

Trust Policy for the Management of Organ Donation

A clinical policy recommended

For use in:	NNUHFT
By:	Medical staff, Registered and non-registered nursing staff, Specialist Nurses in Organ Donation, Mortuary staff.
For:	Staff liaising with actual and potential organ and tissue donors or the families of potential organ and tissue donors.
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If Yes - does the strategy/policy deviate from the recommendations of NICE? If so why?	No

This policy has been approved by the Trust's Clinical Guidelines Assessment Panel and the Professional, Protocols, Policies and Guidelines as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes.

The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.

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Version and Document Control:

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3	06/05/2021	Document reviewed and amended according to current practice Addition of new 'Deemed consent' legislation 'Organ Donation Deemed Consent Act 2019'	Debbie Walford Matthew Overy Katherine Alger

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Background

In 2008, the Organ Donation Taskforce set out 14 recommendations, which if all were implemented, would increase the rate of deceased donation in the UK by 50% by 2013. Through the continued hard work of all involved in implementing these recommendations, there was an increase of more than 50.5% in deceased donations by April 2013 and a 30.55% increase in transplants performed.

Nevertheless, there remained an international shortage of donor organs available for transplantation, resulting in long waiting lists and sadly, a considerable number of people dying whilst awaiting a life-saving transplant. Therefore NHS Blood and Transplant (NSHBT) detailed a strategy entitled: 'Taking Organ Transplantation to 2020' (NSHBT, 2013), which had the primary target of matching world class performance in organ donation and transplantation. The Human Tissues Act (2004) together with best practice guidelines including; NICE Guidelines for Organ Donation, and the Royal College of Physicians Code of practice for the diagnosis of Brain Stem Death help to substantiate this strategy to the realms of professional responsibility and expectation.

As outlined in the strategy, Outcome 2 concerns hospital staff: "Action by NHS hospitals and staff will mean that the NHS routinely provides excellent care in support of organ donation and every effort is made to ensure that each donor can donate as many organs as possible."

To achieve this outcome, the following steps should be taken by each NHS trust:

- Routinely identify and refer all potential donors
- Increase adherence to national standards and guidance
- Increase the number of people who are able to donate following circulatory death
- Provide hospital staff with support, training, resources and information they need to provide an excellent donation service
- Ensure every donor's care prior to retrieval, optimises organ quality

In England 80% of people supported organ donation but only 37% had registered their decision (gov.com, Feb 2020) and this means when approached for donation families are often left uncertain about what their loved wishes. Following public consultation, the Organ Donation (Deemed Consent) Bill received Royal Assent on the 15th March 2019 and was passed in to law on the 20th May 2020. This means that all competent adults who are freely resident in England for >1 year will be considered as potential donors unless they specifically choose to opt out or are excluded. Under the law donation will still be discussed with families to ensure that the most up to date individual decision is known and respected.

The Norfolk and Norwich University Hospitals Foundation Trust (NNUHFT) has a relatively high potential for organ and tissue donation. Donor numbers have continued to increase over recent years, with significant progress having been achieved in the implementation of organisational strategies. It is particularly recognised that the significant advances that have been seen to date are the direct result of cooperation and collaboration between specialities and individuals, and that the importance of strengthening working relationships between those areas most involved in the donation process is paramount.

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Continued analysis of activity demonstrates additional donation potential which can be realised by employing a robust policy to direct and support clinical practice.

Whilst there are strong working relationships between National Health Service (NHS) Blood and Transplant and The East Anglian Eye Bank, the Trust has a separate policy which is dedicated to corneal donation and the activity of the eye bank is not specifically included in this document – East Anglian Eye Bank Guideline EB1 Version 8.

Purpose and scope of policy

This policy is designed to ensure that every patient who dies in the care of the NNUHFT is considered (where appropriate) for organ and/or tissue donation and that an organisational process is in place to support donation activity. It should be standard practice that every effort will be undertaken to support organ donation, taking into account the individual needs and preferences of patients and their families and that logistics will not be a barrier to this.

This document will clarify understanding across the Trust on issues surrounding practice in organ and tissue donation.

The policy will integrate the role of Specialist Nurses for Organ Donation (SN-OD) who are key in establishing and facilitating organ and tissue donation in clinical practice.

The policy will recognise the complexities that arise owing to the majority of potential organ donors lacking the capacity to be directly involved in decision making at the time of their death. It will clarify processes to ensure the legal, ethical and professional compliance of NNUHFT staff.

This policy should be implemented in light of the NNUHFT duty to avoid unlawful discrimination and with regard to the promotion of equal opportunity.

Objectives

- That the consideration of organ and tissue donation continues to be considered a normal part of end of life / bereavement care
- That all staff recognise their duty of care in relation to establishing the decision of every patient with regard to organ/tissue Donation, whether by discussion with their family or via the NHS Organ Donor Register held by NHS Blood and Transplant (NHSBT) and accessed via the Specialist Nurses
- For Trust staff to identify and refer all potential organ and tissue donors to a Specialist Nurse for Organ Donation (SN-OD)
- All potential donor families to be approached and offered organ and tissue donation where there is no medical or social contraindication to such an approach
- Trust staff ensure that every effort is made to involve a Specialist Nurse for Organ Donation in any family approach regarding donation
- Where individuals are not suitable for donation and the next of kin or significant other raise the subject, they are made aware that donation cannot be facilitated through open and sensitive communication
- All communication with the next of kin / significant others is accurately documented in the potential donor's case notes in accordance with Trust and National / EU standards

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- Optimal clinical management of any potential donor in the most appropriate location, to ensure that organs and tissues remain viable for transplantation
- To provide a comprehensive reference document in support of the organ donation process

Rationale

Many people have made the decision to donate their organs or tissues after death to save or enhance the lives of others. Health care professionals caring for the dying and bereaved have an ethical, moral and professional duty of care to facilitate such decisions that have been made in life. Under Deemed Consent law, where a decision to opt-out has not been made during the patients' lifetime and they meet inclusion criteria (Appendix 4) we can deem their consent for organ and tissue donation to proceed with the support of their family members or those closest to them. All appropriate cases should be referred to the Organ Donation Services Team and if suitable for donation on medical grounds the chance to establish and fulfil the decision of the deceased (or their family) regarding organ and tissue donation should be accommodated.

Definitions of Terms Used

Clinical Lead for Organ Donation (CLOD) – A clinician with responsibilities for developing and championing donation within the Trust.

Specialist Nurse – Organ Donation (SN-OD) – A senior nurse employed by NHS Blood and Transplant who is a specialist working with donor families, co-ordinating the donation process and is responsible for working with the CLOD to develop and champion donation within their hospital Trust.

Donation after Brain Stem Death (DBD) – donation of an organ or organs following the diagnosis of death using tests to confirm the absence of brain stem function (formerly defined as heart-beating donation).

Donation after Circulatory Death (DCD) – donation of an organ or organs after death has been confirmed on the basis of permanent cardio-respiratory arrest (formerly defined as non-heart-beating donation).

Human Tissue Act 2004 – Act governing removal, storage and use of organs from the deceased for transplantation in England, Wales and Northern Ireland. This came into force September 2006.

Human Tissue Authority – Oversees the implementation of the requirements of the Human Tissue Act 2004. This covers licensing of premises for retrieval, storage and consent. The licence covering organ and tissue donations for transplant is held by NHS Blood and Transplant – this covers specific tissues which may be taken purely for research with the consent of family members.

Organ Donation – For the purposes of this policy this will refer to the donation of solid organs after death has been diagnosed following brain stem death testing or cardio-respiratory arrest.

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Potential organ donor – Any patient in the Emergency department, Critical Care Complex and Neonatal Intensive Care who meets the criteria laid down for potential solid organ donation as set out in the Trust Policy and NICE CG135.

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Potential tissue donor – Any in-patient of NNUHFT who dies during their stay in hospital.

Tissue donation – The donation of tissues (such as skin, bone, eyes or heart valves) after death has been diagnosed following permanent cardio-respiratory arrest.

Broad recommendations

Required Referral

To comply with the recommendations of the Organ Donation Taskforce and NICE Guideline 135, clinical staff are required to refer all patients who are mechanically ventilated where a clinical decision is being made to withdraw life-sustaining treatment OR they meet criteria for Diagnosing Death by Neurological Criteria (DDNC) There is a Specialist Nurse – Organ Donation (SN-OD) available to discuss and if appropriate attend referrals on a 24 hour basis (Pager no - 03000 20 30 40).

Clinical Triggers

The specific clinical triggers (notification criteria) for referral as detailed in NICE Guideline 135 are:

- The absence of one or more cranial nerve reflexes and a Glasgow Coma Score of 4 or less that is not explained by sedation (unless there is a clear reason why this clinical trigger is not met) and /or a decision is made to perform brainstem death tests) in a patient who is mechanically ventilated
- The intention to withdraw life-sustaining treatment in patients who are mechanically ventilated and with a life threatening or life-limiting condition which will, or is expected to, result in circulatory death

Diagnosis of Death by Neurological Criteria (DDNC)

The Intensive Care Society Guideline (2004) recommends that diagnosis of death using neurological criteria should be performed in all cases where neurological death is suspected and that this should be considered to be unrelated to organ donation. Reasonable and where necessary invasive clinical measures should be taken to stabilise such patients to allow testing to take place. Testing should be performed according to the strict guidelines referred to in the Diagnosis and Confirmation of Death Guidelines (Academy of Medical Royal Colleges 2008).

Early Referral

In order to allow full assessment of the suitability of any patient for donation and to facilitate the presence of a donation specialist in any family approach for organ donation, it is recommended that contact is made with the Organ Donation Services Team at the earliest possible opportunity (ie as soon as neurological death is suspected/anticipated or when withdrawal of life sustaining treatment is provisionally discussed by clinical staff). There is no requirement to discuss donation or other end of life provision with the family before referring to the Organ Donation Services Team. Early referral allows adequate time to assess patient suitability for donation and subsequently plan a clear and collaborative approach to end of life discussions.

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Clinical Stabilisation

The patient should be cared for in an appropriate care setting (Critical Care Complex, Emergency Department, Neonatal Intensive Care Unit or Theatre Recovery) while the assessment for donation is performed. Life-sustaining treatments should not be withdrawn, delayed or limited until the patient's decision around organ donation have been explored and the clinical potential for the patient to donate has been assessed in accordance with legal and professional guidance.

Religious Perspectives

All major religions support the principles of organ donation and transplantation. It is recognised that within each religion there are different schools of thought, which means that that the views of individuals may differ. Referral to the Eastern Organ Donation Services Team should be made regardless of the patients' religion. It should not be assumed that because a patient or their family come from a specific religious background that referral for donation should not be made.

Ethnicity

The need for an organ transplant in the black, Asian and minority ethnic (BAME) community is more than three times higher than that of the general population. A transplant is much more likely to be successful if the donor and recipient have the same ethnic background. In accordance with equality and diversity requirements it is essential that potential donors from all ethnic backgrounds are referred to the Eastern Organ Donation Services Team. It should not be assumed that because a patient or their family come from a specific ethnic background that referral for donation should not be made.

Contraindications and Restrictions

The age range for solid organ donation is between 36 weeks corrected-gestational age and 85, this criteria is extended when considering tissue donation with no formal limits. There are only a few absolute clinical contraindications to organ donation which are reviewed on a regular basis and these can be discussed at the time of referral. To comply with national audit requirements the Organ Donation Services Team should be contacted to assess the suitability of **every** individual who fulfills notification criteria even if clinical staff suspect that donation will not be possible or will not proceed.

Professional Guidance

The General Medical Council specifically addresses issues relating to organ donation in the document "Treatment and Care towards the end of life" (2010). This document states that medical staff "should follow any national procedures for identifying potential organ donors" and "for notifying the local transplant coordinator".

The Organ Donor Register (ODR)

The Organ Donor Register can be accessed by SN-OD's 24 hours a day.

Where an individual has joined the ODR, the registration will detail the date and mode of joining and any restrictions specified by the individual.

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Equally where an individual has opted out the details of this registered decision will also be available – including date of opt-out decision.

It is important to note that under the deemed consent laws, if no registered decision is recorded then a patient can be considered as a deemed consent if they meet the associated criteria.

If requested the SN-OD can provide a printed copy of the ODR registration for the donor family.

A printed copy of the ODR registration will be included in the NHSBT file of any proceeding donor.

After donation the ODR cannot be consulted retrospectively as the details of any deceased individuals are removed.

The ODR will not be consulted until a clear plan regarding withdrawal of treatment or DDNC has been recorded – as earlier knowledge of the ODR status may be perceived to have an influence on care or treatment decisions.

It should be noted many people inform their loved ones verbally about their end of life wishes and may not feel the need to sign the organ donor register. These patients should be cared for in the same manner until their wishes have been explored.

All patients should be considered for donation regardless of ODR status. If a patient has opted out on the ODR it may still be appropriate for the SNOD to meet with the family to confirm whether this is the patients' last known decision.

Approaching the Donor Family

Organ donation should be considered a normal part of end of life care and all families should be given the opportunity, where appropriate, to consider this. If organ donation is not discussed, then we deny a family the opportunity to fulfill their relatives end of life decision.

The family should not be offered donation until a SN-OD has been contacted to establish potential suitability for organ donation and this has been confirmed.

Coronial, legal and safeguarding issues should be clarified prior to raising the subject of donation.

The Organ Donor Register should be consulted as should any Advance Statements or Lasting Power of Attorney for Health and Welfare.

Where a patient has the capacity to make their own decisions, their views on organ donation should be sought directly as should their consent.

All approaches for organ donation should be made collaboratively with the SN-OD, unit clinician and a member of the nursing staff. A SN-OD should be involved in all approaches for organ donation, where possible, as they have a specialist knowledge of organ and tissue donation and can manage the families' expectations with regards to the organ donation process.

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Early referral is essential to allow the suitability for organ donation to be explored prior to offering it to families.

Staff caring for a potential donor should not raise the topic of donation before discussion with the Specialist Nurse Organ Donation.

There is no requirement to inform the family or significant others that an organ donation referral has been made.

The option of donation should be given only when the family has understood that further active treatment is futile and that death is imminent or has occurred.

The SN-OD should be involved at an early stage to allow engagement with the family in order to provide additional support whilst ascertaining family dynamics, as well as their understanding and responses to the ongoing situation. They will pace information given and ensure that donation is not mentioned before the family indicates that they have fully understood futility and that they are ready to consider end of life decisions.

Discussion relating to donation should be undertaken in a setting suitable for private and compassionate communication at a time that best suits the family's circumstances.

The information that families / significant others are given should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities and to people who do not read or speak English (this may necessitate the use of a professional interpreter).

Discussions with those close to potential donors should stress the following:

- The rationale behind the decision to withdraw life-sustaining treatment or DDNC
- The care and dignity of the patient remains paramount.
- The standard of care will be the same
- The interventions that may be required between consent and organ retrieval
- The potential time scales involved in facilitating organ donation

Donation after Brain Death (DBD)

Where Brain Stem Death (BSD) is suspected or anticipated, the patient should be actively managed and maintained for DDNC in accordance with the Intensive Care Society Guidelines.

DDNC testing should be considered to be unrelated to organ donation and the subject of donation should only be raised once the family have understood and are accepting of the prognosis.

It is both lawful and ethically acceptable to take reasonable measures to clinically stabilise and maintain an individual while their decision regarding organ donation is explored or fulfilled.

Temperature should be normalised. DDNC cannot be performed in individuals where the temperature is below 34 degrees centigrade.

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Blood pressure should be supported and central access should be cited if required to facilitate the administration of inotropic agents to maintain cardiovascular stability and a MAP above 60 mmHg during DDNC or discussions regarding organ donation.

Fluid balance should be maintained with output matched by fluid replacement as clinically indicated. The administration of DDAVP (widely known as Desmopressin) should be considered to control diuresis if Diabetes Insipidus is suspected.

Electrolytes should be maintained within normal limits as marked elevation or deficiency will prevent DDNC. The acceptable range is detailed within the Diagnosis and Confirmation of Death Guidelines (Academy of Medical Royal Colleges – 2008).

If consent for Cardiothoracic donation is given the SN-OD will request permission to mobilise a “Donor Management Scout Team” from a specialist cardiothoracic centre if available.

Donation after Circulatory Death (DCD)

A valid Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) order, as per Trust policy (Document ID: 8003) should be included in the medical records, as should a documented intention to withdraw life sustaining treatment.

It is both lawful and ethically acceptable to take reasonable measures to clinically stabilise and maintain an individual while their decision regarding organ donation are explored or fulfilled. However, this would not change previously agreed treatment limitations.

The comfort and care needs of the patient remain paramount throughout the donation process and it is essential that sedative drugs or analgesics are not withheld in patients who are to progress to donation after circulatory death.

Treatment should not be withdrawn until a clear decision with regard to organ donation has been agreed.

When consent and associated arrangements for organ donation are in place the surgical retrieval team will attend and prepare for surgery. Treatment should be continued until the SN-OD advises that the surgical team is ready to commence surgery.

Withdrawal of treatment should not be undertaken until a suitable medical practitioner has been identified and is available to certify death 5 minutes after loss of circulation.

It is appropriate to diagnose death 5 minutes after loss of the central pulses, loss of arterial pressure and the loss of heart sounds.

For the purpose of organ donation the time of death should be documented as at loss of the arterial line trace / loss of cardiac output as opposed to the loss of agonal, electrical activity on the ECG trace.

If the donor family elects to be present at certification of death the ECG monitor should be removed and heart rate monitored via the arterial line trace.

In order to facilitate organ donation the patient will be transferred to theatre immediately after certification of death and surgery will proceed immediately.

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The family should be given the opportunity to remain with the patient who is a potential DCD donor up until the time that they are transferred to theatre.

Where a patient is based on a Critical Care Unit outside of the main CCC, a decision will be made on a case by case basis as to whether to withdraw treatment in the Critical Care unit or in theatres. Consideration should also be given to moving the patient to the main CCC to facilitate withdrawal in a CCC environment but closer to theatres. Where treatment is withdrawn in theatres family presence should be facilitated where they wish to be present.

The family must be made aware that organ donation cannot proceed if death does not occur within a set timeframe from withdrawal of life sustaining treatment. If the patient does not proceed to donation an area suitable for appropriate end of life care should be identified and the patient should be transferred to this area when the non-proceeding donation process is completed.

Organ Donation from the Emergency Department

In order to ensure NNUHFT compliance with NICE Guideline 135 every patient fulfilling notification criteria / clinical triggers (see section 1) should be referred to the Organ Donation Services Team regardless of their location in the hospital.

Whilst in the Emergency Department life sustaining mechanical ventilation should not be withdrawn from any patient with spontaneous circulation unless a referral has been made to the Organ Donation Services Team and the patient has been deemed medically unsuitable for organ donation.

In recognition of time and safety limitations it is recommended that a provisional referral is made at the earliest indication of any un-survivable condition where the patient is intubated and mechanically ventilated. This will allow a SN-OD to initiate early mobilisation to the NNUHFT or to rule out the potential for organ donation in collaboration with transplant surgeons. Care should not be influenced by this referral.

Whilst referrals are welcomed from any member of clinical staff it is essential that the clinician responsible for the care of a patient is aware of any referral to the SN-OD team. Should the patient's prognosis improve or if there is a subsequent plan to transfer the patient for neurosurgery care should be escalated appropriately and the SN-OD should be informed of the change in clinical plan. In this instance the SN-OD would suspend the referral.

If following referral to the Organ Donation Services Team a potential for donation is established, the patient should be stabilised in an appropriate care setting (Critical Care Unit, Emergency Department or Theatre Recovery) until the SN-OD is in attendance and full assessment for donation is undertaken.

If a SN-OD cannot attend within an appropriate time frame it may be necessary for Trust staff to make the approach for donation, remotely supported by the SN-OD.

Organ donation should not be discussed with family members until provisional medical suitability has been established.

In the case of a provisional referral, all care and investigations should continue as they would in a case where organ donation had not been considered, including referral to Critical Care and Neurosurgery.

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If the patient is not accepted for admission to Critical Care the responsibility for the care of the patient remains that of the Emergency Department and all decisions regarding the ongoing care of the patient should be made by an Emergency Department clinician.

In line with NICE guidance life sustaining treatment should not be limited or withdrawn until the potential for organ donation has been fully explored.

The age range for solid organ donation is between 36 weeks corrected-gestational age and 85, this criteria is extended when considering tissue donation with no formal limits. There are only a few absolute clinical contraindications to organ donation which are reviewed on a regular basis and these can be discussed at the time of referral. To comply with national audit requirements the Organ Donation Services Team should be contacted to assess the suitability of every individual who fulfills notification criteria even if clinical staff suspect that donation will not be possible or will not proceed.

Staffing and Capacity

Admission to Critical Care should be facilitated for all patients where the potential for organ donation has been confirmed by a SN-OD.

It is unacceptable to refuse admission because there is only one bed available unless this bed has been previously allocated to a named patient.

Any situations where admission is not facilitated will be investigated as a clinical incident at Trust level

If there are no Critical Care beds the SN-OD/ Emergency Department Staff / Critical Care Complex staff should contact the on-call Site Manager who will consider appropriate patient transfers to create capacity for admission of the potential donor.

If a Critical Care bed cannot be identified or vacated the patient should remain in the Emergency Department and treatment maintained. This should be viewed as a temporary measure and time limited, as the standard of care the patient receives will not be equitable to the 1:1 care received on the Critical Care Complex. If the Critical Care Complex has no capacity, and care of the patient is being affected by capacity, crowding or staffing issues in the ED the operational site team must accommodate the patient to another appropriate area (theatre complex) with support from the on call executive team.

Only if a potential donor cannot be accommodated in Critical Care or Emergency Department should admission to the theatre complex be facilitated.

If admission to any location is limited by staffing issues, all measures should be taken to identify and utilise a suitably trained nurse to be responsible for the provision of direct care to the potential donor.

It is professionally and ethically unacceptable for a SN-OD to be responsible for the provision of direct care for a potential DCD donor prior to death, other than by assisting NNUHFT staff in delivering basic nursing care.

Any cost associated with additional bank, locum, agency or overtime staffing for medical or nursing staff will be met and reimbursed to the department affected by the Organ Donation Committee budget.

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Elective Ventilation

In order to be considered as a potential organ donor a patient must already be mechanically ventilated. The decision to ventilate should have been based only on clinical need and be for the purpose of treatment and full assessment. It is unacceptable and unlawful to ventilate a patient purely for the purpose of organ donation.

Non Invasive Ventilation

Organ donation from a patient who is being treated with non-invasive ventilation (NIV) can be considered for organ donation and can be assessed on a case by case basis if they meet criteria in accordance with NICE guidance 135.

Investigations to support Organ Donation

When consent to organ donation has been given it may be necessary to complete additional investigations to facilitate the donation process.

In every case blood samples will be required to allow virology and tissue typing. Explicit consent for the collection of these samples will be sought and recorded. The samples will be transported to an appropriate laboratory for analysis. The cost of this transport will be met by NHSBT.

Organ Donation cannot be facilitated without a confirmed blood group and a “group and save” will be requested in every case unless a recent result is available via the ICE system.

Intra-operative blood transfusion may be required and cross matched blood may be requested. The SN-OD will ask a member of clinical staff to submit this request according to Trust procedure. It is essential that the laboratory staff are aware that the transfusion is for an organ donor – a checking slip will then be issued to allow safe administration of the transfusion. The SN-OD or circulating theatre practitioner will ensure that an appropriate prescription – signed by a Trust clinician is available prior to the administration of any intra-operative blood transfusion.

If cross matched blood is not administered the circulating theatre practitioner will advise the transfusion laboratory following donation and advise that the blood can be reissued for transfusion.

In individual cases of organ donation, specific blood tests may be requested by the SN-OD on behalf of the transplanting centres in order to fully assess organ function. The SN-OD will request these investigations as urgent and such results should be facilitated accordingly.

In cases where heart donation is anticipated a formal echocardiogram may be requested. This should be treated as an urgent request and may involve an on call echocardiographer attending out of hours. The donation process will effectively be halted until the investigation has been performed and reported.

In every case of donation, a chest x-ray taken on the day of donation (or the most recent available) will be required. This imaging will need to be reviewed by a clinician for evidence of localised pathology which may contraindicate donation (such as malignancy).

In cases where transplant centres request access to imaging results the SN-OD will liaise with the radiology department to facilitate the secure transmission of digital images.

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In cases where heart donation is anticipated a 12 lead ECG is required.

Where specific concerns are raised relating to suitability for donation a consultation with associated NNUHFT clinicians may be requested. Where a clinician is asked to consult this should be regarded as an urgent request. All findings should be documented in the medical notes according to NNUHFT procedure.

Theatre

The SN-OD is responsible for notifying the theatre coordinator at the earliest possible stage of any potential organ retrieval.

In conjunction with the theatre coordinator the SN-OD will coordinate the arrival of the surgical retrieval team(s) at an agreed time, when a theatre is expected to be available.

The SN-OD is responsible for ensuring that all cases of organ retrieval are booked via the trust electronic booking system.

Organ retrieval should be treated as an urgent surgical case. Whilst it will not take precedence over any emergency case, there may be rare circumstances where it is necessary to delay, relocate or cancel routine operating lists to accommodate retrieval.

Where the theatre coordinator anticipates sustained lack of theatre capacity this should be discussed in the first instance with the Duty Site Manager and when necessary escalated to the On-Call Trust Executive.

When possible theatre allocation should be considered in relation to size (to accommodate NORS teams) and location (to minimise transfer time from Critical Care or NICU).

In rare cases it may be impossible to accommodate withdrawal of life sustaining treatment (WLST) in the main Critical Care Complex. In such cases it will be necessary to WLST in the anaesthetic room. Members of the donor family will be given the option of being present in such cases. An identified member of NNUHFT medical staff MUST be available to certify death prior to retrieval surgery.

NNUHFT theatre personnel are expected to support the retrieval team(s) throughout the retrieval process.

The SN-OD is responsible for ensuring that all NNUHFT staff who are to be present at organ retrieval have been briefed on what to expect and have had the opportunity to ask questions before surgery commences.

A Surgical Safety Checklist will be completed by the SN-OD in all cases.

The retrieval team(s) will include surgeons, a scrub nurse and a perfusionist, when cardio-thoracic retrieval is planned a Donor Care Practitioner may also attend. The team(s) will require a member of NNUHFT theatre staff to act as "circulator" within theatre and to assist with locating equipment and advising on local procedures.

For DCD retrieval surgery (with the exception of lung retrieval) there will be no requirement for anaesthetic provision.

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In DBD retrieval the NNUHFT will be required to provide an anaesthetist and Operating Department Practitioner both of whom will be involved in the case until circulation ceases at the point of cross clamp. Such anaesthetic provision should be considered as an urgent case and should be covered by the appropriate clinician. Anaesthetic cover should be negotiated by the SN-OD in conjunction with the theatre coordinator and the senior on-call anaesthetist as soon as a theatre time is agreed.

Funding is available to support overtime, locum or bank payments for nursing or medical staff of all grades from re-imburement funds paid to the Trust by NHSBT. If it is necessary to mobilise additional theatre staff to support organ retrieval such payments will be authorised by the Clinical Lead for Organ Donation.

It should be noted that whilst NHSBT and NNUHFT support staff interest in organ donation, there may be cases where it is inappropriate for multiple staff members to observe retrieval surgery. Should staff wish to observe organ donation procedures this should be discussed and agreed with the SN-OD and lead surgeon prior to the beginning of the theatre process. It is stressed that any staff in theatre during retrieval surgery should be mindful of the privacy, dignity and respect that should be accorded to the situation.

The retrieval team(s) will provide any specialist surgical equipment required including perfusion fluids, transport boxes and ice. The Trust will be asked to provide standard supplies such as gloves, gowns and suction equipment.

Donated organs may be transported by the retrieval team(s) or by specialist couriers. Drivers should be given access to the theatre complex and asked to wait in an appropriate area until the donated organs are available for transit. The SN-OD should be informed that the driver is waiting. The cost of transporting organs will be met by NHSBT.

With the agreement of donor family members, it may be possible to provide follow up information which will be sent to theatre staff within two-four weeks via the Senior Nurse Manager. This letter should include specific provision for trust staff to comment on their experience of the retrieval process.

Should staff have any concerns or questions the embedded SN-OD is available to provide appropriate advice and support on request (pager 07623 512238).

If required a formal debrief for theatre staff is available via the embedded SN-OD on request. In all cases of organ donation a SN-OD (employed by NHSBT) will be present throughout the entire organ donation process.

Solid organ donation can only occur in theatre but this does not necessitate location within the emergency theatre.

Care after Death

Following an organ retrieval operation, the SN-OD assisted by members of the NNUHFT theatre team will perform care after death in accordance with Trust policy.

In some case's particular requests that have been made by the donor family will be followed in theatres. Examples of such requests may be the collection of handprints or locks of hair post operatively or the dressing of the patient in requested clothing during care after death.

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To ensure that appropriate standards of privacy, dignity and respect are maintained, staff in theatre should not undertake cleaning and restocking of the area until the patient has been transferred to the mortuary or anaesthetic room.

Should the donor family wish to view the patient post operatively the SN-OD will negotiate this with the theatre coordinator and agreement will be reached regarding the most appropriate area to facilitate this wish. A member of the SN-OD team will be present to support the donor family at this visit.

Time Frames

The donation process cannot proceed until full written consent has been given by a person in an appropriate qualifying relationship.

Every effort will be made to ensure that the donation process is completed in a timely yet safe fashion.

The process may be delayed by multiple factors, these include but are not limited to – the completion of necessary tests prior to offering, the availability of retrieval surgeons, theatre capacity and family requests.

The retrieval team is obliged to mobilise from their base hospital within one hour of the request to mobilise – failure to do so will be reported to NHSBT via the quality structure.

The SN-OD is responsible for ensuring that any delay and the reason for the delay is effectively communicated to the family, the Consultant responsible for the patient and any other identified persons involved in the progress of the case.

The reason for any time delay should be documented in the patient's medical records to ensure that the information is available to all staff involved in the case.

Post Mortem Examination

Following each proceeding donation the attending SN-OD will make the following entry in the medical notes

“If a Post Mortem examination is performed the pathologist must IMMEDIATELY contact NHS Blood & Transplant (NHSBT) via Hub Operations on telephone number 01179 757580 should the examination identify pathology that is or may be relevant for the health or future health of the transplant recipient(s) and/or the patients family.”

Eye and Tissue Donation

Whilst there are strong working relationships between National Health Service (NHS) Blood and Transplant and The East Anglian Eye Bank, the Trust has a separate policy which is dedicated to corneal donation and the activity of the eye bank is not specifically included in this document – East Anglian Eye Bank Guideline EB1 Version 8. This guideline also refers to the facilitation of tissue donation within the Trust.

Multi-organ donors may also be consented for tissue donation which will be facilitated after the patient has been transferred to the mortuary. In such cases the mortuary staff will be informed and supporting documentation such as consent forms will accompany the patient as well the required blood samples.

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On occasion the SN-OD will receive queries relating to eye and tissue donation in those patients who would not be considered as potential organ donors. In these instances the SN-OD will redirect that query to the Eye Bank or Tissue Services Coordinator.

Donation for Medical Science

An individual, a family member or significant other may express a wish to leave their body to Medical Science via a School of Anatomy. This decision must have been made by the patient in their life-time with full capacity and registered with a School of Anatomy. The potential donor must have informed a designated individual who then has the responsibility to contact the relevant School of Anatomy and inform them of the patient's death. At this point suitability would be assessed by the School of Anatomy.

The donation of a deceased patient to medical science cannot be arranged after death or consented to by a family member after death on behalf of an individual.

The Bereavement Office will be able to provide further advice on this if required.

Coronial Involvement

In every case where organ donation is considered, Her Majesties Coroner (HMC) for Greater Norfolk (or a designated representative) will be contacted by the SN-OD and authorisation to proceed requested.

Organ donation cannot proceed without the explicit agreement of the Coroner.

If the Coroner or a designated representative refuses permission for donation the process cannot proceed. It may however be possible for the SN-OD to negotiate restricted consent (for specified organs and tissues only) or to invite the involvement of Senior Police Officers or Home Office Pathologists.

The donor family cannot overrule the decision of the Coroner although the wishes of the family will be relayed to the Coroner and their wishes will be taken into account as part of the decision-making process.

All conversations with the Coroner or a designated representative must be recorded in the deceased's medical records / NHSBT donor file.

The SN-OD will ensure that Coroners consent for the removal of organs for transplant has been obtained and documented before retrieval surgery takes place.

Discussions between the SN-OD and HMC pertain only to permission for organ and tissue donation and do not replace nor supersede consultation between clinicians and the coroner's office relating to the certification of death, inquest or further coronial requirements. Consultation with the coroner's office should proceed in every applicable case as if donation had not taken place.

If coronial consent for organ donation is denied or restricted the SN-OD will report this via the NHS Blood and Transplant Clinical Governance process. The NNUHFT will not be involved in the investigation of coroner's decisions relating to organ donation, although the involvement of specific clinicians may be documented as part of the reporting process.

Trust Policy for the Management of Organ Donation

Consent

Every case of organ and tissue donation will be coordinated by a SN-OD working collaboratively with NNUHFT nursing and medical teams.

Under Deemed Consent law, where a decision to opt-out has **not** been made during the patients' lifetime and they meet inclusion criteria (Appendix *) we can deem their consent for organ and tissue donation to proceed with the support of their family members or those closest to them

Where a patient has the capacity to make their own decisions, the SN-OD should obtain their views on and their consent to organ and tissue donation.

If a patient lacks the capacity to consent to organ donation staff have a responsibility to seek to establish the patient's prior consent by:

- Establish whether the patient has registered a decision to opt-in or on the NHS Organ Donor Register
- Referring to any advance statement if available
- Establishing the last known decision regarding organ donation with those close to the patient If the patients prior consent has not already been ascertained and in the absence of a person or persons having been appointed as nominated representative(s), consent for organ donation should be sought from those in a qualifying relationship with the patient.

Where a nominated representative has been appointed and there is no evidence that the person has made a decision about donation, consent should be sought from the said nominated representative.

The table below details who is identified by the Human Tissue Authority as able to give consent in the absence of a person or persons having been appointed as a nominated representative. Qualifying relationships are ranked in order in the table below.

Spouse or partner
Parent or child
Brother or sister
Grandparent or grandchild
Niece or nephew
Stepfather or stepmother
Half brother or half sister
Friend of longstanding

Written consent for organ and tissue donation will be taken by the attending SN-OD and this process should be witnessed by a second healthcare professional.

In specific cases it may be necessary to take formal consent for donation by telephone. In such a situation the SN-OD will ask for a second healthcare professional to act as a witness and will also record the call according to NHSBT requirements.

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After donation a copy of the completed consent form will be filed and retained in the medical notes of the patient.

The donor family can request a copy of the completed consent form for their own information and reference.

The SN-OD will ensure that patient details are correct, including name, address, date of birth, hospital number and National Health Service number (this will be checked with family members and against medical records)

The SN-OD will request specific consent for each organ and tissue that may be donated.

Where an organ or tissue cannot be donated for medical or other reasons the SN-OD will explain this to the family.

The family will be assured that no organ or tissue will be retrieved unless specific consent has been given.

The SN-OD will provide core minimum information relating to the retrieval surgery and the anticipated appearance of the patient after donation.

Formal consent will be taken to collect, transport and analyse blood samples for virology and tissue typing. Although samples may be collected and dispatched after verbal consent has been obtained, the analysis of virology will not be undertaken until formal written consent is in place.

The donor family / person giving consent will be advised that after donation blood and tissue samples will be stored by the transplanting centres to facilitate any further analysis that may be required in the future.

The donor family / person giving consent will be informed that tissues donated for transplant (such as skin, heart valves and corneas) may be stored for prolonged periods and will not be allocated for specific transplant recipients prior to retrieval.

Consent will be requested for NHS Blood & Transplant to contact the General Practitioner of the donor in order to identify any previously unknown contraindications or risks to donation. The donor family / person giving consent will also be advised that the SN-OD will access the medical records of the donor and that any pertinent information will be shared with transplant centres.

The donor family / person giving consent will be advised regarding the safe storage of their own contact details and the personal information of the donor by NHS Blood and Transplant. They will be assured that confidentiality will be maintained and follow up arrangements will be agreed and recorded on the consent form.

The SN-OD will discuss with the donor family / person giving consent the circumstances that may arise leading to the non-transplant of donated organs and their options in such circumstances, including ethically approved disposal or ethically approved research projects. The wishes of the person giving consent will be recorded and adhered to.

It may be possible to obtain consent for organs that are outside of donation criteria to be used in specified ethically approved research studies.

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When complete the consent form will be signed, dated and timed by the SN-OD, the witness and the person giving consent (donor family or nominated representative). Any other involved individual will be invited to counter-sign the consent form in support of the primary signatory.

The original copy of this consent form will be retained by NHS Blood and Transplant.

The donor family / person giving consent will be informed that they can withdraw consent at any time up until surgery commences. Although after surgery begins their consent cannot be formally withdrawn their wishes would be taken into account and any request to withdraw from the donation process would be discussed by the SN-OD with a member of the NHSBT management team and senior staff in the donating hospital.

Research

Only in accordance with formal documented consent and as stipulated in the regulation of the Human Tissue Authority, organs retrieved for the purpose of transplant and subsequently found unsuitable may be submitted for ethically approved research.

The SN-OD will ensure that the appropriate consent is in place before submitting any donated organ for research.

If an organ is submitted for research this information will be shared with the donor family / significant others / trust staff. Information regarding the purpose and scope of the specific research study will also be provided by the SN-OD as part of the post donation follow up.

In specific cases consent may be taken for the removal of organs or tissues for the primary purpose of research.

Trust research and development approval is in place for any such activity with copies of said approval available on request.

Appropriate extensions to the Human Tissue Authority License have been requested and approved for the purpose of removing organs and tissues for the purpose of research (license number 11208 HTA 01513).

Positive Virology

Blood samples for virology testing and tissue typing are taken from every potential donor in order to ascertain suitability as outlined above. These samples are tested on behalf of the transplant teams in Public Health laboratories outside the donating hospital. The results are made available to the donation and transplant teams. If the results of any samples tested potentially impact on the health and well-being of the next of kin / significant others they would be contacted by the lead SNOD with recommendations made for them to seek GP guidance.

Any positive virology results will be managed collaboratively by NNUHFT and NHSBT according to NHSBT guidelines to ensure the safety of any transplant recipients or potential transplant recipients.

Follow up

The SN-OD is available to support the family in the first days, weeks and months following donation. An initial follow up letter is also sent to the family 2-4 weeks after donation and

Trust Policy for the Management of Organ Donation

again at around one year. The SN-OD will refer to other agencies as appropriate and provide contact details of the Eastern Organ Donation Services Team.

The SN-OD will ensure that the donation and transplantation outcome is communicated to the family of all donors, within 14 – 28 days of the donation, unless the family request otherwise. In cases of tissue only donation the tissue coordinator will contact the family to confirm which tissues have been retrieved.

Any correspondence following donation will observe the right of organ donors and transplant recipients to maintain confidentiality. Minimal information will be included to identify the date and circumstances of the donation and the history and progress of those who have received transplants.

Follow up from NHS Blood and Transplant will be in addition to any established process within the Trust and information will be shared with Trust staff as required (ie Bereavement Office).

A detailed record of each donation is retained by NHS Blood and Transplant. This patient identifiable data is stored according to Information Governance Regulations and Human Tissue Authority Regulation. The storage of donation records is audited by the Human Tissue Authority.

The SN-OD will ensure that outcome feedback is provided to staff if requested within 14-28 days of the donation with family approval.

The SN-OD will encourage service feedback evaluation from healthcare professionals involved in the donation process.

The SN-OD will offer debriefing sessions and staff support to healthcare professionals involved in the donation process when deemed necessary or as requested.

Donor families will be offered the opportunity to formally feedback on their experiences post donation. These responses will be directed to the Managers of the Organ Donation Services Team. Any comments relating to the donating hospital or staff therein will be passed on to the Trust accordingly.

The Potential Donor Audit (PDA)

The embedded SN-ODs are responsible for the collection and submission of data for the Potential Donor Audit.

All deaths within the Critical Care Complex, Neonatal Intensive Care Unit and the Emergency Department will be reviewed for audit purposes.

The data collected will be submitted securely to NHSBT. Patient confidentiality will be maintained and no patient identifiable details will be entered electronically as part of the audit process.

Information relating to the audit is submitted to the NNUHFT Clinical Audit and Improvement Department for inclusion in trust output and all efforts will be made to comply with the required audit structure.

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The information submitted to NHSBT is used to assess and compare the performance of the NNUHFT against set parameters in National Organ Donation. Reports are compiled by NHSBT and cascaded to the NNUHFT Chief Executive on a six monthly basis.

The CLOD and SN-OD will report on a three monthly basis to the Organ Donation Committee.

The CLOD and SN-OD will report on a six monthly basis to the Critical Care Clinical Governance Meeting.

The SN-OD will bi-annually report a narrated summary of the PDA to the NNUHFT Effectiveness sub-board.

Under the terms of an authorised honorary contract, designated SN-OD's will have access to trust Information Technology systems and the Health Records of patients to allow audit to be completed.

The Organ Donation Committee

The CLOD is responsible for ensuring that a trust Organ Donation Committee exists and is representative.

The committee should meet at least four times a year.

Funding to support the committee is paid by NHSBT annually.

The committee is responsible for supporting the SN-ODs and the CLOD in the development of the organ donation service and for future planning.

Finance

The Human Tissue Act (2004) prohibits commercial dealing in organs including non-regenerative tissue. It is a criminal offence to make or receive payment in return for supplying an organ from a dead or living person intended for transplantation. It is also an offence to broker or negotiate an arrangement involving such payment or to advertise for donors who will be paid.

Each proceeding organ donation is supported by payment from NHSBT.

The funding is paid annually by NHSBT based on the number of proceeding donors in the previous year and is held within the NNUHFT finance structure.

Monies can be accessed by the CLOD and are allocated to projects supported by the Organ Donation Committee.

Any spend over £2000 will be considered and authorised by a sub group of neutral committee members in conjunction with the CLOD and SN-OD.

Complaints

Any formal complaints that are directed to the NNUHFT and which pertain solely to the organ donation process should be passed to the Managers of the Eastern Organ Donation Services

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Team who will take appropriate action according to NHSBT policy, communicating appropriately with the Trust.

The relevant SN-OD will respond to any request made for further information required to address a formal complaint but will be required to take advice from the NHSBT Team or Regional Manager.

Any informal complaints or issues arising will be addressed by the CLOD in conjunction with the SN-OD in an effort to achieve full and early resolution.

Public Promotion of Organ Donation

The SN-ODs are available to support the promotion of organ donation within the wider community although it will be necessary to ensure that such activities do not negatively impact on the availability of the SN-OD to support organ donation activity.

A limited range of promotional literature and items are available free of charge from NHSBT.

At the discretion of the Organ Donation Committee funds may be used to purchase bespoke promotional items or to promote organ donation within the local community.

Education

The SN-OD is available to provide educational sessions for all grades and disciplines of staff.

Education relating to organ donation should be considered essential for all members of NNUHFT staff who are involved in the care of potential organ or tissue donors.

Each relevant ward / department should have a link nurse responsible for local education and awareness of organ and tissue donation, including the Trust policy.

Conscientious objection

Clinical staff who have conscientious objections to donation cannot be expected to take part in the process, but neither can their objection be allowed to deny any patient or their family the opportunity of donation when it involves a process that has received local and national endorsement (Murphy & Logan 2009).

Conscientious objection may be permissible if sufficient medical and nursing staff are available and willing to provide the service.

Conscientious objectors must ensure that patients and their families are aware of the care they are entitled to and should refer care to another suitable professional to facilitate the process.

Conscientious objectors must not compromise the care of their patients, (Savulescu 2006).

Clinical audit standards / monitoring compliance

To ensure that this document is compliant with the above standards, the following monitoring processes will be undertaken: monitoring effectiveness and compliance of the policy will be undertaken by the SN-OD during National PDA data collection and Analysis. The policy will be reviewed annually and updated accordingly to reflect any changes in practice.

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The audit results will be sent to (Chief Executive Officer (CEO) by NHSBT and to Clinical Safety and Effectiveness Sub-board twice a year) who will ensure that these are discussed at relevant governance meetings to review the results and make recommendations for further action.

Summary of development and consultation process undertaken before registration and dissemination

During the development of this guideline it has been assessed by members of Professional, Protocols, Policies and Guidelines (PPPG) Committee, Clinical Guidelines Assessment Panel (CGAP) and solicitor's in the Legal team.

It was reviewed in March 2021 by the Organ Donation Committee and changes made as detailed in the version control box.

This version has been endorsed by the Organ Donation Committee and Clinical Guidelines Assessment Panel

Distribution list / dissemination method

Trust internet

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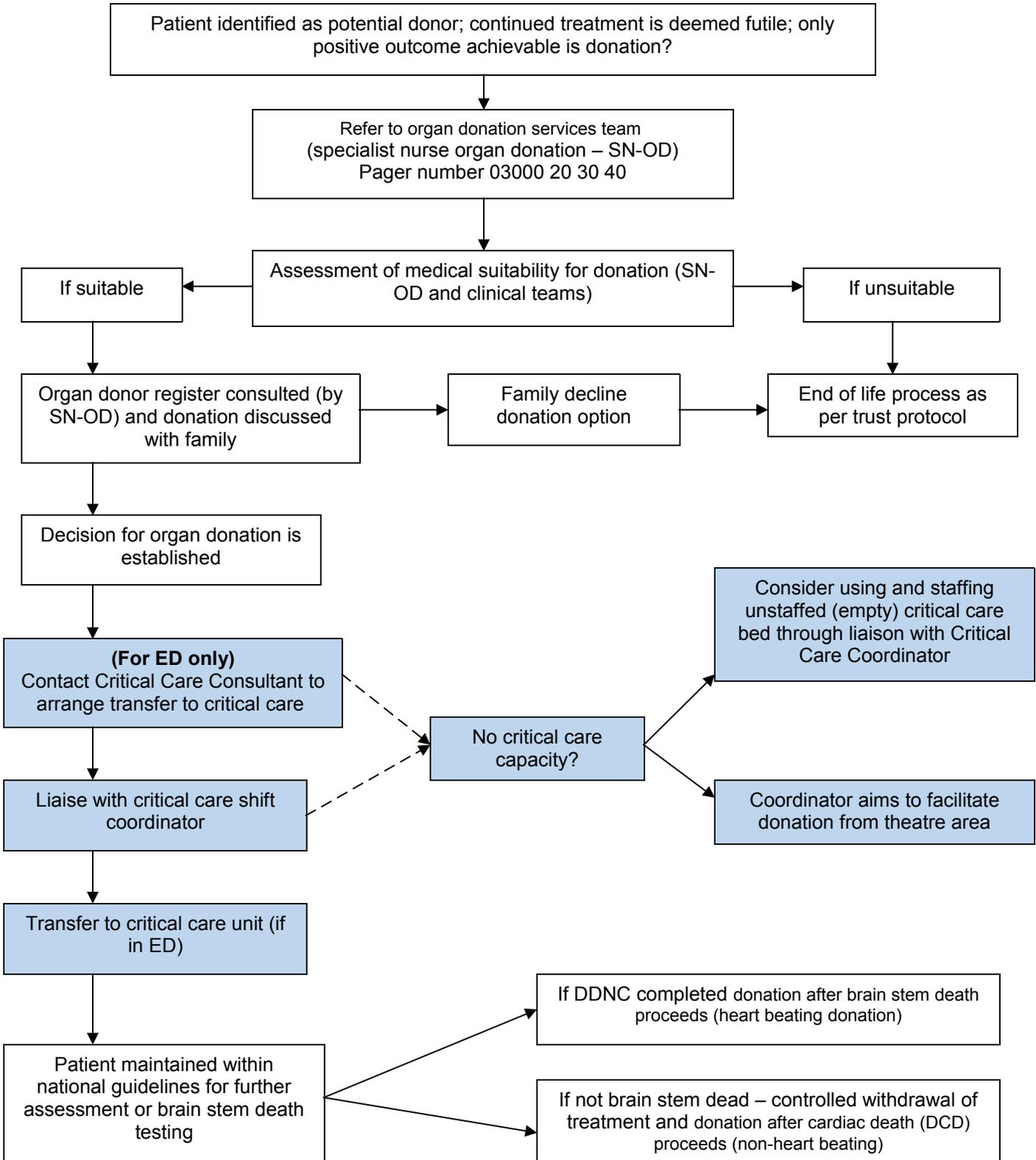
An Ethical Framework for Controlled Donation After Circulatory Death - Academy of Medical Royal Colleges 2011

Taking Organ Donation to 2020 – A detailed strategy
NHSBT 2020 Strategy

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Appendix 1

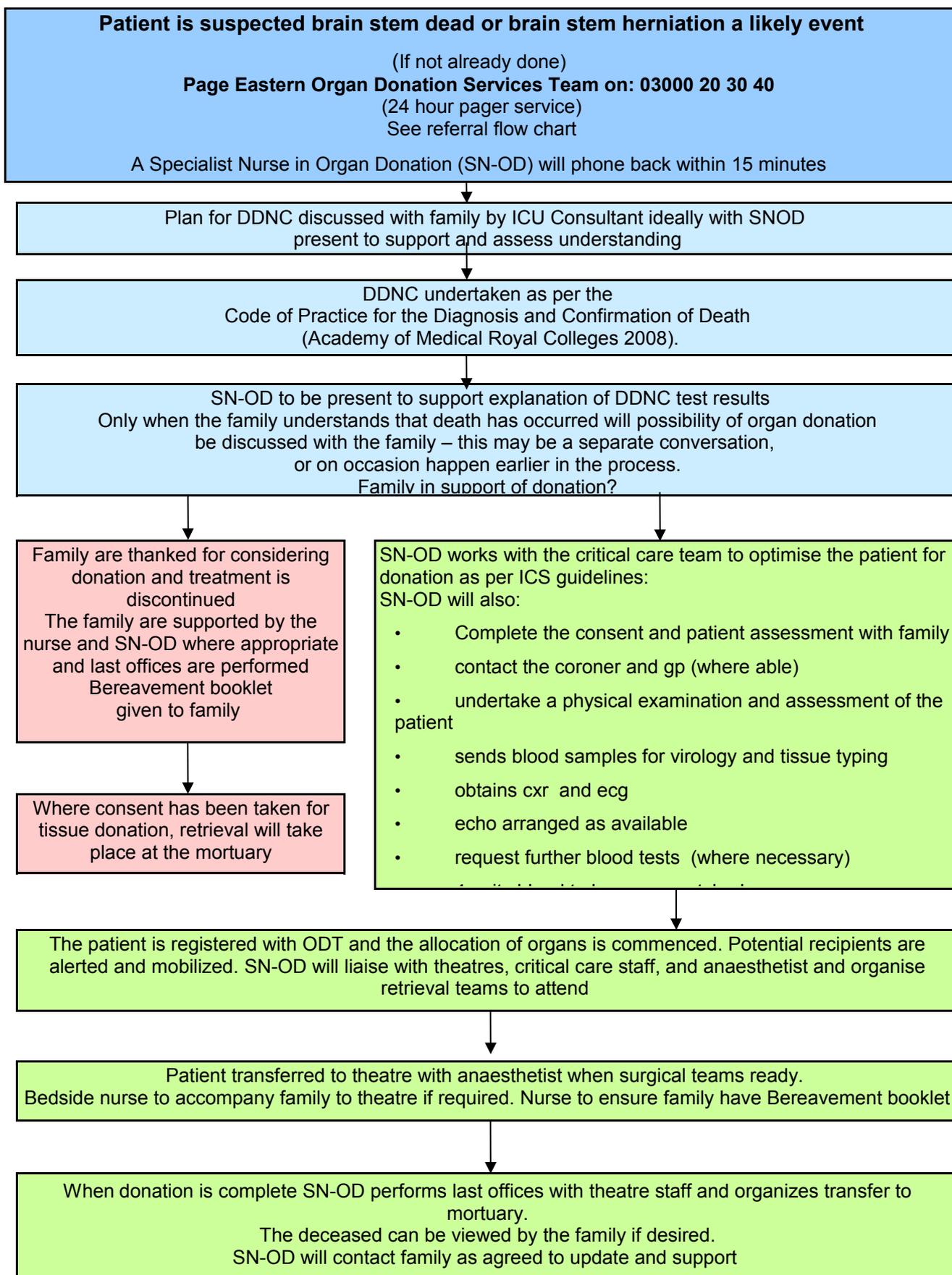
Pathway for potential organ donors



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Appendix 2

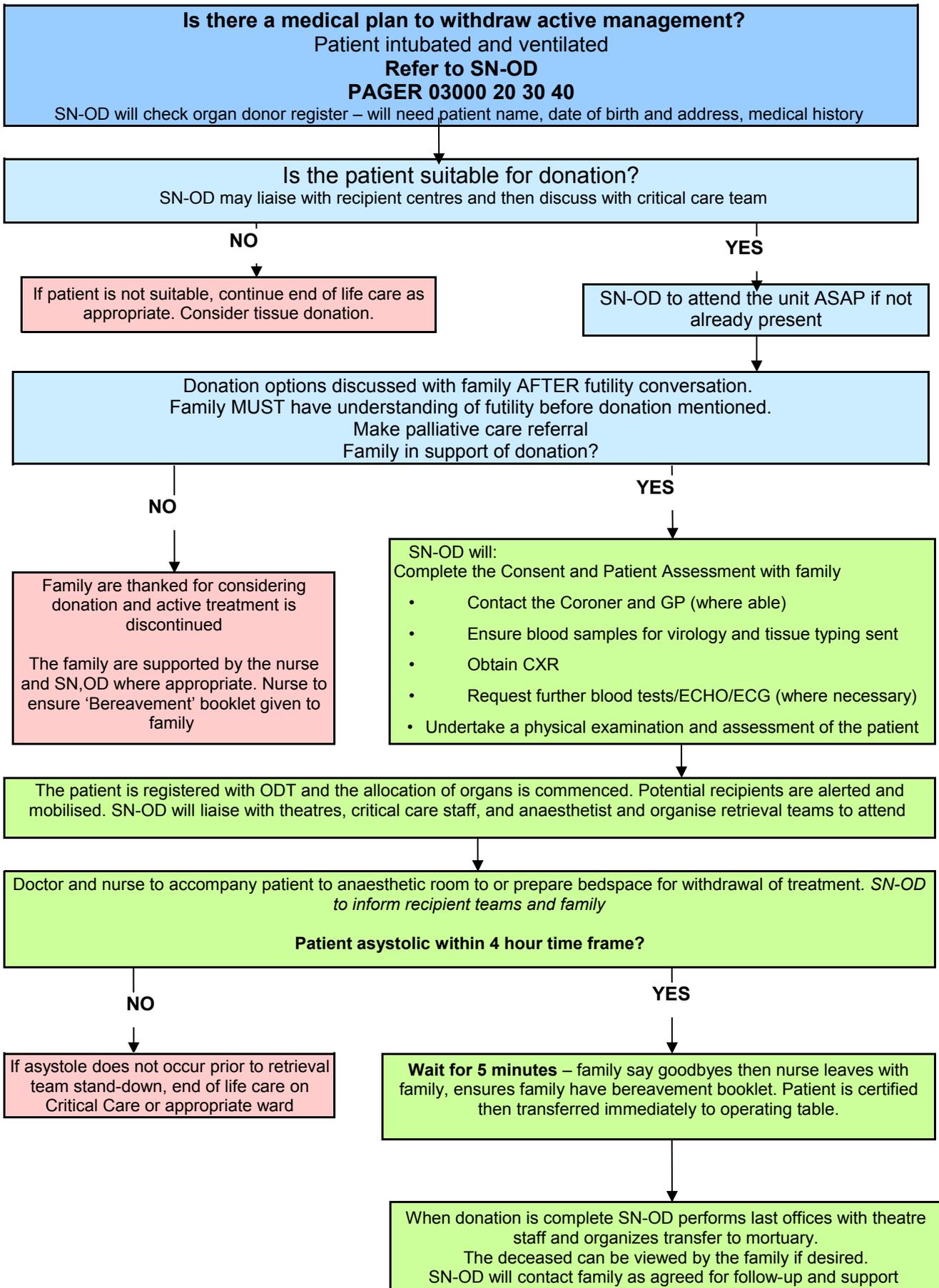
Organ Donation after Brain Stem Death



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Appendix 3

Organ Donation after Circulatory Death (DCD)



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Appendix 4

Organ Donation (Deemed Consent) Act 2019

The excluded groups are:

- Those under the age of 18
- People who lack the mental capacity to understand the new arrangements and take the necessary action
- Visitors to England, and those not living here voluntarily
- People who have lived in England for less than 12 months before their death

<https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/>

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(Monitoring Compliance / Effectiveness Table
Document Name:
Document Owner:

Appendix 5

<i>Element to be monitored</i>	<i>Lead Responsible for monitoring</i>	<i>Monitoring Tool / Method of monitoring</i>	<i>Frequency of monitoring</i>	<i>Lead Responsible for developing action plan & acting on recommendations</i>	<i>Reporting arrangements</i>	<i>Sharing and disseminating lessons learned & recommended changes in practice as a result of monitoring compliance with this document</i>
Actual and potential organ donation activity	Debbie Walford Matthew Overy Katherine Alger (SN-OD)	Potential Donor Audit (National)	Monthly	Debbie Walford Matthew Overy Katherine Alger (SN-OD)	Clinical Effectiveness Sub-board. Organ Donation Committee	