HOW THE UK OVERCAME THE ETHICAL, LEGAL AND PROFESSIONAL CHALLENGES IN DONATION AFTER CIRCULATORY DEATH

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Long transplant lists and a shortage of organ donors has led to an international resurgence in the donation of organs after circulatory death (‘DCD’). Despite being almost entirely absent for nearly 25 years, DCD now accounts for 40 per cent of deceased organ donation in the UK. This rise is in part due to attempts to resolve the ethical, legal and professional challenges inherent to this type of donation. Since 2008 in the UK, seven major ethical, legal and professional guidances have been published relating to deceased donation and DCD in particular. It is now this author’s opinion that the professional framework that underpins the DCD programme in the UK is the strongest in the world. This paper outlines the seven UK publications that justify this bold claim.

I INTRODUCTION

The World Health Organization has called for national self-sufficiency in transplantation to protect the vulnerable from exploitation. While we await a transforming breakthrough in xenotransplantation or the technology for laboratory-grown organs, patients die: three per day in the UK. It is only through the generosity of donors and their families, that the gift of life has been given to so many.

There are four types of donation that are possible from a human body:

1) Living (eg blood, bone marrow, single kidney, liver lobe)
2) Tissue (eg corneas, heart valves, skin and bone)
3) Donation of organs after the neurological determination of death, also known as donation after brain death (‘DBD’) (organs that can be donated: kidneys, liver, pancreas, intestine, lungs and heart)
4) Donation of organs after the circulatory determination of death (DCD) (organs that can be donated: kidneys and lungs (long-term outcomes equal to DBD), livers and pancreas (long-term outcomes inferior to DBD) and heart (single centre experiences: USA, Australia and UK)).

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In the UK, the number of potential organ donors each year is around 5000 from an estimated 500,000 deaths. The vast majority of these potential donors will die in an intensive care unit. Organ donation is effectively limited to intensive care units because only in intensive care can the circulation be maintained after a confirmation of death using neurological criteria (DBD) or the withdrawal of life-sustaining treatment, which will result in circulatory cessation, be delayed until transplant teams are in readiness for the donation (DCD).

It was only with the advent of mechanical ventilation that the simultaneous physiological consequences of lethal brain injury, apnoea and circulatory arrest, could be interrupted. The diagnosis of ‘brain death’ was a discovery made in the intensive care unit. Prior to the acceptance of neurological criteria for human death that allowed DBD, DCD was the original type of deceased organ donation. After the acceptance of neurological criteria, DCD was effectively abandoned in most countries. In DCD, warm ischaemia begins as the circulation fails; organ viability for transplantation likewise rapidly falls (within 20 minutes for example in the liver), and this form of donation was almost entirely absent in the UK for 25 years. It was because of the unmet need on the transplant waiting list and because families in intensive care were advocating organ donation for their relatives who were not brain dead that programmes of donation after circulatory death recommenced. An international resurgence in DCD has occurred over the last decade.

There are a number of types of DCD:

- **Modified Maastricht Classification** (International nomenclature)
  - Category I Dead on arrival
  - Category II Unsuccessful resuscitation (French and Spanish predominant type)
  - **Category III** Waiting cardiac arrest (UK, USA, Netherlands and Australian predominant type)
  - Category IV Cardiac arrest in a brain dead donor.
  - Category V Unexpected cardiac arrest in a critically ill patient
  - (Categories I, II, and V are uncontrolled whilst Categories III and IV are controlled in the sense that the cardiac arrest is expected.)

In the UK, the predominant type of DCD is Category III or controlled DCD. This type of DCD usually involves a mechanically ventilated patient with overwhelming single organ failure, usually the brain, where a prior decision has been made to withdraw life-sustaining treatment because this is to the patient’s overall benefit. If there is a clinical expectation that the circulation will cease imminently upon the withdrawal of life-sustaining treatment (within 3 hours in the UK), DCD may be possible. If consent for organ donation is obtained during discussion with the family by the specialist nurse for organ donation (‘SNOD’), a surgical retrieval team is mobilised. Withdrawal only commences once the surgical team is prepared in theatre and recipients for the organs have been identified. The SNOD supports the family throughout this process. The time from family consent to withdrawal can be greater than 12 hours, and this can occasionally lead some families to revoke their consent.

Donation after circulatory death accounts for 40 per cent of all deceased organ donation in the UK, which along with the Netherlands, makes the UK a world leader in this type of donation.

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2 For further discussion on Modified Maastricht Classification, please see eg, Ana I Sanchez-Fructuosa et al ‘Renal Transplantation from Non-Heart Beating Donors: A Promising Alternative to Enlarge the Donor Pool’ (2000) 11(2) *Journal of the American Society of Nephrology* 350.
This rise has not occurred because more families are proportionally consenting to donation - there has been little change in the family consent rate in the UK over the last decade - but because more families are being approached by intensive care staff and being offered the end of life choice of donation for their loved one. The number of families approached regarding donation from 2007 until 2012 increased by 7 per cent for DBD but increased by a staggering 311 per cent for DCD resulting in a 170 per cent increase in the number of DCD donors (200 to 539 donors over the same five years).\(^3\) Since 2010, more families in the UK consent to DCD each year than DBD, though fewer overall patients progress ultimately to donation.

Such an increase is a direct result of a cultural shift in intensive care attitude and behaviours toward DCD against a background of negativity.\(^4\) While the reasons for this shift are multifactorial, the attempts to resolve the ethical, legal and professional challenges inherent to DCD has been a major contributor to the rise of DCD in the UK. A number of intensive care clinicians in the UK, including this author, once challenged the professional framework in which DCD was operating.\(^5\) In 2008 the Organ Donation Taskforce made 14 recommendations with the anticipation of a 50 per cent increase in donation over five years (successfully met in 2013).\(^6\) Recommendation 3 of the Taskforce report was

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.\(^7\)

The ambition of the Taskforce was to make organ donation a usual, not an unusual event in hospitals and that discussion about donation would become a normal part of all end of life care when appropriate.

Since 2008 in the UK, seven major ethical, legal and professional guidances have been published relating to deceased donation and DCD in particular. It is now this author’s opinion that the professional framework that underpins the DCD programme in the UK is the strongest in the world. This paper outlines the seven UK publications that justify this bold claim.

II THE TWO KEY ETHICAL PRINCIPLES IN DECEASED ORGAN DONATION

Before outlining the seven UK publications, it is worth stating what challenge they were written to answer. In no jurisdiction is there an organ donation and transplantation programme that does not attempt to address (perhaps not always successfully) two key ethical, legal and professional principles. These two principles are the Dead Donor Rule and what can be understood as the Consenting Donor Rule.

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\(^6\) Department of Health (UK), Organs for Transplants: A Report from the Organ Donation Taskforce (2008).

\(^7\) Ibid 9.
Within nine months of Christiaan Barnard performing the world’s first heart transplantation in Cape Town, South Africa in 1967, the Journal of the American Medical Association published two landmark papers, which provided the ethical framework necessary for the future of the emerging transplantation programme. The first paper was the report of the Ad Hoc Committee of the Harvard Medical School, which argued that irreversible coma, as met by their criteria, should be defined as a new criterion for death. The accompanying, but lesser cited paper, was a Judicial Council ethical guidance by the American Medical Association to its members and the wider public regarding the emerging technology of solid organ transplantation. Two ethical principles remained self-evident to the Judicial Council and have been fundamental in transplantation policy and debate ever since. Firstly the principle that would become the Dead Donor Rule, ‘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’. Secondly, ‘A prospective organ transplant offers no justification for relaxation of the usual standards of medical care’, and ‘full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory.’ This combined second principle can be understood as the Consenting Donor Rule.

The term, Dead Donor Rule (‘DDR’), was labelled as such by John Robertson in 1988. He described the DDR as the principle that ‘organs be removed only from dead patients,’ but its origin in the Judicial Council guidance is clear. Over the years, a number of alternative interpretations of the Dead Donor Rule have emerged. The first is a narrow reading, often endorsed in subsequent publications by John Robertson, where the DDR is interpreted to be a prohibition on killing the patient for organ donation. This interpretation would prohibit interventions that bring about the death of the patient in order to retrieve a vital organ and, in particular, those interventions that might bring about the death of the patient by removing a vital organ. From such a reading a proposal was recently published whereby dying but not deceased patients on an intensive care unit might be taken to theatre for kidney removal (analogous to DBD or living donation and therefore not requiring DCD), then returned to the ICU without their kidneys, for withdrawal of life sustaining treatment. Given that death following total kidney failure is likely to take a few days to occur, the death of the patient would follow the withdrawal of life sustaining treatment rather than the donation of the kidneys, and thus the DDR would still be satisfied. The author of this proposal identified that such a program is only suitable for kidneys as the removal of a heart, lungs or liver would rapidly lead to death in the donor.

A broad reading of the DDR would be that procedures for organ donation should not be initiated while the patient is still alive. Arthur Caplan in a New England Journal of Medicine Perspective Roundtable on Organ Donation after Cardiac Death, answered the question ‘What

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10 Ibid 342.
11 Ibid.
12 Ibid.
is the dead donor rule?’ by saying ‘[t]he dead donor rule says we take organs, vital organs, only from those who’ve been clearly, unequivocally pronounced dead. So nothing will happen in terms of procurement, requests, anything, until you’ve got a team that establishes death.’ In practice, controlled DCD, but not DBD, will always violate a broad interpretation of the DDR. Even at a minimum, the premortem interventions for a successful DCD must include referral to an organ procurement organisation, blood tests for tissue typing and virology, consent from families for the donation, delay in time and/or change of location of life-sustaining treatment withdrawal.

From these three readings of the DDR (standard - vital organs can only be removed from dead patients; narrow - prohibition against killing a patient in order to retrieve a vital organ; and broad - procedures for organ donation should not be initiated while the patient is still alive) it is easy to see the challenges inherent to DCD compared to DBD. In DBD, though still some debate persists about whether the donors are truly dead, there is legal acceptance in the UK that brain death is human death, satisfying a standard reading of the DDR. Likewise, nothing the clinicians do in DBD can be said to cause the death of the donor, satisfying a narrow DDR reading and there is no necessity to commence organ donation related activities until after the death has been declared, satisfying a broad DDR reading. In contrast in DCD, prior to 2008 there was no guidance on diagnosing death after cardio-respiratory arrest in the UK so that there was uncertainty over how long a clinician must wait before declaring death in DCD. If interventions such as the administration of the blood thinner heparin, as commonly used in the USA to prevent clots in donor organs, resulted in bleeding in a dying brain-injured patient and thereby hasten death, a narrow DDR interpretation, preventing the killing of patients, would also be breached. As explained above, DCD by practical necessity will never satisfy a broad DDR reading, as actions to plan and facilitate donation are required for many hours before death, and it was unknown if such actions pre-mortem were even legal in the UK.

While not explicitly stated as such, the Consenting Donor Rule is none-the-less addressed in every jurisdiction as to what legal standard is required for consent to donation. Even in systems of hard-presumed consent or where executed prisoners donate organs, the consent issue will have been addressed by a societal or governmental decision rather than at an individual or family level. In the UK, the Human Transplantation (Wales) Act 2013 came into force in December 2015 and will apply only in Wales for Welsh residents over 18 years of age. This change in law introduces the concept of deemed consent, a soft form of presumed consent. Unless a Welsh resident has opted out on the UK Organ Donor Register their consent for donation will be deemed but their families will still be approached, to ascertain if they knew of any expressed objection by the individual to donation. This emphasises that even legal changes to donation policy are referenced with respect to the need to address the Consenting Donor Rule. The impact deemed consent has on Welsh organ donation rates will be reported in September 2017.

All of the following seven guidances below and published in the UK after the Taskforce call in 2008 for resolution of the outstanding legal, ethical and professional issues in organ donation, can be seen as a response to the challenges raised by these two key principles to a lesser or greater degree.

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18 Gardiner and Riley, above n 5.
How The UK Overcame The Ethical, Legal And Professional Challenges In Donation After Circulatory Death

III  THE SEVEN MAJOR UK ETHICAL, LEGAL AND PROFESSIONAL PUBLICATIONS ON DECEASED ORGAN DONATION SINCE 2008

A  Academy of Medical Royal Colleges, Code of Practice for the Diagnosis and Confirmation of Death (2008)\(^{19}\)

This Code of Practice was the successor to previous versions and updated the Codes of Practice published in 1976, 1979, 1983 and 1998 for the diagnosis of death using neurological criteria. It was notable for being the first Code of Practice to provide guidance on the diagnosis of death following cardiorespiratory arrest (circulatory criteria) and the first code of practice to remove organ donation considerations from the guidance. The guidance is intended to be applicable to all deaths, not just the diagnosis of death for the purposes of organ donation – in contrast to guidance in the USA, Australia and most other countries with a DCD programme. The 2008 Code of Practice gave reassurance to intensive care doctors involved in DCD that by following national guidance on when to diagnose and confirm death after cardio-respiratory arrest, they were acting in accordance to the standard reading of the DDR, that deceased organ donors were dead.

B  Legal Guidance from All Four UK Jurisdictions on DCD (2009-2011)\(^{20}\)

All four UK governments have published legal guidance to guide clinical staff involved with DCD. Importantly the legal guidance recognised an important difference in DCD compared to DBD, namely, that the decision and interventions involved in DCD occur on living patients not deceased patients. As such the deceased donation legislation in the UK, the Human Tissue Act 2004 covering England, Wales and Northern Ireland,\(^{21}\) and the Human Tissue (Scotland) Act 2006,\(^ {22}\) which set out the legislative requirements for seeking consent and authorisation to donation for both living donation (where the donors have capacity) and deceased donation, were not applicable as guides for clinicians making decisions about organ donation for living but lacking capacity patients in the hours before death and potential DCD.

Instead, the legal guidance justified procedures to facilitate DCD by referring to other non-donation legislation, which is used to guide clinicians caring for patients without the capacity to make decisions for themselves: Adults with Incapacity (Scotland) Act 2000,\(^ {23}\) and the Mental Capacity Act 2005.\(^ {24}\) These Acts, their associated codes of practice and previous case law make it very clear in the UK that the present and past wishes and feelings of the adult with incapacity should be accounted for, including seeking the views of the nearest relative and the primary


\(^{21}\) Human Tissue Act 2004.

\(^{22}\) Human Tissue (Scotland) Act 2006.

\(^{23}\) Adults with Incapacity (Scotland) Act 2000.

carer of the adult, when deciding if an intervention is of benefit. As stated by the UK’s Department of Health:

Once it has been established that a person wanted to donate, either through direct knowledge of their wishes or as a result of discussions about what the person would have wanted, successful donation may be seen to be in the person’s wider best interests in a number of ways:
(a) by maximising the chance of fulfilling the donor’s wishes about what happens to them after death;
(b) by enhancing the donor’s chances of performing an altruistic act of donation; and
(c) by promoting the prospects of positive memories of the donor after death.25

The following steps were outlined as permissible to facilitate DCD:

2) Changing the patient’s location.
3) Maintaining physiological stability.26

In addition, ‘anything that places the person at risk of serious harm (such as systemic heparinisation) or distress (such as resuscitation) is unlikely ever to be in the person’s best interests in this situation.’27

In reference to the DDR, what this legal guidance offered clinicians was the assurance that, by not giving heparin, the narrow reading of the DDR (not killing patients) was fully satisfied. While the broad reading (procedures for organ donation should not be initiated while the patient is still alive) can never be satisfied in a controlled DCD programme, the legal guidance effectively sidestepped this issue by advancing the legal view that it was the Consenting Donor Rule that was the pre-eminent consideration in a living patient in the hours before their death. While the legal guidance has not been tested in court, subsequent publications in the UK have reinforced this conclusion. With the introduction of deemed consent in Wales from December 2015, the justification for activities to facilitate donation prior to death (if there has been no registration of an objection to donation) may have been legally strengthened in Wales.

C General Medical Council Guidance: ‘Treatment and Care towards the End of Life’ (2010)28

The General Medical Council (‘GMC’), which regulates medical practitioners in the UK, included the following statement in their 2010 end of life guidance: 29

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; and you should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator [specialist nurse - organ donation].30

25 Department of Health, above n 20, 8.
26 Ibid.
27 Ibid 11.
29 Ibid.
30 Ibid 42.
This guidance, by the regulatory body of doctors, effectively established a duty on UK doctors to explore donation at the end of life, where clinically appropriate, and to follow national professional guidance. The impact of this duty would be most felt by intensive care doctors who were the medical practitioners most likely to care for potential deceased organ donors. Again, the emphasis on patient wishes, or those wishes as interpreted by those close to the dying patient, are emphasised.

D Joint Professional Statement from the Intensive Care Society and the British Transplantation Society (2010)\(^{31}\)

This document stated unambiguous professional support from the UK Intensive Care Society for DCD and importantly gave professional support for admission to ICU purely for organ donation. This latter point was important in addressing ethical concerns with respect to the admission of dying patients into a scarce intensive care bed and the opinion that a dying patient’s interests were not advanced by ICU admission. This document provided guidance for intensive care clinicians before and after the patient’s death. After an experience in Australia was reported where the heart restarted during a lung DCD,\(^{32}\) this guidance was able to establish a safer practice for lung DCD, which has allowed lung DCD to rise to 16 per cent of all lung transplants in the UK, with outcomes comparable to DBD lungs.\(^{33}\)

E Joint Professional Statement from the College of Emergency Medicine and the British Transplantation Society (2011)\(^{34}\)

Up to 15 per cent of UK potential deceased organ donors are identified in the Emergency Department\(^{35}\) As such, Emergency Department health professionals have a vital role in identifying and referring to specialist nurses dying patients where it might be appropriate to explore the option of organ donation with their families. This joint statement provided professional support for the robust identification of potential donors in the Emergency Department and support for managing organ donation from the Emergency Department if admission to ICU is not possible (a common occurrence in the UK).

F Independent UK Donation Ethics Committee Guidance on DCD (2011)\(^{36}\)

Recommendation 3 of the Taskforce report included the need to establish an independent UK-wide Donation Ethics Group. The UK Donation Ethics Committee (‘UK DEC’) was established in January 2010, with support from all four UK governments and is hosted by the Academy of Medical Royal Colleges. The purpose of UK DEC is to provide independent advice and resolution on ethical aspects of organ donation and transplantation (but not to

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\(^{35}\) Accessed by the author from NHSBT statistics.

increase organ donation per se). Sir Peter Simpson was the inaugural chair of UK DEC and as well as having been a Past President of the Royal College of Anaesthetists, he had been the Chair of the Working Group that had authored the 2008 Academy of Medical Royal Colleges’ Code of Practice for the Diagnosis and Confirmation of Death. The first major publication by UK DEC was ethical guidance for DCD.

UK DEC identified two guiding principles to their work:

**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.37

Its DCD guidance, published in 2011,38 provided procedural and process ethical guidance for clinicians. Other ethics groups, like the British Medical Association,39 and the Nuffield Council on Bioethics40 have historically focused on big issues of public policy such as presumed consent and paying for the funeral expenses of donors, which were not directly applicable to a dying patient in an intensive care unit. UK DECs focus was on roles, responsibilities, and conflicts of interest. Key statements by UK DEC in their DCD guidance were that:41

- Contact between the clinical team treating the potential donor and the SNOD before the decision has been made to withdraw life-sustaining treatment is ethically acceptable.
- SNODs should not provide medical care to the potential donor whilst they are still alive.
- Two senior doctors, who should both have been registered for at least five years, and at least one of whom should be a consultant, should verify that further active treatment is no longer of overall benefit to the patient. It would be preferable for this to be the case for all patients, not only for those where organ donation is a possibility (although the UK DEC remit extends only to organ donation).
- Care should be in an appropriate environment and provided by staff with the appropriate skills and experience to deliver the end of life care plan.
- After death, it is acceptable for the treating clinician to take actions necessary to facilitate donation, e.g. tracheal re-intubation for lung DCD.

**G NICE Guidance on Organ Donation (2011)**42

The National Institute for Health and Clinical Excellence (‘NICE’) will in some topic areas set the expected standard of practice applicable in England, Wales and Northern Ireland, based on

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37 Ibid 6.
38 Ibid.
41 UK Donation Ethics Committee, above n 36.
a review of the international published medical evidence. Compliance to NICE guidance is auditable and reportable within hospitals.

The 2011 NICE, *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* guidance recommended:

- A triggered referral to a SNOD if there is a:
  - Plan to withdraw life-sustaining treatment.
  - Plan to perform brain stem testing.
  - Catastrophic brain injury (early referral), defined as the absence of one or more cranial nerve reflexes, e.g. one fixed pupil, and a Glasgow Coma Scale score of 4 or less that is not explained by sedation.
- That while assessing the patient’s best interests, the patient be clinically stabilised in an appropriate critical care setting while the assessment for donation is performed — for example, an adult intensive care unit or in discussion with a regional paediatric intensive care unit.
- A collaborative approach to the family for organ donation involving:
  - A specialist nurse for organ donation.
  - A local faith representative if appropriate.

### III Conclusion

When Joseph Murray carried out the world’s first kidney transplant in 1954, it looked like the world was going to change, and it has — but only by one donor at a time. In the UK, it may be a case of one ethical, legal and professional framework at a time. These seven publications outlined in this paper were an answer to the 2008 Recommendation of the Taskforce report to urgently resolve outstanding legal, ethical and professional issues in deceased donation in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. A clear focus of the publications was on resolving uncertainties in DCD. At their heart, they are professional guidance designed to answer how the UK satisfies the *Dead Donor Rule* and the *Consenting Donor Rule*. Whether they were successful in this endeavour will only be known in time but little else in intensive care medicine has received such robust attention, by such a wide body of experts, in such a short period.