Ethical, Legal and Professional Framework for Donation after Circulatory Death

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Deputy National CLOD
Member of the UK Donation Ethics Committee

www.clodlog.com
Donation after Circulatory Death (DCD)

Mechanically ventilated patient with a devastating injury, usually brain, where the decision has been made to withdraw life-sustaining treatment. The expectation is that the circulation will cease imminently upon the withdrawal of life-sustaining treatment.

Kidneys
Liver
Pancreas
Lungs

539 donors
2013/14 data

Modified Maastricht Classification

Category I: Dead on arrival
Category II: Unsuccessful resuscitation
**Category III**: Awaiting cardiac arrest
Category IV: Cardiac arrest in a brain stem dead donor.
Category V: Unexpected cardiac arrest in a critically ill patient

Categories I, II, and V are uncontrolled whilst Category III, IV are controlled in the sense that the death is expected.
Diagnosis of Death Discovered not Invented

- **1962**: 1st successful deceased donor kidney Tx
- **1963**: 1st successful deceased donor liver & lung Tx
- **1966**: 1st successful deceased donor pancreas Tx
- **1968**: 1st successful deceased donor heart Tx

Proposed that the EEG can demonstrate death of the Central Nervous System.

1964, Keith Simpson: “there is life so long as circulation of oxygenated blood is maintained to live brainstem centres”

Ad Hoc Committee of the Harvard Medical School define irreversible coma as a new criterion for death.
UK Deceased Donation

- Total Deceased Donors
- DBD Donors
- DCD Donors
Deceased Donors and the Transplant Waiting List

Transplant waiting list vs. Total Deceased Donors over the years 2000-2013.
Deceased organ donors in the UK

<table>
<thead>
<tr>
<th>Year</th>
<th>DBD</th>
<th>DCD</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-08</td>
<td>609</td>
<td>200</td>
<td>809</td>
</tr>
<tr>
<td>2008-09</td>
<td>611</td>
<td>288</td>
<td>899</td>
</tr>
<tr>
<td>2009-10</td>
<td>624</td>
<td>335</td>
<td>959</td>
</tr>
<tr>
<td>2010-11</td>
<td>637</td>
<td>373</td>
<td>1010</td>
</tr>
<tr>
<td>2011-12</td>
<td>652</td>
<td>436</td>
<td>1088</td>
</tr>
<tr>
<td>2012-13</td>
<td>705</td>
<td>507</td>
<td>1212</td>
</tr>
<tr>
<td>2013-14</td>
<td>781</td>
<td>539</td>
<td>1320</td>
</tr>
</tbody>
</table>

- DBD: Donors Brain Dead
- DCD: Donors Cardiac Death

63.2% increase in deceased organ donors from 2007-08 to 2013-14
Consent / Authorisation

DBD

52% + 72% = 124%

DCD

31% + 62% = 93%

67%

79%

68%

51%

57%

UK, 2012-13

Blood and Transplant
Consent Rates and the ODR

SN-OD Induction
DBD
Donation after Brain Death
Approached 7% more families

DCD
Donation after Circulatory Death
Approached 311% more families

WHO = ICU & ED
UK, 2012-13

SN-OD Induction
The rise and rise of UK DCD

Consents by quarter

Number of potential donors where consent for donation obtained from family

Quarter

0 50 100 150 200 250 300 350 400 450 500

Oct 09 - Mar 10
Apr 10 - Sep 10
Oct 10 - Mar 11
Apr 11 - Sep 11
Oct 11 - Mar 12
Apr 12 - Sep 12

DBD
DCD

SN-OD Induction
DCD percentage increase by year

SN-OD Induction
UK donation and transplantation efficiency

In 2007/08
For every 1 family approached for DCD, 1 patient benefited from transplantation.

In 2012/13
For every 2 families approached for DCD, 1 patient benefited from transplantation.
For every 1 family approached for DBD, 2 patients benefited from transplantation.
Deceased Organ Donation

Donation after Brain Death

705 donors

Donation after Circulatory Death

507 donors

105 family overrules of a known wish to donate

15 overrules

90 overrules

UK, 2012-13
# Family refusal in DCD donation

<table>
<thead>
<tr>
<th>Reason</th>
<th>DBD N</th>
<th>DBD %</th>
<th>DCD N</th>
<th>DCD %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient had stated in the past that they did not wish to be a donor</td>
<td>75</td>
<td>21.1</td>
<td>155</td>
<td>17.5</td>
</tr>
<tr>
<td>Family were not sure whether the patient would have agreed to donation</td>
<td>46</td>
<td>12.9</td>
<td>140</td>
<td>15.8</td>
</tr>
<tr>
<td>Family did not want surgery to the body</td>
<td>42</td>
<td>11.8</td>
<td>49</td>
<td>5.5</td>
</tr>
<tr>
<td>Family felt it was against their religious/cultural beliefs</td>
<td>30</td>
<td>8.4</td>
<td>26</td>
<td>2.9</td>
</tr>
<tr>
<td>Strong refusal - probing not appropriate</td>
<td>30</td>
<td>8.4</td>
<td>63</td>
<td>7.1</td>
</tr>
<tr>
<td>Other</td>
<td>28</td>
<td>7.9</td>
<td>103</td>
<td>11.6</td>
</tr>
<tr>
<td>Family felt the patient had suffered enough</td>
<td>23</td>
<td>6.5</td>
<td>67</td>
<td>7.6</td>
</tr>
<tr>
<td>Family were divided over the decision</td>
<td>20</td>
<td>5.6</td>
<td>52</td>
<td>5.9</td>
</tr>
<tr>
<td>Family did not believe in donation</td>
<td>16</td>
<td>4.5</td>
<td>35</td>
<td>4.0</td>
</tr>
<tr>
<td>Family felt the body needs to be buried whole</td>
<td>15</td>
<td>4.2</td>
<td>29</td>
<td>3.3</td>
</tr>
<tr>
<td>(unrelated to religious or cultural reasons)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family felt the length of time for donation process was too long</td>
<td>11</td>
<td>3.1</td>
<td>128</td>
<td>14.5</td>
</tr>
<tr>
<td>Family had difficulty understanding/accepting neurological testing</td>
<td>10</td>
<td>2.8</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>Family wanted to stay with the patient after death</td>
<td>4</td>
<td>1.1</td>
<td>12</td>
<td>1.4</td>
</tr>
<tr>
<td>Family concerned that organs may not be transplanted</td>
<td>3</td>
<td>0.8</td>
<td>21</td>
<td>2.4</td>
</tr>
<tr>
<td>Family concerned that other people may disapprove/be offended</td>
<td>2</td>
<td>0.6</td>
<td>3</td>
<td>0.3</td>
</tr>
<tr>
<td>Patients treatment may be or has been limited to facilitate organ donation</td>
<td>1</td>
<td>0.3</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Families concerned about organ allocation</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>356</td>
<td>100.0</td>
<td>885</td>
<td>100.0</td>
</tr>
</tbody>
</table>
Deceased Organ Donation

Donation after Brain Death
705 donors

Most commonly commenced donation pathway
Lower consent
Most of the overrules
Different family behaviours

Donation after Circulatory Death
507 donors

Background
Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established.
The ethical, legal and professional framework that underpins the deceased organ donation programme in the UK is arguably, the strongest in the world.

In view of the Madrid Resolution, the Declaration of Istanbul, and the 63rd World Health Assembly Resolution, a new paradigm of national self-sufficiency is needed. Each country or region should strive to provide a sufficient number of organs from within its own population, guided by WHO ethics principles.

Lancet 2011; 378: 1414–18
United Kingdom

Donation after Circulatory Death

Royal Assent to an Act of the Assembly
Human Transplantation (Wales) Act 2013
In accordance with Standing Order 26.75, I hereby notify the Assembly that the Human Transplantation (Wales) Act 2013 was given Royal Assent on 10 September 2013.

Claire Clancy
Chief Executive and Clerk

Human Tissue (Scotland) Act 2006

SN-OD Induction
Deceased Donation

How the UK satisfies the Dead Donor Rule

How the UK satisfies the Consenting Donor Rule
Dead Donor Rule

Narrow
“prohibiting the killing of patients for organ donation”
“donors must be declared dead before their organs are taken”

Broad
“procedures for organ donation should not be initiated while the patient is still alive”

Coined John Robertson 1988

1968 Judicial Council of the AMA
“When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient’s physician. Death shall be determined by the clinical judgment of the physician. In making this determination, the ethical physician will use all available, currently accepted scientific tests.”
Deceased Donation

How the UK satisfies the Dead Donor Rule

How the UK satisfies the Consenting Donor Rule

1968 Judicial Council of the AMA
“A prospective organ transplant offers no justification for relaxation of the usual standards of medical care”

“Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory.”
The Act and its associated codes of practice unequivocally establish the primacy of consent for the control of organs and tissues during life or after death.
The Act and its associated codes of practice unequivocally establish the primacy of consent for the control of organs and tissues during life or after death.

“For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question.”
Human Tissue Act

- **AFTER DEATH**
- Arose after UK scandals
- Governs the removal, storage and use of organs and tissues.

- **Organ Donation**
  - Deceased Donation
  - Living Donation

- **Consent / Authorisation**
  - If there is a known wish to donate, patient has consented to donation and family has no legal right to veto
  - Hierarchy of qualifying relationships

Is a stronger attempt to put the wishes of the deceased first and aims to make the wishes of the deceased paramount.

*Specifically uses the term ‘consent’, even when this is given by families.*
AoMRC 2008 Code of Practice for the Confirmation and Diagnosis of Death

- “The definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe... therefore irreversible cessation of the integrative function of the brain-stem equates with the death of the individual.”
- No mention of organ donation
- First time UK criteria for diagnosing any death following cardio-respiratory arrest.

No legislation defining death, Code accepted in case law.

Re A (A Minor) [1992] English law incorporated into the common law the definition of death recommended by the Royal Colleges, namely brain-stem death.
• Desire to donate gives clinicians authority to take reasonable steps to ensure donation occurs.
• Best interests extend beyond physical care (values, wishes, beliefs)

**In the Person’s Interests**
• By maximising the chance of fulfilling the donor’s wishes about what happens to them after death
• By enhancing the donor’s chances of performing an altruistic act of donation
• By promoting the prospects of positive memories of the donor after death
Legal issues relevant to non-heartbeating organ donation
“While registration on the ODR provides consent for donation after death for the purposes of the HTA, the Department of Health does not consider that registration can be viewed as advance consent to steps to facilitate NHBD.”

“It would, however, be important evidence of a person’s wish to donate.”
MCA (2005)
• Best interests are broader than ‘medical’ best interests.

• When a patient lacks capacity - duty to consult with those close to the patient to ascertain knowledge of the patient’s wishes, preferences, feelings, beliefs and values.
<table>
<thead>
<tr>
<th>Autonomy</th>
<th>Beneficence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wish fulfillment / Respect of wishes</td>
<td>Recipient (lives saved)</td>
</tr>
<tr>
<td>Organ Donor Register (HTA)</td>
<td>Legacy (DH)</td>
</tr>
<tr>
<td>End of Life Goals (GMC)</td>
<td>Positive Memories (DH)</td>
</tr>
<tr>
<td>Unknown wish</td>
<td>Family Grief</td>
</tr>
</tbody>
</table>

**Best interests are WIDER than just physical**

<table>
<thead>
<tr>
<th>Non-Maleficence</th>
<th>Distributive Justice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged time to death (DCD)</td>
<td>ICU resources and effect on other patients</td>
</tr>
<tr>
<td>Death distant from relatives / delayed grief commencement</td>
<td>Moral Distance (responsibility to other patients in the NHS not just the one before you or your own hospital)</td>
</tr>
<tr>
<td>Wishes not fulfilled, interests not fulfilled = harm (UK DEC)</td>
<td>Equity of approaching families</td>
</tr>
</tbody>
</table>
Legal

1. Delay Withdrawal
2. Change patient’s location
3. Maintain physiological stability

Desire to donate gives clinicians authority to take reasonable steps to ensure donation occurs.

Best interests extend beyond physical care (values, wishes, beliefs)

In the Person’s Interests

- By maximising the chance of fulfilling the donor’s wishes about what happens to them after death
- By enhancing the donor’s chances of performing an altruistic act of donation
- By promoting the prospects of positive memories of the donor after death

Legal

1. Delay Withdrawal
2. Change patient’s location
3. Maintain physiological stability
Not in the Person’s Interests
“Anything that places the person at risk of serious harm.”

Harms
• worsening of the patient’s medical condition;
• shortening of the patient’s life;
• pain from an invasive procedure; and
• distress to family and friends.

Not Legal
1. Systemic heparinisation
2. Resuscitation
3. Femoral cannulation
Organ donation

- 81 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.

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

Establishes a duty on doctors to explore donation and follow national procedures.
Joint professional statement from the ICS and the BTS

1. Professional support for DCD
2. Professional support for admission to ICU purely for organ donation
3. Suitability criteria for donation outlined.
4. Guidance for treatments before and after death, including reintubation and reinflation for lung DCD
UK DEC Principles

**Principle 1:** where donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying patient; and

**Principle 2:** if it has been established that further life-sustaining treatment is not of overall benefit to the patient, and it has been further established that donation would be consistent with the patient’s wishes, values and beliefs, consideration of donation should become an integral part of that patient’s care plan in their last days and hours.
Guidance on roles and responsibilities, conflicts of interest:

1. Referral to SN-OD before withdrawal decision is acceptable.
2. Two senior clinicians to make the decision that life sustaining treatment should be withdrawn.
3. Clinical Lead for Organ Donation may act as treating clinician.
4. After death acceptable for treating clinician to take actions necessary to facilitate donation (eg re-intubation).
Guidance on roles and responsibilities, conflicts of interest:

5. UKDEC recommends that SN-ODs should not provide medical care for a potential DCD donor whilst they are still alive. The SN-OD role in relation to donation means that there is a clear conflict of interest. After the potential donor has died this conflict of interest no longer exists, and the SN-OD can take care of the patient if necessary. This commonly happens in patients who have been declared dead following brain stem death.
1. Triggered Referral
   - Plan to withdraw life-sustaining treatment
   - Plan to perform brain stem testing
   - Catastrophic brain injury (early referral)

2. While assessing the patient’s best interests clinically stabilise the patient in an appropriate critical care setting

3. Collaborative Approach
   - SN-OD
   - Local faith representative

NICE Guidance
Non-heart-beating organ donation – solution or a step too far?

The pool of brain stem dead patients who go on to become heart-beating organ donors seems to be shrinking, probably as a result of improved road safety and prehospital care and more aggressive neurosurgery procedures such as decompressive craniectomy. Non-heart-beating organ donation (NHBD) is one way to increase the organ donor pool. The article by Grat-
Recommendation 3

Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice.

Additionally, an independent UK-wide Donation Ethics Group should be established.
Dead Donor Rule

Narrow
“prohibiting the killing of patients for organ donation”

“donors must be declared dead before their organs are taken”

Broad
“procedures for organ donation should not be initiated while the patient is still alive”
Dead Donor Rule

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“procedures for organ donation should not be initiated while the patient is still alive”
For the first time in the UK, criteria for the confirmation of death using cardio-respiratory was defined.

(5 minutes asystole)

Dead Donor Rule

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“prohibiting the killing of patients for organ donation”

“donors must be declared dead before their organs are taken”

Broad
“procedures for organ donation should not be initiated while the patient is still alive”
1. No agreed criteria for diagnosing death after cardio-respiratory arrest.

2. What is legal?

3. No national professional guidance.

4. Conflict of interest?

5. Future?
Lord Browne-Wilkinson’s ruling in Airedale NHS Trust v Bland [1993] AC 789, 883, “…if the responsible doctor comes to the reasonable conclusion………that further continuance of an intrusive life support system is not in the best interests of the patient, he can no longer lawfully continue that life support system: to do so would constitute the crime of battery and the tort of trespass to the person.”
In many cases, actions that can facilitate DCD most successfully will be in the person’s best interests.

- Best interests extend beyond physical care (values, wishes, beliefs)
- Desire to donate gives clinicians authority to take reasonable steps to ensure donation occurs.

Legal
1. Delay Withdrawal
2. Change patient's location
3. Maintain physiological stability
Dead Donor Rule

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“prohibiting the killing of patients for organ donation”

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Broad
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Consenting Donor Rule

No heparin
Dead Donor Rule

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Broad
“procedures for organ donation should not be initiated while the patient is still alive”

Consenting Donor Rule
1. No agreed criteria for diagnosing death after cardio-respiratory arrest.
2. What is legal?
3. No national professional guidance.
4. Conflict of interest?
5. Future?
Joint professional statement from the ICS and the BTS

1. Professional support for DCD
2. Professional support for admission to ICU purely for organ donation
3. Suitability criteria for donation outlined.
4. Guidance for treatments before and after death
Joint professional statement from the College of Emergency Medicine and the BTS

1. Professional support for the robust identification of potential donors in the Emergency Department

2. Professional support for managing organ donation from the Emergency Department if ICU is full.
1. No agreed criteria for diagnosing death after cardio-respiratory arrest.

2. What is legal?

3. No national professional guidance.

4. Conflict of interest?

5. Future?

Gardiner D, Riley B

2007
When we can’t cure
we can only continue to care

Organ donation
81 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.

82 You should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator.
Academy of Medical Royal Colleges (Independent) Donation Ethics Committee

Guidance on roles and responsibilities, conflicts of interest:

1. SN-ODs not to care for the patient before death.

2. Two senior clinicians to make the decision that life sustaining treatment should be withdrawn.

3. Clinical Lead for Organ Donation may act as treating clinician.

4. After death acceptable for treating clinician to take actions necessary to facilitate donation (e.g., re-intubation).
NICE Guidance

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   - Plan to perform brain stem testing
   - Catastrophic brain injury (early referral)

2. Collaborative Approach
   - SN-OD
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Consenting Donor Rule

No heparin
1. No agreed criteria for diagnosing death after cardio-respiratory arrest.
2. What is legal?
3. No national professional guidance.
4. Conflict of interest?
5. Future?

Gardiner D, Riley B

2007

Controlled
Future

1. UK DEC
   - Balancing of benefits and harms to guide interventions – may allow heparin
   - Paediatric guidance
   - DBD guidance
2. Uncontrolled DCD
3. Heart DCD / Re-animation in-situ
4. Elective Ventilation

The stronger the evidence of the patient’s desire to become an organ donor, the greater the weight this should be given in assessing whether a particular intervention would be of overall benefit to the patient.
How far can we / should we manipulate the dying process to allow donation?

Resuscitation
• Titration of oxygen and inotropes
• Ventilation and Central lines

Location of care
Timing of withdrawal = is there an appropriate time (DCD can take up to 24 hours)

Pre-mortem interventions

SN-OD Induction
Dead Donor Rule

Donation following Euthanasia

Resuscitating the newly dead

1. Uncontrolled DCD
2. ECMO
For the first time in the UK, criteria for the confirmation of death using cardio-respiratory was defined.

(5 minutes asystole)

Three vital caveats (page 12)
1. There will be no cardio-pulmonary resuscitation
2. Five minutes is based on the evidence that after this time, spontaneous restoration of the heart and circulation will NOT occur.
3. “It is obviously inappropriate to initiate any intervention that has the potential to restore cerebral perfusion after death has been confirmed.”
Dead Donor Rule

Donation following Euthanasia

Resuscitating the newly dead

1. Uncontrolled DCD
2. ECMO

≠

Uncontrolled DCD ≠ ECMO

UK DEC: “When reperfusion of organs with oxygenated blood is performed as part of the retrieval process, it should, as far as it practical, be restricted to the relevant organs.”
Dead Donor Rule

1. Uncontrolled DCD
2. ECMO

Donation following Euthanasia

Resuscitating the newly dead

Pre - morbid Interventions

1. Heparin
2. Extubation
3. Femoral cannulation
Words matter
Words from our donor families

1. “The letter you sent arrived the day of the funeral, and the lapel pins were worn with pride, to symbolise Mum’s gift and the determination we had to make the tough decision to follow Mum’s wishes”
   September 2011

2. “I was very impressed with the unit: the medical care given to my husband and the friendly, caring attitude towards myself, my daughter and other visitors was first class.”
   Consented DCD patient where DCD didn’t proceed.
   May 2011
I would be in favour of changing to a system where it is presumed that I have consented to donation unless I have registered my objection or my family/close friend says no.

I would be against changing to a system where it is presumed that I have consented to donation unless I have registered my objection or my family/close friend says no.

I would need more information to decide.

Don't know.

Everyone should be presumed to be an organ donor unless they register a wish otherwise.

Agree: 49%
Neutral: 26%
Disagree: 26%

Terminology matters (n=1,012)
Utilitarian words

<table>
<thead>
<tr>
<th></th>
<th>Graft 5 year survival</th>
<th>Patient 5 year survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney (DBD)</td>
<td>85%</td>
<td>89%</td>
</tr>
<tr>
<td>Kidney (DCD)</td>
<td>86%</td>
<td>87%</td>
</tr>
</tbody>
</table>

- 5 year survival on HD in West London 71%
- £240 000 saved over 10 years (median graft survival) v dialysis
- Increased employment, QALY
### Utilitarian words

<table>
<thead>
<tr>
<th>Organ (Source)</th>
<th>1 Year Survival (%)</th>
<th>5 Year Survival (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver (DBD)</td>
<td>93%</td>
<td>78%</td>
</tr>
<tr>
<td>Liver (DCD)</td>
<td>86%</td>
<td>85%$^\alpha$</td>
</tr>
<tr>
<td>Lung (DBD)</td>
<td>82%</td>
<td>51%$^\beta$</td>
</tr>
<tr>
<td>Lung (DCD)</td>
<td>84%</td>
<td>?</td>
</tr>
<tr>
<td>Heart</td>
<td>81%</td>
<td>76%</td>
</tr>
</tbody>
</table>

$^\alpha$ 3 year result

$^\beta$ 4 year survival DCD lungs 85% (Australia)
Attitudes to organ donation by ICU staff?

SN-OD Induction
Kant’s second categorical imperative:
“So act that you use humanity, whether in your own person, or in the person of any other, always at the same time as an end, never merely as a means.”
"It's the most difficult yet rewarding thing we have ever done. It was the most fantastic thing he could have done. It sums up what he was like, that he wanted to help others."

Words from a donor family, April 2010
BUT if all regions adopted BEST PRACTICE
BUT if all regions adopted BEST PRACTICE

50%

13.4 ppm

19.1 ppm

26.3 ppm

TOP 5 in the WORLD