

# National Institute for Health and Care Excellence

4-year surveillance (2016) – [Organ donation for transplantation](#) (2011) NICE guideline CG135

## Appendix B: stakeholder consultation comments table

Consultation dates: 4 to 14 October 2016

Do you agree with the proposal not to update the guideline?			
Stakeholder	Overall response	Comments	NICE response
BAPM	No	<p>Whilst the document states 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, there is no stated proposal to elicit stakeholder's views. There is increasing interest in neonatal organ donation from both parents and healthcare professionals. However, such interest was unfruitful until the recent update of diagnosis of brain stem death in infants between 37 weeks and 2 months gestation. There is a need to prospectively identify the potential neonatal organ donation from DBD. A recommendation to include the feasibility of organ donation in the proposed structured mortality reviews of neonatal deaths should help to obtain this much needed information.</p> <p>We note that NICE is aware of the updated RCPCH guidance on diagnosis of brain stem death in infants between 37 weeks and 2 months gestation in 2015, and that NICE is "... not clear whether organ donation in neonates is common clinical practice and (that) we would like to know the views of stakeholders on this."</p> <p>Organ donation has not been common practice in neonates as we haven't legally been able to say that our patient is dead by DNC and criteria of DCC has not (and will not) give many donations simply for pragmatic organisational reasons. The College document alters this perspective and as DNC in the neonatal population is now possible, neonatal donation can theoretically significantly increase the donor pool.</p> <p>We bring to your attention the wide expertise of the College group making the recommendations, and the number of stakeholder organisations that signed up for it.</p>	<p>Thank you for your comment.</p> <p>NICE guideline CG135 will be amended to include a footnote to the first bullet point of <a href="#">recommendation 1.1.2</a>. This footnote is to make reference to the guidance on <a href="#">diagnosis of brain stem death in infants between 37 weeks and 2 months gestation</a> published by the Royal College of Paediatrics and Child Health (RCPCH) in 2015. The footnote will also include a link to the guidance.</p>
Faculty of Intensive Care Medicine	Yes	<p>The Faculty agrees that a full review is not necessary however, there is more evidence being produced to support the guidance in certain areas.</p>	<p>Thank you for your comment.</p>
RCPCH	No	<p>We understand this but are a little disappointed by the recommendation that, as it is not current practice, neonatal organ donation will not be re-visited in this guideline.</p> <p>Surely this is an opportunity for quality improvement, with the college driving innovative practice, not waiting for it to</p>	<p>Thank you for your comment.</p>

		become established?	NICE guideline CG135 will be amended to include a footnote to the first bullet point of <a href="#">recommendation 1.1.2</a> . This footnote is to make reference to the guidance on <a href="#">diagnosis of brain stem death in infants between 37 weeks and 2 months gestation</a> published by the RCPCH in 2015. The footnote will also include a link to the guidance.
Royal College of Nursing	No	<p><b>Antenatal and neonatal organ donation</b></p> <p>Charles et al's<sup>28</sup> UK research showed that there is the potential for a viable source of neonatal organs for transplantation. The topic expert has also indicated that there is an interest in antenatal donations. As the 'gift of life' from an infant could be an enduring source of comfort to grieving parents, through the realisation of their child's achievement, donation is a choice that should be available to them.</p> <p>Clearly, research in antenatal and neonatal organ donation is limited. An ethnographic approach that focuses on families' experiences of the organ donation discussion, their decision-making and needed follow-up support would make an enormous contribution to knowledge in the field and in UK and serve to normalise donation in these sensitive groups.</p> <p><b>Approach to those close to the patient</b></p> <p>Could this section begin:</p> <p>When a potential donor is identified those close to the patient should always be approached about donation.</p> <p>[Re above: Rationale is that not to give them a choice is unethical particularly where donation may provide some solace in their bereavement]</p> <p>Under 1.1.26 [ Add 2nd bullet]</p> <ul style="list-style-type: none"> <li>• how death is diagnosed using neurological criteria</li> <li>• offer the opportunity to attend neurological death tests</li> </ul> <p>Could the option of tissue donation be added to both types of donation i.e. Sections 1.1.25, 1.1.26 as families</p>	<p>Thank you for your comment.</p> <p>NICE guideline CG135 will be amended to include a footnote to the first bullet point of <a href="#">recommendation 1.1.2</a>. This footnote is to make reference to the guidance on <a href="#">diagnosis of brain stem death in infants between 37 weeks and 2 months gestation</a> published by the RCPCH in 2015. The footnote will also include a link to the guidance.</p> <p>Regarding your comment about the section of 'Approach to those close to the patient', there is a rationale to discuss all cases of potential</p>

	<p>particularly with Donation After Cardiac Death (DCD) may wait a long time for someone to die and they have built themselves up for organ donation and that is snatched away from them when the person 'does not die in time'. Tissue donation could be helpful in them feeling that their donor still made a tremendous contribution. Likewise, with Donation after Brain Stem Death (DBD) if organ donation for some reason cannot take place. [see Sque et al ref 2013 below]</p> <p><b>Factors influencing decision-making by those close to the patient pg 13</b></p> <p>'...and should be offered support' is very vague. Suggest, 'the needs of those close to the patient will be actively explored, respected and met as far as possible'</p> <p><b>Reference</b></p> <p>Leadership Alliance for the Care of Dying People (2014) One change to get it right: Improving people's experience of care in the last few days and hours of life.</p> <p><a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323188/One_chance_to_get_it_right.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/323188/One_chance_to_get_it_right.pdf</a></p> <p><b>Organisation of the identification, referral and consent processes pg 16</b></p> <p>Inserted 'a'</p> <p>1.1.30 The Multiple Disciplinary Team (MDT) involved in the identification, referral to a specialist nurse for organ donation, and consent should have the specialist skills and competencies necessary to deliver the recommended process for organ donation outlined in this guideline.</p> <p><b>What key skills and competencies are important for healthcare 135 – 05 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?</b></p> <p>Inserted 'a'</p> <p>1.1.31 The skills and competencies required of the individual members of the team will depend on their role in the process. However, all healthcare professionals involved in identification, referral to a specialist nurse for organ donation, and consent processes should:</p> <ul style="list-style-type: none"> <li>• have knowledge of the <b>basic principles</b> and the <b>relative benefits</b> of, donation after circulatory death (DCD) versus donation after brainstem death (DBD)</li> <li>• understand the principles of the diagnosis of death using neurological or cardiorespiratory criteria and how</li> </ul>	<p>deceased organ donors before approaching those close to the patient. Please see <a href="#">recommendations 1.1.15 to 1.1.26</a> for further information.</p> <p>During the Evidence Update, there was evidence about the effect on consent rate of relatives' presence during determination of neurological death (<a href="#">Evidence Update January 2014</a>). It was concluded that the limited evidence (1 study, n=8 relatives) indicated that the effect on consent to organ donation of offering relatives the opportunity to be present during determination of neurological death in a family member was unclear. We did not identify any further evidence at this surveillance review that could change the decision made at the 2-year Evidence Update.</p> <p>NICE guideline CG135 covers solid organ donation only. Tissue donation is outside scope and we did not find</p>
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		<p>this relates to the organ donation process</p> <ul style="list-style-type: none"> <li>• be able to explain <b>neurological death</b> clearly to families</li> </ul> <p>Statement 1. is not clear, i.e. what basic principles? Benefits to whom?</p> <p>Statement 3. form of death is now different. Suggest use one form throughout the guidelines.</p> <p>1.1.32</p> <ul style="list-style-type: none"> <li>• communication skills and knowledge <b>necessary to improve consent ratios for organ donation.</b></li> </ul> <p>Section in <b>Red</b>: What does this mean?</p>	<p>evidence to cause an extension of the scope</p> <p>We have now added your suggested wording of 'the needs of those close to the patient will be actively explored, respected and met as far as possible' to the section of 'Factors influencing decision-making by those close to the patient' (see Appendix A, review question 135 – 03).</p> <p>We will send your suggestions regarding the wording of <a href="#">recommendations 1.1.30 and 1.1.31</a> to the editorial team.</p> <p>Regarding <a href="#">recommendation 1.1.31</a>, the relative benefits of DCD and DBD are mentioned by <a href="#">recommendation 1.1.32</a> which states that there is greater potential for transplantation or organs retrieve from DBD donors compared with organs from DCD donors.</p> <p>Neurological death is currently used to refer to brainstem death by NHS Blood and Transplant. Apologies if we</p>
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			<p>misunderstood your comment.</p> <p>The 'Person centred care' section states that '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 guideline committee also acknowledged that there was no direct link between information and support with consent rate but consent may be improved by providing accurate information and support appropriate to the family, and hence consent rates may be improved.</p>
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**Do you agree with the proposal to remove the research recommendation:**

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

Stakeholder	Overall response	Comments	NICE response
BAPM	Yes	No comment	Thank you for your answer.
Faculty of Intensive Care Medicine	Left blank	In particular there is now strong evidence to support the involvement of a SN-OD in the family approach, particularly for DCD (Hulme W, Allen J, Manara AR, et al. Factors influencing the family consent rate for organ donation in the UK. <i>Anaesthesia</i> 2016; 71: 1053-1063). This is stronger evidence than the previous ACRE study that did not show an effect of the SNOD in the approach. There is also strong evidence from that adoption of best practice guidance (NHS Blood and Transplant 2012. Timely identification and referral of potential organ donors. A strategy for implementation of best practice. <a href="http://www.odt.nhs.uk/pdf/timely-identification-and-referral-potential-donors.pdf">http://www.odt.nhs.uk/pdf/timely-identification-and-referral-potential-donors.pdf</a> and the NICE	Thank you for your comment. Although this research recommendation will be

		guidance have driven increased identification and referral of potential donors, and that this increase was the primary reason for the 50% increase in donor numbers between 2008-2013, and the continuing increase now.	removed from the NICE version of the guideline and the NICE database for research recommendations, the research recommendations will remain in the full version of the guideline.
RCPCH	Yes	No comment	Thank you for your answer.
Royal College of Nursing	There is room for other ideas but these five subjects remain outstanding. It is suspected that funding to address these issues directly will need to be allocated via DH?	<p><b>Reading 'Appendix A: summary of new evidence from surveillance'</b> it was striking and hard to ignore how little research about organ donation and its social fundamentals have been carried out in the UK and the enormous extent to which we depend on evidence from other countries, with different health systems, on which to base our guidelines. This small array of national studies has not been helpful to us in solving the issue of a stagnant consent rate of 58% to donation by families of the deceased. This is a long way from the government's target of 80% consent. To mobilise the research that will provide the answers of how this can be achieved there needs to be allocated funding and full co-operation between researchers working in collaboration, on integrated projects, with NHSBT staff, and Trusts and their staff.</p> <p>Sque et al (2013) for instance attempted to address the reasons why bereaved relatives decline organ donation from a deceased family member. Within the study sites there was the potential for 108 declining families to be recruited. Specialist Nurses in Organ Donation (SNODs) approached only 14 families on behalf of the researchers to ask if they would wish to receive information about the study.</p> <p>The issue of increasing referral of potential donors to SNODs, and SNODs involvement in the organ donation discussion, as recommended by NICE, is yet to be fully implemented across board. Likewise, the link between high quality care and communication with bereaved family consent to donation has never been tested. We do have a low base knowledge of Black Minority Ethnic (BME) population's stance to donation but still know very little about our indigenous population and what their feelings and attitudes are about donation. Likewise, we know little about the attitudes of our health professionals, particularly those working in areas where organ donation is most likely to be considered. Last national study of nurses' attitudes, knowledge and behaviour was reported in 2000.</p> <p>There may be mileage in looking into the attributes of high performing donation teams; DCD as the growth area for deceased organ donation; and what about a trial of 'Required request'? We also need to think about how social media can be exploited to increase sign up to the NHS Organ Donor Register and spread positive messages about organ donation. Organ donor memorialisation is increasing. What is the public impact if any? How can memorials be used to positively promote organ donation? We need UK research into bereaved families' experience of attending neurological death testing.</p>	<p>Thank you for your comment.</p> <p>Although this research recommendation will be removed from the NICE version of the guideline and the NICE database for research recommendations, the research recommendations will remain in the full version of the guideline.</p>

		<p>NICE as a respected and influential organisation has the potential to encourage or stifle much needed research in this country. We do not feel that any of the subjects you wish to delete from the research portfolio have been satisfactorily addressed and thus wonder at the reason for their removal? Whatever the outcome we must not be complacent.</p> <p><b>References</b></p> <p>Sque M. Payne S. and Vlachonikolis I. Cadaveric donotransplantation: nurses' attitudes, knowledge and behaviour. <i>Social Science &amp; Medicine</i>, 50: 4, 2000, 541-552.</p> <p>Sque M. Walker W. Long-Sutehall T. Morgan M. Randhawa G. and Warrens A. <i>Bereaved families' experiences of organ and tissue donation, and perceived influences on their decision making</i>. University of Wolverhampton, Final report of a study funded by the Department of Health, June, 2013.</p> <p>General comment: A note is made that the consultation period was extremely short!</p>	
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### Do you agree with the proposal to remove the research recommendation:

Why do families refuse to give permission for organ donation?

Stakeholder	Overall response	Comments	NICE response
BAPM	Yes	No Comment	Thank you for your answer.
Faculty of Intensive Care Medicine	Left blank	One of the main areas that will need guidance moving forward is how to manage a family overriding the wishes of a patient on the Organ Donor Register to donate, as this is happening in 10-12% of potential donors. The Faculty agrees that guidance on the family approach in places with a presumed consent system may be appropriate. Currently this applies only to Wales, but this will potentially be adopted in other parts of the UK.	Thank you for your comment. We decided to retain this research recommendation based on the feedback on its importance.
RCPCH	Yes	No comment	Thank you for your answer.
Royal College of Nursing	There is room for other ideas but these five	Please see comment above	Thank you for your comment. We decided to retain this research recommendation

	<p>subjects remain outstanding. It is suspected that funding to address these issues directly will need to be allocated via DH?</p>		<p>based on the feedback on its importance.</p>
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**Do you agree with the proposal to remove the research recommendation:**  
 What are the key components of an intervention to improve identification and referral rates?

Stakeholder	Overall response	Comments	NICE response
BAPM	No	Lack of experience in newborn care needs intervention(s) to improve identification and referral rates	<p>Thank you for your comment.</p> <p>We decided to retain this research recommendation based on the feedback on its importance.</p>
Faculty of Intensive Care Medicine	Left blank	No comment	Thank you for your answer.
RCPCH	Yes	No comment	Thank you for your answer.
Royal College of Nursing	There is room for other ideas but these	Please see comment above	<p>Thank you for your comment.</p> <p>We decided to retain this</p>



	<p>five subjects remain outstanding. It is suspected that funding to address these issues directly will need to be allocated via DH?</p>		<p>research recommendation based on the feedback on its importance.</p>
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**Do you agree with the proposal to remove the research recommendation:**

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

Stakeholder	Overall response	Comments	NICE response
BAPM	No	Not currently applicable to newborn care – no baseline data, but likely that interventions will be transferrable	<p>Thank you for your comment.</p> <p>We decided to retain this research recommendation based on the feedback on its importance.</p>
Faculty of Intensive Care Medicine	Left blank	No comment	Thank you for your answer.
RCPCH	Yes	No comment	Thank you for your answer.
Royal College of Nursing	There is room for other ideas	Please see comment above	Thank you for your comment.

	<p>but these five subjects remain outstanding. It is suspected that funding to address these issues directly will need to be allocated via DH?</p>		<p>We decided to retain this research recommendation based on the feedback on its importance.</p>
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**Do you agree with the proposal to remove the research recommendation:**

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

<b>Stakeholder</b>	<b>Overall response</b>	<b>Comments</b>	<b>NICE response</b>
BAPM	No	Although not currently applicable as above, it will be very important to establish good processes at this early stage	<p>Thank you for your comment.</p> <p>We decided to retain this research recommendation based on the feedback on its importance.</p>
Faculty of Intensive Care Medicine	Left blank	Finally while not necessarily in the scope of the guidance, recommendations on ways to reduce the length of time of the donation pathways (ie time from consent to organ retrieval) would be helpful for ICUs and also for donor families, and may help increase consent rates	<p>Thank you for your comment.</p> <p>Although we can suggest removing research recommendations, we cannot suggest any new additions.</p>

			New additions can only be proposed by guideline committees during guideline development, including updates.
RCPCH	Yes	No comment	Thank you for your answer.
Royal College of Nursing	There is room for other ideas but these five subjects remain outstanding. It is suspected that funding to address these issues directly will need to be allocated via DH?	Please see comment above	Thank you for your comment. We decided to retain this research recommendation based on the feedback on its importance.

Comment from the Royal College of Nursing:

**A note is made that the consultation period was extremely short!**