The NICE guideline on Organ Donation

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NHS Blood and Transplant
NICE guideline on donor identification and consent

Outline

• Background information
  – Legal framework
• Provenance of the NICE Short Clinical Guideline
• Guideline details
  – Identification and referral
  – Initial assessment
  – Family approach
• Implementation

Background
Provenance of SCG
SCG details
Implementation
BBC DoNate Survey

Would you be prepared to donate your organs after your death for transplant purposes? If your life was at risk would you be prepared to accept an organ from an organ donor?

- N Ireland: Would donate 90%, Would accept 98%
- Wales: Would donate 89%, Would accept 90%
- S West: Would donate 85%, Would accept 92%
- S East: Would donate 60%, Would accept 93%
- London: Would donate 83%, Would accept 90%
- E Anglia: Would donate 84%, Would accept 98%
- W Mids: Would donate 87%, Would accept 94%
- E Mids: Would donate 87%, Would accept 89%
- Yorks / Humber: Would donate 89%, Would accept 89%
- N West: Would donate 88%, Would accept 91%
- N East: Would donate 88%, Would accept 91%
- Scotland: Would donate 84%, Would accept 92%
- UK average: Would donate 87%, Would accept 92%

Background  Provenance of SCG  SCG details  Implementation
Legal framework – best interests

Key features

- Best interests applies to ante-mortem interventions
  - Adults with Incapacity (Scotland) Act 2000
  - Mental Capacity Act 2005
- Opt-in framework for consent
  - Human Tissue Act 2004
  - Human Tissue (Scotland) Act 2006

Within the context of end of life care, best interests extends beyond a person’s physical care.

If donation is consistent with a person’s interests, clinicians are authorised to take actions to promote it, providing other interests are not jeopardised by doing so.
Legal framework - consent

Key features

- Best interests applies to ante-mortem interventions
  - Adults with Incapacity (Scotland) Act 2000
  - Mental Capacity Act 2005
- Opt-in framework for consent
  - Human Tissue Act 2004
  - Human Tissue (Scotland) Act 2006

Neither of the Human Tissue Acts in the UK affords next of kin the legal authority to overturn an individual’s stated wish to donate.
Donor identification and referral

Key features

- 86% and 46% of potential DBD and DCD donors are identified and referred
- True denominator for potential donation in UK is unknown
- Different approaches to end of life care may account for differences in overall donor numbers

Wrong place of death
Wrong kind of death
Wrong time frames
Donor identification and referral

Key features

- 86% and 46% of potential DBD and DCD donors are identified and referred
- Physiological instability is a significant obstacle
- Different approaches to end of life care may account for differences in overall donor numbers

By quickly withdrawing or limiting treatments, do we deny our patients their opportunity to donate after their death?
## Consent / Authorisation in UK

### DBD

<table>
<thead>
<tr>
<th>Consent rate</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>DBD on ODR</td>
<td>92%</td>
</tr>
<tr>
<td>DBD not on ODR</td>
<td>56%</td>
</tr>
<tr>
<td><strong>All DBD</strong></td>
<td><strong>65%</strong></td>
</tr>
<tr>
<td>DCD on ODR</td>
<td>76%</td>
</tr>
<tr>
<td>DCD not on ODR</td>
<td>44%</td>
</tr>
<tr>
<td><strong>All DCD</strong></td>
<td><strong>51%</strong></td>
</tr>
<tr>
<td>DBD and DCD on ODR</td>
<td>84%</td>
</tr>
<tr>
<td>DBD and DCD not on ODR</td>
<td>49%</td>
</tr>
<tr>
<td><strong>All deceased donors</strong></td>
<td><strong>57%</strong></td>
</tr>
</tbody>
</table>

### Background

Provenance of SCG

SCG details

Implementation
International consent ratios, 2009

<table>
<thead>
<tr>
<th>Country</th>
<th>Consent Ratio (%)</th>
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</thead>
<tbody>
<tr>
<td>Malta</td>
<td>90</td>
</tr>
<tr>
<td>Poland</td>
<td>88.8</td>
</tr>
<tr>
<td>Cuba</td>
<td>85.5</td>
</tr>
<tr>
<td>Greece</td>
<td>83.6</td>
</tr>
<tr>
<td>Spain</td>
<td>83.6</td>
</tr>
<tr>
<td>Ireland</td>
<td>82.7</td>
</tr>
<tr>
<td>Venezuela</td>
<td>73.6</td>
</tr>
<tr>
<td>Italy</td>
<td>69.6</td>
</tr>
<tr>
<td>Lithuania</td>
<td>69.6</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>59.7</td>
</tr>
<tr>
<td>Latvia</td>
<td>54.2</td>
</tr>
<tr>
<td>Israel</td>
<td>54.1</td>
</tr>
<tr>
<td>Estonia</td>
<td>52.4</td>
</tr>
<tr>
<td>Romania</td>
<td>37.5</td>
</tr>
<tr>
<td>Turkey</td>
<td>31.3</td>
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</table>
## Provenance of the Guideline

<table>
<thead>
<tr>
<th>Remit</th>
<th>To produce a clinical guideline on improving donor identification and consent rates for cadaveric organ donation</th>
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<tbody>
<tr>
<td>Jurisdiction</td>
<td>England, Wales and Northern Ireland</td>
</tr>
<tr>
<td>Out of scope</td>
<td>Tissue donation, living donation, Promotion of organ donation, Organ assessment and allocation</td>
</tr>
</tbody>
</table>

Fulfilling the wishes of our patients and the needs of others
## Timeline

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Activity</th>
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<tbody>
<tr>
<td>February 2010</td>
<td>Remit received from Department of Health</td>
</tr>
<tr>
<td></td>
<td>Stakeholder registration</td>
</tr>
<tr>
<td>June - July 2010</td>
<td>Scoping consultation</td>
</tr>
<tr>
<td>August 2010</td>
<td>Appointment of Guideline Development</td>
</tr>
<tr>
<td>September – December 2010</td>
<td>Guideline Development</td>
</tr>
<tr>
<td></td>
<td>Consultation on draft guideline</td>
</tr>
<tr>
<td>March 2011</td>
<td>Guideline review</td>
</tr>
<tr>
<td>April – October 2011</td>
<td>Pre-publication checks, including legal review</td>
</tr>
<tr>
<td>December 2011</td>
<td>Publication</td>
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**Background**

**Provenance of SCG**

**SCG details**

**Implementation**
<table>
<thead>
<tr>
<th>Name</th>
<th>Specialist area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gary McVeigh</td>
<td>Professor of Cardiology, Chair</td>
</tr>
<tr>
<td>Karen Morgan</td>
<td>Regional Manager, Donor Coordination</td>
</tr>
<tr>
<td>Tim Collins</td>
<td>Critical Care Nursing</td>
</tr>
<tr>
<td>Angus Vincent</td>
<td>Consultant in Intensive Care Medicine</td>
</tr>
<tr>
<td>Huw Twamley</td>
<td>Consultant in Intensive Care Medicine</td>
</tr>
<tr>
<td>James Fraser</td>
<td>Consultant in Paediatric Intensive Care</td>
</tr>
<tr>
<td>Gurch Randhawa</td>
<td>Professor of Biodiversity</td>
</tr>
<tr>
<td>Paul Murphy</td>
<td>Clinical Lead for Organ Donation</td>
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<tr>
<td>Ronan O’Carroll</td>
<td>Professor of Psychology</td>
</tr>
<tr>
<td>Jane Nix</td>
<td>Donor Family Network</td>
</tr>
<tr>
<td>Barry Williams</td>
<td>ICS Patient Liaison Committee</td>
</tr>
<tr>
<td>Simon Bramhall</td>
<td>Consultant Transplant Surgeon</td>
</tr>
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</table>
Review Questions

Five key questions

- What structures and processes are appropriate and effective for
  - identifying potential DBD and DCD donors?
  - obtaining consent for organ donation?
- When is the optimal time for approaching the families of potential donors for consent?
- How should the care pathway of deceased organ donation be coordinated to improve potential donors giving consent?
- What key skills and competencies are important for the above?
Evidence base

Very limited and very weak

- Qualitative, reflective, uncontrolled
- ACRE study
  - was not blinded
  - possibly asked wrong question
- Much of the published material is audit or service development rather than research
Evidence base

Very limited

- Qualitative, reflective, uncontrolled
- ACRE study
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  - possibly asked wrong question
- Much of the published material is audit or service development rather than research

Impact of the Organ Donation Breakthrough Collaboratives in USA, 2003 onwards
If a patient is close to death and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility.

You should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator.

The NICE guideline seeks to build on guidance from the GMC and to promote the fulfilment of a person’s wishes to donate their organs after death.
Donor Identification and Referral

Objectives
- Increase referral
- Improve timeliness of referral

Extension of Taskforce recommendations
- Addition of ‘clinical triggers’

Intended impact
- Earlier advice for difficult cases
- Better service for donor hospitals / families from donor care and organ retrieval services

Key features

- Identify potential donors as early as possible.
- Base identification on either of the following criteria, while recognising that clinical situations vary.
- Whichever is the earlier, either:
  - use defined clinical trigger factors in patients who have had a catastrophic brain injury:
    - the absence of one or more cranial nerve reflexes and
    - a Glasgow Coma Scale 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 and/or
  - a decision is made to perform brainstem death tests.
- The intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death.
- Initiate discussions with the specialist nurse for organ donation at the time the above criteria are met.
Donor Assessment

When time is limited and decisions are needed, how do clinicians decide whether donation **could** and **should** be part of a person’s end of life care?

**Key features**

- **Objective**
  - No patient to have treatment withdrawn until the potential for donation has been assessed

- **Intended impact**
  - Increased numbers of people have their wishes to donate identified and fulfilled

- **Legal authority**
  - Mental Capacity Act 2005

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**Background**

Initiate discussions with the specialist nurse for organ donation at the time the above criteria are met.

**Provenance of SCG**

Clinically stabilise the patient in an appropriate critical care setting while the assessment for donation is performed.

**SCG details**

Provided that delay is in the patient’s overall best interests, life-sustaining treatments should not be withdrawn or limited until the patient’s wishes around organ donation have been explored and the clinical potential for the patient to donate has been assessed in accordance with legal\(^3\) and professional\(^4,5\) guidance.
Donor Assessment

- Initiate discussions with the specialist nurse for organ donation at the time the above criteria are met.

- Clinically stabilise the patient in an appropriate critical care setting while the assessment for donation is performed.

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

Objectives
- To inform a best interests assessment
- To seek consent for organ retrieval

Intended impact
- To promote the identification and fulfillment of a person’s wish to donate

Legal authorities
- Mental Capacity Act 2005 / Adults with Incapacity (Scotland) Act 2000
- Human Tissue Act 2004 Human Tissue (Scotland) Act 2006
Preparation for the family approach

Before approaching the family

- Define medical potential for donation in consultation with Specialist Nurse
- Check Organ Donor Register
- Clarify any Coronial, legal or safeguarding issues
- Identify key family members, and relevant social, cultural and religious issues

Preparation and planning are essential. It is vital that the family have accepted the inevitability of their loss before the approach.
Planning the family approach

Preparation and planning are essential. Base discussions on the known wishes of the patient wherever possible.

Key features

- Plan the approach in collaboration with the Specialist Nurse for Organ Donation
- Present donation as a positive part of end-of-life care
- Avoid apologetic or negative language
- Have the knowledge and the time to support the family through the process

Plan the approach with the multidisciplinary team and approach those close to the patient:
- in a setting suitable for private and compassionate discussion
- at a time that suits the family's circumstances
- in a professional, compassionate and caring manner
- when it is clearly established that they understand that death is inevitable or has occurred.

Discuss with those close to the patient and offer information (see also box 2):
- explain that donation is a usual part of end-of-life care
- use open-ended questions
- use positive ways to describe organ donation
- avoid the use of apologetic or negative language.
  Give them sufficient time to consider the information.
Organisation and Policy

Consultants require specific knowledge and skills in:

- The relevant law and ethics
- The diagnosis and confirmation of death using neurological and cardio-respiratory criteria
- Key differences between donation after neurological and circulatory death
- Donor optimisation
- Communication, specifically in regards to the family approach

Preparation and planning are essential. The team should have the specialist skills and competencies necessary to deliver the process.
It is implementation not publication that makes the difference!

Donor identification, referral and consent / authorisation

- Sponsored by National Donation Committee at NHS BT
- Lead by strategy groups on donor identification and consent / authorisation
- Delivered via the 12 UK Regional Donation Collaboratives
- Implemented via local Donation Committees