National Institute for Health and Clinical Excellence

Organ donation
Guideline Consultation Comments Table
16 February – 16 March 2011

Type	Stakeholder	Order No	Document	Page No	Line No	**Comments** Please insert each new comment in a new row.	**Developer's Response** Please respond to each comment
SH	British Association of Critical Care Nurses	21.00	Full	4	80	The whole section from line 80-89 is wholly appropriate. Are you going to suggest the sorts of communication leaflets that should be used?	Thank you. This section had been rewritten to make it more appropriate for this guideline.
SH	British Association of Critical Care Nurses	21.01	Full	5	113	Recommendation 1.1.3. Will there be adequate numbers of Specialists Nurses for Organ Donation (SNODs) to enable this to occur for every patient 24 hours a day / 7 days a week? We are aware that many hospitals share SNODs	Thank you for your comment. NICE produce costing and implementation tools that will be made available when the guideline is published.
SH	British Association of Critical Care Nurses	21.02	Full	5	121	Recommendation 1.1.4. We welcome that these patients should be cared for in adult critical care units but many adult critical care units frequently have no beds to admit patients. This is a concern. If these potential donors cannot be cared for in adult critical care units are you saying they should not be considered and the potential for donation is lost? We acknowledge the gold standard should be to care for these patients in adult critical care units but in the absence of a critical care bed could these patients be cared for in another area by critical acre staff. The decision could be defined locally	Thank you. The recommendation that you refer to has been amended to make it clearer where the care for patients should take place. The text now reads that this care should take place in an 'appropriate critical care setting such as an adult critical care unit or in discussion with a regional paediatric intensive unit'. The guideline also recommends that each hospital has its own policies and protocols that are consistent with this guideline to guide the organ donation process.
SH	British Association of Critical Care Nurses	21.03	Full	6	134	"Sufficient" time. This is difficult to define because for some families this may be a very short time and for others could be hours or	Thank you for your comment. We recognise that the time taken for individuals to understand (or come to terms) with the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						days. This may cause problems in units with very high occupancies	inevitability of death will vary, which is why have not specified the duration of the time.
SH	British Association of Critical Care Nurses	21.04	Full	8	206	"Where" donation is likely to occur is easy generally but the "when" is usually rather more difficult. The uses of an "approximation" may be better.	The use of the term 'likely' in the existing sentence reflects that the 'where' and 'when' may not be possible to specify. Thus the sentence has not been changed.
SH	British Association of Critical Care Nurses	21.05	Full	9	235	Recommendation 1.1.22. What are the competencies and how are they to be measured?	Thank you. Competencies will differ depending on an individual's role, and where they are in the organ donation process. It is not within our remit to outline the competencies, or how they will be measured. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	British Association of Critical Care Nurses	21.06	Full	9	241	Recommendation 1.1.23 How are we going to measure that healthcare professional can do this?	Thank you. Competencies will differ depending on an individual's role, and where they are in the organ donation process. It is not within our remit to outline the competencies, or how they will be measured. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	British Association of Critical Care Nurses	21.07	Full	9	255	Recommendation 1.1.24 23 How are we going to measure that Consultants can do this	Thank you. Competencies will differ depending on an individual's role, and where they are in the organ donation process. It is not within our remit to outline the competencies, or how they will be measured. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	British Association of Critical Care Nurses	21.08	Full	General		It appears that due to the nature of some of the questions being answered by this guideline that the RCT research approach may not be the best method to answer the questions and	Thank you. We use the highest quality evidence available, including studies using qualitative methods, which were included in the evidence base for this guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						qualitative methodologies could have been investigated	We use GRADE tables to appraise the biases and uncertainties of study outcomes, not to describe studies as poorly or well conducted. Where evidence is classified in GRADE as low quality this does not mean that the GDG exclude this evidence. Please see guidelines manual for further information. http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	British Association of Critical Care Nurses	21.09	Full	General		There is qualitative research which has been undertaken very rigorously but as it does not follow an RCT approach it looks like it may have either been disregarded or classed as low level evidence. Some of the recommendations may not be supported by high level evidence (such as a multi-centre RCT) but it is informed by best practice or "common sense" which may also been more effectively tested via a qualitative methodological approach.	Thank you. We use the highest quality evidence available, including qualitative studies, which were included in the evidence base for this guideline. We use GRADE tables to appraise the biases and uncertainties of study outcomes, not to describe studies as poorly or well conducted. Where evidence is classified in GRADE as low quality this does not mean that the GDG exclude this evidence. Please see guidelines manual for further information. http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	British Association of Critical Care Nurses	21.10	Full	General		The BACCN support this document and hope that clinical colleagues throughout the country take all the recommendations on board	Thank you.
SH	British Liver Trust	35.00	Full	General		The British Liver Trust welcomes the NICE clinical guidance aimed at improving Organ Donation. We fully support the need for research to increase understanding on why 90% of the general public support organ donation yet only 28% are registered on the ODR.	Thank you. The guideline is about improving identification and consent and as such your comments are outside the scope of this guideline. We do make recommendations on when families are approached for consent and by whom, as you suggest.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Following consultation with liver patient groups, we do support presumed consent will be a successful option. Presumed consent throws up lots of ethical as well as practical issues. These issues affect people getting the new organs as well as the bereaved families of donors. Patients are in agreement that a donated organ is a precious gift, freely given, and it is the fact it is a gift rather than a right that makes it so valuable to recipients and so meaningful to donors and their relatives. We know that the best quality organs come from young, healthy heart-beating donors who are often donors who are people still warm and pink, albeit brain-stem dead and who often have not planned or discussed arrangements for their death. This often tragic situation makes it incredibly difficult for relatives and the ideal would be to discuss and agree donation with their relatives' consent rather than impose this on them. Instead of presumed consent, we would like to see a package of measures put forward fully implemented, including: • Measures like improved support for doctors and nurses at the front line of organ donation, to help them have those difficult conversations with people who are dying and their relatives. • Measures like extra transplant co-ordinators who can work with hospitals to help them organise their transplants. • Dedicated teams	

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						• Better data on which hospitals are doing well and which need support to do better. • Campaigns to encourage people to sign the organ donor register and discuss this step with their families. We also believe that there needs to be increased understanding of the management of donor families at the decision point for donation must be a key requirement, with clear policies on how and when families are approached for consent, by whom and what support will be offered to the family following a positive decision. It should also include clear explanations of the benefits and legacy of organ donation.	
SH	British Medical Association (BMA)/Royal College of Surgeons	34.00	Full	5 & 57	117 & 925	It is unclear what is meant by "clinically stablilise" and what steps would be considered appropriate. In most cases, the patient will not have capacity and therefore any intervention must be in his or her best interests. Where it is known that the patient wanted to donate organs, it is appropriate to take steps that do not cause the patient harm or distress in order to preserve the organs. Where the individual's wishes are not known, it would also be appropriate to take minimally invasive steps to keep the patient stable for a short period of time whilst enquiries are made about the patient's wishes. It should be made clear in the guideline, however, what the limits of legally and ethically acceptable interventions would be in these circumstances.	Thank you. The recommendation has been rewritten to make it clearer that life sustaining treatments should not be withdrawn or limited until the potential for the patient to donate has been assessed, and that patient should be clinically stabilised while the assessment is performed.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	British Medical Association (BMA)/Royal College of Surgeons	34.01	Full	8 & 71	197 & 1021	The guideline states that the information to be given should include that "the parents', family's or guardians' wishes will be respected". Where the patient has expressed wishes it is these that should be respected. Families should be strongly encouraged to support the patient's wishes where these are known. As currently drafted, the guideline implies it is the family's, rather than the patient's, views that should be followed.	Thank you. The guideline has been changed. Recommendation 1.1.5 now makes it clear that patients that have the capacity to consent can do so. Recommendation 1.1.6 now refers to exploring the patient's intentions to consent, rather than the patient's wishes, as the GDG felt that this strengthened the discussions around following the patient's views.
SH	British Medical Association (BMA)/Royal College of Surgeons	34.02	Full	8 & 71	204 & 1028	The family of potential donors should be given as much information as they need and want about the process of donation and retrieval. It would be inappropriate to force detailed and explicit information about procedures on those who clearly do not want to know. The guideline should emphasise this point so that it is not interpreted as requiring detailed information to be provided in every case.	The recommendation states that information should be given as appropriate so that health care professionals, in discussion with those close to the patient, can use their discretion to decide how much information is provided, and how it is provided, and the level of detail that is provided. It is beyond the remit of this guideline to state what is inappropriate, for whom, and when.
SH	British Medical Association (BMA)/Royal College of Surgeons	34.03	Full	8 & 71	207 & 1031	As above.	The recommendation states that information should be given as appropriate so that health care professionals, in discussion with those close to the patient, can use their discretion to decide how much information is provided, and how it is provided, and the level of detail that is provided. It is beyond the remit of this guideline to state what is inappropriate, for whom, and when.
SH	British Medical Association (BMA)/Royal College of Surgeons	34.04	Full	9 & 76	243 & 1072	It is not clear what the "relative benefits" of DCD and DBD are given that they are simply different methods of diagnosing death. This may relate to the "benefits" in terms of the number of organs that can be retrieved but, if	Thank you. It is beyond the scope of this guideline to provide detailed information on the relative benefits of DBD versus DCD. The health professionals involved in organ donation should have this knowledge.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						so, this should be clarified.	
SH	British Medical Association (BMA)/Royal College of Surgeons	34.05	Full	10 & 77	265 & 1095	This should be qualified to refer to "legally and ethically appropriate" clinical techniques.	Thank you. This has been added as suggested.
SH	British Medical Association (BMA)/Royal College of Surgeons	34.06	Full	11	302	The document states that it is intended to be "relevant" to healthcare professionals involved in the process of donation and that the "target population" is families, carers or guardians of potential donors. For those not familiar with NICE terminology this is confusing as it seems to imply that the guideline is intended for use by families rather than by health professionals. It would be clearer if this were reworded to say 'This document sets out NICE guidelines for health professionals involved in the process of organ donation, including their interactions with potential donors, their families, carers or guardians.'	Thank you. We have amended this section as suggested.
SH	British Medical Association (BMA)/Royal College of Surgeons	34.07	Full	11	285	It would be helpful to amend to read "Nearly 17 million people (28% of the population) are already .." . This more clearly demonstrates the contrast with the 90% who support donation (as mentioned in the previous line).	Thank you. We have added this as suggested.
SH	British Society of Gastroenterology	23.00	Full	6	145	Use of the term 'specialist nurse for organ donation' – may be too restrictive as not all transplant co-ordinators are trained as nurses, indeed in our institution one of the donor co-ordinators was trained as an ODA. Also on line 156, 233, 960 etc. later in the text the term 'organ donation professional' is utilised and as the successful Spanish Model utilises doctors in this specific role, it might be that 'specialist	Thank you. The GDG discussed this issue extensively and it was decided that the appropriate term should be Specialist Nurse for Organ Donation. Therefore the text has not been changed.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						nurse for organ donation' is not sufficiently flexible.	
SH	British Society of Gastroenterology	23.01	Full	7	172	Add 'at an appropriate time'	The issue of timing the discussion is addressed in recommendation 1.1.8 where it is stated that the discussion should take place at a different time from discussing the anticipated death of the patient, unless those close to the patient initiate the discussion. It would be difficult to determine what an 'appropriate' time is as this will vary from individual to individual and so your suggested insertion has not been included.
SH	British Society of Gastroenterology	23.02	Full	51	839	Modelling is more difficult for liver transplantation, where death as a default for no transplant is not costly (as no dialysis equivalent exists), compared with late stage chronic liver disease (variceal bleed, large volume paracentesis, hepatorenal syndrome etc) which tends to be expensive. Data is poor (Sagmeister Transplantation 2002).	Thank you for your comment, due to the poor data available no modelling was conducted for liver transplantation.
SH	British Society of Gastroenterology	23.03	Full	59	941	The word 'register' should be on the previous line (line 940)	Thank you. This has been corrected.
SH	British Society of Gastroenterology	23.04	Full	70	1003	Apparent conflict of only approaching the family when they have understood the process and inevitability of death and 'optimizing the timing of approach' p68 line 996.	Thank you. The guideline recommends discussing organ donation when those close to the patient *understand* the inevitability of death, not simply when death is inevitable.
SH	British Society of Gastroenterology	23.05	Full	75	1062	In the box on 'Quality of Evidence' there is an extra *the* between that and where to process	Thank you. This has been deleted.
SH	British Society of Gastroenterology	23.06	Full	76	1094	Add 'and better organ and patient outcomes for DBD over DCD in liver transplantation'.	Thank you. It is beyond the scope of this guideline to provide detailed information on the relative benefits of DBD versus DCD.
SH	British Society of Gastroenterology	23.07	Full	78	1098	Term "consent ratios" for organ donation needs clarification	Thank you. The term consent ratio refers to the number of people for whom consent was sought and who actually consented

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							This definition has been added to the glossary. Some people use the term rates instead which we feel is misleading. The term consent ratio is correct.
SH	British Society of Gastroenterology	23.08	Full	General		Thank you for allowing the BSG to comment on this draft guideline. This draft guideline has been produced in an effort to improve donor organ availability. The 'evidence review' is hampered by the paucity/absence of good quality data. However this review is important, not least, for its emphasis on incorporating *discussion* around organ donation in end-of-life care discussions with patients and/or families (as per GMC). Many clinicians feel ill at ease bringing up the subject of organ donation when they have been striving to preserve the life of an individual and consider such discussions may be anything from insensitive to perhaps suggesting less than wholesome motives for 'withdrawing care'. The use of the term "organ donation professional" may sound a little clumsy but does allow for the non-nurse trained individual to be incorporated in this role and as many of these individuals in the successful Spanish model are doctors perhaps hints at the importance of recognising the responsibility for this activity across the entire MDT. Finally, the liver transplant community are increasingly concerned at the graft and patient outcomes for DCD derived organs, compared with DBD's. Whilst i recognise that the purpose of this document is not to get bogged down in the complexities of individual organ techniques and outcomes, it is important that clinicians do	Thank you for your comments. The GDG extensively discussed the issues that you have raised. The lack of good quality evidence is in part due to the complexities of the issues covered in this guideline that preclude high quality RCTs being conducted in this area. Thus the quality of evidence will generally be low. However, the GDG did use this level of evidence in their decision making processes. Whilst the term organ donation professional may be appealing for encompassing a wider range of individuals, the term SNOD refers a specific role within organ donation. Thus the GDG agreed that the term Specialist Nurse for Organ Donation should be kept in the guideline. Although quality and quantity of organs is an important issue, it is outside the scope of this guideline which was set by the Department of Health. Our remit was to specifically focus on increasing donor identification and consent rates, therefore specific guidance around the quantity and quality of DBD organs versus DCD organs is not included in this guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						not get the impression that these organs are of identical quality and utility, which may influence both their discussions with potential donors/families and their decisions over treatment withdrawal.	
SH	British Society of Neuroradiologists	13.00	Full	General		This guideline relates to the obtaining of consent, and does not cover diagnostic tests related to suitability for transplant. BSNR does not, therefore, have any comment to make regarding the contents of the guideline.	Thank you.
Non SH	British Thoracic Society	19.00	Full	General		Although we appreciate the importance of this area, the view of the British Thoracic Society Respiratory Critical Care Specialist Advisory Group is that the document is focussed on increasing the quantity of organs available for transplantation. The goal should be to increase the quantity of quality organs available. The clinic state of the patient needs to be taken into account. Also the non-clinical context of the patient admission needs to be considered i.e. presumed medical negligence on general ward, diagnostic delay, post surgical etc. Finally, this document has low level evidence base and there is predominantly based on expert opinion, which to be fair is true for a number of guidelines.	Thank you. The scope for this guideline which was provided by the Department of Health was to improve donor identification and consent rates. Although the quality and quantity of organs is important, it falls outside the remit and is therefore not explicitly addressed in the guideline. The evidence base for the guideline is based on low quality evidence due to the nature and complexity of the issues involved. GRADE tables were used to appraise the biases and uncertainties of study outcomes, not to describe studies as poorly or well conducted. Thus, 'Low quality' evidence is considered by the GDG in their decision making process and recommendations are not made purely on expert opinion. Please see guidelines manual for further information: http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
Non SH	British Thoracic Society	19.01	Full	5	117	It may not be possible to, nor in the patient's best interest to try to, "clinically stabilise" patients with "a life-threatening or life-limiting	The recommendation that you refer to has been rewritten to make it clearer that all actions should be in the patients best

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						condition which will, or is expected to, result in cardiac death".	interest.
Non SH	British Thoracic Society	19.02	Full	5	120	If read literally, this paragraph would appear to mandate that this would include ALL expected deaths occur in critical care. This is clearly neither possible nor desirable. We are concerned that a proportion of patients admitted to ICU may not be suitable e.g. patients with metastatic cancer with neutropenic sepsis secondary to chemotherapy. We should be aiming to increase the quantity of quality organs that are available, not just the quantity of organs available.	The recommendation has been rewritten to make it clearer that patients should be assessed for their potential to donate in an appropriate critical care setting, or in discussion with a critical care team.
Non SH	British Thoracic Society	19.03	Full	5	113	The insistence that every anticipated death is discussed immediately with an organ donation specialist nurse is not appropriate as it takes no account of clinical context and is analogous to the 4-hour wait in A&E. If this approach is to be adopted clinicians involved in the treatment of patients will not be able to participate further. This approach may increase the quantity of referrals to organ donation specialist nurses but do little to increase the supply of quality organs for transplantation.	The involvement of a Specialist Nurse for Organ Donation does not preclude the involvement of the treating clinicians. Evidence shows that having a SNOD in addition to the clinical team can improve donation rates through coordinating and planning the process.
Non SH	British Thoracic Society	19.04	Full	11	299	We feel it is misleading to describe the recommendations made in this document as "evidence based recommendations" given the low level evidence available. It would be preferable to acknowledge that the majority of the published evidence is weak and that much of the guidelines is 'expert opinion', as many guidelines are.	Thank you for your comment. The text has been changed to make it clearer that the recommendations are based on evidence where available.
Non SH	British Thoracic Society	19.05	Full	6	141	Clinicians managing the patient will find it difficult to be involved in obtaining consent if all	Thank you. Only patients who meet the trigger criteria listed in recommendation

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						patients are referred. Involvement can only occur if referral for donation is felt appropriate.	1.1.2 should be referred.
Non SH	British Thoracic Society	19.06	Full	6	147	Continuity is only possible if the clinician considers the referral is appropriate	Thank you. The evidence suggests that both automatic referral and continuity are required to improve donation.
Non SH	British Thoracic Society	19.07	Full	6	155	Identifying if a patient is a potential for organ donation is within the capability of the clinician	Thank you. The decision on suitability of donors rests with the transplant service.
Non SH	British Thoracic Society	19.08	Full	6	189	This is counterintuitive if all patients are referred with no reference to the non-clinical context (e.g. family angry at death, aggressive towards staff who they blame) then this procedure is following a policy.	Thank you. The evidence suggests that avoiding apologetic language when discussion organ donation improves donation rates in the majority of cases. The guideline therefore recommends avoiding the use of apologetic language. It does not recommend that such language should never be used. It would be entirely appropriate, and within the healthcare professionals discretion to assess the context and use the language that they feel is appropriate especially in the instances that you have suggested.
SH	British Transplantation Society	22.00	Full	1	3	We welcome any steps to increase both donor identification and consent rates. But regarding an increase in total *donor* numbers as the only aim is too simplistic. The greatest benefit is achieved if the total number of *organs* transplanted can be increased. For some organs, particularly the heart and the lungs, increasing the number and the success rates of transplant operations requires steps (revolving around good donor management) beyond a mere increase in donation rates	Thank you. Whilst increasing the quality and quantity of organs for donation is important, the scope for this guideline which was set by the Department of Health was to increase donor identification and consent rates. Thus the comments you have made are outside the scope of the guideline.
SH	British Transplantation Society	22.01	Full	4	93	We particularly welcome this opening statement that organ donation should be regarded as a normal part of end of life care	Thank you.
SH	British	22.02	Full	5	112	The term "cardiac death" should be replaced	Thank you. 'Cardiac death' has now been

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Transplantation Society					throughout by "circulatory death"	replaced with 'Circulatory death' throughout the guideline.
SH	British Transplantation Society	22.03	Full	5	117	We feel the text would be better saying...."who satisfy the clinical trigger criteria..."	The recommendation that you refer to has been rewritten to make it clearer that it refers to the patients that have already been identified as potential donors.
SH	British Transplantation Society	22.04	Full	5	117	Clinical stabilization of patients who meet trigger factors should be extended into much more thorough and active management of the potential donor. Whilst not affecting donor identification or consent rates, there is copious evidence that aggressive management can increase the number and quality of *organs* not just the number of donors. For hearts and lungs the increase in number of donors has not translated into more transplants. The benefit of these efforts so far lies only in the number of organs transplanted.	The recommendation has been rewritten, but extending the recommendation into managing potential donors is outside the scope of the guideline.
SH	British Transplantation Society	22.05	Full	5	132	This should read **tissue and** organ donation	Tissue donation is outside the scope of this guideline. An earlier reference to Thymus transplants has been removed.
SH	British Transplantation Society	22.06	Full	8	214	It is important to clarify that completion of Consent Documentation should only be undertaken by a trained professional in this process i.e a SN-OD. As this section discusses the role of the whole MDT (Dr, Nurse or Chaplain etc), the document should reflect that Consent can only be completed by a SN-OD.	This recommendation refers to providing consent documentation to those who are able to consent on behalf of the patient. The recommendation does not refer to who should complete this documentation, as this is out of the scope of the guideline. Instead we have made recommendations that state that the MDT should have the appropriate specialist skills and competencies for their role (recommendations 1.1.23 and 1.1.24). Furthermore, each hospital should have its own local policies and procedures that should be followed which will determine who can complete the consent

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							documentation (recommendation 1.1.20).
SH	British Transplantation Society	22.07	Full	8	217	The second bullet point: for brainstem **death** patients - shouldn't this read "for brainstem **dead** patients...?	Thank you. We have reworded this and it now reads: 'potential donors who death has been confirmed using neurological criteria'.
SH	British Transplantation Society	22.08	Full	10	263	We applaud the reminder about GMC guidance regarding the greater potential for transplantation of organs retrieved from DBD donors compared with DCD donors The increase in DCD donors, driven at least in part by the target of "more organ donors" rather than "more organs" has had an adverse effect on heart transplant activity in particular. There is a greater overall benefit if a potential donor can be declared brain dead, and have all organs retrieved with the circulation intact. Whilst this clearly affects heart transplantation, liver transplants are also disadvantaged. A smaller proportion of DCD donors provide liver grafts suitable for transplantation and the outcome of liver transplantation using DCD donor livers is inferior.	Thank you. The scope for this guideline which was set by the Department of Health was to increase the identification and consent rates for organ donation. Although quality and quantity of organs is an important issue, it is outside the scope of and is therefore not included in the guideline.
SH	British Transplantation Society	22.09	Full	10	274	Thymus should not be listed here. It would probably be included as a tissue and not an organ. No Thymus transplants are currently performed in the UK.	Thank you. Thymus has been removed from the guideline.
SH	British Transplantation Society	22.10	Full	11	283	Not only are there deaths whilst awaiting transplant amongst patients listed, there is a very large unmet need amongst patients who, because of organ scarcity, are not presently considered for transplant	Thank you. The text has been changed to include those who are not presently considered for transplant.
SH	British Transplantation Society	22.11	Full	11	284	"UKTransplant" commissioned this 2003 survey	Thank you. This has been changed in the text to state that UK transplant commissioned the survey.
SH	British Transplantation	22.12	Full	51	853	The health economic argument is straightforward for renal transplantation,	Thank you for your comment. Within the timeframe of this guideline it was decided to

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Society					because of the easily calculable costs of dialysis support. There is equally convincing data, although more difficult to analyse, of the cost-benefit of other organ transplants	focus on kidney transplantation as it forms the majority of transplants and consumes the most resources.
SH	Department of Health	25.00	Full	General		Thank you for the opportunity to comment on the draft for the above clinical guideline. We wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.	Thank you.
SH	Donor Family Network	17.00	Full	General		When discussion is mentioned it should contain an additional phrase including 'partner/spouse or nominated next of kin'	Thank you. The terminology used to describe parents, family, relatives, friends and partners has been changed throughout the guideline to refer to those 'close' to the patient, or those in a 'qualifying relationship' with the patient. Both these terms have been added to the glossary.
SH	Donor Family Network	17.01	Full	8	206	to be a note here that parents, guardians etc. 'Need to be informed that the consent process involves asking a lot of personal questions relating to the patient and their lifestyle. This needs to managed ethically and can take quite a time to complete'	Thank you for your comment. We are unable to specify the content of the discussions, however throughout the recommendations we have emphasised the need for healthcare professionals to provide clear information and explanations of the process of organ donation.
SH	Donor Family Network	17.02	Full	5	122	'Where possible' to be added at end of sentence	This recommendation has been rewritten, and your suggested insertion is no longer necessary.
SH	Donor Family Network	17.03	Full	6	135	Should read 'death or anticipated death' as in DBD the person may already be dead	Thank you this has been amended as suggested.
SH	Donor Family Network	17.04	Full	6	137	And should have in addition'/or neurological death'	This has been amended as suggested.
SH	Donor Family Network	17.05	Full	6	146	Should there be an additional note regarding different pathways e.g. military personnel?	Thank you. We follow the Human Tissue Authority's hierarchy of qualifying

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							relationships with the potential donor to identify people who can give consent for the deceased person if the deceased person has not indicated their consent.
SH	Donor Family Network	17.06	Full	8	218	Should state 'clear and easily understood language tailored to their needs'	Thank you. Clear and easily understood language that is tailored to the patients needs should be used at all times. This is implicit throughout the guideline. 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'.
SH	Donor Family Network	17.07	Full	9	248	As above	Thank you. Clear and easily understood language that is tailored to the patients needs should be used at all times. This is implicit throughout the guideline. 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'.
SH	Donor Family Network	17.08	Full	9	224	'and what happens next' to be added to end of sentence	Thank you. We have added this to the recommendation.
SH	Donor Family Network	17.09	Full	11	287	Should read 'The donor pool is reducing but transplantation is increasing although more needs to be done'	Thank you. The aim of this guideline is to increase the donor pool through the use of clinical triggers and required referral.
SH	Human Tissue Authority	31.01	Full	4	78	It would add clarity to reference that under the Human Tissue Act (2004), a person is a child if they are under 18 years of age.	Thank you. We have added a reference to the department of health guidance on consent.
SH	Human Tissue Authority	31.02	Full	4	94	Replacing 'possible' with 'appropriate' would ensure language is consistent with the Human	Thank you. The recommendation refers to situations in which it may be appropriate to

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Tissue Act.	discuss organ donation with the patient, parents, family or guardians, but we are acknowledging that this is not always possible. Therefore the use of the word 'possible' has not been changed.
SH	Human Tissue Authority	31.03	Full	4	95	In the list of qualifying relationships in the Human Tissue Act (s27, (4)) spouse or partner is at the top of the hierarchy. Consent should be sought from that person, if they exist. It is also possible that a friend of long standing may consent on behalf of the deceased. This is not reflected in the wording 'parents, family, or guardians' as the person giving consent may not fall into any of these categories.	Thank you. We have changed the terminology throughout the guideline to refer to those close to the patient when referring to family, friends, partners etc. And used the term 'those in a qualifying relationship' to refer to those who are in a position to provide consent on behalf of the patient. These terms have been added to the glossary.
SH	Human Tissue Authority	31.04	Full	5	124	Replacing 'obtain views' with 'seek consent to' as this provides clarity where the person has capacity to consent.	Thank you. This recommendation specifically refers to patients who are unable to consent.
SH	Human Tissue Authority	31.05	Full	6	133	A line should be added to clarify that the steps in the section on consent are only appropriate if the patient lacks capacity to consent.	Thank you. Recommendations 1.1.5 and 1.1.6 have been amended to make it clearer that patients can give their own consent when they have the capacity to, and that consent from a person in a qualifying relationship with the patient is only needed when the patient lacks capacity.
SH	Human Tissue Authority	31.06	Full	6	159	Replace 'judicial' with 'statutory'.	Thank you. The GDG discussed the meaning of the term 'judicial' and decided that the term 'legal' was the correct term. Thus 'legal' rather than 'judicial' or 'statutory' is used throughout the guideline.
SH	Human Tissue Authority	31.07	Full	7	166	We recommend this is amended to state that bereavement services should always be offered, as detailed in paragraph 52 of the HTA code of practice 1 on Consent: http://www.hta.gov.uk/legislationpoliciesandcod	The recommendation refers to members of the MDT who should be involved in the assessment of the information and support needs of those from whom consent is sought not services that should be offered

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						esofpractice/codesofpractice/code1consent.cfm	to patients.
SH	Human Tissue Authority	31.08	Full	7	170	Add a bullet point to ensure that the MDT identify the person highest in the qualifying relationship hierarchy to give consent.	Thank you. Changes in line with your suggestion have taken place throughout the guideline. People who are able to provide consent on behalf of the patient are now referred to as 'those in a qualifying relationship with the patient' and the HTA hierarchy has been included in the glossary.
SH	Human Tissue Authority	31.09	Full	7	183	First bullet point to be amended to read 'discuss with them that donation should be considered as a usual part of the end of life care that the patient will receive' to ensure it is in line with the wording of the GMC guidance: http://www.gmc-uk.org/guidance/ethical_guidance/6858.asp	Thank you. The recommendation has been developed using the evidence available and GDG expert opinion and is independent of any other guidance.
SH	Human Tissue Authority	31.10	Full	7	185	It may be helpful to provide an example of an open question here, as the example of negative language given on page 7, line 189 is very helpful.	Thank you. We have added an example of an open ended question.
SH	Human Tissue Authority	31.11	Full	8	197	Consideration should be given to revising the wording of this line as 'respected' could potentially be interpreted as 'upheld' or 'accepted'. It would be useful to clarify this i.e. whether their views will be considered or followed.	The GDG agreed that the issue of respecting wishes is implicit throughout this guideline. Thus the sentence that you refer to has been removed.
SH	Human Tissue Authority	31.12	Full	8	211	Addition of a bullet point to ensure that the MDT can identify the person in a qualifying relationship to give consent would add an important step to the process.	Thank you. Changes in line with your suggestion have taken place throughout the guideline. People who are able to provide consent on behalf of the patient are now referred to as 'those in a qualifying relationship with the patient' and the HTA hierarchy has been included in the glossary.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Human Tissue Authority	31.13	Full	10	254	Addition of a bullet point to state that the individual must have received training in the requirements of the Human Tissue Act and have a working knowledge of the HTA codes of practice 1 and 2.	Thank you. It is not within the scope of this guideline to specify the training that individual involved in the organ donation process should have.
SH	Human Tissue Authority	31.14	Full	10	257	A link or other form of identifying reference to the GMC guidance would be helpful: http://www.gmc-uk.org/guidance/ethical_guidance/6858.asp	Thank you. This section has been removed from the recommendation. However a reference to the GMC guidance has been added to recommendation 1.1.4.
SH	Human Tissue Authority	31.15	Full	11	284	As these statistics are eight years old they may not support the point convincingly. More up-to-date figures would help further the point made. Results from a recent survey the HTA commissioned Ipsos MORI to undertake may be useful: http://www.hta.gov.uk/publications/evaluations/publicevaluation2010.cfm	Thank you. The statistics you refer to were taken from the scope to this guideline which was signed off before the survey that you have suggested was undertaken. The survey that you suggest has addressed different questions to those that were addressed in the existing survey.
SH	Human Tissue Authority	31.16	Full	11	303	This line should be amended to reflect that the target audience will be the person giving consent (who may not be part of the family), a carer or a guardian of the donor.	Thank you. Changes in line with your suggestion have taken place throughout the guideline. People who are able to provide consent on behalf of the patient are now referred to as 'those in a qualifying relationship with the patient' to distinguish them from 'those close to the patient' which may include a wider range of individuals who may or may not have capacity to provide consent. Both terms and the HTA hierarchy have been included in the glossary.
SH	Human Tissue Authority	31.17	Full	General		The National Assembly for Wales has recently stated their intention to introduce an 'opt out' scheme in Wales (presumed consent for organ donation). If this was introduced, the way in which consent was obtained from people in Wales would change and this would need to be	Thank you. Our guidelines are based on the evidence that is available at the time of development and are reviewed every 3 years. Guidelines may be reviewed sooner if we are aware of significant changes in the evidence. If this is the case, a formal

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						reflected in the Guidelines.	consultation with stakeholders will take place to determine if a full update is required. http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Human Tissue Authority	31.18	Full	General		The provisional recommendations in the guidance seem practical and the document is written in a clear and accessible manner.	Thank you.
SH	ICUsteps	32.00	General			As an organisation primarily dealing with survivors of critical illness, it was felt this lies slightly outside our scope but are happy to support the recommendations.	Thank you.
Non SH	James Cook University Hospital	16.00	Full	1.1.4	117	While we agree that action is needed to improve donor identification and consent rates in general, we disagree with the statement 1.1.4, line 117. In many patients meeting the under 1.1.2.defined clinical trigger factors, mean that further organ support has been deemed futile. Any treatment should be in the patient's best interests. Only if there are clear indicators that such a patient would have wanted his/her organs to be donated (e.g.registered donor or discussions with the family have already revealed that the patient would have wanted to become a donor), would we would feel comfortable to continue treatment in order to optimise organs for donation. Our approach is in line with the Department of Health Guidance "Legal issues relevant to non-heartbeating donation published in November 2009 (http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_1	Thank you for your comments. The recommendations that you refer to have been rewritten to make it clearer that all decisions made about the patient are in his or her best interest, and that the relevant legal and professional guidelines are followed when making such decisions. A legal opinion will be sought prior to publication of this guideline to ensure that all recommendations are in line with current legislation.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						09864.pdf). This guideline specifically stipulates that "any decision about the futility of further treatment and whether or not such treatment should be withdrawn must be made purely in the interests of the person and independently of any consideration of possible organ donation" (page 5). It is possible that the guidance as it stands could be considered illegal. We would be grateful if our views could be taken into consideration as we would not be able to follow the guidance as it stands	
SH	Lancashire Teaching Hospitals NHS Foundation Trust	29.00	Full	9	241	It is vitally important that those health professionals involved in identification, referral and consent for organ donation have knowledge of grief responses / theory. The need to understand bereavement and how reactions can manifest themselves is of equal importance. Sque, Long et al (2006, 2005) explored decisions families had made with regard to proceed to donate or not and issue that where important to them. Their research shows donor families should be seen as bereaved families who may wish to donate so making the option inextricably link to bereavement and end of life care	Thank you. It is not within the remit of the guideline to specify what training the healthcare team involved in organ donation should receive.
SH	Lancashire Teaching Hospitals NHS Foundation Trust	29.01	Full	General		The chance to consider donation should be a normal part of end of life care. The document outlines this. It follows then that end of life / bereavement and donation must be linked in all hospital practices. At Lancashire Teaching Hospitals we have embraced all government	Thank you. We feel that these are important points and will forward them for consideration by the implementation team.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						drivers and recommendations to build our bereavement and donation model. Donation is a normal part of end of life care. This model was presented as a poster last October at the European Transplant Coordinators Organisation Congress and received international acclaim. We are in the process of publishing our experiences and model development in their journal. Our donor numbers are the highest for the region arguably due to the organisations model of linking end of life / bereavement care with donation. It really does work the figures show this. Linking together dying death and donation makes the care seamless and the pathway to ensure the option of donation is considered fits comfortably for staff. We have Bereavement and Donor Support Nurses to assist the SNODs in ensuring equitable care for all bereaved families whether they chose to donate or not and whether the donation occurs or not. This collaboration is only part of the model but is at the centre of it. Evidence for the bereavement and donation model can be drawn from the above references along with DOH guidance When a patient dies / The organ donor task force recommendations / End of life care strategy.	
SH	Live Life Then Give Life	12.00	Full	General		Having read it through completely, we have no comments other than it is a very thorough and comprehensive document.	Thank you.
SH	Muslim Doctors & Dentist Association/	36.00	Full	8	189	It is important to stress the positive experience of organ donation & transplantation esp Ethnic minorities	Thank you. We had GDG members with expertise in equality and diversity and it was felt that the guideline adequately addressed the experiences of organ

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							donation for all, including those of ethnic minorities.
SH	Muslim Doctors & Dentist Association/	36.02	Full	8	202	As is well known, Muslims believe in early burial of the dead body. It is very important to stress that the organ donation process will be carried out as soon as possible with minimal delay.	Thank you. We feel that your comment is addressed throughout the guideline. In particular, Recommendation 1.1.12 refers to health care providers being adequately trained to provide accurate information about the donation process. And recommendation 1.1.14 refers to obtaining information regarding cultural, religious and other information before discussing organ donation with those close to the patient.
SH	Muslim Doctors & Dentist Association/ South Asian Health Foundation	36.03	Full	11	294	Agreed – race or religion should not deter the health professionals from approaching potential donor family for consenting. It is important to approach everyone	Thank you.
SH	Muslim Doctors & Dentist Association/ South Asian Health Foundation	36.04	Full	38	472	This association has been running organ donation campaigns specifically directed towards muslims and other south Asian communities – we have discovered that the main opposition for donation comes from the older members of the family (perhaps with less command of English language). We think it would be beneficial for an interpreter (with an insight into organ donation and related issues) to be present when the family is approached. This strategy may be more successful	Thank you. The guideline does recommend that an assessment of whether support from an interpreter is required prior to approaching those close to the patient about organ donation.
SH	Muslim Doctors & Dentist Association/ South Asian Health Foundation	36.05	Full	79	1117	Quality research in ethnic groups is lacking regarding attitudes towards organ donation and needs to be looked at – our organisation can help with this.	Thank you.
SH	Muslim Doctors &	36.06	Full	77	1088	Staff involved in approaching families for organ	Thank you for your comment, this guideline

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Dentist Association/ South Asian Health Foundation					donation should have knowledge about outcomes after organ transplant as this will help them to give more positive emphasis	considers organ donation for transplantation and the outcomes after the transplant is outside the scope for this guideline.
SH	National Kidney Federation (NFK)	14.00	Full	9	227	We believe that more needs to be done to identify potential donors from Accident & Emergency settings – in terms of trained staff and protocols in place to allow greater referral for retrieval of DCD organs.	Thank you. It is not within our remit to specify protocols and where they should be implemented. Each hospital should have its own policies and protocols that are consistent with this guideline for identifying donors.
SH	National Kidney Federation (NFK)	14.01	Full	11	297	We feel that the importance of ethnicity and religion needs greater emphasis within the draft guidelines. The needs of these groups of people are not well represented and would benefit from greater research in this particular area.	Thank you. We had GDG members with expertise in equality and diversity and it was felt that the issue of ethnicity and religion was adequately covered by the guideline. We have made a research recommendation on why families do not give consent, and would hope that ethnicity and religion would be included within any further research into this area.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.00	Full	General		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** No, the health economics portion fulfils the declared intention of the guideline	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.01	Full	General		**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** The health economics portion appears of good quality.	Thank you.
SH	NETSCC, Health	37.02	Full	51-52	840-	**2.2 Please comment on the health**	Thank you for your comments.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Technology Assessment (Ref 1)				882	**economics and/or statistical issues depending on your area of expertise.** First, just some general thoughts on the health economic modeling present in the guideline. The overall approach of looking at how shorter waits on organ transplant lists have implications of cost savings for the NHS is a good one. Agreed, that there is no existing literature on the cost-effectiveness of increasing consent and conversion rates. While this approach of looking only at kidney transplantation as a case study is fine, some of the details could be better explained to make the analysis more clear for readers of the guideline. I will highlight these in the boxes below.	
SH	NETSCC, Health Technology Assessment (Ref 1)	37.03	Full	51	851	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Someone just reading this guideline may not be entirely clear why the analysis cannot look at all transplantations so I would add a clause starting with 'because' at the end of this sentence briefly explaining why looking at an individual transplant sitution makes much more sense.	Thank you for your comment. A sentence has been added to the introductory section.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.04	Full	51	853	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** 'data available on kidney transplantation' – please clarify what data such as transplant rates, etc.	Thank you for your comment. Additional information has been added to the section explaining that the data related to survival (both overall and graft, cost of alternatives to transplantation and this data was available for both DBD and DCD.
SH	NETSCC, Health	37.05	Full	51	855-	**2.2 Please comment on the health**	Thank you for your comment. Additional

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Technology Assessment (Ref 1)				856	**economics and/or statistical issues depending on your area of expertise.** Sentence is unclear. Data about cost-effectiveness of other renal replacement therapies?	information has been added to the section highlighting that it was both clinical and cost effectiveness information.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.06	Full	51	861	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** I would add something after Spain to say why Spain was chosen as the low end – i.e., the country with the shortest kidney transplant wait time	Thank you for your comment. Additional information has been added to the section highlighting that Spain is a potential optimum.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.07	Full	52	Table 1	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** For each of the first 3 columns, I would recommend labelling where the data comes from. While sources are mentioned on the page prior, it seems opaque as to how one got from those sources to these figures.	Thank you for your comment. The clinical data came from a clinical review done on the Peritoneal Dialysis guideline. Utility data was obtained from a meta analysis and cost data was obtained from a published study. Unfortunately it's not possible to include this detail here as additional data to label where the data comes from would not normally be included in the table.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.08	Full	52	867-868	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The explanation of the results could be even more straightforward – for example, 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.	Thank you for your comment the section has been amended with the suggested text.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.09	Full	52	867-872	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.**	Thank you for your comment. An explanatory note has been added to the section.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						There is a comment about how the results are robust to more transplantations and the cost of maintenance therapy. It is not entirely clear was the base case scenario for treatment includes. Perhaps a footnote would be useful for this or a quick reference to the peritoneal dialysis guideline.	
SH	NETSCC, Health Technology Assessment (Ref 1)	37.10	Full	52	878-80	**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** Do not know if it is entirely accurate to say that the recommendations do not appear to be associated with significant costs. These added costs are not reported in this report. The recommendations do propose various changes in the way practice is done which have cost implications (but agreed not significant). The more precise way to put this would be – Improving transplant rates and organ availability for transplant would not be associated with significant costs and therefore... (as already written).	Thank you for your comment. The section has been amended with the suggested text.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.11	Full	General		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** For health economics, they are complete	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.12	Full	General		**3.2 Are any important limitations of the evidence clearly described and discussed?** Yes, barring the comment from above about explaining a little more on why kidney transplants were used as an example	Thank you for your comment, an explanation has been added to the introductory section.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	NETSCC, Health Technology Assessment (Ref 1)	37.13	Full	General		**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Yes, the report is generally readable and well presented. A few minor points below	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.14	Full	17	367	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Under 'number of potential and effective donors' – unclear for what reasons the number of potential donors increased in either case.	Thank you for your comments. This increase in referrals was because of the use of clinical triggers. The grade table is headed by the title 'Use of clinical triggers', therefore we feel that it is clear that we are referring to their use.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.15	Full	18	368	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** 14% in 'comparison hospitals' – are the comparison hospitals those with no project IHC LITCs, if so it would be good to clarify	The table has been clarified as you have suggested.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.16	Full	19	369	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Why are the first two boxes not grouped together? – there may be a good reason, they just look to me to be covering the same issue.	The two boxes that you refer to are not grouped because one of the studies (in the first box) is of low quality, where as the other 5 studies (in the second box) are of very low quality.
SH	NETSCC, Health	37.17	Full	19	369	**4.1 Is the whole report readable and well**	The header of the table that you refer to

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Technology Assessment (Ref 1)					**presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** Unclear why there is an increase in referral rates for all of these studies. I think there needs to be more info on study findings there.	makes it clear that the studies are measuring referral rates when required referral is used.
SH	NETSCC, Health Technology Assessment (Ref 1)	37.18	Full	54-78		**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** A general comment on the section – the criteria around when to include economic considerations or not is not always clear. The economic consideration given is about reducing waiting lists and that this saves money. That is fine but there are recommendations for which no economic considerations are given but for example – training staff to approach parents, family, etc in a caring, professional manner might require training courses and extra resources so there are economic considerations there (p. 69 line 1001). A similar economic consideration was included for having a MDT (pp.61-62), which would have economic considerations. I would recommend having a look through the recommendations and picking up the 2 or 3 others that may have re-training costs associated.	Thank you for your comment. Given the limited time during development certain topics are required to be prioritised over others and it was considered at the scoping workshop, and by the GDG that this was the key area for analysis.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.19	Full	General		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** The guideline has broadly addressed the	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						scope	
SH	NETSCC, Health Technology Assessment (Ref 2)	37.20	Full	General		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** Disappointing to see so little good quality information, so that the guideline is largely based on poor quality or low relevance studies, many published in very low impact or non peer reviewed journals.	Thank you. The evidence presented is what was available at the time of conducting the searches. The research recommendations address some of this.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.21	App E	171 & 188	General	**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)** The 2 UK national audits in 1989 (Gore et al) and 2005 (Barber et al) are not included and I think they both contain information on the number of potential donors that could be converted. The 1989 audit at least contains information on age, sex and ethnicity associated with consent rates. Since these are the only 2 large, directly relevant studies it seems unwise to exclude them.	Both audits that you have mentioned do not address the issue of consent which is the focus of this guideline.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.22	Full	General		**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** The systematic review is appropriate and well conducted.	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	NETSCC, Health Technology Assessment (Ref 2)	37.23	Full	General		**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).** I agree that meta-analysis of results is not possible due to the heterogeneity in study methods and lack of consistent outcomes. In addition many studies are qualitative.	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.24	Full	General		**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** There is very little quantitative data and very little scope for analysis of the results from the literature.	Thank you. This is due to the nature of the evidence base which is largely qualitative.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.25	Full	General		**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The most irritating aspect of the report is the focus on relative % increase, which is difficult to interpret unless we know either the baseline or final proportion. On page 17 we have relative increases of relative increases which is doubly confusing. The information can often, but not always, be found in Appendix D but it should be in the summaries of evidence in the main guideline.	Thank you. Absolute values are reported in appendix D when available. Where absolute values are not shown it is because they were not reported in the studies where they were extracted from.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.26	Full	51-52		**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.** The health economics section is highly	Thank you for your comment. Such an analysis while attractive from a methodological standpoint would only reinforce the cost effectiveness of kidney

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						speculative and the conclusions are questionable. I think they are overstated. A more detailed (but admittedly time consuming) analysis could use the UK audits to estimate the maximum and realistic achievable donors and therefore the potential reduction in waiting times. This should be weighed against the number of units/personnel that would need to be trained and the cost of such training. My feeling is that the cost equation may not be so clear cut.	transplantation and is not feasible for other transplantations due to a lack of evidence. Therefore the approach taken while admittedly limited was considered a pragmatic choice.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.27	Full	General		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** Largely appropriate although, as above, I would have included the 2 UK audits.	The audits that you have mentioned do not address the issue of consent which is the focus of this guideline.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.28	Full	General		**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?** There is little review of the kinds of intervention that might be effective. Is this considered outside the scope?	Thank you. You have not made reference to a specific example. In general the guideline does review the kinds of interventions that are effective for increasing potential organ donor identification and consent.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.29	Full	53	883	**3.2 Are any important limitations of the evidence clearly described and discussed?** There is a very brief statement of the limitations of the study which is adequate.	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	NETSCC, Health Technology Assessment (Ref 2)	37.30	Full	53	883	**3.2 Are any important limitations of the evidence clearly described and discussed?** Most studies are poor or very poor and are published in journals that are non-peer reviewed (e.g. Transplant proceedings) or very low impact (e.g. Journal of Transplant Coordination). This should be added.	Thank you. This has been taken into consideration during the evaluation of the studies, and they have been assessed as low or very low quality. Therefore your suggested insertion will not be included in the guideline.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.31	Full	53	883	**3.2 Are any important limitations of the evidence clearly described and discussed?** There is no discussion of the limitations of the cost impact analysis.	Thank you for your comment. An explanation of the limitations is in the section above.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.32	Full	53	883	**3.2 Are any important limitations of the evidence clearly described and discussed?** Only English language studies were considered. How big a limitation is this likely to be?	We follow the process outlined in the guidelines manual for identifying and appraising studies. This process stipulates that only English language studies are included in all of the guidelines that NICE guidelines. Please see guidelines manual for further information: http://www.nice.org.uk/page.aspx?o=guidelinesmanual
SH	NETSCC, Health Technology Assessment (Ref 2)	37.33	Full	53	883	**3.2 Are any important limitations of the evidence clearly described and discussed?** How much does the donation process rely on national characteristics? It clearly depends on ethnic background so it seems likely that it will vary by nationality. What proportion of the studies, were directly relevant to the UK and how did they differ?	Thank you. Answering your question would require a review and analysis of the literature which is not feasible to do at this stage in the process.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.34	Full	General		**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.**	Thank you. We currently present information is in both a narrative and tabular format which is summarised at the front of the guideline, and some people find this repetitive. However, we are in the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Generally the report is very clear and easy to read. My only major complain is that it is very repetitious. The guidelines repeat the information in the tables rather than summarizing and prioritizing the main themes. The initial summary is better.	process of revising the way in which evidence is presented for our future guidelines which we hope will improve the readers' experience.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.35	Full	38	457	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** What does "cause of death with natural causes of death" mean?	The cause of death had a significant influence on whether discussions with families occurred, which was higher when the cause of death was natural. This has been clarified in the table.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.36	Full	33	General	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** (3rd panel) - This summary is ambiguous. Does this mean that the time from (?? donor identification) to initiation of BSD protocol was15.5 hours in donors and 7.0 in non-donors?	The study authors state that it was from time of admission. This has been clarified in the table.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.37	Full	49	796	**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.** As it reads it looks like there was an enforced minimum time to BSD initiation but I suspect that is not the case. This affects the interpretation of the results.	Thank you for your comment. The study reported delays but did not make this clear if they were enforced or incidental delays to initiation of brain stem death protocol.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	NETSCC, Health Technology Assessment (Ref 2)	37.38	Full	General		**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** The recommendations are largely clear and, given the evidence described, are justified.	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.39	Full	5	131	**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** There is confusion about when the subject of donation should first be raised.	Thank you. We feel that the timing of when to raise the subject of donation is as clear as possible, as the precise timing will depend on a range of factors that are dependent on each person's circumstances.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.40	Full	6	134	**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** The evidence is conflicting, one study saying prior to BSD, one after BSD and several suggesting that relatives need time.	Thank you. It is unclear what you are referring to as the page and line numbers you have referenced do not match with the comments you have made.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.41	Full	49	787	**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** Time at which the question is raised is clearly considered important and it's difficult to know which studies are most compelling.	Thank you.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.42	Full	49	792	**4.2 Please comment on whether the research recommendations, if included, are clear and justified.** Can the recommendation be clarified?	Thank you for your comment. We are not clear on which recommendation you are referring to. The text that you are referring to is an evidence statement, not a recommendation, and summarises what the evidence shows.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.43	Full	26 31	table table	**4.2 Please comment on whether the research recommendations, if included, are**	Thank you. The subgroups with high/low rates of consent for organ donation are described in appendix D when available.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				45 46	655, 660 693, 696	**clear and justified.** We are told that ethnicity, age, sex, socioeconomic status etc are important factors for consent but not which subgroups have low/high rates. Sometimes this is given in Appendix D but not always.	Where these rates are not shown it is because they were not reported in the studies where they were extracted from.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.44	Full	General		**Section five – additional comments** **Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.** Is it possible to highlight UK studies in some way since they are most relevant and we might expect some cultural differences in attitudes to donation/consent?	The GDG considers the relevance of the study populations to the recommendations that are made in the guideline. It is not necessary to highlight studies based purely on the location where they were conducted.
SH	NETSCC, Health Technology Assessment (Ref 2)	37.45	Full	General		**Section five – additional comments** **Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.** Given the generally very low quality of information it would seem important to introduce methods for increasing donation rates in the context of an experimental study. This might include a clinical trial in which hospitals are randomised to standard methods or an optimal approach to training/organ identification/consent etc. (cluster randomized trial) This could involve assessment of both clinical- and cost-effectiveness.	Thank you.
SH	NHS Blood and Transplant	24.00	Full	4	86	Emphasis on 'if the patient agrees' indicates that the patient is fully conscious which for most patients is not the case. This could be	Thank you. This section had been rewritten to make it more appropriate for this guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						confusing and may be reworded to clarify the point.	
SH	NHS Blood and Transplant	24.01	Full	4	90	Summary- it may be clearer if the difference between DCD and DBD is clarified at the outset.	Thank you. For those whom the guideline is intended clarification of the differences between DCD and DBD is not required.
SH	NHS Blood and Transplant	24.02	Full	4	95	Document refers to discussions being held with the patient – in the majority of situations this would not be possible.	Thank you. The recommendation refers to situations in which it may be possible to discuss organ donation with the patient. By using the phrase 'where possible' we are acknowledging that this is not always the case.
SH	NHS Blood and Transplant	24.03	Full	4	102	Regarding the trigger it may be useful to have a clear divider to show what is meant by criteria for DBD and DCD.	Thank you. For those whom the guideline is intended clarification of the differences between DCD and DBD is not required.
SH	NHS Blood and Transplant	24.04	Full	5	110	Refers to withdrawal of treatment but doesn't mention anything about ventilatory/ respiratory support so the inference is that all patients on wards etc should be referred - could this be clarified. The intention to 'withdraw treatment' may be better phrase as withdrawing 'active' treatment to differentiate between non escalation and withdrawing treatment.	Thank you. The recommendation has been rewritten to make this clearer that we are referring only to patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death. The term 'withdraw treatment' has been changed to 'withdraw life sustaining treatment' to differentiate between non escalation and withdrawing treatment.
SH	NHS Blood and Transplant	24.05	Full	5	117	This section needs to fit with the DEC DCD Guidance as it suggests that treatment to preserve organ function may be instituted if there is consent for donation. In this instance the family may not have been told about withdrawal plans (or may have had prior discussions about the likelihood of withdrawal).	Thank you. We have been asked by the Department of Health to write a guideline on Organ Donation, which are independent of any other guidance including the DEC DCD guidance. The recommendations have been made based on the available evidence and GDG expert consensus and are independent of other guidance.
SH	NHS Blood and Transplant	24.06	Full	5	117	Clinically stabilise - it would be useful to have clinical guidance / parameters for blood	Thank you. This recommendation has been rewritten. However your suggestions have

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						pressure and CVP and medication etc.	not been incorporated as it is not within our remit to provide clinical guidance of this type for this guideline.
SH	NHS Blood and Transplant	24.07	Full	5	121	Not all potential paediatric DCD's are cared for in regional paediatric ICU's. Could include - in discussion with specialist care.	Thank you. This has been changed in line with your suggestion.
SH	NHS Blood and Transplant	24.08	Full	5	132	Cart before the horse perhaps when you go on to the next section which clearly outlines how the consent process should take place.	Thank you. The order of the recommendations has now been changed. The recommendation that you refers to now falls under the heading of 'Seeking consent' rather than 'Identifying and referring potential donors'
SH	NHS Blood and Transplant	24.09	Full	5	131	In the consent section there is nothing in there about actually planning the approach. It does outline what you need to ascertain but nothing about the MDT taking time to plan.	Thank you. It is out of the scope of this guideline. Individual hospitals will determine how the MDT plan for consent, and this should be covered in their local policies and protocols that are consistent with this guideline.
SH	NHS Blood and Transplant	24.10	Full	6	133	Obtaining consent- maybe consider separating consent for DBD and DCD as the timings in approach differ due to the determination of death	Thank you. The recommendations have been separated as suggested.
SH	NHS Blood and Transplant	24.11	Full	6	153	before discussing consent for donation with parents...the health care team caring for the patient should: identify a patient's potential for donation with the SN-OD, check ODR and coronial issues. Could be rephrased to indicate referral to the SN-OD who will ascertain potential for organ donation and in turn check ODR and coronial, judicial and safeguarding issues.	Thank you. This has been rewritten in line with your suggestion.
SH	NHS Blood and Transplant	24.12	Full	7	179	Important to include approaching the family for consent when it is clearly established that they understand the inevitability of death, it could go on to further clarify and in the case of DBD	Thank you. At this stage in the guideline, reference is being made to organ donation in general, not to the specific types of donation which are explained later in the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						donation when BSDTs have been undertaken and death confirmed	text. Thus, the suggested insertion has not been included.
SH	NHS Blood and Transplant	24.13	Full	7	182 - 189	When approaching for consent an opening part of the discussion may include (depending on the timing) acknowledgement of their grief and offering condolences. Open *ended* questions allowing the family to communicate their thoughts and feelings as opposed to closed ended questions may give a rationale for this type of questioning	Thank you. We have amended this as suggested.
SH	NHS Blood and Transplant	24.14	Full	7	186	Positive ways of describing organ donation, *particularly the benefits of transplantation* (could be added)	Thank you. We have added an example of a positive way to describe organ donation.
SH	NHS Blood and Transplant	24.15	Full	8	192	Would be useful to identify who should provide this information.	Thank you. The text has been changed to reflect that the healthcare team providing care for the patient should provide the information.
SH	NHS Blood and Transplant	24.16	Full	8	201	Rationale for treatment being withdrawn or withheld should be explained before organ donation discussions	Thank you this recommendation has been amended and now distinguishes between the explanation and discussion.
SH	NHS Blood and Transplant	24.17	Full	8	201-203	'timing will be coordinated to support organ donation' in conjunction with the family and loved ones wishes (could be added)	Thank you. We discuss the timing in a previous recommendation.
SH	NHS Blood and Transplant	24.18	Full	9	231	The term pathway could imply that a written pathway is to be used. If this is the case it would be useful to identify the pathway i.e. Map of Medicine.	Thank you. Each hospital should have its own policy, protocol and pathway for identifying potential donors and managing the consent process. It is not within our remit to specify this.
SH	NHS Blood and Transplant	24.19	Full	9	228	Essential that the hospital has a policy includes referral. Would be useful to clarify if the policy should be a nationally or locally produced.	Thank you. Each hospital should have its own policy, protocol and pathway for identifying potential donors and managing the consent process. It is not within our remit to specify the policy.
SH	NHS Blood and Transplant	24.20	Full	9	235	Competencies are a good idea however may be worth identifying how competence will be	Thank you. Competencies will differ depending on an individual's role, and

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						assessed and by whom.	where they are in the organ donation process. It is not within our remit to outline the competencies, or how they will be measured. However, we feel this is an important point and will forward this for consideration by the implementation team.
SH	NHS Blood and Transplant	24.21	Full	10	272-283	Could more clearly state the benefits of transplantation and state the number (rather than significant) of deaths as a result of the lack of organs.	It would be difficult to quantify the number of deaths that occur as a result of the lack of organs as some patients are not considered for transplant because of organ scarcity and therefore are difficult to 'count'. This has been added to the text.
SH	NHS Blood and Transplant	24.22	Full	14	364	A study showed that there was an improvement in identification of potential donors in hospitals with a 'donor action programme', it would be useful to define 'donor action programme'.	The definition of the donor action programme has been added to the table.
SH	NHS Blood and Transplant	24.23	Full	33	388	'Studies showed that when families of potential donors were asked about donation before death of their loved one, they tended to have higher chance of giving consent than those at the time of death' This research/recommendation should be treated with caution as findings very significantly between hospitals.	Your comment refers to a summary of two studies where these results were found. The GDG considered this and the rest of the evidence for this review question when making the recommendations.
SH	NHS Blood and Transplant	24.24	Full	35	394	Terminology - In-House Coordinators now know as Resident Specialist Nurse – Organ Donation	Thank you for your comment. The section you refer to relates to the reported evidence, where the term 'in-house coordinator' is used in these individual studies. When we have made recommendations we have used the term 'specialist nurse for organ donation'.
SH	NHS Blood and Transplant	24.25	Full	41	544	This practice in UK varies, anecdotal evidence from hospitals shows more integrated working	Thank you. Anecdotal evidence is not considered in the GDG decision making

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						when in uniform is worn from a staff perspective. It would be good to further understand family perspective in the UK.	process, although GDG experience and opinion are used when developing the recommendations. We agree that understanding the family perspective in the UK would be beneficial.
SH	NHS Blood and Transplant	24.26	Full	54	906	Perhaps make suggestions or examples of 'defined' clinical triggers	Thank you. There are no defined clinical triggers as such we recommend that local policies are used.
SH	NHS Blood and Transplant	24.27	Full	57	931	Should withdrawal of treatment only include patients that are ventilated, for the purposes of DCD donation? Language – 'trade off' is there a more appropriate phrase?	Thank you. The recommendation suggests that once the decision to withdraw life sustaining treatment has been made, then that patient may be identified as a potentially suitable donor. The titles in the table are from a standard template.
SH	NHS Blood and Transplant	24.28	Full	57	931	...whether a potential donor is 'unsuitable', would 'suitable' would be a more optimistic phrase.	Thank you we have changed this to 'suitable'.
SH	NHS Blood and Transplant	24.29	Full	65	981 / 982	Need to be clear that clinical history includes behavioural / social history.	Thank you. The evidence did not specify that the clinical history should include a behavioural/social history, and as such are unable to report this.
SH	NHS Blood and Transplant	24.30	Full	67	991	Families may not always include N.O.K.	Thank you. We have changed the terminology throughout the guideline to refer to those close to the patient when referring to family, friends, partners etc. And used the term 'those in a qualifying relationship' to refer to those who are in a position to provide consent on behalf of the patient. These terms have been added to the glossary.
SH	NHS Blood and Transplant	24.31	Full	70	1014	Quality of evidence box- Needs rewording to be clearer as could imply that apologetic and negative language is associated with increased rates.	Thank you. The table has been amended in line with your comments.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Nottingham University Hospitals NHS Trust	30.00	Full	2	46	As identified by NICE, the quality of evidence used for this clinical guideline is overwhelming of very low quality. It is impossible to see how NICE can make recommendations when there is insufficient evidence base for those recommendations. In such circumstances, expert consensus of best practice is the best that modern medicine can achieve. There is insufficient experience in the field of organ donation from within the NICE Development Group to consider the recommendations expert consensus. What is extremely concerning is that donation practice is changing rapidly, especially in the field of donation after circulatory death, that recommendations based on very low quality donation after brain death studies are being used to guide donation after circulatory death practice, with potentially legal and ethical harm resulting to patients. What is surprising, is that NICE has decided to directly oppose current clinical expert opinion by insisting that every death, even where there is no chance for organ donation, must be referred for organ donation, which will inevitably lead to patient harm and suffering. Given the lack of evidence for all the recommendations it would seem far more appropriate that this guideline be rewritten as suggestions from NICE, rather than recommendations.	Thank you. The recommendations in this guideline were developed by an expert Guideline Development Group after considering the available evidence including information from the Potential Donor Audit, and NHSBT, incorporating the GDG clinical experience and expertise. We have removed the word 'referral' from the title of the first section to clarify that these recommendations refer to the identification of potential donors. We do not recommend that every death should be referred for organ donation.
SH	Nottingham University Hospitals NHS Trust	30.01	Full	4	97	It should not be the remit of NICE to maximise potential donation, rather it should be to maximise the opportunity that those who wish to donate at the end of life, have.	Thank you for your comment. The Department of Health provided the remit for this guideline which was to specifically improve identification and consent rates.
SH	Patient Concern	8.00	Full	General		We welcome the stress on good communication and the involvement of families	Thank you for your comments. Refusal of consent is outside the scope of this

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						and carers. The document is rightly aimed at maximising the potential for organ donation. However we feel it lacks specific advice to professionals on how to react if patient or relative refuses consent. This is a crucial aspect of dealing with the question of organ donation.	guideline.
SH	Patient Concern	8.01	Full	4	94	Families are unlikely to view organ donation as s routine part of end of life planning. Care must be taken that no discussion is forced on families who indicate they do not wish to participate.	The word normal has been replaced with the word usual in order to be consistent with the Organ Donation Taskforce, and the GMC who also state that organ donation is usual in end of life care.
SH	Patient Concern	8.02	Full	6	134-152	Sound advice. However, it is important to stress to families that any decision on suitable candidates for donation will be made by the transplant team, not the team providing treatment	Thank you. Your comments are outside the scope of this guideline which makes recommendations consent, not on assessing suitability.
SH	Patient Concern	8.03	Full	6	158	Add 'or Lasting Power of Attorney for welfare (LPA)	This has been included in the text and added to the glossary.
SH	Patient Concern	8.04	Full	7	165	Add 'advocates'	This has been included in the text.
SH	Patient Concern	8.05	Full	7	168	Examples of key families' issues would be helpful.	It is beyond the scope of the guideline to identify possible issues as these may vary substantially from family to family.
SH	Patient Concern	8.06	Full	7	183	It cannot really truthfully be claimed that donation is a 'usual' part of the end of life care the patient will receive – given that it involves actions that are not in the patient's interests.	The word 'usual' is consistent with the Organ Donation Taskforce and the GMC who state that organ donation is a 'usual part of end of life care'. Thus the text has not been changed.
SH	Patient Concern	8.07	Full	7	179	Well said – very important aspect	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Patient Concern	8.08	Full	7	189	We agree that negative language (because it is policy) is out of place, but a hint of apology for having to broach the subject at such a sensitive time shows empathy and may encourage rather than discourage a positive response.	The recommendations made in relation to this part of the pathway are to guide the interactions between the healthcare professionals and those close to the patient, not to specify the language used. It is the discretion of the healthcare professional to choose the language that they feel is appropriate for the interaction. Further examples of language that should be encouraged have been added to the guideline to assist with such interactions.
SH	Patient Concern	8.09	Full	8	195	Many intensivists are concerned that the primary focus has to be on ensuring organs are preserved in optimum condition and actions to this end may have to be taken before a decision is made either way	Thank you. We agree that ensuring organs are preserved in an optimum condition is an important factor, and we would expect that this is considered when identifying potential suitable donors.
SH	Patient Concern	8.10	Full	10	267	This sounds like advocacy. Increasing consent ratios to organ donation is a laudable aim. But the skills and knowledge should be aimed at enabling those affected to decide what is best for them. If the result is more organs fine	Thank you. An objective of this guideline is to improve consent ratios.
SH	Resuscitation Council (UK)	9.00	Full	General		This document has been reviewed by the Resuscitation Council UK and we have no comments to make	Thank you.
SH	Royal College of Anaesthetists	6.00	Full	General - definitions		Minor point, yet important. We emphasise early referral to improve donor rates, and therefore in my mind a potential donor is someone in whom brain stem death tests or treatment withdrawal is planned, (rather than carried out as in these definitions). After all this is the time we are encouraged to now refer to get the potential donor in the system earlier than has historically been the case. Feel this philosophy should equally transfer to the NICE guidance.	Thank you. Recommendation 1.1.2 has been rewritten to emphasise early identification of potential donors before brainstem death tests have been carried out.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Whilst the counterargument to this might be the patient is only a truly a potential donor after treatment is actually withdrawn, this is not strictly any truer as they can only actually donate after death, so one would have to say for definitions one in whom death had been confirmed by brain stem testing or by cardiorespiratory criteria, but this definition would be so late in the process it would run counter to current philosophy and not serve to promote donation.	
SH	Royal College of Anaesthetists	6.01	Full	3.1.b Epidemiology		Uncertain why the basic epidemiology characteristics are shown or why the only breakdown for donors is ethnicity, where for potential recipients this includes age, sex and ethnicity. If data is shown for both groups, is this data just as important for donors, i.e. how many paediatric donors related to paediatric potential recipients etc.	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Royal College of Anaesthetists	6.02	Full	3.4 Epidemiology		Accept there may be some differences in definitions here but I thought 448 people dies in 2008/9 on the transplant list (NHSBT stats) where this document says 1178. I assume the difference in waiting list stats is due to the suspended waiting list patients and it may be that the excess deaths were also here?	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Royal College of Anaesthetists	6.03	Full	3.1f Epidemiology		Numbers where patients were not referred is from the PDA data are still open to debate (as we have debated many times) as it depends on the interpretation of the answer to the question asked on the PDA. The only way to answer this question accurately is to lock a couple of Intensivists in a room for 3 days with a couple of hundred sets of notes and a	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						telephone to ask the relevant clinicians whey the patient was not referred, in may of these cases it was due to Coroner or family prior refusal etc but not properly recorded. We had this recorded in the PDA for a couple of our patients and this was due to Coroner/police refusal when we looked into it. The potential for donation after cardiac death is even greater than the suggestion here, as it depends on local resource, as one could retrieve for example from failed resuscitation in hospital etc if there was someone on site (e.g. vascular surgeon) who could cannulate femoral arteries and perfuse organs whilst waiting for transplant teams, so believe we are still in the early days of evaluating this potential.	
SH	Royal College of Anaesthetists	6.04	Full	3.2 a		Comparison with Spain is always mentioned, but given the fact that the PDA shows we have less than 2000 possible brain stem dead patients per year, we actually have fewer deaths per million population from head trauma than Spain has donors! Some of this is their higher rate of death following RTAs etc as well as an older donor population as some of these patients are following stroke who are rarely admitted to our ITUs for a variety of reasons but with more aggressive thrombolysis etc may increase in the future.	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see: http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Royal College of Anaesthetists	6.05	Full	4.1.1.		A clinical guideline applies primarily to clinicians. Why does the 'population covered' by the guideline scope only refer to families, relatives and legal guardians? This appears to concentrate on families, whereas just as important of we wish to increase donation is to look at educating and engaging clinicians and	Thank you. This section had been rewritten to make it more appropriate for this guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						nurses in the process.	
SH	Royal College of Anaesthetists	6.06	Full	4.3.1		The Organ Donation Programme Board External Reference Group has developed clinical pathways in most of these areas, and has the capacity to develop the competencies expected of different groups involved in organ donation. The pathways will soon be available via Map of Medicine, and the competencies may be developed in partnership with the new Faculty of Intensive care Medicine. How will the developers of the NICE guideline work with these groups to ensure a common process and outcome? All recommendations must be compatible at the very least	Thank you for your comment. We have been asked by the Department of Health to issue guidance for the NHS. We produce our guidance based on evidence and clinical expertise in accordance with the NICE guidelines manual: http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Royal College of General Practitioners	10.00	Full	5	125	Delete 'is close to death and'	Thank you. We have amended this recommendation to remove 'is close to death'.
SH	Royal College of General Practitioners	10.01	Full	5	127	'Advance' rather than 'Advanced'	Thank you. This has been corrected.
SH	Royal College of General Practitioners	10.02	Full	7	179-181	Surely it's possible to have sensitive discussions at an earlier stage than when death is 'inevitable'? Good to introduce the idea as early as possible, when discussing that death is probable, to allow adequate time for consideration – at a later stage emotions may become more of an issue and rational discussions less feasible.	Thank you. The text that you refer to recommends discussing organ donation when those close to the patient *understand* the inevitability of death, not simply when death is inevitable. Bringing discussions up with those close to the patient before they have understood this may also be as problematic as leaving it to a later stage as you have suggested.
SH	Royal College of General Practitioners Wales	28.00	Full	General		This guideline is extremely valuable and will be of benefit to both individual practitioners and LHB's by following their recommendations. The importance of organ donation is well recognised especially by GPs who care for	Thank you. Although Primary Care has an important role, it is out of the scope for this guideline which focuses specifically on NHS hospitals.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						patients suffering long term conditions and are awaiting organ transplant. However, the recommendations relate principally to secondary care and there is little or no mention of the role of primary care practitioners. ❖ Primary care plays a vital role in Advance Care Planning and discussions on organ donation should be included in these discussions. ❖ Primary care has a duty to record the outcome of these discussions and share with those who need to know. ❖ Primary Care can facilitate discussions and inform the patient of Advance Directives (Advance Decision for refusal of treatment). Again Primary Care can hold a copy and inform those who need to know of the existence of the Advanced Directive (which may include information on organ donation). ❖ General Practitioners provide longitudinal care resulting in continuity of care and trust between the patient and doctor. The GP also cares for the family and carers of the patient and may be valuable in assisting discussions between the patient, carers, families and the MDT when organ donation is being discussed. The GP will continue to provide care to the carer/families after the death of the patient and this link could prove valuable in bereavement.	

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						❖ Primary Care provides an essential public health role. Primary care consults with over 90% of the population in a three year period. There are huge opportunities for general practice to promote organ donation when the patient visits the practice. The guideline is also oriented towards the last few days or hours of life. Its focus is on improving consent to removal of organs and increasing the rate of organ removal. The evidence base is poor with most studies identified being of low quality (which the guideline development group recognise). However none of the studies present evidence against the recommendations which seem to have face validity. There needs to be increased awareness still both amongst health professionals and the public. All practitioners (nurses and doctors) should be encouraged to be prepared to discuss organ donation. There is a role here for GPs to include discussions opportunistically at consultations and promote the use of the organ donation card - perhaps by having regional campaigns with stalls etc in practices. GPs should be prepared to speak with distressed relatives who may attend whilst patients are in intensive care etc	

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						All FYI doctors should have some CPD on this area but only senior doctors or nurses should be involved in the final agreement or consent process with the patient or relatives as it does require specific skills/ expertise Consent should not be presumed. Families need time to consider their decision so the initial approach should be made early. The approach should be positive rather than apologetic or hiding behind formal procedures and policies - ideally from someone they have got to know but supported by a local coordinator who can follow up with more detail. It is important to be able to respond to the concerns of patients or relatives however bizarre, unreasonable or unexpected. There must be adequate recognition and thanks given to the enormity of the decision - not only at the time but probably also afterwards. Processes need to fairly easy for the caring MDT otherwise they wont give it priority over caring for other patients	
SH	Royal College of General Practitioners Wales	28.01	Full	4	100	There was a reference to clinical triggers to identify patients who may be suitable to offer organ donation but a statement that these could be altered by sedation. It wasn't clear what the recommendation might be wrt sedation and how clinicians can objectively	Thank you. If a patient has a GCS of 4 or less and has been chemically sedated the clinical trigger factors do not apply.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						assess its influence without withdrawing it, which might be seen as creating a risk of distress if the patient is not brain dead. Clarity round this area would be appreciated.	
SH	Royal College of Nursing	18.00	Full	General		The Royal College of Nursing welcomes this guideline. It is comprehensive and timely.	Thank you.
SH	Royal College of Nursing	18.01	Full	General	Re-cost implication	While this document does try to give some projection of costs and the authors do highlight that it may not be accurate due to many impacting variables, it needs to be clarified that the more transplants that are done the more re-transplants will need to be done. It was unclear whether this factor had been taken into consideration. While we expect that techniques will improve with time, we would suggest that some cost estimation of the available statistics is added or at least it should be noted that the impact of re-transplantation could be considerable.	Thank you for your comment. The Costing report/template has been amended to discuss this potential cost impact in more detail.
SH	Royal College of Nursing	18.02	Full	General	Format	The document is very comprehensive, however, as it stands is not suitable for application in busy clinical areas or in the amount of time clinicians have to read and process information. This will only be one document of many that healthcare professionals received on a regular basis. We would suggest therefore that the actual recommendations should be included in the Quick Reference Guide, in a standalone monograph with the supporting rationale i.e. 2.1.4 could be included as an Appendix; or all the analyses and 2.14 produced as a separate document and with a web reference or link for	Thank you for your comments. We do produce a Quick Reference Guide which summarises the recommendations. This is produced after the full guideline has been developed, but is published alongside the full guideline.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						further information. (See Organ Donation Taskforce 2008).	
SH	Royal College of Nursing	18.03	Full	General	1366 - 1397	We would suggest that the Glossary and Abbreviations be moved to the front of the document so as to enable the reader to become familiar with the terms before going to read the document, rather than having to keep referring to the back of the document. Again this would be a good time saver for healthcare professionals.	Thank you. The current layout of the document is in line with NICE style.
SH	Royal College of Nursing	18.04	Full	General		The terminology of the Human Tissue Act 2004 should be used when referring to persons who can give consent to donation after death and are in a 'qualifying relationship' to the potential donor.	Thank you. The term 'qualifying relationship' has been used throughout the guideline to refer to people who can consent on behalf of the patient. This term has been included in the glossary.
SH	Royal College of Nursing	18.05	Full	5	123-132	This section needs to start the document, (not come in after death is certified) as it deals with the patients' own views of donation. It also needs to state who can access the NHS Organ Donor Register.	This recommendation has been moved to the start of the subsection dealing with seeking consent, which was felt to be a more appropriate place within the guideline. Individual hospitals should follow the relevant local and national protocols to identify who can and cannot access the NHS organ donor register. It is not within the scope of this guideline to do this.
SH	Royal College of Nursing	18.06	Full	6	133-226	How does this section on obtaining consent sit with NHSBT's Donor Family Care Policy?	Thank you. We have worked closely with NHSBT throughout the development of this guideline and had a member from this organisation as a member of the GDG. Wewould therefore not expect the policies of NHSBT to conflict with the recommendations made by NICE.
SH	Royal College of Nursing	18.07	Full	6 and through out	134	Parents, family or guardians seems very 'clunky'. 'Relatives, family members' might be better or you could define the term in the glossary so it is clear who the term refers to.	Thank you. The terminology used to describe parents, family, relatives, friends and partners has been changed throughout the guideline to refer to those 'close' to the

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							patient, or those in a 'qualifying relationship' with the patient. Both these terms have been added to the glossary.
SH	Royal College of Nursing	18.08	Full	7	181	Suggest add 'or death.' to the end of this sentence for clarity.	This sentence has been amended to include the deaths that occur whilst a patient is on a waiting list for transplant, and deaths that occur in patients that are not considered for transplant.
SH	Royal College of Nursing	18.09	Full	9	228	Not sure why it is suggested that each hospital is to have their own policy when it is already suggested at line 100 that certain clinical triggers are used. Also is not the point of this document that it is based on the best evidence available?	Thank you. The recommendation has been rewritten to state that individual hospital policies should be in line with the recommendations made in this guideline.
SH	Royal College of Nursing	18.10	Full	9	231	Is it appropriate for a consultant to lead pathway for donation or should this be the Specialist Nurse - Organ Donation?	The GDG felt that it is entirely appropriate and necessary for a consultant to lead the pathway for donation, as this person will have the overall clinical responsibility. Consultants should work closely with Specialist Nurses for Organ Donation.
SH	Royal College of Nursing	18.11	Full	14-35	364-395	We are concerned that the developers have gone down the route of only accepting 'RCTs' as being valuable in production of viable evidence. In our view, this could be considered a fundamental lack of insight into the contribution and sometimes the only acceptable method of obtaining evidence and that is by using qualitative methods. Therefore we strongly contest that many good qualitative studies that have added greatly to our understanding of the donation process have been measured by inappropriate criteria and scored as being of low or very low quality.	Thank you. We use the highest quality evidence available, including studies using qualitative methods, which were included in the evidence base for this guideline. We use GRADE tables to appraise the biases and uncertainties of study outcomes, not to describe studies as poorly or well conducted. Where evidence is classified in GRADE as low quality this does not mean that the GDG exclude this evidence. Please see guidelines manual for further information: http://www.nice.org.uk/page.aspx?o=guidelinesmanual.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						There appears to be short sightedness in the way these studies have been assessed. Qualitative data provides evidence, if it is a good study, which can be reflected in persons in similar circumstances, so while there maybe some issues with using data from other jurisdictions, the human condition of people in Greece, USA and UK experiencing donation from a loved one and their loss will have many similar traits. So to disregard these studies as low quality may be considered as showing a lack of understanding that qualitative studies build one on the other until a substantial data base is accrued. This could be seen as a flaw of this document and should be a real concern.	
SH	Royal College of Paediatrics and Child Health	26.00	Full	General		The College thinks this draft guideline, as many others, has problems in trying to include paediatric practice into a document based largely on adult practice. The presence of an expert in these areas on the panel from a children's ICU is noted and the document could not really be improved for paediatric practice without becoming less useful for adult practice. In the absence of a separate document the below comments are in our view the most important to address.	Thank you
SH	Royal College of Paediatrics and Child Health	26.01	General			We think it might be helpful to have explicit reference to contraindications to donation from a paediatric perspective. This could include a lower age limit for donation. We note that the	The GDG agreed that explicit contraindications should not be included in the guideline due to the rapidity at which changes to contraindications, particularly to

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						guideline does not discuss en bloc donation.	paediatric patients, occur.
SH	Royal College of Paediatrics and Child Health	26.02	General			The College thinks this draft guideline addresses well the issue of organ donation where there has been brain stem or cardiac death in an intensive care setting. Increasing numbers of children where death is expected die at home or in hospital or hospice, and not in an intensive care setting. Their parents may ask about organ donation. We think this will apply also to adults. We think the guideline could comment on this situation and what advice should be given to families about whether any organs can be donated and to what use they can be put. (We note this may be outwith the scope of this guideline.)	Thank you for your comments. The scope of this document is to provide guidance for organ donation in NHS hospitals. Home and hospice deaths are outside the scope of this guideline.
SH	Royal College of Paediatrics and Child Health	26.03	Full	4	78-79	We are pleased that issues of children, e.g. consent under 16, are considered.	Thank you.
SH	Royal College of Paediatrics and Child Health	26.04	Full	4 9	100-104 249	There is little data on the validity of such trigger tools in paediatric practice. To have recommendations based on something far from accepted practice, and with no evidence, makes little sense.	The GDG made their decisions using the best available evidence, and where this was not available or lacking, the GDG based their recommendations on their clinical experience.
SH	Royal College of Paediatrics and Child Health	26.05	Full	5	113	This recommends that the specialist nurse for organ donation (SN-OD) is contacted once the suggested criteria are met, defined as either brain stem death testing or a decision to withdraw life-sustaining treatment. There are circumstances in paediatric practice at least when earlier contact can be helpful especially if the SN-OD is some distance from the site, either at another hospital, or on call.	Thank you. As you suggest, earlier contact between the clinical team and Specialist Nurse for Organ Donation may not be appropriate in all circumstances. The recommendations made in the guideline are applicable to the majority of cases when contact once the criteria are met will be the most appropriate timing.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						This can avoid the parents/family having a potentially distressing delay if the SN-OD is not contacted until after completion of brain stem death testing. However, there is a balance and earlier contact between the clinical team and SN-OD may not be appropriate in all circumstances.	
SH	Royal College of Paediatrics and Child Health	26.06	Full	9	222-223	While each Trust has a clinical lead for organ donation (CLOD), many are not trained in PICU; however, the recent new 'PICS standards' have suggested every Paediatric Intensive Care Unit must have just such an 'identifiable consultant' intensivist to work with the SN-OD to oversee local pathways.	Thank you. The recommendations have been changed, and recommendation 1.1.4 now reflects your suggestion.
SH	Royal College of Paediatrics and Child Health	26.07	Full	10	251-2 265-266	'Donor management' is a less established practice in paediatrics. However, this will shortly be addressed with Map of Medicine protocols.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	26.08	Full	29	380	Regarding GRADE profile 6 table: We think it is good that paediatric donors specifically are considered, and this is important.	Thank you for your comment.
SH	Royal College of Paediatrics and Child Health	26.09	Full	79	1102 - 1103	We are unclear on which evidence there is a recommendation for research. However, it is clear that one of frustrations is lack of research.	Research recommendations are developed in areas where there is no evidence, or the evidence is very limited.
SH	Royal College of Paediatrics and Child Health	26.10	Full	General		The College thinks this draft guideline, as many others, has problems in trying to include paediatric practice into a document based largely on adult practice. The presence of an expert in these areas on the panel from a children's ICU is noted and the document could not really be improved for paediatric practice without becoming less useful for adult practice. In the absence of a separate	Thank you

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						document the below comments are in our view the most important to address.	
SH	Royal College of Physicians London	20.00	Full	General		The RCP is grateful for the opportunity to respond to this draft guideline. In so doing, we have liaised with our Committee on Ethical Issues in Medicine and overall, we broadly welcome the work and have few criticisms. However, we would like to make the following comments.	Thank you.
SH	Royal College of Physicians London	20.01	Full	General		Throughout the document our experts were struck by the constant rating of evidence as 'very low'. We wonder if the criteria were too strict and whether there is a difference between a technology assessment of a new drug and a complex intervention such as organ donation? We believe that the NICE panel may wish to address this.	Thank you. The GDG recognise the differences between technology appraisals (such as a quantitative assessment of a drug for example) and the development of a complex intervention (such as organ donation). We follow the methods outlined in the guidelines manual to appraise the highest quality evidence available, including qualitative studies. GRADE tables are used to appraise the biases and uncertainties of study outcomes, not to describe studies as poorly or well conducted. Where evidence is classified in GRADE as low quality this does not mean that the GDG exclude this evidence. Please see guidelines manual for further information. http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	Royal College of Physicians London	20.02	Full	6	155	Although early involvement of the specialist nurse may be desirable, this would involve passing confidential information to an individual who, at that stage, has no role in the patient's care and whose concern is actually for the (anonymous) recipient. We therefore think that information should be anonymised, as far as possible, although we believe that the	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						moral desirability of transplantation is such that strict standards of confidentiality can be broken if essential.	
SH	Royal College of Physicians London	20.03	Full	52	875	These health economic data and the 2% figure are particularly valuable and we were glad to see them in the guideline.	Thank you for your comment.
SH	Royal College of Physicians London	20.04	Full	61	955	In the table above there is a box on 'trade-off'. This is welcome as there are situations (such as that on line 155 mentioned above) when one moral good must be 'traded off' against another.	Thank you.
SH	Royal Liverpool and Broadgreen University Hospitals NHS Trust	15.00	Full	4	100-105	The concern is that the phrase has to be completely unambiguous. Does it mean that any patient who has an absence of one or more cranial nerve reflexes etc should be screened prior to brain stem death testing? Needs to be a clear and easy to follow statement for the non expert	Thank you. This recommendation has been rewritten to make it clearer. The recommendation now reads '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 brain stem death tests, whichever is the earlier'.
SH	Royal Liverpool and Broadgreen University Hospitals NHS Trust	15.01	Full	5	110-112	Is this a bit too broad? Might generate a lot of unnecessary work on wards where there is no real prospect of organ donation ever occurring because of the time to death in a non	Thank you. It is recognised that not all potential donors will result in organ donation, however, the aim of this guideline is to improve identification.

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

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						ventilated patient. However, it is a clear an unambiguous statement, so worth further discussion	
SH	Royal Liverpool and Broadgreen University Hospitals NHS Trust	15.02	Full	General		There ought to be something on prognosis surely when determining a patient's best interests? Page 3 on patient centred care offers an opportunity for this	Thank you. Prognosis is out of the scope for this guideline.
SH	South Asian Health Foundation	36.01	Full	8	195	Similar to other religions and cultures, Muslims also stress (perhaps more so) on maintaining the dignity of the dead body and cite this as a reason for refusal. It is important to stress to the family that the whole team involved in the process takes extreme care in maintaining the dignity of the donor.	Thank you. We had GDG members with expertise in equality and diversity. All GDG members agreed that maintaining dignity for all patients, whatever their culture or religion, is implicit throughout the guideline.
SH	Transplant 2013	33.00	Full	General		Transplant 2013 is a coalition of patient, professional and industry groups whose aim is to promote leadership of organ donation and transplantation in Parliament and other relevant institutions and facilitate communication within the transplant community in order to 1) Support the implementation of the Organ Donation Taskforce's recommendations, 2) Ensure that the target to increase organ donation after death by 50% in 2013 is met, and 3) Significantly increase the number of organ transplants. Transplant 2013 is very supportive of the aims and content of this NICE clinical guideline and has few additional comments to make.	Thank you.
SH	Transplant 2013	33.01	Full	5	123& 124	It would be an unusual situation 'If a patient has the capacity to make their own decisions, obtain their views on organ donation.' – and it	Thank you. We have added 'in circumstance where' to this to the recommendation, taking your comment into

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						may read better to say 'In the exceptional situation where a patient has the capacity…'	account.
SH	Transplant 2013	33.02	Full	8	220	The term 'Donation after Cardiac Death' has recently been changed to 'Donation after Circulatory Death' and this change should be reflected in this document	Thank you. This has been changed throughout the document.
SH	Transplant 2013	33.03	Full	10	263	It is very important to recognise the greater potential for transplantation of organs retrieved from DBD donors compared with organs from DCD donors – and this needs to emphasise throughout. DBD donors in general will provide more organs for transplantation; and whilst DCD donation is good for kidney and lung transplantation, it is not as good for liver transplantation and is not currently possible for heart transplantation.	The scope for this guideline which was provided by the Department of Health was to improve donor identification and consent rates. Although the quality and quantity of organs is important, it falls outside the remit and is therefore the differences between DBD and DCD are not explicitly addressed in the guideline.
SH	UK Donation Ethics Committee	11.00	Full	General		Overall the draft guideline is in accordance with the draft ethical principles for donation after circulatory (formerly cardiac) death set out by UKDEC. For more detail see http://www.aomrc.org.uk/publications/reports-guidance.html	Thank you.
SH	UK Donation Ethics Committee	11.01	Full	5	110-112	This is quite a stark trigger, and lacks any reference to the reason for the decision to withdraw treatment. It would be helpful to make it clear that the decision has no connection to the issue of organ donation. A suggested alternative might be: "A decision that the withdrawal of treatment from a patient with a life-threatening or life-limiting condition is in that patient's best interests, where the implementation of that decision will, or is expected to, result in cardiac death." (See also lines 916-918)	Thank you. The recommendation suggests that once the decision to withdraw life sustaining treatment has been made, then that patient may be identified as a potentially suitable donor.
SH	UK Donation Ethics	11.02	Full	5	113	This recommends that the SN-OD is contacted	The guideline does not state that earlier

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Committee					once the criteria are met, defined as either brain stem death testing or the decision to withdraw life-sustaining treatment. There are circumstances when earlier contact can be helpful – if the SN-OD is based at a distant location the family may have a potentially distressing delay if the SN-OD is not contacted until after brain stem death testing is complete. It would be unhelpful for this guideline to suggest earlier contact between the clinical team and the SN-OD is inappropriate in all circumstances.	contact between the clinical team and the Specialist Nurse for Organ Donation is inappropriate at all times. The recommendation has been amended to make this clearer.
SH	UK Donation Ethics Committee	11.03	Full	5	123	This gives the misleading impression that the competent patient can only give their 'views' on donation (rather than provide a legally sufficient consent for donation). (also lines 923-934)	The recommendations of the guideline have been amended to make it clearer that patients can consent to organ donation themselves.
SH	UK Donation Ethics Committee	11.04	Full	5	127	What does 'advanced care directive' mean? Is it an 'advance decision to refuse treatment' under the Mental Capacity Act, or something broader? Similar issues where the same term is used elsewhere in the document.	Thank you. We have included this definition in the glossary.
SH	UK Donation Ethics Committee	11.05	Full	6	133	Change 'obtaining consent' to 'seeking consent', to reflect that consent is something freely given.	Thank you. We have amended this as suggested.
SH	UK Donation Ethics Committee	11.06	Full	6	159	What are the judicial issues? This is mentioned but never explained. (Also line 977)	The term judicial has been replaced with the term legal throughout the document. It is not within our remit to specify the range of legal issues that may be applicable to individual cases as these may vary substantially between individuals and with their circumstances.
SH	UK Donation Ethics Committee	11.07	Full	8	195	Is it always possible to provide assurance that the "parents', family's, or guardian's wishes will be respected?" What if the wishes of the	The GDG feel that it is possible to respect the wishes of those close to an individual. If wishes conflict, donation will not go ahead

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						various relatives conflict? (Also 1019)	unless this is resolved.
SH	UK Donation Ethics Committee	11.08	Full	8	201	Avoid the word 'rationale' here. A reference back to the patient's best interests might be helpful. And separate out these two issues. Explaining the reason for the decision to withdraw treatment (that it is in the patient's best interests) is a separate issue from discussing how the timing of the implementation of that decision might be influenced by the need to support organ donation. Linking them in one paragraph risks giving the impression that the two decisions are linked, ie that the decision to withdraw treatment might be influenced by the possibility of organ donation. (also lines 1025-1027)	Thank you. The word 'rationale' was felt to be appropriate for this context. The guideline endeavours to ensure that all the recommendations are in the patient's best interests. This recommendation has been amended and split into 3 separate recommendations to ensure the distinction between the explanation and the discussion.
SH	UK Donation Ethics Committee	11.09	Full	8	207	Are these post-death or pre-death interventions? This seems quite vague. Would the explanation envisaged include the reasons why the intervention is 'required'? (Also lines 1030-1032)	Thank you. It is not within our remit to specify the range of possible interventions that may take place, and the timing of these interventions (e.g. pre or post death), as these will vary depending on circumstances and patient factors.
SH	United Kingdom Clinical Pharmacy Association (UKCPA)	27.00	General			We do not have any comments to make on this consultation.	Thank you.
SH	West Midlands Renal Network	38.00	Full	51	839	**Economic aspects of donation**: The SCT concluded an economic review of transplants in October 2010 as part of a project funded by the Department of Health. This also included data from the National Commissioning Team for Highly Specialised Services and data from West Midlands Services. The output of our work is summarised on the WM SCT website and include a number	Thank you for your comment. The report's findings are broadly in line with the findings of the economics analysis conducted for this guideline and also support the recommendations. However, there is not sufficient information to expand the analysis to other organs.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						papers exploring various other aspects of organ donation that you may find helpful in developing your guideline http://www.wmsc.nhs.uk/uploaded_media/OfT%20Implementation_Lesson%20Learnt%20for%20SHAs_Oct2010%20inc%20links.pdf	
SH	West Midlands Renal Network	38.01	Full	77	1085	**Skills and competencies**: An analysis in 2010 of west midland trusts looking at the reasons why organ donation did not proceed has been helpful in recognising some of the misconceptions around potential donors. If you would be interested in discussion our findings we would be pleased to share them.	Thank you.
SH	West Midlands Renal Network	38.02	Full	89	1396	Most Trusts now have a donation champion and this should be highlighted as part of the guideline (CLOD or Clinical Lead for Organ Donation	Thank you. Recommendation 1.1.10 now states that an identifiable consultant should lead the organ donation process, and recommendation 1.1.22 now states that adult and paediatric intensive care units should have a named lead consultant for organ donation.
SH	West Midlands Renal Network	38.03	Full	51	841	When considering conversion rates it would be interesting to consider how an increase in donation rates affects different ethnic groups on the list. It is known that the rate of donation by BME group is lower and thus whilst we may see a reduction in the waiting list this may only relate to particular groups of people.	Thank you for your comment. There was not enough data available to help inform an analysis of different population groups. However, any reduction would be cost effective for the NHS.
SH	West Midlands Specialised Commissioning Team	7.00	Full	General		The Department of Health established a Programme Delivery Board for implementation of the recommendations outlined in the National Taskforce Report, 'Organs for Transplants' (Department of Health, 2008). West Midlands Strategic Health Authority	Thank you.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						accepted an invitation to join that Board and become a national pilot site for the implementation of a number of the Taskforce recommendations over a 24 month period from February 2009. This work is being led on behalf of WMSHA by the West Midlands Strategic Commissioning Group and Specialised Commissioning Team (SCT). The comments below are based on the experiences of the SCT working closely with NHS Organisations within the West Midlands as part of the project.	
SH	West Midlands Specialised Commissioning Team	7.01	Full	Section 2		Terminology in this area has in our experience been confusing with different aspects of the NHS using descriptions that differ. Consider including: Donation after cardiac death otherwise known as non heart beating donors Donation after brain stem death otherwise known as heart beating donors	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	West Midlands Specialised Commissioning Team	7.02	Full	Section 3.1 d		We have recently reviewed an analysis of reasons for non donation within acute trusts within the West Midlands from information collected by NHSBT. This predominantly showed that the involvement of the Specialist Nurse for Organ Donation where embedded in acute hospital Trusts would improve donation rates.	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	West Midlands Specialised Commissioning Team	7.03	Full	Section 4.4		It would be helpful if these could be defined in greater detail identifying potential data sources	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guideli

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
							nesmanual.
SH	West Midlands Specialised Commissioning Team	7.04	Full	Section 4.4 a		At what level are these to be reported i.e. individual hospital trust or higher level? Will this also include rates of potential donors not approached?	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	West Midlands Specialised Commissioning Team	7.05	Full	Section 4.4 b		How will these be measured e.g. from the Potential Donor Audit?	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	West Midlands Specialised Commissioning Team	7.06	Full	Section 4.4 c		Can this be defined further?	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.
SH	West Midlands Specialised Commissioning Team	7.07	Full	Section 4.5		We have recently concluded a similar exercise working with the Health Economic Research Group at Brunel University as part of a project working with the Department of Health. This also included data from the National Commissioning Team for Highly Specialised Services and data from West Midlands Services. Will the work cover technologies that are available to support patients long term where there is an lack of available organs e.g. Ventricular Assist Devices for cardiac failure?	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.

Type	Stakeholder	Order No	Document	Page No	Line No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						Our experience of working with Brunel to search for published papers on the clinical and cost effectiveness was that there is a dearth of information and where this does exist it is dated; mainly non UK based and has little transference to a UK setting; do not reflect the significant progress on the development of tariffs for clinical services with the NHS over the past 10 years and reflected clinical practice that has probably changed significantly since the studies were conducted.	
SH	West Midlands Specialised Commissioning Team	7.08	Full	Section 4.3.1		The identification of a UK Donor pathway Guideline that specifies clinical triggers and the full and timely involvement of Specialist Nurses for Organ Donation in the process would enable hospitals to be held to account using national contracting mechanisms	Thank you. Your comments relate to the scope which has been consulted on with stakeholders and signed off by NICE in accordance with our policies and procedures. Please see http://www.nice.org.uk/page.aspx?o=guidelinesmanual.

These organisations were approached but did not respond:

Alder Hey Children's NHS Foundation Trust
Association of Paediatric Anaesthetists of Great Britain and Ireland
Association of Paediatric Emergency Medicine
Association of Renal Industries
Assosiation of Anatomical Pathology Technology
Barnsley Hospital NHS Foundation Trust
BMJ
Bolton Hospitals NHS Foundation Trust
British Association for Nursing in Cardiovascular Care (BANCC)
British Heart Foundation
British National Formulary (BNF)
British Paediatric Respiratory Society
British Psychological Society, The
British Renal Society

British Society for Histocompatability and Immunogenetics
British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Care Quality Commission (CQC)
Children's Liver Disease Foundation
College of Emergency Medicine
College of Occupational Therapists
Connecting for Health
Coroners Society of England and Wales
Department for Communities and Local Government
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
Department of Health, Social Services & Public Safety, Northern Ireland (DHSSPSNI)
Dudley PCT
Guys and St Thomas NHS Foundation Trust
Healthcare Quality Improvement Partnership
HeartWare Inc.
Herts & Beds Critical Care Network
ICNARC
Institute of biomedical Science
Intensive Care Society
Intensive Care Society Patient Liaison Committee
Kidney Research UK
Lambeth Community Health
Leeds Teaching Hospitals NHS Trust
Lewy Body Society, The
Lothian University Hospitals Trust
Luton & Dunstable Hospital NHS Foundation Trust
Medicines and Healthcare Products Regulatory Agency (MHRA)
Medway NHS Foundation Trust
Ministry of Defence (MoD)
National Commissioning Group
National Council for Palliative Care
National Patient Safety Agency (NPSA)
National Treatment Agency for Substance Misuse
Newcastle Upon Tyne Hospitals NHS Foundation Trust
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Direct
NHS Plus
NHS Quality Improvement Scotland
NHS Sheffield

NHS Western Cheshire
Paediatric Intensive Care Society
Papworth Hospital NHS Trust
PERIGON Healthcare Ltd
Pfizer Limited
Public Health Wales
Public Health Wales
Rotherham NHS Foundation Trust
Royal Brompton & Harefield NHS Foundation Trust
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Pathologists
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Pharmaceutical Society of Great Britain
Royal Society of Medicine
Scottish Executive Health Department
Scottish Intercollegiate Guidelines Network (SIGN)
Sheffield Teaching Hospitals NHS Foundation Trust
Social Care Institute for Excellence (SCIE)
Social Exclusion Task Force
Society and College of Radiographers
Society of British Neurological Surgeons
Southampton University Hospitals NHS Trust
Swansea University
The Renal Association
UK Clinical Pharmacy Association (UKCPA)
Welsh Assembly Government
Western Health and Social Care Trust
Whipps Cross University Hospital NHS Trust
York Teaching Hospital NHS Foundation Trust