). Participants were contacted 8 to 10 months after the death and were asked about the emotional, practical and informational support they had received during the consent process. Provision of informational support correlated most strongly with consent to donation, followed by provision of emotional support and practical support. Family members who agreed to donation were more likely to feel that they and their relative had been treated with dignity and respect. The evidence was considered to be consistent with the guideline, which recommends that those close to the patient should be given a clear explanation of how neurological death is confirmed using neurological criteria and the process of organ donation and retrieval, as well as sufficient time to understand the inevitability of the death or anticipated death and to spend time with the patient.

4-year surveillance summary

A qualitative study[75] (n=43 participants from 31 donor families) reported the experience of donor families during end-of-life care in the ICU. Donor families viewed compassion, respect, dignity, and choice as hallmarks of good quality and communication. It was concluded that organ donation might provide a balance between hope and despair when the wishes of the dying, deceased, and bereaved are fulfilled.

Eleven studies[76-86] were identified related to the support for those close to the patient. However, these studies were done in other countries outside the UK including Turkey, Norway, Netherlands, Brazil, Sweden, Spain, Australia, US, Poland, and Iran.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

Through surveillance, new evidence was found about the importance of providing emotional, practical and informational support to family members during organ donation. The evidence was considered to be consistent with recommendations 1.1.22 – 1.1.26 that those close to the patient should be given a clear explanation of how neurological death is confirmed using neurological criteria and the process of organ donation and retrieval, as well as sufficient time to understand the inevitability of the death or anticipated death and to spend time with the patient. There were also 11 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Organisation of the identification, referral and consent processes

135 – 04 How should the care pathway of deceased organ donation be coordinated to improve potential donors giving consent?

Recommendations derived from this question

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

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

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

1.1.30 The MDT involved in the identification, referral to 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.

Surveillance decision

This review question should not be updated.

2-year evidence update summary

No relevant evidence was identified.

4-year surveillance summary

A national online survey included lead physicians for intensive care or organ donation within acute NHS trusts in England[87] (n=119). Most of the participant trusts and transplant centres had done DCD, had a local DCD protocol, and were in favour of a national DCD protocol.

Sixteen studies[88-103] were identified related to the organisation of the identification, referral and consent processes. However, these studies were done in other countries outside the UK including Saudi Arabia, US, Mexico, Japan, Israel, Australia, Korea, Brazil, Poland, and Switzerland.

Topic expert feedback

No topic expert feedback was relevant to this evidence.

Impact statement

During the 4-year surveillance review, it was reported that there were local DCD protocols at the acute NHS trusts and lead physicians were in favour of national DCD protocols. It was considered that this evidence was in line with recommendation 1.1.27 that each hospital should have a policy and protocol for identifying patients who are potential donors and managing the consent process. There were also 16 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

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135 – 05 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?

Recommendations derived from this question

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

- have knowledge of the basic principles and the relative benefits of, donation after circulatory death (DCD) versus donation after brainstem death (DBD)
- understand the principles of the diagnosis of death using neurological or cardiorespiratory criteria and how this relates to the organ donation process
- be able to explain neurological death clearly to families

- understand the use of clinical triggers to identify patients who may be potential organ donors
- understand the processes, policies and protocols relating to donor management
- adhere to relevant professional standards of practice regarding organ donation and end-of-life care.

1.1.32 Consultant staff should have specific knowledge and skills in:

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

Surveillance decision

This review question should not be updated.

2-year evidence update summary

A systematic review[104] looked at the attitudes of the general public and of healthcare professionals to DCD (20 peer-reviewed qualitative, quantitative and case studies). The themes identified among the included studies were: levels of support for DBD versus DCD; attitudes to post-mortem measures without previous consent; lack of knowledge about DCD; concerns about the 'dead donor rule' (which states that organs should be taken only from people who are dead); the potential for conflict of interest; making donation happen; and the call for standardised DCD protocols. This evidence was considered to strengthen the guideline recommendation that healthcare professionals should understand the basic principles DCD and DBD, and of diagnosis of death using neurological or cardiorespiratory criteria, and be able to explain these concepts clearly to families.

4-year surveillance summary

A study[105] (n=108 intensive care staff) reported positive and negative views on organ donation and SNOD. There were significantly more positive words associated with DBD compared to DCD and more negative words associated with DCD compared to DBD. There were significantly more positive than negative words attributed to the SNOD.

A prospective audit[106] (n=1,437 potential deceased donors referred to Coroner/ Procurator Fiscal) showed that 87% and 9% of cases had full and partial permission for organ retrieval, respectively. Only 77 organs could have been available for transplant in cases with full permission but without autopsy or with unjustified restrictions.

A systematic review and narrative synthesis was used to report on hospital studies about staff practices and influences on family consent and interviews with bereaved families[107] (35 nurses, 28 clinicians, 19 hospital chaplains, 25 members of local Organ Donation Committees, 17 bereaved family members). The findings for hospital studies showed that many ICU staff reported lack of confidence during family consent to donation regarding communication and support to families from ethnic minorities. There was also evidence that a high proportion of family donation discussions take place without a SNOD. Hospital chaplains were different regarding their involvement in ICUs. A training package to enhance cultural competence among ICU staff was also developed and evaluated (n=66 health professionals). Feedback was positive but no significant differences were found in consent rate during the short follow-up after training.

A cross-sectional online survey[108] (n=523 junior doctors) reported that nearly half of the participants knew that organ donation consent is sought for all potential deceased donors. Knowledge, perceptions and attitudes of organ donation and transplantation were better in participants who were registered as donors compared to those not registered. Inadequate exposure and lack of undergraduate education to organ donation and transplantation were reported by most of the participants.

A pre-test-post-test study[109] (n=100 preregistration nurses) reported that participants attitude and knowledge towards organ donation improved after the intervention regarding the identification, referral and consent processes.

Thirty-six[110-145] studies were identified related to the skills and competencies of healthcare professionals involved in the process of identification, referral and consent of organ donation. However, these studies were done in other countries outside the UK including India, Saudi Arabia, Morocco, France, Belgium, Brazil, US, Sweden, Norway, Turkey, China, Iran, Poland, Taiwan, Spain, Mexico, Cuba, Costa Rica, Germany, Japan, Belgrade, Australia, and Netherlands.

Topic expert feedback

A topic expert referred to the 'Interventions before death to optimise donor organ quality and improve transplant outcomes: guidance from the UK Donation Ethics Committee (2014).

Impact statement

At the 2-year evidence update, new evidence was found about healthcare professionals' understanding of DCD and DBD, diagnosis of death using neurological or cardiorespiratory criteria, and being able to explain these concepts to families. During the 4-year surveillance review, there was new evidence about various topics related to organ donation from different health care professionals such as more positive views towards DBD compared to DCD; positive views towards the SNOD; lack of SNOD involvement at ICU; lack of confidence from ICU staff during family consent to donation with ethnic minorities without improvement in consent rate after cultural competence training; inadequate exposure and lack of undergraduate education to organ donation and transplantation; and improvement of nurses' attitude and knowledge towards organ donation improved after an intervention. There was also evidence of a small increased of organ donation in cases involving referred to Coroner/ Procurator Fiscal. New evidence was considered to strengthen recommendations 1.1.31 and 1.1.32 that healthcare professionals should have knowledge, skills and competences related to the identification, referral and consent processes during organ donation. Guidance was reported regarding interventions before death to optimise donor organ quality and improve transplant outcomes which strengthens recommendation 1.1.32 which recommends that consultant staff should have specific knowledge and skills about legally and ethically appropriate clinical techniques to secure physiological optimisation in patients who are potential organ donors. There were also 37 studies in countries outside the UK. None of these studies were considered to have an impact on current recommendations.

New evidence is unlikely to change guideline recommendations.

Research recommendations

Prioritised research recommendations

At 4-year and 8-year surveillance reviews of guidelines published after 2011, we assess progress made against prioritised research recommendations. We may then propose to remove research recommendations from the NICE version of the guideline and the NICE database for research recommendations. The research recommendations will remain in the full versions of the guideline. See NICE's research recommendations process and methods guide 2015 for more information.

These research recommendations were deemed priority areas for research by the Guideline Committee; therefore, at this 4-year surveillance review time point a decision **will** be taken on whether to retain the research recommendations or stand them down.

We applied the following approach:

- New evidence relevant to the research recommendation was found and an update of the related review question is planned.
  - The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database. If needed, a new research recommendation may be made as part of the update process.
- New evidence relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.
  - The research recommendation will be retained because there is evidence of research activity in this area.
- New evidence relevant to the research recommendation was found but an update of the related review question is not planned because evidence supports current recommendations.
  - The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.
- Ongoing research relevant to the research recommendation was found.
  - The research recommendation will be retained and evidence from the ongoing research will be considered when results are published.
- No new evidence relevant to the research recommendation was found and no ongoing studies were identified.
  - The research recommendation will be removed from the NICE version of guideline and the NICE research recommendations database because there is no evidence of research activity in this area.
- The research recommendation would be answered by a study design that was not included in the search (usually systematic reviews or randomised controlled trials).
  - The research recommendation will be retained in the NICE version of the guideline and the NICE research recommendations database.
- The new research recommendation was made during a recent update of the guideline.
  - The research recommendation will be retained in the NICE version of the guideline and the NICE research recommendations database.

RR – 01 What are the factors and processes that would encourage the general public to sign up on the UK NHS organ donor register (ODR)?

New evidence relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.

During the 4-year surveillance review new evidence showed that a survey[146] related to organ donation registration might identify people with intention to register as donors and that no additional questions are necessary to identify these people. There was also evidence related to UK Polish migrants showing positive views towards organ donation without cultural barriers and a need of more knowledge about processes of deceased organ donation [147-150]. New evidence also showed factors affecting deceased organ donation such as lack of registration as organ donors; deceased disapproval to donation; body integrity; religion; and quality of care [151-153]. It seems that a peer outreach initiative of lay members of Black, Asian and minority ethnic (BAME) was effective and that factors acting as barriers for signing up were related to fear about signing up, not previously consider signing up, and family and religious disapproval[154]. Two studies[155,156] were identified related to the factors and processes associated to signing up to organ donor registers. However, these studies were done in other countries outside the UK including Australia and the US. It was considered that the new evidence might not have an impact on current guidance which is focused on families, relatives and legal guardians of potential DBD and DCD donors as well as health professionals involved in these processes rather than in the general public.

Surveillance decision

The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.

RR – 02 Why do families refuse to give permission for organ donation?

New evidence relevant to the research recommendation was found but an update of the related review question is not planned because evidence supports current recommendations.

During the 4-year surveillance review, new evidence was found about factors related to family permission for organ donation such as religion; family relationship; education level; ethnicity; knowledge of a patient's wishes; involvement of a specialist nurse during organ donation; age; knowledge about brain death; what happens during organ donation and transplantation; family support during organ donation; staff communication with families[46,71,75] (see review question 135 – 03).

Surveillance decision

The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.

RR – 03 What are the key components of an intervention to improve identification and referral rates?

New evidence relevant to the research recommendation was found but an update of the related review question is not planned because evidence supports current recommendations.

During the 4-year surveillance review new evidence about an intervention[107] to enhance cultural competence among ICU staff (n=66 health professionals). Feedback was positive but no significant differences were found in consent rate during the short follow-up after training (see review question 135 – 05).

Surveillance decision

The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.

RR – 04 What are the key components of an intervention to improve consent rates?

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

The research recommendation will be removed from the NICE version of guideline and the NICE research recommendations database because there is no evidence of research activity in this area.

RR – 05 Does a positive experience of approach and process of consent for families increase consent rates?

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

Surveillance decision

The research recommendation will be removed from the NICE version of guideline and the NICE research recommendations database because there is no evidence of research activity in this area.

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