**National Institute for Health and Clinical Excellence**

## Organ donation
## Scope Consultation Table
## 21 June - 19 July 2010

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | Association of Anatomical Pathology Technology | 20.00 | General | AAPT feel that more use could be made of Anatomical Pathology Technologists (APTs) in the consenting process. Many APTs currently have an interest in improving donor identification and consent rates for cadaveric organ donation especially regarding the donation of corneas which many APTs are actively involved in.<br>Many more APT's are involved in post mortem authorisation and consent which often involves discussion about organ retention and disposal.<br>Often the first time that organ donation is discussed is when the family ask about it in the mortuary and by that time there are limits on which tissues can be retrieved. | Thank you. We are not covering tissue donation in this guideline. These competencies would be required after the consent has been taken under the retrieval process which is not covered by this guideline as well. We stop at the stage of consent being given. |
| SH | Association of Paediatric Emergency Medicine | 18.00 | General | Our comments are as follows: the document should cover tissue donation to cover heart valves and corneas. Is there a need for guidance on facilities in the Emergency department that should be available to support organ donors prior to harvesting of organs? | Thank you. Tissue donation is outside the remit sent to us from DH and also not covering process of organ retrieval. |
| SH | British Association for Nursing in Cardiovascular Care | 13.00 | General | The BACCN welcome the development of this NICE guideline within the scope of this document | Thank you. |
| SH | British Heart Foundation | 19.00 | General | The British Heart Foundation (BHF) is the nation's heart charity. We're fighting to eradicate premature death from heart and circulatory disease, the UK's | Thank you for your comment.. This is outside the remit sent from the DH. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | biggest killer, and provide support and voice for heart patients around the UK.<br><br>We welcome the opportunity to respond to this draft scope for guidance aimed at improving donor identification and consent rates for cadaveric organ donation. Heart transplants offer the best chance of long term survival for critically ill heart failure patients. Unfortunately there is a shortage of donor hearts for use in transplantations across the UK.<br><br>The BHF supports measures to improve the UK's rate of organ donation. These measures include consistent national promotion coupled with a strong infrastructure of organ retrieval and professional training. Whilst such measures will go a long way to improving donor organ availability, we believe that an opt out system (presumed consent) where close relatives retain the power of veto should underpin organ transplantation in the UK.<br><br>We believe NICE should include as part of its future guidance in this area recommendations that take into consideration the benefits that a change to an opt out system would bring. | |
| SH | British Heart Foundation | 19.01 | 3.2.a | Spain is highlighted as having a substantially higher organ donor rate than the UK. Spain has an opt out system for organ donation, which has contributed to this higher rate.<br><br>An American study analysed the impact of opt out legislation on donation rates by evaluating datasets on organ donation rates and potential factors affecting organ donation for 22 countries over a 10- | Thank you. . We agree with your comments and as such have removed the comparison with Spain and added the average European values (17.8 donors per million of population) in section 3.2.a. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | year period. The study concluded that presumed consent legislation has a positive and sizeable effect on organ donation rates.[1] | |
| SH | British Heart Foundation | 19.02 | 3.2.e | The support for organ donation remains very high at around 90 per cent, yet the number of people signed up to the Organ Donor Register is just 27 per cent. This highlights the need for a system that better captures the intentions of the public. A change to an opt out system for organ donation would better reflect the substantial public support for organ donation. | Thank you for your comments. This is outside the remit of this guideline. |
| SH | British Heart Foundation | 19.03 | 3.2.f | We note that the guideline will focus exclusively on identifying potential donors and obtaining consent for organ donation (solid and tissue) under current legislation. We would like to see this extended to include areas outside the current legislation in order to consider an opt out system.<br><br>This clinical practice guideline will be ultimately used within England, Wales and Northern Ireland. The National Assembly for Wales are in the process of taking significant steps towards a change to an opt out system for organ donation. We therefore believe this should be taken into account in producing this guideline. | Thank you. Although the system of consent by individuals ante-mortem is outside the remit sent from DH, we will interpret any evidence within the context of the national systems in place. |
| SH | British Society for Histocompatibility & Immunogenetics | 23.00 | 4.3.2 | Translating increased availability of organs for transplant into actual transplants performed requires increased support from the Histocompatibility & Immunogenetics ('Tissue Typing') laboratories which support clinical solid organ transplant programmes. Adequate laboratory resources and trained scientific staff must be available in order to meet this need. | Thank you. These competencies would be required after the consent has been taken under the retrieval process which is not covered by this guideline. The guideline ends at the stage of consent being given. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | British Transplantation Society | 2.00 | 4.1.1 | In addition to views from ethnic groups, views from different religious groups should be explored as these might be different. | Thank you. We agree with your comment and have added a subgroup for people with different religious beliefs in section 4.1.1.c. |
| SH | British Transplantation Society | 2.01 | General | Cadaveric organ donation is probably best known as deceased organ donation (as in deceased after cardiac death – DCD and deceased after brain death – DBD) | Thank you. This has been changed throughout the scope. |
| SH | British Transplantation Society | 2.02 | 3.1.a | Cornea is general thought of as tissue not an organ | Thank you. This has been deleted from the scope in section 3.1.a. |
| SH | British Transplantation Society | 2.03 | 3.1.a | Small bowel should be included | Thank you. Small bowel is now included in section 3.1.a. |
| SH | British Transplantation Society | 2.04 | 3.1.e | 2009/10 data should now be available | Thank you. At the time of signing off the scope the yearly report for 2009/10 was not yet available. When we write the introduction to the guideline we will ensure that we include the latest report |
| SH | British Transplantation Society | 2.05 | General | UK Transplant is now known as NHSBT Directorate of Organ Donation | Thank you. This has been changed in section 3.1.f and 3.2.d. |
| SH | British Transplantation Society | 2.06 | 3.2.e | ODR registrants is now 17 million | Thank you. The current figure has been updated to 17 million in section 3.2.e. |
| SH | Children's Liver Disease Foundation | 11.00 | 3.1 d | A group of particular note is the increasing incidence of fatty liver disease within the population which may in itself give rise to an increasing need for liver transplantation but may, in the presence of another underlying liver condition, precipitate liver damage and the need for liver transplantation. | Thank you for your comment |
| SH | Children's Liver Disease Foundation | 11.00 | 3.1a | Please add small bowel to the list of organ failure in the first sentence.<br>FYI - this group of patients wait a considerable time for an appropriate organ. CLDF is aware of a lack of knowledge of the procedure and the increasing success in outcome of small bowel and multivisceral transplantion in children. | Thank you. Small bowel is now included in section 3.1.a |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | Children's Liver Disease Foundation | 11.00 | 4.3.1 | Children's Liver Disease Foundation would like the scope to also address the awareness within the hospital setting generally by staff, patients and visitors (including families) of organ donation and the fact the hospital has a pro-donation stance and will ask for consent. This is about a general mind-set and is a pre-cursor/background to the clinical issues identified within the scope, for which CLDF is in agreement. | Thank you. This is outside the remit from the DH and hence won't be covered in this guideline, however, we are looking at the competencies for all staff throughout the process of organ donation which may influence awareness. |
| SH | Children's Liver Disease Foundation | 11.00 | 4.4.4 | Rate of hospitals general commitment to organ donation and ensuring their pro-donation stance is clearly promoted around the hospital. E.g. showing figures for the number donations the hospital has made and signage saying this is an organ donating hospital. | Thank you. This measure is not key to assessing the effectiveness of methods to increase donation consent, but may be an important factor for implementation. |
| SH | Department of Health | 15.00 | General | In our view the draft scope looks fine overall, as it also covers children. | Thank you. |
| SH | Department of Health | 15.01 | 1.1 | We would prefer either 'Organ Donation' or 'Organ Donation for the purposes of Transplantation'. | Thank you. We have amended the short title to 'Organ Donation for Transplantation' |
| SH | Department of Health | 15.02 | 2 (Brain stem death) | You may wish to be aware that guidance for the diagnosis of brain stem death is provided by the Academy of the Medical Royal Colleges. The following is used to describe brain stem death*: 'Death that is diagnosed and confirmed following the irreversible cessation of brain stem function.'* The process of making this diagnosis is best described as death that is confirmed using neurological criteria. By definition, this is a diagnosis that is made in circumstances where the patient is on a mechanical ventilator, and the heart is still beating. We therefore feel that the use of the term 'can' is little misleading.<br><br>In our view, the term 'certification' is best reserved for the issue of a death certificate. | Thank you. This has been changed in section 2 and now reads as follows:<br><br>Brain-stem death: Death diagnosed after irreversible cessation of brain stem function and confirmed using neurological criteria. The diagnosis of death is made while the body of the person is attached to an artificial ventilator and the heart is still beating.<br><br>Cardiac death: Death diagnosed and confirmed by a doctor after cardiorespiratory arrest. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | Although usage varies, the Academy document uses the term 'brain-stem' rather than 'brain stem' or 'brainstem'. | We have now used the term 'brain-stem' throughout the document |
| SH | Department of Health | 15.03 | 2 (Cardiac death) | Could you please consider amending the text to read: 'Death that is diagnosed and confirmed following cardiorespiratory arrest'. | Thank you. This has been changed in section 2 and now reads as follows:<br><br>Cardiac death: Death diagnosed and confirmed by a doctor after cardio respiratory arrest. |
| SH | Department of Health | 15.04 | 2 (Potential donors) | The current preferred terminology for deceased donation is as follows:<br><br>**Donation after brain-stem death (DBD):** donation that occurs after death that is diagnosed and confirmed by using neurological criteria. A potential DBD donor is a patient whose death is confirmed by using neurological criteria, and who does not have an absolute medical contra-indication to donation.<br><br>**Donation after cardiorespiratory death (DCD):** donation that occurs after death that is diagnosed and confirmed by using cardiorespiratory criteria. DCD may occur after an expected death that follows the withdrawal of cardiorespiratory support (controlled DCD) of after unanticipated cardiac arrest (uncontrolled DCD). A potential controlled DCD donor is a patient whose death follows the withdrawal of cardiorespiratory support, and who does not have an absolute medical contra-indication to donation.<br><br>We believe that it would be helpful to use these definitions, and to use the terms DBD and DCD donors elsewhere in the document where there is | Thank you. This has been changed to deceased in section 1 and the terms DBD and DCD have been inserted throughout the scope.<br><br>Yes it's restricted to those groups (DBD and controlled DCD in a hospital ) only. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | currently reference to, for example,. donors after brain death or donors after cardiac death.<br><br>There is also a tentative move to uncontrolled DCD. In order to future-proof the document, we feel that it may be advisable to cover both forms of DCD. | |
| SH | Department of Health | 15.05 | 3.1 d) | There are approximately 8 000 patients on the active transplant waiting list. We are not aware of the number who are suspended from the list, nor of the number of patients who do not ever get on to the list | Thank you. We have changed the figure to 8000 people in section 3.1.d |
| SH | Department of Health | 15.06 | 3.1 f) | You may wish to be aware that UK Transplant has now been replaced by the Directorate of Organ Donation and Transplantation (ODT). This is a directorate within NHS Blood and Transplant (NHS BT). | Thank you. . We have now changed sections 3.1.f and 3.2.d.to reflect your comments |
| SH | Department of Health | 15.07 | 3.2 a) | Could you please note that international rates of organ donation are available by visiting www.tpm.org. 2009 data for the UK and Spain are 15.5 and 34.4 donors per million of population (pmp) respectively. Respective rates of DBD (the preferred mode of donation) are 10.3 and 32.1 donors pmp respectively, the remainder being DCD (mainly controlled in the UK and mainly uncontrolled in Spain). | Thank you. . We agree with your comments and as such have removed the comparison with Spain and added the average European values (17.8 donors per million of population) in section 3.2.a. |
| SH | Department of Health | 15.08 | 3.2 b) | The conversion rate is the ratio of actual to potential donors, expressed as a percentage. There is a considerable variation in conversion rates around the country, literally ranging from zero to 100% for individual Intensive Care Units. Average UK conversion rates are 49% for DBD and 15% for DCD. Regional data is obtainable from ODT. | Thank you. We are using 51% for DBD and 15% for DCD in section 3.2.b |
| SH | Department of Health | 15.09 | 3.2 c) | Kidney transplantation improves quality of life, and extends life expectancy. The average half-life of a deceased kidney transplant is 11 years, and it is | Thank you for your comments. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | estimated that the costs of haemodialysis over this period of time exceed the costs of transplantation by around £250 000 (please refer to the report from the Organ Donation Taskforce). | |
| SH | Department of Health | 15.10 | 3.2 e) | In our view, opinion polls vary in their precise wording. A BBC survey in 2005 indicated that a minimum of 85% of the population would be prepared to both receive an organ (were they in need of one), or donate an organ after their death. However, only a quarter of the population is on the NHS Organ Donor Register (ODR). The current figure is just over 17 million people, and the register accrues approximately one million new registrations annually. Only one in five of current organ donors are on the ODR.<br><br>You may wish to be aware that there is a comprehensive programme of work that is underway in the UK Department of Health and NHS BT to implement the Organ Donation Taskforce's recommendations to develop a UK-wide approach to organ donation, which is structured and systematic. | Thank you. The current figure has been updated to 17 million in section 3.2.e.<br><br>We are aware of its development and will liaise with the appropriate department. |
| SH | Department of Health | 15.11 | 3.2 f) | Could you please try to ensure that the guideline covers not only the identification of all potential donors. but also their timely referral. Regarding consent, this paragraph mentions 'tissue' as well as (solid) organs, and we are concerned that this may be misunderstood. | Thank you. We have amended section 4.3.1a to include timing of referral and criteria for consideration.<br>We will only be covering solid organ donation in this guideline and section 3.2.f has been changed to reflect this. |
| SH | Department of Health | 15.12 | 4.1.1 | Could you please consider the use of DBD and DCD terminology, for example, 'Families, relatives and legal guardians of potential DBD donors (adults and children).' | Thank you. This has been changed in section 4.1.1.a and it reads as follows:<br>'Families, relatives and legal guardians of potential DBD donors (adults and children). |
| SH | Department of Health | 15.13 | 4.1.1.c | This section appears to be ambiguous. It discusses | Thank you. It has been removed from the scope. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | groups requiring special consideration and states "parents of children who are potential donors". We would hope that this means that the parents are the donors, and that the children are the recipients. | |
| SH | Department of Health | 15.14 | 4.2 | In our opinion, this guidance will only be relevant to Acute Hospitals, that is, those with critical care and emergency medicine Departments. | Thank you for your comments. |
| SH | Department of Health | 15.15 | 4.3.1 a) | *'Structures and processes for the identification and timely referral of potential DBD and DCD organ donors.'*<br><br>In our view, it would be helpful if the guidance could also explore the relationship between referral and acceptance criteria. | Thank you. We have amended section 4.3.1a to include timing of referral and criteria for consideration.<br>But acceptance criteria is outside the remit from the DH and hence won't be covered in this guideline. |
| SH | Department of Health | 15.16 | 4.3.1. b) | We consider that important specifics include not only the timing of approach, but also who the requestor might be and family support ahead of donation. | Thank you. We aim to look at all these factors in our evidence search. |
| SH | Department of Health | 15.17 | 4.3.1 c) | As noted elsewhere, the term 'conversion' is conventionally used to describe and quantify the transition from potential to actual donation, and goes further than identification and consent. It extends, for instance, into coronial/judicial refusal, failure to maintain stability ahead of retrieval, time delays in retrieval and variations in acceptance criteria by individual retrieval teams. | Thank you. We agree with your comment and have changed section 4.3.1.c to remove the term conversion and it now reads 'coordination of the care pathway from identification to consent.' |
| SH | Department of Health | 15.18 | 4.4 b) | Rates of consent for donation (not transplantation). | Thank you. This has been changed to rates of consent for donation in section 4.4.b |
| SH | Department of Health | 15.19 | 4.4 c) | This is expressed as donors per million population per annum. Could you please consider the use of national and regional data. | Thank you. This is stating the outcomes that we will be looking for in published papers and these maybe expressed in different ways, so we have not specified a particular measure. . We anticipate that we will look at all levels of data where appropriate |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | Department of Health | 15.20 | 4.4 d) | As noted above, the pathway beyond consent concerns a variety of factors, including Coronia judicial obstruction, donor instability, delays in retrieval, withdrawal of consent. | Thank you. This guideline focuses on the process of consent by families or legal guardians. |
| SH | Department of Health | 15.21 | 4.4 e) | Could you please clarify the meaning of 'rates of successful transplants', that is, does it refere to a transplant being performed, graft survival (six months, one year, five years etc.) or recipient survival (six months, one year, five years etc.). We feel that this is rather vague, as it stands.<br><br>More specific metrics include:<br><br>• Organs retrieved/donor;<br>• Organs transplanted/donor (lower because not all organs are used) and;<br>• Patients transplanted (with solid organs)/donor (lower because some patients receive two or three organs. | Thankyou and we will use metrics as reported in the papers, but we anticipate that measures such as graft survival.(six months, one year, five years etc.) will be considered as appropriate measures of transplant rates . |
| SH | Donor Family Network | 7.00 | 3.1.a | Small bowel is not listed | Thank you. Small bowel is now included in section 3.1.a. |
| SH | Donor Family Network | 7.01 | 3.2.e | No mention of families not being refered to DTCs or not asked about organ donation | Thank you. We aim to cover these points in this guideline as in section 4.3.1.b which reads as follows:<br>Structures and processes for obtaining consent for deceased organ donation for transplantation, including the optimum timing for approaching the families about consent. |
| SH | Donor Family Network | 7.02 | 4.2.a | Does the setting include both ED and ITU? | Thank you. Yes the setting includes both ED and ITU |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | Intensive Care Society Patient Liaison Committee | 14.00 | 3.1.(b) | The figures as presented are confusing in that they are given for recipients in percentage terms without actual numbers and then go on to give the percentages of people on the transplant list, again without actual numbers, for ethnic and age groups.<br><br>It would be much clearer and aid the arguments if the figures were given for:<br>1. **Recipients**, for the last three years, showing numbers and percentages for ethnic groups and by age and sex within the ethnic groups<br>2. **Transplant list** in the same format as 1 above<br>3. **Donor register** in the same format is 1 above<br>4. **Population** of UK in the same format as 1 above.<br><br>With the figures shown in this way it would be easier to understand and make comparisons | Thank you. These details are mentioned in the subsequent points-3.2d and e.<br>There are approximately 8,000 people waiting for an organ transplant in the UK.<br>In 2008/09 there were 2552 transplants using organs from deceased donors. In 2008/09 there were another 1178 patients listed for transplant of which 448 died before receiving one and 730 removed from the list. |
| SH | Intensive Care Society Patient Liaison Committee | 14.01 | 3.1.(f) | Showing percentages only is confusing. What for example is the actual number of potential donors after cardiac death because the percentages can mean anything without the hard numbers from which they are derived. The paper should be showing the actual number of potential donors after cardiac death and after brain stem death.<br><br>The 4th sentence refers to refusal by relatives. If there are other reasons for losing donors they should be given. The numbers for each reason might be relevant to the debate and to gloss over them, as the Draft does, raises doubts or uncertainties about their relevance. For example what does refusal by | Thank you. This is the available data we have which is in percentage format and not actual numbers..<br>The 4th sentence highlights one of the key problems in organ donation which we aim to address this by identifying the structure and processes for obtaining consent for cadaveric organ donation from the families, relatives and legal guardians.<br>We don't know what those reasons are and hence, would like to identify and address those in this guideline. Relatives or carers will be part of the guideline development group to give their input in formulating the recommendations. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | relatives amount to in numerical terms and percentages when compared with other reasons. Do we have the reasons for refusal by relatives, if so they should be quoted. | |
| SH | Intensive Care Society Patient Liaison Committee | 14.02 | 4.3.2(a) | Systems for declaring ante mortem a wish to donate must be included in the Scope. It seems perverse that a person places their name on the Donor Register and then after death that decision can be negated by relatives or next of kin. The system for receiving, recording and retaining a person's wish to donate and remain on the Donation Register should be tightened and made a legally binding request to be implemented after their death much as a Will is. This element of organ donation should be included in the Scope. | This is outside the remit sent by the DH and therefore will not be covered by this guideline. |
| SH | Intensive Care Society Patient Liaison Committee | 14.03 | 4.3.2 (b) | The exclusion of the process of organ retrieval from the Scope implies that we are 100% sure that the present systems and procedures cannot be improved. Is this a fair assumption and where is the evidence to support it? Are their guidelines elsewhere which deal with this aspect and if so they should be referenced in the Scope | This is outside the remit sent by the DH and therefore will not be covered by this guideline. Please see the NICE website for referral of additional guideline topics http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp |
| SH | Intensive Care Society Patient Liaison Committee | 14.04 | 4.3.2 (d) | The exclusion of the procedures and systems for the assessment of organs for transplantation again points to the assumption that systems and procedures are in place which are 100% satisfactory. If this is the case the evidence to support this must be given in the Scope otherwise an examination of this aspect should be included in the Scope | This is outside the remit sent by the DH and therefore will not be covered by this guideline. |
| SH | National Kidney Federation (NFK) | 10.00 | 3.1f | It is also the case that whilst, overall, families of 40% of potential donors refuse consent at the critical time, this figure is 75% when the potential donor comes from a BME background. This is a difficult area not | Thank you. Under the population to be covered (4.1.1), special consideration will be given to people from BME subgroups (4.1.1.c) |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | well understood with wide ranging reason for refusal. Will this be examined? | |
| SH | National Kidney Federation (NFK) | 10.01 | 3.2c | There is no doubt that for the right patient at the right time a transplant is the best treatment option with a good transplant giving circa 60% of the function of two normal kidneys (compared with only 5% from either form of dialysis). Quality of life improves considerably. | Thank you for your comments. |
| SH | National Kidney Federation (NFK) | 10.02 | 4.11 | Since 2001/2 there has been a 9% fall in the number of DBD should we not be also examining other categories?<br>'**Uncontrolled' donation after cardiac death**, where the donor dies outside hospital of a heart attack, is also possible, despite the inevitable delays before organs may be obtained. French researchers (1) recently suggested that, for kidneys, such donors could provide a "significant proportion of the functional organs provided for transplant".<br><br>(1) (Richards L (2009) Kidneys from non-heart-beating donors *Nature Reviews Nephrology* **5**: brain stem death)<br><br>**Extended criteria donations**: One approach to meeting the shortfall in donated kidneys, for example, has been to employ 'extended criteria' for accepting offered organs, making it possible to use kidneys removed after death which are of poorer quality, but still acceptable to use. | Thank you. We are not covering uncontrolled DCD as this is outside the scope of this guideline. |
| SH | National Kidney Federation (NFK) | 10.03 | 4.2 | The Health care setting would need to be changed if Uncontrolled' donation after cardiac death is considered | Thank you. We are only looking at uncontrolled DCD in a hospital setting. Death outside the hospital is outside the scope of this guideline. |
| SH | National Kidney Federation (NFK) | 10.04 | 4.3.1a | Given the emphasis placed upon clinical triggers in other domains, will consideration be given to looking | Thank you. We have amended section 4.3.1a to include timing of referral and criteria for |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | at the introduction of clinical indicators as a trigger for notification? The importance of the trigger point referral system has been established in the US and underpins the success of the American programme. We also understand this system has been introduced in Birmingham with some success. | consideration.<br>Thank you. This is outside the scope of this guideline and hence we won't be covering the clinical triggers for identification and donation. |
| SH | National Kidney Federation (NFK) | 10.05 | 4.3.1b | The Organ Donation Task Force after examining the part Families and Relatives<br>play in donation after death recommended more work was needed to understand the differing reasons for non-donation and how best to encourage engagement with the option of organ donation after death. Timing the approach to the family is only one element in this consideration. | Thank you. We will be looking for evidence on the reasons for donation or non-donation. |
| SH | National Kidney Federation (NFK) | 10.06 | 4.3.1c | There are still concerns however about organ donation after cardiac death where a conflict of interests may be felt to arise between the duty of care of the doctor to the dying patient who is a potential donor after death and the steps needed to facilitate donation. This is an area that raises many legal and ethical issues and a range of differing opinions. It is essential that these concerns are resolved. | Thank you. There is already existing legislation on these issues. |
| SH | National Kidney Federation (NFK) | 10.07 | 4.3.1c | If the death of a potential organ donor occurs in circumstances that require notification to the Coroner it is necessary to obtain their agreement before donation can take place, even where the donor has explicitly stated a wish to donate. Whilst some Coroners understand donation and cooperate as much as they can in the circumstances. There is considerable variation nationally in the practice of | Thank you. Noted, however this guideline will focus on the consent by the family or legal guardian and consent from the coroner is outside the scope of this guideline.. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | individual Coroners and donations can be lost | |
| SH | National Kidney Federation (NFK) | 10.08 | 4.4 | Would a reduction in the family / relatives refusal rate be a more direct main outcome | Thank you. It's been added as Rate of family, relatives and legal guardians refusal under section 4.4.f. |
| SH | National Kidney Federation (NFK) | 10.09 | 4.5 | There is a detailed analysis of the Organ Donation Task Force work on the cost effectiveness of Transplantation in the report supplement that should be considered as part of this work | Thank you. Any such work may be considered as evidence, if appropriate and following the NICE process as outline in the Guidelines Manual (www.nice.org.uk) |
| SH | NHS Blood and Transplant | 8.00 | 1 | Prefer deceased organ donation rather than cadaveric (would also need to be changed in opening para of 2 -Remit | Thank you. We have amended the title from 'cadaveric' to 'deceased organ donation. We are unable to change the remit given to us from the Department of Health. |
| SH | NHS Blood and Transplant | 8.01 | 1.1 | Prefer either 'Organ Donation' of 'Organ Donation for the purposes of Transplantation' | Thank you. We have amended the title to 'Organ Donation for Transplantation' |
| SH | NHS Blood and Transplant | 8.02 | 2 (Brain stem death) | Guidance for the diagnosis of brain stem death is provided by the Academy of the Medical Royal Colleges. The following is used to describe brain stem death: 'Death that is diagnosed and confirmed following the irreversible cessation of brain stem function.' The process of making this diagnosis is best described as death that is confirmed using neurological criteria. By definition this is a diagnosis that is made in circumstances where the patient is on a mechanical ventilator and the heart is still beating. The use of the term 'can' is therefore a little misleading.<br><br>The term 'certification' is best reserved for the issuing of a death certificate.<br><br>Although usage varies, the Academy document uses the term 'brain-stem' rather than 'brain stem' or 'brainstem' | Thank you. This has been changed in section 2 and now reads as follows:<br><br>Brain-stem death: Death diagnosed after irreversible cessation of brain stem function and confirmed using neurological criteria. The diagnosis of death is made while the body of the person is attached to an artificial ventilator and the heart is still beating.<br><br>Cardiac death: Death diagnosed and confirmed by a doctor after cardiorespiratory arrest.<br><br>We have now used the term 'brain-stem' throughout the document |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | | |
| SH | NHS Blood and Transplant | 8.03 | 2 (Cardiac death) | 'Death that is diagnosed and confirmed following cardiorespiratory arrest | Thank you. This has been changed in section 2 and now reads as follows:<br><br>Cardiac death: Death diagnosed and confirmed by a doctor after cardio respiratory arrest. |
| SH | NHS Blood and Transplant | 8.04 | 2 (Potential donors) | Current preferred terminology for deceased donation is as follows:<br><br>Donation after brain-stem death (DBD): donation that occurs after death that is diagnosed and confirmed using neurological criteria. A potential DBD donor is a patient whose death is confirmed using neurological criteria and who does not have an absolute medical contraindication to donation.<br><br>Donation after cardiorespiratory death (DCD): donation that occurs after death that is diagnosed and confirmed using cardiorespiratory criteria. DCD may occur after an expected death that follows the withdrawal of cardiorespiratory support (controlled DCD) or after unanticipated cardiac arrest (uncontrolled DCD). A potential controlled DCD donor is a patient whose death follows the withdrawal of cardiorespiratory support and who does not have an absolute medical contraindication to donation.<br><br>We would suggest that you use these definitions, and use the terms DBD and DCD donors elsewhere in the document where there is currently reference to e.g. donors after brain death or donors after cardiac death. | Thank you. This has been changed to deceased in section 1 and the terms DBD and DCD have been inserted throughout the scope.<br><br>Yes it's restricted to those groups (DBD and controlled DCD in a hospital) only. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | **Q: are you restricting this scope to DBD and controlled DCD? (A small number of Emergency Departments in England support uncontrolled DCD)** | |
| SH | NHS Blood and Transplant | 8.05 | 3.1a | Should read: Organ *transplantation* plays a major role in the management of patients with single organ failure of the kidneys, cornea, liver, pancreas, heart, lung, bowel and thymus, and combined organ failure of the heart and lung, of the kidney and pancreas, of the liver and kidney or liver and bowel. | Thank you. We have amended this section 3.1.a to reflect your comments to include the small bowel and thymus, and also the additional combined organ failure of the liver and kidney, or liver and small bowel (assuming you meant small bowel) |
| SH | NHS Blood and Transplant | 8.06 | 3.1 b) | Percentages presented relate to recipients of deceased heart beating donor kidneys and kidney transplant list only and not to all organ recipients as implied. | Thank you. This has been changed in section 3.1.b |
| SH | NHS Blood and Transplant | 8.07 | 3.1 d) | There are approximately 8 000 patients on the active transplant waiting list. We are not aware of the number who are suspended from the list, or the number of patients who do not ever get onto the list. The correct figure for the increase in the waiting list is 5% between 07/08 and 08/09 and not 8% as reported. | Thank you. We have changed the figure to 8000 people in section 3.1.d, and amended the increase on the waiting list from 8% to 5%. |
| SH | NHS Blood and Transplant | 8.08 | 3.1 e) | 1178 relates to patients who died or were removed from the transplant list. 448 died, 730 removed | Thank you. We have changed this to; 448 died before receiving a transplant and 730 removed from the list in section 3.1.e. |
| SH | NHS Blood and Transplant | 8.09 | 3.1 f) | UK Transplant has now been replaced by the Directorate of Organ Donation and Transplantation (ODT) – a directorate within NHS Blood and Transplant (NHSBT). Please refer either to data from NHS Blood and Transplant or from the UK Transplant Registry. Also applies to 3.2.d<br>These data were presented in the 2008/09 activity report but relate to the time period 1 January 2007 to 31 December 2008. Second sentence should start "Of those families approached….." | Thank you. We have now changed sections 3.1.f and 3.2.d.to reflect your comments |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | NHS Blood and Transplant | 8.10 | 3.2 a) | International rates of organ donation are available at www.tpm.org. 2009 data for UK and Spain are 15.5 and 34.4 donors per million of population respectively. Respective rates of DBD (the preferred mode of donation) are 10.3 and 32.1 donors pmp respectively, the remainder being DCD (mainly controlled in the UK, mainly uncontrolled in Spain). | Thank you. . We agree with your comments and as such have removed the comparison with Spain and added the average European values (17.8 donors per million of population) in section 3.2.a.. |
| SH | NHS Blood and Transplant | 8.11 | 3.2 b) | The conversion rate is the ratio of actual to potential donors, expressed as a percentage. There is a considerable variation in conversion rates around the country – literally ranging from 0 to 100% for individual Intensive Care Units. Mean UK conversion rates are 51% for DBD and 15% for DCD. Regional data will be available from ODT. Time period and conversion rates misrepresented in second sentence. The conversion rates are for two separate groups of patients, they are not a range and data relate to the time period 1 January 2007 to 31 December 2008 | Thank you. This has been changed to 51% for DBD and 15% for DCD in section 3.2.b. |
| SH | NHS Blood and Transplant | 8.12 | 3.2 c) | Kidney transplantation improves quality of life and extends life expectancy. The average half life of a deceased kidney transplant is 11 years, and it is estimated that the costs of haemodialysis over this time period exceed the costs of transplantation by around £250 000. (Ref: report from the Organ Donation Taskforce). | Thank you for your comments. The sentence refers to cost effectiveness. It is unlikely that standard HE modelling techniques will apply to this guideline. In the absence of these a cost impact analysis will be under taken that looks at how identification and consent impacts on current resources.. |
| SH | NHS Blood and Transplant | 8.13 | 3.2 d) | Data misrepresented - 25% of kidney transplant waiting list includes patients categorised as Chinese or Other, whereas 3% of donors doesn't include these patients.<br>If exclude Chinese and Other then % are 3% and 23%<br>If include Chinese and Other then %'s are 5% and 25% | Thank you. This has been changed in section 3.2.d using figures with Chinese and others included. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | NHS Blood and Transplant | 8.14 | 3.2 e) | Opinion polls vary in their precise wording. A BBC survey in 2005 indicated that a minimum of 85% of the population would be prepared to both receive an organ were they in need or donate an organ after their death. However, only a quarter of the population are on the NHS Organ Donor Register (ODR) - the current figure is just over 17 million people on the ODR, and the register accrues approximately 1 million new registrations annually. Only 1 in 5 of current organ donors are on the ODR. | Thank you. The current figure has been updated to 17 million in section 3.2.e. |
| SH | NHS Blood and Transplant | 8.15 | 3.2 f) | We strongly advise that the guideline covers not only the identification of all potential donors but also their timely referral. As far as consent is concerned, this paragraph mentions 'tissue' as well as (solid) organs, and may be misunderstood. It is our understanding that this guideline covers consent for organ and tissue donation from potential DBD and DCD organ donors – not tissue only donors who are identified by entirely separate (and very disparate) mechanisms. | Thank you. We have amended section 4.3.1a to include timing of referral and criteria for consideration.<br><br>We will only be covering solid organ donation in this guideline and section 3.2.f has been changed to reflect this. |
| SH | NHS Blood and Transplant | 8.16 | 4.1.1 | Would suggest that you use the DBD and DCD terminology, e.g 'Families, relatives and legal guardians of potential DBD donors (adults and children).' | Thank you. This has been changed in section 4.1.1.a. and it reads as follows:<br>'Families, relatives and legal guardians of potential DBD donors (adults and children).' |
| SH | NHS Blood and Transplant | 8.17 | 4.2 | Might wish to give more detail, e.g. critical care units, departments of emergency medicine | Thank you. All these areas would be covered under the heading 'NHS hospitals' and evidence will be looked at for all these areas. |
| SH | NHS Blood and Transplant | 8.18 | 4.3.1 a) | 'Structures and processes for the identification and timely referral of potential DBD and DCD organ donors.'<br>**Q: to be covered comprehensively, this will require the relationship between referral and acceptance criteria to be explored. Will this be part of the scope?** | Thank you. We have amended section 4.3.1a to include timing of referral and criteria for consideration.<br>But acceptance criteria is outside the remit from the DH and hence won't be covered in this guideline. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | NHS Blood and Transplant | 8.19 | 4.3.1. b) | Important specifics include not only timing of approach but also who the requestor might be, family support ahead of donation, training for requesting | Thank you. We aim to look at all these factors in our evidence search. |
| SH | NHS Blood and Transplant | 8.20 | 4.3.1 c) | As noted elsewhere, the term 'conversion' is conventionally used to describe and quantify the transition from potential to actual donation, and goes further than identification and consent – it extends, for instance, into Coronial / judicial refusal, failure to maintain stability ahead of retrieval, time delays in retrieval and variations in acceptance criteria by individual transplantation teams. | Thank you. We agree with your comment and have changed section 4.3.1.c to remove the term conversion and it now reads 'coordination of the care pathway from identification to consent.' |
| SH | NHS Blood and Transplant | 8.21 | 4.4 b) | Rates of consent for donation (not transplantation).<br><br>**Q: might also like to consider the very striking regional variation in the rates of consent for donation of eye tissue from organ donors.** | Thank you. This has been changed in section 4.4.b. We are not covering tissue donation as it's outside the remit sent to us by DOH. |
| SH | NHS Blood and Transplant | 8.22 | 4.4 c) | Expressed as donors per million population per year. Suggest national and regional data. | Thank you. This is stating the outcomes that we will be looking for in published papers and these maybe expressed in different ways, so we have not specified a particular measure. We anticipate that we will look at all levels of data where appropriate |
| SH | NHS Blood and Transplant | 8.23 | 4.4 d) | As noted above, the pathway beyond consent concerns a variety of factors, including Coronial / judical obstruction, donor instability, delays in retrieval, withdrawal of consent | Thank you. This guideline focuses on the process of consent by families or legal guardian and the process after that is outside the scope of this guideline. |
| SH | NHS Blood and Transplant | 8.24 | 4.4 e) | What does 'Rates of successful transplants' mean – a transplant being performed, graft survival (6 months, 1 year, 5 years etc) or recipient survival (6 months, 1 year, 5 years etc). This is a bit vague as it stands. More specific metrics include:<br>• Organs retrieved / donor<br>• Organs transplanted / donor (lower because not all organs are used) | Thankyou and we will use metrics as reported in the papers, but we anticipate that measures such as graft survival.(six months, one year, five years etc.) will be considered as appropriate measures of transplant rates . |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | • Patients transplanted (with solid organs) / donor (lower because some patients receive two or three organs | |
| SH | NHS Blood and Transplant | 8.25 | General | Scope should include religious groups not just ethnicity | Thank you. A subgroup on people with different religious beliefs has been added under section 4.1.1.c |
| SH | Resuscitation Council (UK) | 5.00 | General | The Resuscitation Council has looked through this and there is nothing specific in the scope that we need to comment about. | Thank you. |
| SH | Royal College of Anaesthetists | 3.00 | Definitions | Minor point, yet I feel 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. I feel this philosophy should equally transfer to the NICE guidance.<br><br>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. | Thank you. This has been changed in section 2 and the definition now states 'People for whom brain-stem death or cardiac death has been diagnosed and active treatment is planned to be withdrawn, and who have no medical contraindications to solid organ donation.' |
| SH | Royal College of Anaesthetists | 3.01 | 3.1.b Epidemiology | I am 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 | Thank you. The second sentence in section 3.1.b does break it down into according to sex and age groups. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | important for donors, i.e. how many paediatric donors related to paediatric potential recipients etc. | |
| SH | Royal College of Anaesthetists | 3.02 | 3.4 Epidemiology | I 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. This has been changed to number of people who died and have been removed from the list in section 3.2.a. |
| SH | Royal College of Anaesthetists | 3.03 | 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 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 I believe we are still in the early days of evaluating this potential. | Thank you, we will consider these factors when looking at the evidence during the development. |
| SH | Royal College of Anaesthetists | 3.04 | 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 | Thank you. We agree with your comments and as such have removed the comparison with Spain and added the average European values(17.8 donors per million of population) in section 3.2.a. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | 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. | |
| SH | Royal College of Anaesthetists | 3.05 | 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 nurses in the process. | Thank you. The 'population' section of the scope describes those people that the clinicians will need to approach to gain consent. The issue of training and engaging clinicians will be addressed and covered under 4.3.1.d which reads as follows:<br>Competencies of healthcare professionals involved in the activities described in sections 4.3.1 a, b and c.<br>This key clinical issue would address the training needs and education required for all health care professionals involved in the entire process. |
| SH | Royal College of Anaesthetists | 3.06 | 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. Any such work may be considered as evidence, if appropriate and following the NICE process as outline in the Guidelines Manual (www.nice.org.uk) |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| SH | Royal College of General Practitioners Wales | 1.00 | General | The scope appears fit for purpose and extensive in content.<br>We would be keen to support any potential for increase in organ donation and are surprised that processes for ante mortem declaration of willingness to donate are excluded from the process | Thank you. These points were outside of the remit sent from DH. And although the system of consent by individuals' ante-mortem is outside the remit sent from DH, we will interpret any evidence within the context of the national systems in place. |
| SH | Royal College of Nursing | 12.00 | General | The Royal College of Nursing welcomes proposals to develop this clinical guideline. It is timely. | Thank you. |
| SH | Royal College of Nursing | 12.01 | General | Individual discussing organ donation with ethnic minority patients or family or carers should have a good knowledge of culture and beliefs of that patient and family. If necessary need to gain advice and support from the elder (e.g. religious leader such as priest or community worker specific to that culture) to discuss organ donation. | Thank you. We will be guided by the evidence on the most appropriate process of approach. We have recruited to our guideline development group an expert in diversity related matters who will also be able to advise the group.. |
| SH | Royal College of Nursing | 12.02 | General | Organ donation process needs to be a very transparent process. There needs to be written information on all major languages and should have a named individual available to answer any questions from patients or family or cares at any time via phone or email. | Thank you. We will be guided by the evidence on the most appropriate process of approach. |
| SH | Royal College of Nursing | 12.03 | General | Discussion needs to be involved with religious or cultural leaders and specific ethnic minority community workers to clarify any inappropriate beliefs/myths and provide information in a sensitive manner to the individuals who are potential organ donors. | Thank you. We have included a subgroup of people with different religious beliefs and will look for evidence on this. We have recruited to our guideline development group an expert in diversity related matters who will also be able to advise the group.. |
| SH | Royal College of Nursing | 12.04 | General | We would suggest that the developers actively seek to recruit people from the groups which have been identified as less likely to give consent to organ donation when asked i.e. people of African-Caribbean and Asian descent, to be members of the guideline development group. Representation from this group might be beneficial and informative as to | Thank you. We have advertised for a professional with expertise in diversity with specific reference to BME groups, to become a member of the guideline development group |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | the likely factors that present as challenges in getting consent for organ donation from people from this ethnic background. | |
| SH | Royal College of Nursing | 12.05 | General | The draft scope makes references to cardiac death, however, there is little reference to Non-Heart Beating Organ Donation (NHBOD) in this term. Currently in UK ICUs there is great variation between units which participate on NHBOD. Some ICUs are very active whilst other ICUs undertake little or no NHBOD. There should be reference to ways in which this can be enhanced. Whilst obtaining organs from Brain Stem Dead patients is very applicable, it seems the scoping is very biased towards referring to brain stem dead retrieval with less emphasis placed on NHBOD. The way forward is to enhance donation from NHBOD but this form of donation creates lots of debate within practice. | Thank you. NHBOD is the same as DCD and we are covering this group in this guideline. |
| SH | Royal College of Nursing | 12.06 | Terms used in scope | In the definition terms, it might be helpful to have definitions for Non-heart beating organ donation as well as tissue donation. | Thank you. NHBOD is the same as DCD and we clearly define cardiac death and potential donors. Also we are not covering tissue donation in this guideline, hence don't require a definition for it. |
| SH | Royal College of Nursing | 12.07 | 3f | The document states that the guideline will focus on identifying donors and obtaining consent for organs (solid or tissue).<br><br>Throughout the document there is consistent reference to solid organs e.g. heart, liver but there is no reference to tissues. From this statement in 3f, one assumes tissue donation (e.g. skin, corneas, heart valves etc) consent is being investigated. However, the document is consistent in only mentioning organs. There is a difference between organ and tissue donation. This appears heavily | Thank you. This guideline will cover solid organ donation only. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | biased towards organ donation. Is this guideline only focusing upon organs and not tissues, or is it looking at both? Up until the statement in 3f and apart from statement in 3f, it appears that it is only focusing upon solid organs but this statement alludes to tissue consent as well.<br><br>If this guideline will be looking at tissues donation, there needs to be more emphasis on tissue donation in the scoping in terms of descriptors, transplant waiting list etc as this is currently biased towards solid organs with no discussion and relevance to tissue. | |
| SH | Royal College of Paediatrics and Child Health | 9.00 | 3 | The College notes that there is mention of small bowel transplantation.<br><br>This entity includes the following variations:<br>• small bowel transplantation alone<br>• small bowel transplantation combined with liver transplantation<br>• multi-visceral transplantation (which includes small bowel and other part of gastro intestinal tract such as stomach and/or colon and/or pancreas)<br><br>This form of transplantation is expanding as more children and adults are discharged from hospital on home PN [reference: Koglmeier et al. Clinical outcome in patients from a single region who were dependant on parenteral nutrition for 28 days or more. Arch Dis Child 2008; 93: 300-302].<br><br>There are now two designated centres for paediatric small bowel transplantation (at Birmingham | Thank you For your comment. We have now added small bowel in section 3.1.a. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | Children's Hospital and Kings College Hospital London) and two adult centres (Cambridge and Oxford) in the UK. | |
| SH | Royal College of Paediatrics and Child Health | 9.01 | 3.1 a | We note that patients with cystic fibrosis now receive bilateral lung transplant as standard rather than heart and lung as stated. | Thank you. We have removed the word 'heart' and left it as lungs, but not specified bilateral, as it may be partial lung transplant as well in section 3.1.a |
| SH | Royal College of Paediatrics and Child Health | 9.02 | 4.3.1 | We note there is no specific mention of organ donor management. Many organs are deemed unsuitable for transplantation because of poor donor management. We would like clarification on whether this will be discussed as part of the care pathway for conversion of potential to actual donors, and whether the training needs of intensive care staff will be addressed. | Thank you. Organ donation management is outside the remit sent by the DH and therefore we will not be covering it but we would be looking at evidence for training needs of all the key competencies required in the care pathway. |
| SH | Royal College of Paediatrics and Child Health | 9.03 | 4.3.1 d | We think that competencies should include ability and willingness of retrieval team to perform split liver transplants.<br><br>Since there are currently very few organ donations from donors weighing les than 20 kg, the younger and smaller paediatric liver transplant candidates are dependant on the ability of organ retrieval teams to split the liver from adolescent and adult donors into two halves; the larger right lobe going to an adult recipient and the smaller left lobe to a child. | Thank you. We are not looking at how to perform transplants and by who because this is outside the Scope of this guideline. |
| SH | Royal College of Physicians London | 21.00 | General | The Royal College of Physicians is grateful for the opportunity to comment on this draft scope consultation. We believe this to be an important area and support the scope as stands. | Thank you. |
| SH | Scottish Government Health Directorates | 24.00 | General | Donors should be consented for organs and tissues at the same time. This generally happens, but tissues can also be obtained from sources other than organ donors. More emphasis needs to be | Thank you. Tissue donation is outside the remit sent to us by DH and hence we will not be covering it in this guideline. |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | placed on tissue donation - this concept could be strengthened in this document. It currently appears to focus entirely on organ donation. | |
| SH | Society of British Neurological Surgeons | 17.00 | General | The SBNS fully supports the Organ Donation Programme.<br>There are no specific changes to the Scope from our point of view.<br>In the discussions to facilitate and enhance the donor rate it is important to recognise that the local infrastructure is well supported so that neurosurgical units and staff are able to utilise their time effectively on patient care. | Thank you for your comments |
| SH | South Asian Health Foundation | 4.00 | Definitions | Minor point, yet I feel 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. I feel this philosophy should equally transfer to the NICE guidance.<br><br>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. | Thank you. This has been changed in section 2 and the definition now states 'People for whom brain-stem death or cardiac death has been diagnosed and active treatment is planned to be withdrawn, and who have no medical contraindications to solid organ donation.' |
| SH | South Asian Health | 4.01 | 4 | It might be beneficial to involve the hospital Chaplain | Thank you. We have added that religious beliefs will |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | Foundation | | | when approaching Asian families for organ donation. Numerous groups cite religious and cultural reasons (most of them baseless) when refusing organ donation. The chaplain (who has received prior training and guidelines from Asian religious groups) may be able to assuage some of the negative doubts. There are certain groups who run ethical courses for the chaplains and provide practical guidelines in different aspects of patient care including end of life issues. I have had the opportunity to tutor this group in the past and most of them are receptive to this concept. Of course, it might involve practical issues of availability of chaplains etc. | be considered as a special group (Section 4.1.1c) and will be guided by the evidence on the appropriate methods of approach. We have recruited a member of the GDG who an expert in relation to diversity who will be able to offer some advice on these matters |
| SH | South Asian Health Foundation | 4.02 | General | Promote a positive image of transplantation | Thank you for your comments |
| SH | UK Donation Ethics Committee | 22.00 | General | The UK Donation Ethics Committee was established earlier this year to consider and provide guidance on ethical issues relating to organ donation and transplantation. Our first major pieces of work are ethical issues in donation after cardiac death (publication likely later this year), and ethical issues in transplantation research (timescale not yet finalised).<br><br>There is other work going on in this area. The Department of Health held a meeting on 7 June bringing together the Intensive Care Society, British Transplantation Society and others with a view to developing a consensus statement on clinical practice in donation after cardiac death. We understand that publication is likely towards the end of the year. | Thank you. Noted and any such work may be considered as evidence, if appropriate and following the NICE process as outline in the Guidelines Manual (www.nice.org.uk) |

| Type | Stakeholder | Order No | Section No | Comments<br>Please insert each new comment in a new row. | Developer's Response<br>Please respond to each comment |
|---|---|---|---|---|---|
| | | | | It is important that different national level guidance documents on this topic are not confusing so we welcome the opportunity to contribute to the consultation process as the NICE guidelines develop. | |
| SH | UK Donation Ethics Committee | 22.01 | 4.1.1 c | We note that you are planning to give special consideration to people from black and minority ethnic groups given the epidemiology of the transplant waiting list and the mismatch with the ethnic background of donors. The UKDEC is taking a complementary approach to this, as we are looking at faith issues relating to donation. We are opening dialogue with different faith groups with a view to identifying faith-related concerns about organ donation, and working to resolve these where possible. | Thank you. We will also consider faith within this guideline and have added a sub group for people with different religious beliefs in section 4.1.1.c. |
| SH | UK Donation Ethics Committee | 22.02 | 4.3.1 b | *Structures and processes for obtaining consent…. Including timing*. This is an area where UKDEC is considering the ethical issues associated with who should seek consent, and when. | Thank you for your comments |
| SH | Welsh Assembly Government | 16.00 | General | Thank you for giving the Welsh Assembly Government the opportunity to comment. Please note that we have no comment to submit at this stage | Thank you. |

**These organisations were approached but did not respond:**

Alder Hey Children's NHS Foundation Trust
APA
Association of Renal Industries
BMJ
British Association of Critical Care Nurses
British Medical Association (BMA)
British National Formulary (BNF)

British Paediatric Respiratory Society
British Renal Society
British Society of Gastroenterology
British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN)
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)
Care Quality Commission (CQC)
College of Emergency Medicine
College of Occupational Therapists
Commission for Social Care Inspection
Connecting for Health
Department for Communities and Local Government
Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)
Dudley PCT
HeartWare Inc.
Herts & Beds Critical Care Network
ICNARC
ICUsteps
Institute of biomedical Science
Intensive Care Society
Intensive Care Society Patient Liaison Committee
Kidney Research UK
Lambeth Community Health
Lancashire Teaching Hospitals NHS Foundation Trust
Leeds Teaching Hospitals NHS Trust
Live Life Then Give Life
Luton & Dunstable Hospital NHS Foundation Trust
Medicines and Healthcare Products Regulatory Agency (MHRA)
Medway NHS Foundation Trust
Ministry of Defence (MoD)
Muslim Doctors & Dentist Association
National Council for Palliative Care
National Patient Safety Agency (NPSA)
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NETSCC, Health Technology Assessment
Newcastle Upon Tyne Hospitals NHS Foundation Trust
NHS Clinical Knowledge Summaries Service (SCHIN)
NHS Plus
NHS Quality Improvement Scotland
NHS Sheffield
NHS Western Cheshire
Paediatric Intensive Care Society
Papworth Hospital NHS Trust

PERIGON Healthcare Ltd
Royal Brompton & Harefield NHS Foundation Trust
Royal College of General Practitioners
Royal College of Pathologists
Royal College of Radiologists
Royal College of Surgeons of England
ROYAL LIVERPOOL UNIVERSITY HOSPITAL
Royal Society of Medicine
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
Southampton University Hospitals NHS Trust
The Renal Association
UK Clinical Pharmacy Association (UKCPA)
Welsh Scientific Advisory Committee (WSAC)
West Midlands Renal Network
Western Health and Social Care Trust
Whipps Cross University Hospital NHS Trust
York NHS Foundation Trust