Donation Actions Framework

For use in England, Wales and Northern Ireland

A Professional, Ethical and Legal Framework
for Deceased Organ Donation Actions.

Intensive Care Society

NHS
Blood and Transplant

The Faculty of Intensive Care Medicine

BTS
British Transplantation Society

Welsh Intensive Care Society
Cymdeithas Gofal Dwys Cymru

PCCS Paediatric Critical Care Society

NIICS

BACCN
British Association of Critical Care Nurses

Contents

Foreword 1

In 2018 the Welsh Government and the Department of Health and Social Care asked NHS Blood and Transplant (NHSBT) to work with the relevant stakeholder groups to review the current legal, ethical and professional framework for donation after circulatory death in the UK and obtain consensus on best clinical practice. It was recognised that it was now neither desirable nor practicable for the health departments to continue to publish guidance and it would be much more appropriate for the national professional bodies and healthcare agencies that have responsibility for organ donation and transplantation to issue guidance consistent with the law. The Human Tissue Authority (HTA), the regulator of human tissue and organs in England, Wales and Northern Ireland, shares this view.

To this end, NHSBT worked with support from the Intensive Care Society to create a widely representative executive. A stakeholder event was held on the 7th November 2019 in Birmingham but further progress was delayed by the onset of the COVID-19 Pandemic. When work recommenced in 2021 a writing group including representatives from multiple professions covering the whole donation and transplant journey was convened. Representatives of the Scottish Intensive Care Society and Scottish Department of Health have supported this work from its inception, but in Scotland a different approach has been taken with Scottish government guidance on "pre-death procedures" as part of deemed authorisation legislation. The resulting Framework is therefore applicable in England, Wales and Northern Ireland.

Donation Actions are defined in the Framework as: activities or interventions carried out in relation to a potential organ donor, either before or after death, for the purpose of exploring donation eligibility, facilitating deceased organ donation, increasing organ utilisation, and/or optimising transplant outcomes. Donation actions can range in complexity from simple activities like checking the NHS Organ Donor Register or talking to family about a person's willingness to be an organ donor after death, to more complex interventions such as investigations to ascertain suitability for donation or after death procedures to enhance organ function.

The professional, ethical and legal foundation that all deceased donation is built upon is always to act in the best interests of the patient. This ethos is fundamental to the Framework and is achieved by explicitly incorporating and referencing previous published UK guidance from government bodies and from professional organisations including the General Medical Council, National Institute for Health and Clinical Excellence, and the former UK Donation Ethics Committee. Additionally, the Framework outlines a multi-professional agreement on how new donation actions should be incorporated into clinical practice in the future.

We commend it to you.

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Foreword 2

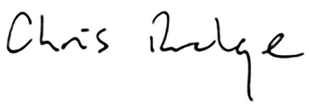
The UK Donation Ethics Committee (UKDEC) was an independent committee, hosted by the Academy of Medical Royal Colleges and funded by all four UK health departments. It ran from 2010-2016 and was established following a recommendation of the Organ Donation Taskforce that:

> "*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 purpose of UKDEC was to address the ethical questions that arise in organ donation, in order to remove barriers to effective decision-making in donation and transplantation. It promoted ethical practice but did not seek to increase the number of donations per se. In its time UKDEC published ethical frameworks for donation after circulatory death and donation after confirmation of death using neurological criteria, position statements on paediatric organ donation and donor recipient research consent, and discussion papers on involving the family in deceased organ donation and non-therapeutic elective ventilation. A key area of guidance UKDEC was developing at the time of its closure was an ethical framework for interventions before death to optimise donor organ quality and improve transplant outcomes.

We take great satisfaction from seeing the legacy of UK DEC incorporated into this expanded and comprehensive Donation Actions Framework. Organ donation can present many difficult ethical dilemmas and the need for a single formal body to which clinical staff may turn for advice and resolution remains just as necessary as it did in 2010. We therefore wholeheartedly support the recommendation in the Framework that the UK actively pursue the re-establishment of a donation and transplantation ethics advisory group.

Dr Sir Peter Simpson
Chair UKDEC, 2010-2013



Prof Chris Rudge
Chair UKDEC, 2014-2016

Dedication

To all Organ and Tissue donors and their families. The brave decision made by the families in the time of great tragedy and the Gift of Life given by the donors can change the lives of so many people. A light goes out but in the distance a glow appears through their legacy. They are remembered with pride by all those who loved them and held in honour by the recipients of a very special gift.

This document will help to ensure that the decisions of donors and their families are fulfilled.

Donor Family Network

Terminology

Clinical Stabilisation.

The use of intensive care treatments and interventions to maintain patient physiological stability while allowing time to assess best interests and donation potential.

Diagnosis and confirmation of death.

The determination of death by health care professionals using either **circulatory** (cardio-respiratory) **criteria** after cardiorespiratory arrest, or **neurological** criteria (DNC) in mechanically ventilated patients after devastating brain injury. The procedures required to satisfy these criteria are set out in the 2008 Academy of Medical Royal Colleges' Code of Practice for the Diagnosis and Confirmation of Death (AoMRC 2008) and for infants less than 2 months old in whom death is being diagnosed by neurological criteria, the 2015 recommendations of the Royal College of Paediatrics and Child Health (RCPCH 2015).

Donation actions.

Activities or interventions carried out in relation to a potential organ donor, either before or after death, for the purpose of exploring donation eligibility, facilitating deceased organ donation, increasing organ utilisation, and/or optimising transplant outcomes.

DBD

An acronym for 'donation after brain(stem) death'. Organ donation that takes place following the diagnosis of death using neurological criteria (DNC). In DBD, deceased donors have intensive care treatments continued after death is confirmed so that the heart, kidneys and other organs are supported, optimised and remain functioning up to the point that the donor's organs are retrieved.

DCD

An acronym for 'donation after circulatory death'. Organ donation that takes place following the diagnosis of death using circulatory criteria.

- **Controlled Donation after Circulatory Death (DCD).**
  In the UK, DCD involves a mechanically ventilated patient with overwhelming single organ failure, usually the brain, where a decision is made to withdraw life-sustaining treatment. Once consent for organ donation is confirmed following discussion with the patient's family by a Specialist Nurse for Organ Donation (SNOD), a surgical retrieval team is mobilised. Withdrawal of life sustaining treatment only commences once the surgical team is prepared in theatre and recipients for the organs have been identified. This type of DCD is called 'controlled' DCD because the death is expected, and the surgical team are already prepared.

- **Uncontrolled Donation after Circulatory Death (uDCD)**.
  A version of DCD carried out in other countries and historically in specific centres in the UK. It involves organ retrieval following an unexpected death, hence the term 'uncontrolled' compared to a planned, 'controlled' withdrawal of life-sustaining treatment. The usual case involves failed cardiopulmonary resuscitation either in the Emergency Department or in the community. Currently, this version of DCD is not practised in the UK but a pilot in Edinburgh occurred 2014-2015. A supplementary donation actions framework on uDCD is planned.

Donor Optimisation.

Interventions in a consented potential donor to increase organ utilisation and optimise transplant outcomes.

End of Life Care.

Care delivered by health care professionals to a potential or actual donor encompassing the time before and after death.

Family.

The term family should be taken to mean people involved in the end of life care of an individual, who may be able to provide information about them and their decision with regard to organ and tissue donation. Family encompasses those in a qualifying relationship to the deceased person immediately before death and may also include other family members, close friends and those who may have been familiar with the faith and beliefs of the potential donor.

Non-therapeutic elective ventilation (NTEV).

The instigation of invasive ventilation for the sole purpose of facilitating organ donation with no expectation of therapeutic benefit for the person ventilated.

National Organ Retrieval Service (NORS).

A commissioned service of abdominal and cardiothoracic surgical teams that perform organ retrieval or organ recovery in a donor hospital. The team usually includes the following members: lead surgeon, surgical assistant, organ preservation practitioner, theatre practitioner and a scrub practitioner.

Organ recovery procedures.

Strategies and interventions that seek to repair organ injury, often caused by the dying process, thereby increasing organ utilisation and optimising transplant outcomes. At present these procedures take place either during organ retrieval in the donor after death (in-situ) or on the organ following retrieval from the donor with machine perfusion (ex-situ).

Organ retrieval.

Organ retrieval is the process of surgical removal of an organ from a deceased donor in theatre. Terms such as ‘procurement’ or ‘harvest’ can be offensive to donor families and should not be used.

Withdrawal of life sustaining treatment.

The discontinuation of intensive care treatments and interventions, after a best interests decision to do so, where the condition of the patient is such that death is expected to follow. It is advised to avoid the phrase ‘withdrawal of care’.

Executive Summary

Background

This document, 'A Professional, Ethical and Legal Framework for Deceased Organ Donation Actions' (Donation Actions Framework) relies on, incorporates and is built upon the previous published UK guidance produced by multiple professional organisations. The need for updated guidance was driven by the recognition of several factors. Previous guidance on donation actions had become impractical due to the large number of different but related publications. Aspects of public and professional opinion and practice have changed regarding the acceptability of some donation actions over the last decade. New opt-out legislation in the UK has provided the opportunity to explore how donation actions can contribute to facilitating safe, respectful and high quality organ donation and transplantation. Technology has evolved significantly with the development of techniques for organ recovery following death. The application of such technologies was not covered adequately in existing guidance.

The Donation Actions Framework explores donation actions within the context of a valid and appropriate diagnosis and confirmation of death and valid and appropriate consent for organ donation, where robust Codes of Practice already exist by the Academy of Medical Royal Colleges and the Human Tissue Authority respectively.

The purpose of the Framework is to:

a) Summarise into one document the current professional, ethical and legal guidance for donation actions under which deceased organ donation should be practised in England, Northern Ireland and Wales.

b) Establish a process that allows the assessment of new Donation Actions, and if they are agreed to be professionally, ethically, and legally acceptable, enables them to be incorporated into future practice.

Donation actions are activities or interventions carried out in relation to a potential organ donor, either before or after death, for the purpose of exploring donation eligibility, facilitating deceased organ donation, increasing organ utilisation, and/or optimising transplant outcomes. Donation actions can range in complexity from simple activities like checking the NHS Organ Donor Register or talking to family about a person's willingness to be an organ donor after death, to more complex interventions such as investigations to ascertain suitability for donation or after death procedures to enhance organ function. In general terms it will be seen that donation actions that are acceptable before consent for organ donation are equally acceptable after consent; and donation actions after death are usually less ethically complex than actions before death.

While some of the broad principles in this Framework apply equally, there are sufficient legal differences for it not to be applicable to Scotland; therefore, the Framework is for use in England, Wales and Northern Ireland.

Structure

Conceptually the Framework categorises donation actions depending on two variables in time:

1. **Whether the patient is deceased.**
2. **Whether there is consent for organ donation.**

This results in four professional, ethical and legal categories where donation actions can occur (see Section 4 for details):

1. **Before death and before consent.**
2. **Before death and after consent.**
3. **After death and before consent.**
4. **After death and after consent.**

Applicable actions at each stage will depend on numerous factors, in particular whether donation is expected to occur after death confirmed using neurological criteria (DBD) or circulatory criteria (DCD).

Guidance

The prime principle of the Framework is to assess whether a proposed donation action is in the best interests of the potential donor by balancing potential benefits against potential harms which cannot be avoided or mitigated. For proposed actions that can be carried out on, or on behalf of, the potential donor, the Framework balances these potential benefits and harms to offer professional, ethical and legal guidance on each action. It does this by categorising each potential action as either:

a) **Very likely** to be in the patient's best interests.

b) **Likely** to be in the patient's best interests.

c) **Unlikely** to be in the patient's best interests.

d) A**gainst current professional, ethical or legal guidance.**

These categories do not, except the last, dictate the action that should be taken by the decision maker. They should be taken alongside an assessment of the strength of desire to donate from the potential donor, including information gathered from discussion with the patient's family, to guide the professional in making a decision in individual circumstances.

The categories, and common and proposed donation actions which would fit into each category, are set out in **Table 1**.

Roles and Responsibilities

The Framework provides guidance as to the responsibilities of professionals involved in the facilitation of organ donation and addresses areas of potential conflict of interest (see Section 5 for details). Key groups with specific responsibilities include:

Health care professionals in the donor hospital

Clinical staff caring for the potential donor are the primary decision makers in best interests decisions. They are responsible for confirmation of death and share the care of the donor with the retrieval team after death.

Specialist nurses for organ donation

Specialist nurses for organ donation have a primary obligation to the donor and their family rather than the transplant teams. The specialist nurse works with donor families to seek consent for donation, ascertain the strength of the donor's willingness to donate, and will continue to have an essential contact role with the family to support any decision to donate throughout the donation process.

Clinical leads for organ donation

Clinical leads for organ donation have a managerial role in promoting and facilitating donation, rather than a clinical role in transplant. As such they can care for, and make decisions on behalf of, a potential donor.

Organ retrieval teams

Organ retrieval teams must not be involved in the decision to withdraw life-sustaining treatment, the diagnosis and confirmation of death, and can only perform pharmacological or treatment interventions on the donor after death. They can provide information to inform a best interests decision around a proposed donation action but must not make the decision. After death the care of a donor is shared between the donor hospital clinical team who treated the patient in life and the team who are carrying out the organ retrieval procedure. Retrieval teams must ensure that cerebral perfusion is not restored at any point following a diagnosis of death using circulatory criteria.

The future

Technology, guidance and the law around organ donation changes frequently and for a working document to remain up to date there must be a mechanism for future proposed donation actions to be incorporated into the Framework (see Section 6 for details).

The Framework recommends that new proposed donation actions should be considered by NHS Blood and Transplant's Research, Innovation and Novel Technologies Advisory Group (RINTAG) to provide scientific justification; the muti-professional represented National Organ Donation Committee (NODC) to consider the burden of any proposed donation action on the donor, their family and the donor hospital; and NHS Blood and Transplant's Organ and Tissue Donation and Transplantation Directorate to assess and manage operational feasibility.

Where required, particularly if novel or finely balanced, new donation actions may need review and input from an even wider stakeholder engagement exercise. The Framework recommends that the UK actively pursue the re-establishment of a donation and transplantation ethics advisory group.

The Donation Actions Framework

1.0 Introduction

1.1 It is now well established in the United Kingdom (UK) that where deceased organ donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying or deceased patient (GMC 2010, UK DEC 2011).

1.2 Donation actions are activities or interventions carried out in a relation to a potential donor, either before or after death, for the purpose of exploring donation eligibility, facilitating deceased organ donation, increasing organ utilisation, and/or optimising transplant outcomes.

1.3 Organ donation and transplantation is highly complex and usually occurs at a time of great emotional distress to families. Therefore, it is vital that there is clear and accessible consensus guidance when considering the appropriateness of any given donation action. Moreover, any guidance must engender trust.

1.4 The purpose of this framework is to:

a) **Summarise** into one document the current professional, ethical and legal guidance for donation actions under which deceased organ donation should be practised in England, Northern Ireland and Wales.

b) **Establish a process** that allows the assessment of new Donation Actions, and if they are agreed to be professionally, ethically, and legally acceptable, enables them to be incorporated into future practice.

1.5 The intended audience of this Donation Actions Framework is specialist nurses in organ donation, emergency medicine and intensive care staff or other clinical staff who may be involved in caring for a potential donor, or planning this care, in England, Northern Ireland and Wales. It is also relevant to National Organ Retrieval Service teams and transplant clinicians accepting donated organs for transplant.

1.6 There are significant legal differences in Scotland, particularly regarding the legal concept of 'benefit' (Adults with Incapacity (Scotland) Act 2000) compared to 'best interests' in England, Wales and Northern Ireland. Additionally, the Human Tissue (Authorisation) (Scotland) Act 2019, establishes a category in law of Pre-Death Procedures relevant to deceased donation. While some of the broad principles in this framework overlap, there are sufficient differences for it not to be applicable to Scotland in its current form.

1.7 This framework was written with wide stakeholder engagement and endorsement (see Acknowledgements).

1.8 The need for this updated framework was the recognition of several factors. Previous guidance on donation actions had become impractical due to the large number of different but related publications. Aspects of public and professional opinion and practice have changed regarding the acceptability of some donation actions over the last decade. New opt-out legislation in the UK has provided the opportunity to explore how donation actions can contribute to facilitating safe, respectful and high quality organ donation and transplantation. Technology has evolved significantly with the development of techniques for organ recovery following death. The application of such technologies was not covered adequately in existing guidance.

1.9 A key historic document on donation actions was the Department of Health and Welsh Government legal guidance document published in 2009 (DH 2009). Before its closure in 2016, the UK Donation Ethics Committee (UK DEC) had called for the Department of Health and Welsh Government to update this element of its guidance. This led to these two bodies withdrawing their DCD legal guidance document in 2018 to allow for national professional bodies and healthcare agencies, that have responsibility for organ donation and transplantation, to issue guidance in this area that is consistent with the law. This document therefore updates and replaces the 2009 Department of Health and Welsh Government legal guidance document.

1.10 Similarly, the Human Tissue Authority (HTA) considers that it is appropriate that other national professional bodies and healthcare agencies, who have responsibility for, or are involved in organ and tissue donation, issue guidance consistent with the law, ethics and best clinical practice (HTA Code F Part two 2020).

1.11 Conceptually this framework categorises donation actions depending on two variables in time:

1. **Whether the patient is deceased.**
2. **Whether there is consent for organ donation.**

This results in four professional, ethical and legal categories where donation actions can occur:

1. **Before death and before consent** (Section 4.1)
2. **Before death and after consent** (Section 4.2)
3. **After death and before consent** (Section 4.3)
4. **After death and after consent** (Section 4.4)

1.12 This framework relies on, incorporates and is built upon previous published UK guidance. Appendix A summarises how this guidance has been applied in each of the four conceptual donation action categories.

1.13 The diagnosis of death must always be carried out in accordance with the Academy of Medical Royal Colleges Code of Practice for the Diagnosis and Confirmation of Death (AoMRC 2008) or any successor Code. For infants less than 2 months old in whom death is being diagnosed by neurological criteria, the 2015 recommendations of the Royal College of Paediatrics and Child Health (RCPCH 2015), or any successor document, must be followed. This framework assumes that any diagnosis of death is valid and was carried out appropriately.

1.14 How consent for organ donation is gained is summarised in Section 2. This framework assumes that any consent gained for deceased organ donation is valid and was obtained appropriately.

1.15 This framework therefore explores donation actions within the context of a valid and appropriate diagnosis and confirmation of death and valid and appropriate consent for organ donation.

1.16 Donation actions can range in complexity from simple activities like checking the NHS Organ Donor Register or talking to family about a person's willingness to be an organ donor after death, to more complex interventions such as investigations to ascertain suitability for donation or after death procedures to enhance organ function. In general terms it will be seen that donation actions that are acceptable before consent for organ donation are equally acceptable after consent; and donation actions after death are usually less ethically complex than actions before death.

1.17 This framework is applicable to the two types of deceased organ donation practised in the UK, DBD (donation after brain(stem) death) and controlled DCD (donation after circulatory death). Uncontrolled DCD is currently not practised in the UK but has been in the past and is common in some countries. A supplement to this framework, covering uncontrolled DCD, is planned.

2.0 Consent for Organ Donation

2.1 This section summarises the law around consent for organ donation. Specifically, this covers the following statutes – Human Tissue Act 2004 covering England, Wales and Northern Ireland; Human Transplantation (Wales) Act 2013; Organ Donation (Deemed Consent) Act 2019 covering England, also known as Max and Keira's law. There are two relevant Codes of Practice from the Human Tissue Authority (HTA) – one for Wales the HTA Code of Practice on the Human Transplantation (Wales) Act 2013 (HTA Code Wales 2020) and one for England and Northern Ireland the HTA Code of Practice F, Part two: Deceased organ and tissue donation (HTA Code F Part 2 2020) – which provide guidance to Specialist Nurses for Organ Donation and others who seek consent for deceased organ and tissue donation.

2.2 The NHS Organ Donor Register (ODR) operates throughout the UK to allow individuals to record their decision about organ and tissue donation or nominate/appoint a representative. The ODR allows people to record whether they want to donate all, some, or no organs and tissue.

The ODR allows the following decisions to be recorded:

a) I consent to donate all my organs and tissue after death;

b) I consent to donate some (specified) organs and tissue after death; or

c) I do not consent to donate my organs and tissue after death.

d) Whether faith and/or beliefs are important to the individual in relation to organ donation. The text on the ODR reads, "I would like NHS staff to speak to my family and anyone else appropriate about how organ donation can go ahead in line with my faith or beliefs".

2.3 As long as a potential donor registered on the ODR voluntarily, had the information they needed to make the decision to register and had mental competence or capacity when they registered, then the record on the ODR constitutes valid and appropriate consent at the time of registration. For children this is a test of competence, for adults it is capacity (HTA Code F Part two 2020).

2.4 Types of Consent for Organ Donation

a) **Expressed consent from an individual in life.** This can be verbally or in writing, such as registering on the ODR.

b) **Expressed consent from a nominated/appointed representative** who makes a decision on the individual's behalf after death.

c) The consent is **deemed** (applicable in Wales and England) – see 2.6.

d) A person in a **qualifying relationship** (a ranked hierarchy of relationships established in the Human Tissue Act 2004) makes a decision on the individual's behalf.

2.5 **Expressed consent** from an individual in life is sufficient to allow organs and tissue to be retrieved for transplantation where they have decided to donate. Similarly, in circumstances where they have decided not to donate, donation cannot proceed. There is no legal right for anyone in a qualifying relationship to revoke a legally valid decision to give or withhold consent (HTA Code F Part two 2020).

2.6 **Deemed Consent.** In England and Wales, all individuals aged 18 and over are considered potential organ and tissue donors after death unless they:

a) Make a decision that they do not want to be a donor.

b) Have nominated/appointed a representative to make a decision on their behalf after death.

c) Are an excepted adult. An excepted adult is a person who had not been ordinarily resident in that nation for a period of at least 12 months immediately before their death; or who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

An important point to state is that a person who had expressed consent for organ donation, either verbally or in writing, cannot have their consent deemed.

Deemed consent only applies to certain organs and tissues for transplantation and does not apply to novel transplants and/or research. Novel transplants are those that are new and are usually at a research or practical evaluation stage, or have gone through research and service evaluation stages, but are still rare and unusual. Examples of novel transplants would include face, hand, limb or uterus.

For detailed information on how deemed consent is applied in England visit:
HTA Code F part two: Deceased organ and tissue donation

For detailed information on how deemed consent is applied in Wales visit:
HTA Code of Practice on the Human Transplantation (Wales) Act 2013

In Northern Ireland the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 has passed but has yet to be implemented. Implementation is planned for the Spring of 2023 and a new HTA Code of Practice is being developed for use in Northern Ireland. The legislation closely mirrors that found in England and Wales, so it is expected that this Framework will remain fully applicable.

2.7 While the presence of appropriate consent permits organ and tissue donation to take place, it does not mandate that it must proceed.

2.8 The family play a crucial role in the donation process. The role of the family is to help establish the last known decision of the individual with regard to donation. With respect to consent to organ donation, the nature of the role of the family will depend on a number of factors including whether consent has been expressed by the potential donor in life, whether the circumstances are such that consent may be deemed, or whether a person in a qualifying relationship will be asked to make the decision.

2.9 The individual leading the approach to the family for organ donation must be suitably trained and qualified, have the time to support the family and have sufficient knowledge and skills to sensitively answer any questions. The HTA is of the opinion that specialist nurses are the most suitable person to lead a donation discussion with the family, working in collaboration with the treating clinical team (HTA Code F Part two 2020).

2.10 Where the potential donor is a child, consent cannot be deemed and donation can only proceed where consent has been expressly given either by the child before their death, providing the child was competent when the consent was expressed, or by a person with parental responsibility. If there is nobody with parental responsibility, consent can be given by a person in a qualifying relationship. A child cannot appoint or nominate a representative in England, but the Human Transplantation (Wales) Act 2013 allows them to do so in Wales.

2.11 Appropriate consent for organ donation, in isolation, is insufficient to guide all donation action decisions.

This is because:

a) Interventions before death are governed by the Mental Capacity Act 2005 (England/Wales) and the Mental Capacity (Northern Ireland) Act 2016 (Northern Ireland), rather than the Human Tissue Act 2004 and Human Transplantation Act (Wales) 2013.

b) The Acts and associated Codes are mostly silent on permissible actions before death (see 2.12).

c) The law permits organ donation after death; it does not mandate that it should occur or how it should occur.

d) Organ donation is a process that can carry professional, ethical and legal expectations prior to the completion of any necessary consent documentation.

2.12 Except for the taking and storage of blood samples the HTA does not specifically address the permissible donation actions which may be taken prior to the death of a potential donor who may become a donor after death. The HTA Code states that blood samples should only be taken in cases where expressed consent for donation has been given (by the potential donor, their nominated representative or someone in a qualifying relationship) or consent has been deemed (which could only occur following discussion with the family).

3.0 Guiding Professional, Ethical and Legal Principles

3.1 Patients who are potential organ donors will almost always lack the capacity to make their own contemporaneous treatment decisions because they are unconscious. This framework assumes the potential organ donor lacks capacity and is mechanically ventilated unless stated otherwise. If the patient has capacity, explicit consent from the patient for organ donation and any required actions must be sought.

3.2 The diagnosis of death must always be carried out in accordance with the Academy of Medical Royal Colleges Code of Practice for the Diagnosis and Confirmation of Death (AoMRC 2008), or any successor code. The Code states that **'it is inappropriate to initiate any intervention that has the potential to restore cerebral perfusion after death has been confirmed'**. For infants less than 2 months old in whom death is being diagnosed by neurological criteria, the 2015 recommendations of the Royal College of Paediatrics and Child Health (RCPCH 2015), or a successor document, must be followed.

3.3 Any decision about the benefit of further treatment and whether or not such treatment should be withdrawn must be made purely in the best interests of the patient and independently of any consideration of possible organ donation (DH 2009). These decisions should be made transparently and consistently (ICS/BTS 2010, FICM 2019).

3.4 Where donation is likely to be a possibility, full consideration should be given to the matter when caring for a dying or deceased patient (GMC 2010, UK DEC 2011).

3.5 Even if there is a willingness on the part of the patient and family for donation to occur, it is never mandated. Donation must always be balanced against resource and the care of other patients. This would include patients in the same hospital as the potential donor but also patients elsewhere in the UK, who may be no less affected by the decision to proceed or not proceed with donation. This can make the decision difficult and requires an open consideration of the wider consequences.

3.6 Before death has been confirmed, including the period of time between the two sets of brain stem tests when death is diagnosed using neurological criteria, the Mental Capacity Act 2005 in England and Wales, and the Mental Capacity (Northern Ireland) Act 2016 in Northern Ireland, govern decisions about the care of a patient who lacks capacity (MCA 2007, UK DEC 2016a).

3.7 The Mental Capacity Act allows health professionals to treat someone who lacks capacity, provided that they reasonably believe their actions to be in the person's best interests (MCA 2007, DH 2009). The courts have established that best interests are wider than simply treating a person's medical condition and include a person's social, emotional, cultural and religious interests. It has also been held that "best interests" are not restricted to the person's "self-interest" and "could include altruistic sentiments and concern for others"; nor is it necessary for the patient to be aware of the fact that his or her wishes have been carried out for something to be in the person's best interests.[1]

1 Case law example: In the Matter of G (TJ) [2010] EWHC 3005 (COP) (particularly paragraph 35, 43, 56)

3.8 Importantly, the courts have held that some:

"*best interests do not cease at the moment of death. We have an interest in how our bodies are disposed of after death, whether by burial, cremation or donation for medical research. We have… an interest in how we will be remembered… we have an interest in being remembered as having done the "right thing", either in life or, post mortem.*"[2]

3.9 An assessment of a person's best interests takes into account not only the risks and benefits of a proposed intervention, but also its wider emotional, psychological and social aspects (HTA Code F Part two 2020). Therefore, a clinician needs to consider not only all the factors relevant to the patient's medical condition but also consult their family to take full account of the person's previously expressed wishes, general preferences and beliefs including how they might wish to act altruistically to others and how they might wish to be remembered (DH 2009).

3.10 Additionally, the patient's family and others close to them, their memories of the death, and of the person who has died, may be affected by the way in which healthcare professionals behave at this very difficult time (GMC 2010).

3.11 Since best interests do not come to an end after death, professional responsibility to the patient does not come to an end after death (GMC 2010, UK DEC 2016a). After death the responsibility for care of a potential donor is shared between the clinical team who treated the patient in life and the team who are carrying out the organ retrieval procedure.

Both teams have a responsibility to ensure that (UK DEC 2011):

a) The potential donor receives appropriate care.

b) The potential donor is treated with dignity and respect.

c) The potential donor's best interests are respected.

d) The potential donor's family is kept informed.

e) No conflicts of interest arise which interfere with a)-d).

3.12 There are a number of factors to consider when assessing a patient's best interests, including (MCA 2007, DH 2009):

a) The patient's known decisions or views.

b) The beliefs or values that would be likely to influence the patient's decision if they had the capacity to make it.

c) Any other factors they would be likely to consider if they were able to do so.

d) The views of the patient's family, friends and anyone involved in their care as appropriate as to what would be in the patient's best interests.

e) Anyone named by the patient to be consulted about such decisions.

2 Case law example: In Re M [2009] EWHC 2525 (Fam) (paragraph 38).

3.13 It is therefore essential to establish a patient's decisions, views and beliefs regarding organ donation, either through knowledge of recorded decisions (for example, by registration on the ODR or through an assessment of what the individual would have been willing to do (for example through the patient's family and their knowledge of them) (DH 2009)).

3.14 While registration on the ODR provides consent for donation after death for the purposes of the Human Tissue Act(s), it cannot be viewed as advance consent to actions to facilitate donation that may occur before death. It would, however, be important evidence of a patient's willingness to donate (DH 2009).

3.15 The role of the family is to help establish the decision of the individual with regard to donation (HTA Code F Part two 2020). Families must be sensitively supported while making these decisions and throughout the donation process (UK DEC 2016b).

3.16 To be an organ donor after death, adjustments will be needed to end of life care as well as specific donation actions (UK DEC 2016a).

3.17 In assessing whether any proposed donation action is in the best interests of the patient, the clinical team need to consider a **balance** between the potential benefits of that action and any potential harms which cannot be prevented or alleviated.

3.18 Before the balancing process is undertaken in relation to a particular donation action (UK DEC 2014a):

a) There should be a clear **justification** for the donation action in terms of its potential to optimise donor organ quality and improve transplant outcomes. If an action is routinely undertaken but the evidence for its potential to optimise donor organ quality and improve transplant outcomes is weak, then the potential for benefit from the action will be proportionately reduced. However, where the evidence for an action's potential to optimise donor organ quality and improve transplant outcomes is strong, then the potential for benefit from the action will be proportionately increased.

b) Where there is genuine uncertainty about whether an action has the potential to optimise donor organ quality or improve transplant outcomes, clinical research and service evaluation should, where possible, be undertaken.

c) The **minimum** level of intervention on the donor should be used that is required to facilitate optimal transplant and recipient outcomes.

3.19 **Potential benefit.** Potential benefits may accrue to the patient by facilitating their willingness to be an organ donor, including actions aimed at optimising the successful use of retrieved organs (UK DEC 2014a).

Examples of potential benefit include (DH 2009):

a) Maximising the chance of fulfilling the donor's decisions about what happens to them after death.

b) Enhancing the donor's chances of performing an altruistic act of donation.

c) Promoting the prospects of positive memories or legacy of the donor after death.

3.20 **Potential harm.** Some donation actions may potentially cause harm or distress to the patient (DH 2009, UK DEC 2014a). Many, but not all, of these potential harms can be treated or mitigated against.

Examples of potential harms or distress include:

a) Worsening of the patient's medical condition (DH 2009).

b) Shortening of the patient's life (DH 2009).

c) The undesirable physical effect that may be caused by an intervention, such as the risk of unpleasant side-effects of a medication, pain or discomfort from an invasive procedure, and distress (DH 2009, UK DEC 2011).

d) Emotional distress could include feelings of suffocation, choking, gasping, panic, weakness, isolation, loneliness and invasion of privacy (UK DEC 2014a).

e) Doing wrong to the patient by ignoring their expressed desires for end of life care or to become an organ donor after death (UK DEC 2011).

f) Causing distress to the patient's family or friends (UK DEC 2014a).

3.21 Once the patient has died, the concept of physical harm is no longer relevant (UK DEC 2016a). However other potential harms remain and may include concerns about bodily integrity, not respecting values, beliefs and wishes held in life, and causing distress to those close to the deceased. As stated above, the courts have held that some best interests do not end at the moment of death (3.8).

3.22 The risk of causing distress to the patient's family may be affected by factors such as the level of intrusiveness of the intervention or the impact on their ability to spend time with their loved one. Careful explanation of both the need for particular interventions in order to facilitate the patient's desire to be a donor and what is involved in those interventions can help reduce this risk.

3.23 Blood and other samples (e.g., urine or sputum) are property over which the patient is entitled to exercise control (DH 2009). Taking blood from a person who lacks capacity must be carried out in line with the MCA and will only be lawful if it would be in that person's best interests (DH 2009). This will include considering if the person wanted to be a donor and whether these steps contribute to fulfilling that desire. Clinicians will also need to consider the risk of any harm or distress that may be caused to the person, including consideration of the information the tests may generate (DH 2009). The HTA provides specific guidance for the timing of blood and other samples for organ donation (HTA of Practice F Part two 2020).

3.24 Donation actions must not compromise respectful treatment. In particular, cultural and religious views in life must be respected (UK DEC 2016a).

3.25 The **strength of the person's willingness to donate will play an important role**. Clinical teams must balance the risk of harm or distress against the knowledge that they have regarding a person's willingness to donate (DH 2009).

a) In the balancing assessment for any donation action, the wider social, emotional, cultural and religious interests should be considered.

b) Information from the patient's family and friends will help clinical teams to understand the strength of the patient's willingness to donate and what degree of intervention they might have been willing to accept (UK DEC 2014a).

3.26 The stronger the evidence of a patient's willingness to become an organ donor, the greater the weight this should be given in assessing whether a particular donation action would be in their best interests. If, for example, a patient has provided consent to a particular donation action in advance of the loss of capacity, this should be regarded as compelling evidence that the action would be in their best interests unless it would cause them harm or distress (or a significant risk of harm or distress) which cannot be mitigated (UK DEC 2014a).

3.27 Some donation actions may cause potential harm but never-the-less remain in the best interests of a person willing to be an organ donor after death. For example, puncture wounds caused by taking blood samples for tissue typing purposes are assumed to be in accordance with a person's desire to become a donor (UK DEC 2014a).

3.28 On the other hand, some donation actions pose a risk of harm that may outweigh even a strong desire to become a donor (UK DEC 2014a). A clinician would need compelling reasons to consider donation actions that place the person at risk of serious harm or distress. In these circumstances a declaration from the Court may be necessary (DH 2009).

3.29 Decision-makers must balance the evidence of a person's willingness to donate, along with the potential benefits and harms of any proposed donation action. The depth of consideration the person had given to the decision and the strength of their desire to be a donor after their death will not be discovered simply by consulting the ODR, and decision-makers will need to explore what is known about the strength of the person's willingness to be a donor in more depth by talking to those closest to them. Appropriate consent to donate is only a starting point for seeking further information about their decisions, values and beliefs in relation to organ donation. Such information will enable clinicians to make a full and considered judgement as to what degree of donation actions will be in the best interests of the person (UK DEC 2014b).

3.30 Regardless of the type of consent to organ donation the fact that a proposed donation action is legally permissible does not make it mandatory, or automatically in the best interests of the patient. Donation actions still need to rely on the balancing process as outlined above. In practice, establishing appropriate consent to donation is unlikely to ever be the only relevant factor in making decisions about whether a donation action is in a potential donor's best interests.

3.31 Decision-making about what is in the best interests will involve a series of decisions that are influenced by many factors and may require a different balancing process for each proposed donation action assessing potential benefits and harms.

3.32 No guidance can take into account all possible donation actions or the multitude of individual factors which clinicians, specialist nurses and families may need to consider when undertaking a balancing process for deciding if a proposed donation action would be in the patient's best interests.

3.33 While it is not possible to cover every circumstance, this guidance, through wide stakeholder engagement and endorsement, seeks to create a Professional, Ethical and Legal Framework (Section 4.0) that is helpful to decision-makers.

3.34 The Framework categorises the most common donation actions, and those that are potentially possible, as either:

a) **Very likely** to be in the patient's best interests.

b) **Likely** to be in the patient's best interests.

c) **Unlikely** to be in the patient's best interests.

d) **Against current professional, ethical or legal guidance.**

3.35 Decision-makers must use their own judgement, knowledge of the strength of a person's willingness to donate and the exact circumstances which are occurring at the end of life, to help guide their use of these categorisations. It is acknowledged there may be some overlap in categories 3.34 a) – c).

3.36 Where the decision is finely balanced the use of an established ethical framework, tool or template may be useful to support clinical decision making.[3]

3.37 In the '**very likely**' category decision-makers should feel confident that the donation actions outlined will, *unless there is information to the contrary*, be in a patient's best interests.

3.38 In the '**likely**' category decision-makers should feel confident that the donation actions outlined will, *in most circumstances*, be in a patient's best interests.

3.39 In the '**unlikely**' category decision-makers will *require compelling evidence of a strong willingness by the patient to be a donor after death* for these donation actions to ever be in a patient's best interests.

3 For example, by adapting the Warwick Model or using the MORAL Balance ethical decision-making framework (FICM 2019). www.criticalcarenice.org.uk

3.40 Donation actions in the '**against current professional, ethical or legal guidance**' category, cannot currently be supported.

These may be either:

3.40.1 Actions that are allowed in other countries but not in current UK practice. An example could be before death administration of heparin or phentolamine, or elective ventilation. Section 6 outlines how such donation actions might be assessed, and if concluded to be professionally, ethically, and legally acceptable, incorporated into future practice, and recategorised in an updated version of this framework.

3.40.2 Actions against fundamental professional, ethical and legal norms. An example would be acting against the wishes of the patient or risking serious harm to the patient. These will never be acceptable.

4.0 Professional, Ethical and Legal Framework

Conceptually this framework categorises donation actions depending on two variables in time (see Section 1.11):

1. Whether the patient is deceased.
2. Whether there is consent for organ donation.

This results in four professional, ethical and legal categories where donation actions can occur:

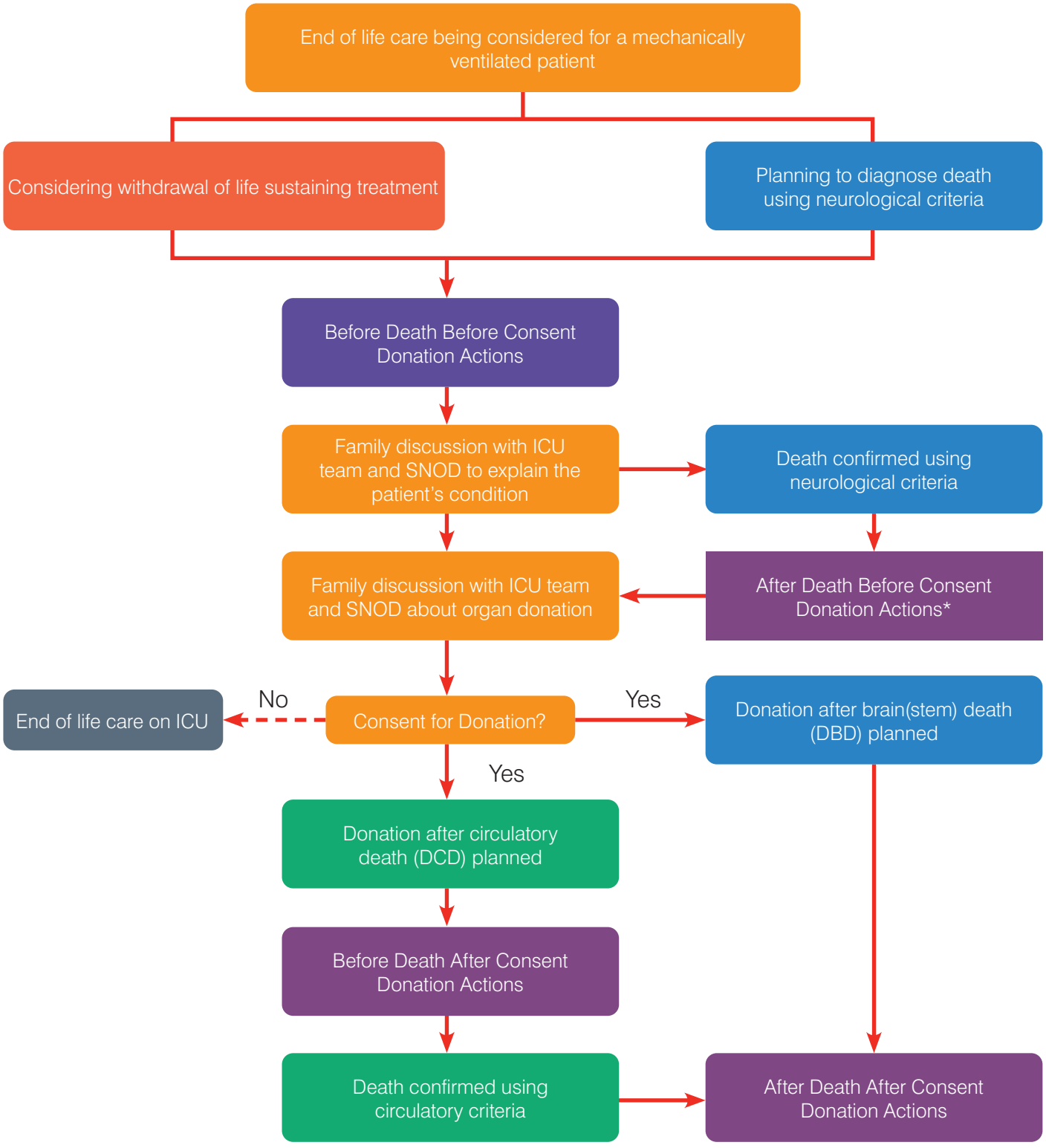
1) **Before Death and Before Consent (4.1)**. Usually this is the time after end of life care is first considered but before discussion with a family regarding donation. The emphasis is on establishing knowledge of a patient's willingness to donate and other end of life care and family needs.
2) **Before Death and After Consent (4.2)**. The majority of the controlled DCD process occurs here.
3) **After Death and Before Consent (4.3)**. A more limited situation in UK practice, which may occur in the time after death has been confirmed using neurological criteria (DNC) but before a donation discussion has been had with the patient's family. The emphasis is on establishing knowledge of a patient's willingness to donate and other end of life (after death) care and family needs. Uncontrolled DCD (uDCD) is currently not practised in the UK but is an area of worldwide practice where this category is applicable.
4) **After Death and After Consent (4.4)**. For DBD this includes the period of donor optimisation, organ retrieval and other cares. For DCD this includes the organ retrieval and interventions inside the body after death such as normothermic regional perfusion.

In general terms donation actions that are acceptable before consent for organ donation are equally acceptable after consent; and donation actions after death are usually less ethically complex than actions before death.

Figure 1 is a schematic overview of the process of DBD and DCD highlighting where possible donation actions might be applicable. Table 1 summarises the best interests recommendations of the Framework.

Some of the Donation Actions in Table 1, while potentially justifiable on best interests grounds, are not routinely part of current UK donation practice. To implement these actions outside of unique and individual circumstances (i.e., to propose as routine or expected practice), will first require a process of consensus and policy development as outlined in Section 6. Examples of such actions have been identified by a * in Table 1.

Figure 1. Schematic overview of the typical decision steps in DBD and DCD with categories of possible donation actions.



* This category of donation actions can also occur in uncontrolled DCD (not shown), a future supplement is planned.

Table 1 Summary of the Donation Action recommendations of the framework.

Note – In general terms donation actions that are acceptable before consent for organ donation are equally acceptable after consent (and are therefore not repeated in the table unless the applicable category alters).

The inclusion of a donation action in this table does not imply a clinical indication; all actions should be clinically justified as part of best interests balancing.

	BEFORE Death BEFORE Consent	BEFORE Death AFTER Consent	AFTER Death BEFORE Consent	AFTER Death, AFTER Consent
Donation actions VERY LIKELY to be in a patient's best interests.	• Identifying potential organ donors and alerting the donation team. • Gathering and sharing clinical information with the donation team or HM Coroner. • Speaking to the patient's family about donation. • Temporarily continuing life-sustaining treatments and clinically stabilising the patient in an appropriate critical care setting while a decision regarding donation is made. • Confirming death using neurological criteria. Section 4.1.3 - 4.1.5	• Ascertaining the strength of the person's willingness to donate and accept a particular donation action, by speaking to family. • Seeking details from family members of the patient's medical history relevant to donation. • Detailed review of the patient and medical records. • Carrying out blood tests for virology screening, blood group and tissue typing. Sampling and testing urine or sputum. • Minimally invasive investigations such as physical examination; bedside chest X-Ray; transthoracic echocardiography or (chest/abdominal ultrasound *). • Temporarily maintaining life by continuing cardiorespiratory support, adjusting existing treatments, introducing routine intensive care treatment to maintain physiological stability and facilitate organ donation. • Ensuring the chosen method of withdrawal of life-staining treatment is carried out in a planned, respectful and professional manner. This should include treatment to alleviate pain and distress and can include extubation. Section 4.2.4 - 4.2.7	• Identifying potential organ donors and alerting the donation team. • Gathering and sharing clinical information with the donation team or HM Coroner. • Speaking to the patient's family about donation. • Maintaining intensive care support and stabilising the physiology of the potential donor while a decision regarding donation is made. Section 4.3.4 - 4.3.5	• Ascertaining the strength of the person's willingness to donate and accept a particular donation action, by speaking to family. • Seeking details from family members of the patient's medical history relevant to donation. • Detailed review of the patient and medical records. • Carrying out blood tests for virology screening, blood group and tissue typing. Sampling and testing urine or sputum. • Minimally invasive investigations such as physical examination; bedside chest X-Ray, transthoracic echocardiography or chest/abdominal ultrasound. • Administration of blood, blood components and blood products. • Bronchoscopy. • Biopsy or small excision of a suspicious skin lesion. DBD • Maintenance of mechanical ventilation and physiological stability. • Following organ optimisation national protocols. • Transoesophageal echocardiography. • Insertion and monitoring with a pulmonary artery catheter. DCD • Steps for lung DCD e.g., reintubation, reinflation and delayed cyclical ventilation until the retrieval team have vented the left atrium. Section 4.4.2 - 4.4.9

	BEFORE Death BEFORE Consent	BEFORE Death AFTER Consent	AFTER Death BEFORE Consent	AFTER Death, AFTER Consent
Donation actions LIKELY to be in a patient's best interests.	• The introduction of routine intensive care treatment to maintain physiological stability such as introducing inotropic support, anti-arrhythmic or the siting of central and arterial lines. • The taking, storage and testing of blood or other samples (e.g., urine or respiratory samples) for the purpose of transplantation from patients known to be willing to donate. Section 4.1.5 - 4.1.7	• Altering the timing or location of withdrawal of life-sustaining treatment. • Administration of blood, blood components and blood products. • Antibiotics.* • Bronchoscopy.* With very strong patient willingness to donate and a very clear indication that the investigation is necessary: • Biopsy or small excision of a suspicious skin lesion.* • CT imaging.* • Transoesophageal echocardiography.* Section 4.2.8 - 4.2.12	• Temporarily maintaining organ function by using more intensive but routine intensive care actions such as introducing inotropic support, anti-arrhythmic or the siting of central and arterial lines. • The taking, storage and testing of blood or other samples (e.g., urine or respiratory samples) for the purpose of transplantation from patients known to be willing to donate. Section 4.3.6 - 4.3.7	DCD • Normothermic regional perfusion. DBD • CT imaging, departmental chest Xray or ultrasound.* • MRI.* • Coronary angiography.* • Invasive biopsy of organs or tissues.* • Lumbar puncture.* • CPR.* Section 4.4.10 - 4.4.11
Donation actions UNLIKELY to be in a patient's best interests	• Treatment where the sole intention of which is to enhance the prospects of a successful organ transplant.* • Where the degree, complexity and duration of the actions to facilitate confirming death using neurological criteria are excessive.* Section 4.1.8 - 4.1.9	• MRI imaging.* • Coronary Angiography.* • Invasive biopsy.* • Actions against the wishes of the family.* Section 4.2.13 - 4.2.14	• Treatment where the sole intention of which is to enhance the prospects of a successful organ transplant e.g., administration of methylprednisolone.* • Actions that present a significant risk of harm (even if non-physical).* Section 4.3.8 - 4.3.9	• Actions against the wishes of the family.* Section 4.4.12
Donation actions Against Current Professional, Ethical or Legal Guidance	• The taking, storage and testing of blood or other samples (e.g. urine or respiratory samples) for the purpose of transplantation from patients not known to be willing to donate. Section 4.1.10	• Actions against the wishes of the patient. • Pre-mortem venous and arterial cannulation to allow normo-thermic regional perfusion. • Instituting CPR. • Instituting ECMO. • Heparin. • Phentolamine. • Non-therapeutic elective ventilation (NTEV). • Interventions which carry risk of serious harm. Section 4.2.15 - 4.2.20	• The taking, storage and testing of blood or other samples (e.g., urine or respiratory samples) for the purpose of transplantation from patients not known to be willing to donate. Section 4.3.10	DCD • Actions against the wishes of the patient. • Actions that could restore cerebral perfusion and function. Section 4.4.13 - 4.4.14

* Identifies Donation Actions, which although may be able to be justified on best interests, are not routinely part of current UK donation practice. To implement these actions outside of unique and individual circumstances (i.e., to propose as routine or expected practice), will first require a process of consensus and policy development as outlined in Section 6.

4.1 Before Death and Before Consent

4.1.1 This section applies before death and before consent. Usually this is the time after end of life care is first considered but before discussion with a family regarding donation. The emphasis is on establishing knowledge of a patient's willingness to donate and other end of life care and family needs.

4.1.2 This section applies to the potential start of a DCD pathway as well as situations where death is expected to be diagnosed using neurological criteria allowing for a DBD pathway to commence, but the tests and confirmation have not yet occurred.

Donation actions which are VERY LIKELY to be in a patient's best interests.

4.1.3 Actions to **establish a person's willingness and initial suitability** to be a donor:

a) Following any national procedures for identifying potential organ donors (GMC 2010) and alerting the donation team (DH 2009, NICE 2011).

b) Gathering and sharing clinical information with the donation team and allowing the donation team to look at the person's medical history to assess suitability for donation (DH 2009, GMC 2010).

c) Discussion with HM Coroner prior to speaking to the family about organ donation in order to avoid unnecessary distress to families by offering donation where it cannot proceed (Chief Coroner 2017).

d) Accessing the ODR.

e) Speaking to the patient's family about donation (DH 2009, GMC 2010).

4.1.4 Actions to **temporarily maintain life** in order to establish whether donation is in the best interests of the patient (NICE 2011, UK DEC 2016a):

a) While assessing best interests clinically stabilise the patient in an appropriate critical care setting while the assessment for donation is performed – for example, an adult intensive care unit or regional paediatric intensive care unit (ICS/BTS 2010, NICE 2011).

b) *Provided* that delay is in the best interests of the patient, life-sustaining treatments should not be withdrawn or limited until the patient's willingness to donate has been explored and the clinical potential for the patient to donate has been assessed (NICE 2011).

4.1.5 Actions to **confirm death using neurological criteria**.

Potential benefits to confirming death using neurological criteria are:

a) Establishing whether a patient is alive or dead. This is of benefit to the family and to hospital staff, because it eradicates doubt.[4] This is true whether or not the patient is a potential donor. If the patient is found to be alive, care for the patient and the family can be continued or adapted accordingly (UK DEC 2016a).

b) Allows futile and/or inappropriate treatment to cease. This is not only a benefit for the patient and family, but also a benefit for wider society because it allows valuable resources to be used for other patients (UK DEC 2016a).

c) When donation is a possibility the test results clarify the clinical context in which discussions about donation can take place (UK DEC 2016a).

Most of the benefits and harms that might be associated with confirming death using neurological criteria apply whether or not the patient is a potential donor (UK DEC 2016a). In the absence of strong constraining factors, allowing time for test preconditions to be met or providing interventions to stabilise a patient to facilitate neurological testing are acceptable; even if it becomes apparent that the patient in life, or their family, are opposed to donation (UK DEC 2016a).

Clinicians should consider offering families the opportunity to observe the neurological tests to confirm death being carried out. A careful and sensitive explanation of the methodology of and certainty provided by the tests should be provided as a matter of good clinical practice. Where appropriate, support from a member of the family's cultural or religious community should be facilitated (UK DEC 2016a).

Donation actions which are LIKELY to be in a patient's best interests.

4.1.6 The **introduction of routine intensive care treatment** to temporarily maintain life and physiological stability (clinical stabilisation) in order to allow time to establish whether donation is in the best interests of the patient (DH 2009, NICE 2011, UK DEC 2016a). For example, inotropic support, anti-arrhythmic medication or the siting of routine intensive care monitoring such as central and arterial lines.[5]

4 Case law example: [2022] EWHC 1165 (Fam) (paragraph 95).
5 There are a number of other reasons why using intensive care treatment and skill to temporarily maintain life will be entirely appropriate regardless of any organ donation consideration. For example, stabilising to allow accurate prognostication for patients who have suffered a devastating brain injury or allowing time for family to arrive so that planned end of life care can occur.

4.1.7 **For patients known to be willing to donate, the taking, storage and testing of blood or other samples** (e.g., urine or respiratory samples) for the purpose of transplantation is acceptable in some specific circumstances. Stored whole blood (cellular material) or serum (non-cellular material) samples are property over which the patient is entitled to exercise control (DH 2009). Taking blood from a person who lacks capacity must be carried out in line with the MCA and will only be lawful if it would be in that person's best interests (DH 2009). This will include considering if the person wanted to be a donor and whether these steps contribute to fulfilling that desire. Clinicians will also need to consider the risk of any harm or distress that may be caused to the person, including consideration of the information the tests may generate (DH 2009).[6]

Donation actions which are UNLIKELY to be in a patient's best interests.

4.1.8 **Treatment where the sole intention of which is to enhance the prospects of a successful organ transplant** (ICS/BTS 2010).

4.1.9 Where the **degree, complexity and duration of the actions to confirm death using neurological criteria are excessive** or likely to compromise continuing supportive treatment, including where there are clear family or patient-centred reasons not to pursue this diagnosis. For example, when the time taken to conduct tests might increase the burden on the patient's family or increase their distress, by prolonging uncertainty as to whether their loved one is alive or dead, or, for some, by giving false hope of recovery. In such circumstances it would be acceptable clinical practice to withdraw mechanical ventilation when such treatment is no longer in the best interests of the patient; and confirm death using circulatory criteria (UK DEC 2016a).

Donation actions Against Current Professional, Ethical or Legal Guidance

4.1.10 The **taking, storage and testing of blood or other samples** (e.g., urine or respiratory samples) for the purpose of transplantation **from patients not known to be willing to donate**. See Footnote 6.

6 NHSBT policy, developed in consultation with the HTA, is that if a patient is registered on the ODR as willing to donate, it is acceptable to send the blood samples to the laboratory prior to discussion with the patient's family but not to analyse the samples until agreement with the family. This applies even to testing existing samples from a person who lacks capacity (HTA Code F Part two 2020). The benefit to the patient and the family is that the length of the donation process can be shortened, as sending bloods to a distant laboratory is a common cause for delay. In some circumstances families may verbally support donation as being in the patient's best interests prior to the completion of formal consent. In such circumstances, and with family agreement, this could allow both the taking, storage and testing of blood or other samples. Please be aware that the donation of gametes is not included and is governed by separate legislation and the Human Fertilisation and Embryology Authority.

4.2 Before Death and After Consent

4.2.1 This section applies before death and after donation consent. The majority of the controlled DCD process occurs here. It could also, rarely, apply to a DBD pathway where there is consent for donation but before death is confirmed using neurological criteria.

4.2.2 Every effort should be made to mitigate potential harm or distress to the patient consistent with facilitating the success of the transplant. This may include, where relevant, delaying a donation action if such delay would decrease the risk of causing such harm or distress (UK DEC 2014a). Account should be taken of the extent to which symptoms of pain, discomfort or distress which might be so caused could be alleviated (UK DEC 2014a).

4.2.3 The risk of causing distress to the patient's family should also be considered a potential risk of harm to the patient (see Section 3.20). Ways of minimising this should be explored through careful explanation of both the need for particular interventions in order to facilitate the patient's wish to be a donor and what is involved in those actions (UK DEC 2014a).

Donation actions which are VERY LIKELY to be in a patient's best interests.

4.2.4 Actions to **ascertain the strength of the person's willingness to donate and accept a particular donation action**. Speaking to the patient's family may be important in order to ascertain whether a proposed donation action will be in the best interests of the patient (DH 2009, NICE 2011).

4.2.5 **Actions to establish a person's suitability to be a donor**.

Such as:

a) Seeking details from family members of the patient's medical history relevant to donation (DH 2009).

b) Carrying out a detailed review of the patient and medical records.

c) The taking, storage and testing of blood for virology and microbiological screening, blood group and tissue typing analysis. Prior to gaining agreement for donation from the family it is acceptable to take and store blood and other simple samples from donors who have registered on the ODR. This can bring benefits to the donor and family though speeding up the donation pathway. Testing of the samples for virology should not occur prior to family agreement for donation (see footnote 6, section 4.1).

d) Sampling and testing urine or sputum.[7]

e) Minimally invasive investigations such as:

- Physical examination.
- Bedside chest X-Ray.
- Bedside transthoracic echocardiography.
- Bedside chest/abdominal ultrasound.

7 Urine samples accessed by an existing urinary catheter; sputum samples accessed by an existing endotracheal tube but not bronchoscopy to acquire the samples e.g., COVID-19 endotracheal aspirate.

4.2.6 **Actions to temporarily maintain life**:

a) Continuance of cardiorespiratory support so as to gain a fuller understanding of the strength of the patient's willingness to donate and coordinate its withdrawal with the availability of an organ retrieval team (DH 2009). This could include the continuation of established ECMO.

b) Reversing haemodynamic or ventilatory instability by adjustment of existing treatments (for example, increase in inspired oxygen concentration, adjustment to the ventilator settings or alteration of the rate of administration of existing fluid and drug therapies) (DH 2009).

c) The introduction of routine intensive care treatment to maintain physiological stability and facilitate organ donation (DH 2009). This could include the introduction of new therapies, such as inotropic support, anti-arrhythmic medications and the siting of venous and arterial cannulae including central lines (DH 2009).

4.2.7 **Ensuring the chosen method of withdrawal of life-sustaining treatment is carried out in a planned, respectful and professional manner** remains the responsibility of the consultant in charge of the patient's overall care and should not be delegated to staff unfamiliar with the process (ICS/BTS 2010). It is critically important that families understand the nature and the reasons behind the various elements of the end of life care that their loved one will receive (ICS/BTS 2010). The patient and family should always have an identified member of staff to be with them. This would usually be the bed side intensive care nurse (ICS/BTS 2010).

a) Individuals, regardless of whether they may be potential organ donors, are entitled to and, where appropriate, should receive, **treatment to alleviate pain and distress following any withdrawal of life sustaining treatment** (UK DEC 2014c). Not providing appropriate relief for pain and distress to a patient following withdrawal of treatment is not acceptable (UK DEC 2014c). It is acceptable to commence pharmacological treatments prior to the withdrawal of life-sustaining treatment in anticipation of preventing possible pain and distress provided such treatments are then titrated to patient symptoms and signs and doses do not significantly deviate from usual practice (FICM 2019). Current evidence suggests that if used in this way the time to death is not artificially shortened (Chan et al. 2004, Edwards 2005, APM 2009, Mazer and Alligood 2011, Munshi et al. 2015).

b) **Extubation** is an acceptable form of treatment withdrawal, regardless of whether it has been decided that organ donation is part of the end of life care for the patient (ICS/BTS 2010, UK DEC 2014c).

Donation actions which are LIKELY to be in a patient's best interests.

4.2.8 Actions with respect to the timing or location of withdrawal of life-sustaining treatment. It should be noted that many of these donation actions are intrinsic for successful DCD.

a) It is generally understood and accepted that there is some flexibility in **timing**, for example to allow family members to be present or to make sure the relevant healthcare professionals are available to oversee the donation process. In practice, the timing of withdrawal of treatment is a matter for discussion and agreement between the person's family and clinicians (DH 2009). However, the interests of the patient's family must always be recognised (ICS/BTS 2010). The family should be fully informed about the process of withdrawal and what may happen afterwards, including the possible timescales and their implications.

b) Local circumstances and/or a desire to reduce warm ischaemic damage to the organs may justify moving the patient to a different **location**. For example, moving a patient close to or within the operating theatre complex, ahead of withdrawal of treatment (DH 2009). There should be clear on-going responsibility for the care of the patient and their family, regardless of the location of treatment withdrawal (ICS/BTS 2010). There should also be a robust and acceptable plan for subsequent care should donation not take place (ICS/BTS 2010).

Factors to consider when balancing a decision to withdraw in a theatre complex:

- Local practice, familiarity and policy.
- Maximising the desire of the patient to be a donor of safe and long-lasting organs (ICS/BTS 2010).
- The comfort, dignity and privacy of the patient and family (ICS/BTS 2010).
- Access for close family and friends (ICS/BTS 2010).
- The need for continuity of clinical care from the Intensive Care Unit / Emergency Department team (ICS/BTS 2010).
- Achieving a manner of death that family, those who were caring for the individual and members of the theatre team will be comfortable with (ICS/BTS 2010).

Moving a patient to a different hospital to allow donation would require a strong justification.

4.2.9 **Pharmacological treatments with low risk of harm, where the sole intention of which is to enhance the prospects of a successful organ transplant**. In this circumstance attention to providing explanation to the patient's family will be required. An example could be antibiotics. Antibiotics carry little risk to the donor and may be given if clinically indicated (ICS/BTS 2010).

4.2.10 **Administration of blood, blood components and blood products**.

Transfusion of blood and blood products to maintain physiological stability in the donor or to improve the condition of donated organs. This would include transfusion to allow donor blood to be used to prime an external organ support device.

4.2.11 **Organ specific investigations to decide suitability for donation or exclude contraindications in higher risk donors, which have a low risk of harm or distress**. In these circumstances a more careful balancing should occur with greater attention to providing explanation to the patient's family as well as to mitigate any risks (DH 2009). An example would be **bronchoscopy** to assess the potential for lung donation, provided any patient distress could be alleviated (ICS/BTS 2010).

4.2.12 **More invasive or interfering investigations to decide suitability for donation or exclude contraindications in higher risk donors**. If there was a strong patient willingness to donate and a clear indication that the investigation is necessary, these actions could still be appropriate but would require careful consideration on a case-by-case basis, with specific attention to patient comfort and family explanation and agreement.

Examples of such investigations might be:

- Biopsy or small excision of a suspicious skin lesion.
- CT imaging which will require the patient to be transferred to the radiology department.
- Transoesophageal echocardiography.

Donation actions which are UNLIKELY to be in a patient's best interests.

4.2.13 **Highly invasive or interfering investigations to decide suitability for donation or exclude contraindications in higher risk donors**. Such investigations would need very careful balancing as to the benefits and potential harms. Interventions of this kind require detailed and specific discussion with the patient's family. Balancing the strength of the patient's decision or wish to donate, the ability of clinical team to minimise potential harms and the justification of the need for the investigation to ensure successful donation will play determining roles.

A prudent decision maker would seek direct justification from the transplant team requesting the investigation and seek a second consultant medical opinion independent of the transplant team; as well as gaining informed family assent.

Examples of such investigations might be:

a) More complicated and time-consuming radiological examinations, such as MRI.

b) Higher risk investigations such as coronary angiography.

c) Invasive biopsy to ascertain either organ suitability or exclude malignancy or active infection (ICS/BTS 2010).

4.2.14 To institute **actions against the wishes of the family**, even if there was legal consent for organ donation (ICS/BTS 2010). Such circumstance might require a declaration from the Court.

Donation actions Against Current Professional, Ethical or Legal Guidance

Actions that are allowed in other countries but not in current UK practice.

4.2.15 Institution of highly intrusive actions to temporarily maintain life such as:

a) Cardio-pulmonary resuscitation (DH 2009).

b) Extracorporeal Membrane Oxygenation (ECMO) or normothermic regional perfusion before death (ICS/BTS 2010). Note, the continuation of established ECMO, including necessary actions to maintain physiological stability, are appropriate and is covered in 4.2.6.

4.2.16 **Pharmacological treatments for the sole intention of enhancing the prospects of a successful organ transplant or enhancing organ quality, which have not been approved for this purpose in the UK**. Medications of this nature need to have been approved by the steps outlined in Section 6 or be part of an approved research protocol.

a) **Heparin**. Heparin is the most common medication used for this purpose elsewhere in the world. The evidence for its use is debatable as are its risks. Further research is required before its use could be considered acceptable in the UK.

b) **Phentolamine** is a medication used to enhance organ quality in the USA and is administered at the time of treatment withdrawal in DCD. Phentolamine will decrease peripheral vascular resistance and cause vasodilatation and risks shortening the patient's life. It cannot be recommended in the UK unless evidence emerges which counters the expected physiological effect (ICS/BTS 2010).

4.2.17 **Non-therapeutic elective ventilation (NTEV)**. NTEV cannot currently be recommended in the UK but is practised elsewhere in the world.[8] UK DEC considered that the perception that elective ventilation is unlawful is driven by legal advice that is no longer reliable because the legal context has changed (UK DEC 2016a, UK DEC 2016c). Possible use in the UK should be formally re-examined but it cannot be currently supported.

Actions against fundamental professional, ethical and legal norms.

4.2.18 **Actions against the known wishes of the patient**.

4.2.19 **Interventions that have could have an ongoing deleterious effect on the patient if death doesn't promptly follow a planned withdrawal of life sustaining treatment**. An example would be pre-mortem venous and arterial cannulation to allow normo-thermic regional perfusion, or similar actions (DH 2009).

4.2.20 **Interventions which carry risk of serious harm** (see Section 3.20 for a list of harms) would need overwhelmingly strong evidence of potential benefits in order for them to be in the best interests of the patient (UK DEC 2014a) and in practice are unlikely ever to satisfy a legal test of 'best interests' (DH 2009). This could require a declaration from the Court of Protection in relation to the person's best interests before doing so (DH 2009).

8 Martín-Delgado, MC, Martínez-Soba, F, Masnou, N, et al. Summary of Spanish recommendations on intensive care to facilitate organ donation. Am J Transplant. 2019; 19: 1782– 1791.

4.3 After Death and Before Consent

4.3.1 This section applies after death and before consent. In the UK this is a more limited situation, which may occur in the time after death has been confirmed using neurological criteria but before a donation discussion has been had with the patient's family. The emphasis is on establishing knowledge of a patient's willingness to donate and other end of life (after death) care and family needs.

4.3.2 Uncontrolled DCD (uDCD) is currently not practised in the UK but is an area of worldwide practice where this category could also be applicable but is not covered in this framework. A supplementary framework on uDCD is planned.

4.3.3 As per 3.21, once a person has died, the concept of physical harm is no longer relevant. However other potential harms remain and may include concerns about bodily integrity, not respecting values, beliefs and wishes held in life, and causing distress to those close to the deceased. Family might be affected by factors such as the level of intrusiveness of the intervention, or the impact on their ability to spend time with their deceased loved one (UK DEC 2016a). As stated in 3.8, the courts have held that best interests do not end at the moment of death.

Donation actions which are VERY LIKELY to be in a patient's best interests.

4.3.4 Actions to **establish a person's willingness and initial suitability** to be a donor:

a) Following any national procedures for identifying potential organ donors (GMC 2010) and alerting the donation team (DH 2009, NICE 2011).

b) Gathering and sharing clinical information with the donation team and allowing the donation team to look at the person's medical history to assess suitability for donation (DH 2009, GMC 2010).

c) Discussion with HM Coroner prior to speaking to the family about organ donation in order to avoid unnecessary distress to families by offering donation where it cannot proceed (Chief Coroner 2017).

d) Accessing the NHS Organ Donor Register, if not done previously.

e) Speaking to the patient's family about donation (DH 2009, GMC 2010).

4.3.5 If death has been confirmed but the patient's wishes, values and beliefs regarding donation are not yet established, or agreement with the family has not been reached; it is acceptable to **maintain intensive care support and stabilise the physiology of the potential donor while a decision regarding donation is made** (UK DEC 2016a). This is likely to be required for only a short period of time. The most common circumstance would be after death is confirmed using neurological criteria but prior to discussing donation with the patient's family.

Donation actions which are LIKELY to be in a patient's best interests.

4.3.6 **Temporarily maintaining organ function by using more intensive but routine intensive care actions** such as introducing inotropic support, anti-arrhythmic drugs or the siting of central and arterial lines (UK DEC 2016a).

4.3.7 **For patients known to be willing to donate the taking, storage and testing of blood or other samples** (e.g., urine or respiratory samples) for the purpose of transplantation is acceptable in some specific circumstances. See footnote 6, section 4.1.

Donation actions which are UNLIKELY to be in a patient's best interests.

4.3.8 **Actions where the sole intention is to optimise organ quality or suitability for transplantation**. For example, the administration of methylprednisolone.

4.3.9 Any **actions that present a significant risk of harm** (even if non-physical) are unlikely to be justified (UK DEC 2016a).

Donation actions Against Current Professional, Ethical or Legal Guidance

4.3.10 The **taking, storage and testing of blood or other samples** (e.g., urine or respiratory samples) for the purpose of transplantation **from patients not known to be willing to donate**. See footnote 6, section 4.1.

4.4 After Death and After Consent

4.4.1 A far wider range of donation actions are likely to be in a patient's best interests after death and after consent for organ donation has been established. Donation actions must still be evaluated individually, balancing the benefits against any potential harm to the donor and/or their family, and must be carried out as respectfully as possible (UK DEC 2016a). The **minimum** level of intervention on the donor should be used that is required to facilitate optimal transplant and recipient outcomes.

Donation actions which are VERY LIKELY to be in a patient's best interests.

4.4.2 Actions to **ascertain the strength of the person's willingness to donate and accept a particular donation action**. Speaking to the patient's family may be important in order to ascertain whether a proposed donation action will be in the best interests of the patient (NICE 2011).

4.4.3 **Actions to establish a person's suitability to be a donor**.

Such as:

a) Seeking details from family members of the patient's medical history relevant to donation.

b) Carrying out a detailed review of the patient and medical records.

c) The taking, storage and testing of blood samples for virology, blood group and tissue typing analysis. Prior to gaining agreement for donation from the family it is acceptable to take and store blood and other simple samples from donors who have registered on the Organ Donor Register. This can bring benefits to the donor and family though speeding up the donation pathway. Testing of the sample for virology should not occur prior to family agreement for donation.[9]

d) Sampling and testing urine or sputum.[10]

e) Minimally invasive investigations such as:

- Phys ical examination.
- Bedside chest X-Ray.
- Bedside transthoracic echocardiography.
- Bedside chest/abdominal ultrasound.

4.4.4 Biopsy of organs or tissues during the organ retrieval surgery for the purpose of establishing the safety or suitability for transplantation.

9 See Footnote 6, section 4.1.
10 See Footnote 7, section 4.2.

4.4.5 **Administration of blood, blood components and blood products**.

Transfusion of blood and blood products to maintain physiological stability in the donor or to improve the condition of donated organs. This would include transfusion to allow donor blood to be used to prime an external organ support device.

4.4.6 **Invasive actions which may be used to assess a patient's suitability to be a donor, optimise organ quality for transplantation, or identify contraindications that may exclude donation**. These interventions will need more careful balancing and greater attention to explanation and care of the patient's family if appropriate. The location and the duration of these actions, and the impact on the family's ability to spend time with their deceased loved one will be key considerations. Some of these interventions may be performed on ICU by a trained member of the cardiothoracic retrieval team (sometimes referred to as a scout), in theatre by the retrieval team prior to commencing organ retrieval or requested of the intensive care team.

Possible examples are:

a) Bronchoscopy.

b) Biopsy or small excision of a suspicious skin lesion.

c) Transoesophageal echocardiography. *(DBD only)*

c) Insertion and monitoring with a pulmonary artery catheter. *(DBD only)*

DBD

4.4.7 **Maintenance of mechanical ventilation and physiological stability** to allow organ donation to proceed, including the use of additional monitoring or medications.

4.4.8 Care should be directed toward **maximising the quality of consented organs**. ICU teams, and others who have care for the donor, should follow organ optimisation national protocols, including recommended physical, physiological and pharmacological actions.

DCD

4.4.9 For successful **lung DCD** the following steps must be followed (ICS/BTS 2010; UK DEC 2011, Lung DCD 2015):

a) **Airway management**. If the patient has been extubated as part of treatment withdrawal, the airway should be re-intubated after death has been confirmed in order to prevent soiling with stomach contents. It is essential to identify in advance who has responsibility for re-intubation. Once death has been confirmed it is acceptable, and often routine, for the re-intubation to be performed by a member of the donor's clinical team who took part in the treatment withdrawal.

b) **Single vital capacity breath**. The lungs should be inflated with a single vital capacity breath of oxygen-enriched air to reduce lung ischaemia. A minimum period of ten minutes from the onset of mechanical asystole must elapse before performing this manoeuvre.

c) **Cyclical ventilation**. Cyclical ventilation of the lungs is not allowed until the retrieval team have started to flush the lungs and have vented the left atrium.

Donation actions which are LIKELY to be in a patient's best interests.

4.4.10 *DCD*

a) Normothermic regional perfusion (NRP).

- The donor's family must be informed in advance if there is a plan to restore heart function in the deceased donor. If the family object it should not go ahead.
- Good practice would be to inform the family in a similar way for the other organs where organ recovery procedures are planned which will restore organ function inside the donor.
- Good practice would be to inform the donor hospital staff in advance if NRP organ recovery procedures are planned.
- Vascular cannulation to allow NRP can be undertaken at any time following the diagnosis and confirmation of death.
- NRP cannot commence until measures (including any appropriate monitoring) to exclude cerebral perfusion are completed in accordance with current national guidance (UK/Canadian Proposal 2020, NRP National Policy 2021a and 2021b).

b) All retrieval surgeons should have guidance on what to do should the exceptional circumstance of inadvertent restoration of cerebral circulation ever occur (ICS/BTS 2010).

4.4.11 *DBD*

a) Sometimes, in order to establish a patient's suitability to donate, **additional investigations** are required and these may be invasive and/or time consuming. Such investigations require detailed and specific discussion with the patient's family and will need careful balancing as to the benefits and potential harms. Balancing the strength of the patient's willingness to donate, the ability of clinical team to minimise potential harms to the family and the justification of the need for the investigation to ensure successful donation will play determining roles.

Examples of such investigations might be:

- Radiological investigations that require moving the patient from the bedside to the radiology department e.g., CT imaging, departmental chest Xray, ultrasound or MRI imaging.
- Coronary angiography.
- Lumbar puncture.
- Biopsy of organs or tissues prior to organ retrieval.

b) During the wait for organ retrieval a potential donor can sometimes become haemodynamically unstable and have a cardiac arrest. In such circumstances cardiac massage, defibrillation, and other resuscitative measures might allow the option of organ donation to be preserved where it would otherwise be lost. Clinicians faced with this situation should balance the strength of the known wish to donate with the degree, complexity and duration of the proposed cardiac massage and resuscitation and the impact this may have on the patient, their family and other staff. Ideally the prospect of such a scenario should be discussed with the family prior to any deterioration in the potential donor's haemodynamic condition (UK DEC 2016a).

Donation actions which are UNLIKELY to be in a patient's best interests.

4.4.12 To institute **actions against the wishes / strong objections of the family**, even if there was legal consent for organ donation (ICS/BTS 2010). Such circumstance might require a declaration from the Court.

Donation actions which are Against Current Professional, Ethical or Legal Guidance.

4.4.13 **Actions against the known wishes of the patient**.

4.4.14 **Actions that restore cerebral perfusion and function after a diagnosis of death using circulatory criteria** are NOT permitted under any circumstances (AoMRC 2008, ICS/BTS 2010).

5.0 Roles and Responsibilities

5.1 Health Care Professionals in the Donor Hospital

5.1.1 Responsible for care of the potential donor and their family and ensuring all actions are in the best interests of the patient (UK DEC 2011). After death the care of a donor is shared between the donor hospital clinical team who treated the patient in life and the team who are carrying out the organ retrieval procedure.

5.1.2 Undertake the balancing process to decide if any proposed donation action is in the best interests of the patient.

5.1.3 Lead and deliver on actions in the best interests of the patient before death to facilitate donation (UK DEC 2011).

5.1.4 Responsible for the safe and timely diagnosis and confirmation of death (UK DEC 2011).

5.1.5 Provide after death actions, and where appropriate, work with the retrieval team to do so. This can include re-intubation for lung DCD (ICS/BTS 2010, UK DEC 2011).

5.1.6 Any health care professional from the donor hospital and involved in the care of the donor, should not, at that time, have a duty of care to a proposed organ recipient (UK DEC 2011).

5.2 Specialist Nurses for Organ Donation (SN-OD)/ Specialist Requesters

5.2.1 The specialist nurse's primary obligation is to the donor and their family, rather than to the transplant team (UK DEC 2016a).

5.2.2 The specialist nurse works with donor families to seek consent for donation, ascertain the strength of the donor's willingness to donate, and will continue to have an essential contact role with the family to support any decision to donate throughout the donation process (UK DEC 2011).

5.2.3 The specialist nurse has an important role in discussing any cultural, faith or belief-related wishes the donor or the family may have around death or organ donation (UK DEC 2011).

5.2.4 Have a liaison role between family, donor hospital staff and transplant teams (UK DEC 2011).

5.2.5 Should not provide pharmacological or treatment interventions to the donor before death (UK DEC 2011). Providing advice to the clinical team regarding such treatments is acceptable.

5.2.6 Can provide pharmacological or treatment interventions to the donor after death (UK DEC 2016a).

5.2.7 It is appropriate for the specialist nurse to hold initial discussions about patients with the clinicians caring for them, or with transplant teams, and to check the ODR status of a patient before death has been confirmed or before family discussion; this is an important part of establishing if there is donation potential, which will be of benefit to the patient and the patient's family (UK DEC 2016a).

5.3 Organ Retrieval Teams

5.3.1 Must not be involved in the decision to withdraw life-sustaining treatment (UK DEC 2011).

5.3.2 Must not be involved in the diagnosis and confirmation of death (AoMRC 2008, UK DEC 2011).

5.3.3 Liaise with donor hospital staff and specialist nurses (UK DEC 2011). May advise on actions to secure the best outcome of the donation and transplantation but it is for the donor hospital staff to undertake the balancing process and decide if the proposed donation action is in the best interests of the patient (UK DEC 2011).

5.3.4 Must not provide pharmacological or treatment interventions to the donor before death (UK DEC 2011).

5.3.5 Provide after death actions necessary for organ retrieval and the safe transfer of transplantable organs. After death the care of a donor is shared between the donor hospital clinical team who treated the patient in life and the team who are carrying out the organ retrieval procedure.

5.3.6 Must ensure that no action restores cerebral perfusion after a diagnosis of death using circulatory criteria (AoMRC 2008).

5.4 Clinical Leads for Organ Donation (CLOD)

5.4.1 The role of clinical lead is a managerial rather than a clinical responsibility (UK DEC 2011).

5.4.2 Clinical leads should not be considered, simply by nature of their role, to have any specific conflict of interest (UK DEC 2016a).

5.4.3 Therefore, a clinical lead:

a) Can care for any potential donor when this occurs as part of usual clinical duty and in accordance with national guidance (UK DEC 2011).

b) Should act as a source of knowledge and expertise on organ donation and the diagnosis of death using neurological criteria.

c) Should examine missed opportunities for organ donation in their hospital in line with national guidance.

d) Can be one of the 'two medical practitioners registered for more than five years' required, by the Academy Code of Practice, to conduct neurological tests to confirm death (UK DEC 2016a).

e) Can be one of the two senior doctors recommended by UK DEC to confirm that withdrawal of life-sustaining treatment in DCD is in the best interests to the patient (UK DEC 2011).

f) Should ensure that all actions remain in the best interests of the patient who is a potential donor, both for when the patient is under the clinical lead's direct care (UK DEC 2016a) and taking a governance responsibility within the hospital.

6.0 Recommended Process for Approving Future Donation Actions

6.1 The framework above primarily deals with the current professional, ethical and legal practise under which deceased organ donation occurs in England, Northern Ireland and Wales.

6.2 There is a need to consider how new donation actions (interventions or processes) should be assessed, and if professionally, ethically and legally acceptable, incorporated into future practice. While this guidance was not written to be applied in Scotland the approval process outlined below would be applicable, except where it falls under Pre-Death Procedure legislation.

6.3 The evidence relating to the risks of harm or distress associated with particular donation actions and their potential to optimise donor organ quality and improve transplant outcomes is likely to change over time. This evidence should be regularly reviewed and transparently governed to ensure that clinicians are able to make evidence-based assessments of those risks and benefits (UK DEC 2014a).

6.4 This Framework recommends that new donation actions, or donation actions which are intended to become a routine part of practice, should be approved by three groups:

1) NHS Blood and Transplant's **Research, Innovation and Novel Technologies Advisory Group (RINTAG)**. The primary role of this group is to provide the scientific justification for the transplant benefit of the proposed intervention.
2) The **National Organ Donation Committee (NODC)**. The primary role of this committee is to consider the burden of the proposed donation action on the donor, their family and the donor hospital. NODC membership includes representation from:
    - British Association of Critical Care Nurses
    - British Society of Neurological Surgeons
    - British Transplantation Society
    - Faculty of Intensive Care Medicine
    - Intensive Care Society
    - Paediatric Critical Care Society
    - Royal College of Anaesthetists
    - Royal College of Emergency Medicine
    - Lay representation.

3) **NHS Blood and Transplant Organ and Tissue Donation and Transplantation Directorate**. Even if a proposed new donation action may have a justifiable transplant benefit and be minimally burdensome on the donor, their family or the donor hospital; it may still not be feasible or economically viable to deliver. NHSBT, as the national organ donation organisation, must agree to the resource implications for training and operationalising any new donation action.

6.5 Where required, particularly if novel or finely balanced, new donation actions may need review and input from:

- An Ethics Advisory Group (see below)
- National Retrieval Committee
- Organ Advisory Groups
- British Transplantation Society
- Other relevant Professional Body/s
- NHSBT's Donor Family Advisory Group
- The Donor Family Network charity
- Other organisations as felt to be necessary.

6.6 The outlined approval process does not apply to appropriately registered research studies which have their own governance and approval processes. Ongoing donation and transplantation research is strongly encouraged.

6.7 The closure of the UK DEC in 2016 has been a great loss to UK donation and transplantation. The number of references to UK DEC in this framework is testament to the committee's impact.

6.8 In line with the UK strategy document Organ Donation and Transplantation 2030: Meeting the Need, the authors of this Framework support the recommendation that the UK actively pursue the re-establishment of a donation and transplantation ethics advisory group.

6.9 UKDEC and the ICS/BTS consensus meeting in 2010 both recommended the development of nationally agreed guidance for the withdrawal of life-sustaining treatment in a critical care setting (UK DEC 2011, ICS 2010). The Faculty of Intensive Care Medicine document, 'Care at the end of life: a guide to best practice, discussion and decision-making in and around critical care' (FICM 2019) may provide a useful starting point to developing this.

6.10 Future revisions of this framework should be planned at five-year intervals.

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Stakeholder Representation

A stakeholder event to review the documents first draft was held on the 7th November 2019 in Birmingham.

Organisations and groups represented included:
Association of Anaesthetists
Association for Perioperative Practice
British Transplantation Society
Department of Health – Northern Ireland
Department of Health – Scotland
Department of Health – Wales
Donor Family Network
Ethics Committee – British Transplantation Society
Faculty of Intensive Care Medicine
Legal and Ethical Advisory Group – Intensive Care Society
Institute for Health Research – University of Bedfordshire
Intensive Care Society
NHS Blood and Transplant
Northern Ireland Intensive Care clinicians
Organ Advisory Groups – NHS Blood and Transplant
Organ recipients
Paediatric Intensive Care Society
Royal College of Anaesthesia
Royal College of Emergency Medicine
UK Critical Care Nursing Alliance
Welsh Intensive Care Society

A draft of this document was reviewed by the Human Tissue Authority.

Endorsing Organisations

British Association of Critical Care Nurses
British Transplantation Society
Donor Family Network
Faculty of Intensive Care Medicine
Intensive Care Society
National Organ Donation Committee
Northern Ireland Intensive Care Society
NHS Blood and Transplant
Paediatric Critical Care Society
Welsh Intensive Care Society

Appendix A

Summary of how this framework incorporates and is built upon previous published UK guidance in each of the four conceptual donation action categories.

	BEFORE Consent	AFTER Consent
BEFORE Death	DH 2009 GMC 2010 ICS/BTS 2010 NICE 2011 UK DEC 2016a Chief Coroner 2017	DH 2009 ICS/BTS 2010 UK DEC 2011 UK DEC 2014a UK DEC 2014b UK DEC 2014c UK DEC 2016a UK DEC 2016b FICM 2019 HTA Code Wales 2020 HTA Code F Part two 2020 UK DEC – heparin
AFTER Death	UK DEC 2016a HTA Code Wales 2020 HTA Code F Part two 2020 Chief Coroner 2017	AoMRC 2008 Lung DCD 2015 ICS/BTS 2010 UK DEC 2011 UK DEC 2014b UK DEC 2016a

Donation Actions Framework

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