Organ and Tissue Donation Policy

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Associated Documentation:

Appendix 1. Identification of potential donors. - DTI
Appendix 2. Collaborative approach
Appendix 3. Guideline for management of devastating brain injury
Appendix 4. Theatre SOP.
Appendix 5. Referral to the SNBTS and the National Referral Pathway-Tissue only donors

Board Controlled Documents

Resuscitation policy (Dec, 2020).
Withholding and withdrawing of treatment guidance. (EOLC policy currently being updated)
NHS Lothian Child Protection Procedures 2016
Anticipatory Care Pathway Guidelines- Children & Young People (June 2020)
Resuscitation planning policy for children and young people

External Documentation

Treatment and care towards the end of life: good practice in decision making (2010). General Medical Council.

'Withholding or Withdrawing Life Sustaining Treatment in Children: A Framework for Practice', Royal College of Paediatrics and Child Health (2015).
Paediatric organ donation information and practice guidelines (2016).
Children and young people's acute deterioration and management (2012).
Framework for the Delivery of Palliative Care for Children and Young People in Scotland.
Ethical issues in paediatric organ donation - a position paper by the UK Donation Ethics Committee (2015).
Organ donation from infants with anencephaly —guidance from the UK Donation Ethics Committee (2016).
Organs for Transplants: a report from the Organ Donation Taskforce (2008). Department of Health.
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Legal issues relevant to non-heart beating organ donation (2009). Department of Health.

Academy of Medical Royal Colleges: An ethical Framework for donation after circulatory death (2011).

The diagnosis of death by neurological criteria in infants less than two months old (2015). RCPCH.
Scottish Education for Organ Donation, NHS Education for Scotland Website.

The NHS Blood and Transplant Organ Donation and Transplantation Clinical Website.

Timely identification and referral potential donors. A Strategy for implementation of best practice. NHSBT(2012)

Approaching the families of potential organ donors: Best practice guidance (2013). NHSBT.

Organ Donation and Transplantation 2030: Meeting the Need

A Donation and Transplantation Plan for Scotland 2013-2020 (2013). Scottish Government .

Paediatric and Neonatal Donation Strategy 2018

Guidance on deceased organ and tissue donation in Scotland: Authorisation requirements for donation and pre-death procedures

Legal Framework
Human Tissue (Scotland) Act 2019.
Human Tissue (Scotland) Act 2006
Adults with Incapacity Scotland Act 2000.

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Executive Summary

Organ and Tissue Donation Policy Document Objectives:	To ensure that organ and tissue donation after death occurs wherever appropriate.
Group/Persons Consulted:	Donation Committee; Scottish Fatalities and Investigation Unit; General Critical Care; Neurosciences; Cardiothoracic Intensive Care; Paediatric Intensive Care; Neonatal Intensive Care; Clinical Ethics Group; Operating Theatres and Anaesthetics; Emergency Medicine; Medical Director; Primary and Community Care Services Group: Bereavement Services; Palliative Care team; Mortuary staff.
Monitoring Arrangements and Indicators:	Potential Donor Audit, Comparative data locally, regionally and nationally. Bi-annual report to Organ Donation Sub-Group.
Training Implications:	Initial awareness and updates of practice. Induction of new employees. To be delivered by Clinical Lead for Organ Donation and Specialist Nurses for Organ Donation.
Equality Impact Assessment:	Completed Organ Donation Sub-Group
Resource implications:	Can be implemented within current resources.

Intended Recipients:
Who should:-

¬ be **aware** of the document and where to access it	Clinical Directors, Nurse Directors, Service Managers.
¬ **understand** the document	Clinical Directors, Nurse Directors, Service Managers.
¬ have a **good working knowledge** of the document	

Staff working in all clinical areas, especially critical care units, emergency department and operating theatres.

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1 INTRODUCTION

Consideration of organ and tissue donation after death should become a normal part of end of life care in all areas of NHS Lothian. This will be facilitated by identification of potential donors and timely referral to Specialist Nurses in Organ Donation (SN). The Human Tissue (Scotland) act 2019, places a duty on certain healthcare workers, mainly SN/Tissue Donor Coordinators (TDC) to make inquiries about a potential donor and their last known views on Organ and Tissue donation with the closest or nearest relative.
Organ donation is an important activity within NHS Lothian. The health board works in partnership with NHS Blood and Transplant (NHSBT) and the Scottish Government to deliver the national strategy for organ donation. In the UK this is guided by the current strategy document *Organ donation and Transplantation 2030: Meeting the Need,* along with the Scottish Government document *A Donation and Transplantation Plan for Scotland 2013-2020*. This latter document states in Section 6.2 that "It is the responsibility of NHS managers to champion and support donation and transplantation locally. Lessons from other parts of the world show that to increase donation rates the whole health system and all parts of individual hospitals, should be knowledgeable about and embrace and support donation and transplantation. This is known as the "whole hospital" approach. It is important therefore that all parts of the hospitals in NHS Lothian support donation.

Organs suitable for donation and transplantation include, but are not limited to heart, lungs, liver, kidneys, pancreas and small bowel.

General Medical Council (GMC) guidance advocates that: "If a patient is close to death, and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility.
You should follow any national procedures for identifying potential organ donors, and in appropriate cases, for notifying the regional Specialist Nurse."

Current guidance states that "although donation occurs after death, there are steps that health professionals may need to take before the death of the patient if donation is to take place." This policy covers such steps and in the case of clinical triggers, action that might take place even before the inevitability of death has been recognised.

Tissue only donation can be facilitated by the Scottish National Blood Transfusion Service who are the primary provider of tissues for therapeutic use in Scotland. Anyone who dies in hospital has the potential to become a tissue donor as unlike organ donation, tissue donation can take place up to 48 hours after death. Organ donors may also be able to donate tissue.

Tissue donation after death includes the potential of donating life-saving heart valves, skin, life-enhancing tendons and corneas.

2 IDENTIFICATION OF POTENTIAL ORGAN DONORS

2.1 Identification of potential donors by the doctor in charge, by means of clinical triggers, must initiate discussion with the SN at the time the triggers are met. See appendix 1

2.2 Identification should be based on the following criteria, while recognising that clinical situations vary, in accordance with timely identification and referral of potential donors. *A Strategy for implementation of best practice NHSBT (2012).*

(i) Any patient with a potentially devastating neurological injury that is expected to be non-survivable.
(ii) A decision is made to confirm Death by Neurological Criteria (DNC), by completing brain stem death tests (BSDT)
(iii) The intention to withdraw life sustaining treatment in patients with a life-threatening or life limiting condition which will, or is expected to, result in circulatory death. In this context, examples of life sustaining

treatment are positive pressure ventilation, extra corporeal circuits such as ECMO/ Ventricular Assisted Devices, Intra- Aortic Balloon Pumps and/or inotropic drugs.

2.3 Patients may present in areas out with critical care units (albeit rare) e.g. emergency departments, who are receiving positive pressure ventilation but a decision may have been made to withdraw life sustaining treatment.

2.4 When appropriate, the patient should be made clinically stable for a period of prognostication. The patient should be moved from the emergency department to a Critical Care area, in line with the national Emergency Department strategy and management for devastating brain injury guidance.

2.5 Provided this period of prognostication is in the patient's best interests, life-sustaining treatments should not be withdrawn or limited until the Duty to Inquire and the patient's latest views around organ and tissue donation have been explored and the clinical potential for the patient to donate has been assessed in accordance with legal and professional guidance.

2.6 Where a patient has the capacity to make their own decisions, obtain their views on, and seek authorisation for organ donation.

3 DONATION AFTER NEUROLOGICAL DEATH

3.1 All patients in whom brain stem death is the suspected clinical diagnosis should have brainstem death testing performed.

3.2 Discussion with Procurator Fiscal for those who would fit the criteria for a reportable death and in addition if the clinician or SN is uncertain if the death meets reporting criteria.

3.3 The patient is assessed by the SN and if they are a potential donor, the Duty to Inquire (DTI) must be carried out with the family/nearest relative to determine patients' most recent views regarding organ and tissue donation. The legislation advises 'the duty to inquire may only be carried out by a health worker, which in most cases will be a Specialist Nurse and if not possible should only do so following discussion with the Specialist Nurse'.

3.4 The approach to the family must be planned on an individual basis, where necessary with due regard given to issues of culture and beliefs. The standard of best practice is that the family approach should be a collaborative effort between senior medical staff and the SN see Appendix 2

3.5 If the family supports the patient's latest views/shows no unwillingness to donation, organ support continues, authorisation is obtained and donation proceeds. If the family state unwillingness as the latest known view of the patient, or they themselves do not wish to proceed with organ or tissue donation, end of life care planning should continue as per the EOLC policy.

4 DONATION AFTER CIRCULATORY DEATH

4.1 The intention to withdraw life sustaining treatments in patients with a life threatening or life limiting condition, which will, or is expected to result in circulatory death, should initiate discussion with the SN

4.2 Discuss with the Procurator Fiscal those who would fit the criteria for reportable death and in addition if the clinician or SN is uncertain.

4.3 The patient is assessed by the SN and if they are a potential donor, the DTI must be carried out to determine the patients' last known wishes regarding organ and tissue donation. The legislation advises 'the duty to inquire may only be carried out by a health worker, which in most cases will be a Specialist Nurse and if not possible should only do so following discussion with the Specialist Nurse'.

4.4 The approach to the family must be planned on an individual basis. The standard of best practice is that the family approach should be a collaborative effort between senior medical staff and the SN. Appendix 2

4.5 If the family supports the patient's latest known views/shows no unwillingness to donation, life sustaining treatment continues, authorisation is obtained and donation proceeds. If the family state unwillingness as the latest known view of the patient, or they themselves do not wish to proceed with organ and tissue donation, life sustaining treatment is discontinued, and end of life care planning continues as per the local EOLC policy

4.6 The closest available National Organ Retrieval Services (NORS) teams will attend to perform the retrieval surgery. There may be requests from the SN or accepting center's for pre death procedures (PDP's) to be carried out on the patient. Some of these may have conditions that must be met before these procedures can be carried out. The attending SNOD/SR will have this information in relation to the Human Tissue (Scotland) act 2019.
4.7 Withdrawal of life sustaining treatment should occur according to normal unit practice. A clinician should be readily available throughout the period of withdrawal to enable prompt confirmation of death, accompany the patient and SN to theatre and confirm with the retrieval surgeons they have pronounced this patient as life-extinct. There may be cases where it is necessary to move the patient to the anaesthetic room withdrawal of life sustaining treatment. The SN will offer guidance regarding this.

5 PAEDIATRIC AND NEONATAL ORGAN DONATION

5.1 There may be an opportunity for children and infants with a life-limiting or life-threatening condition of any age to be considered for organ or tissue donation.

5.2 While many of the donation options and processes offered to adults are similar, additional consideration is required around donation in children or infants. In particular, a paediatrician/paediatric intensivist should be involved when considering withholding or withdrawing life sustaining treatment or diagnosing death using neurological criteria.

5.3 If a child is subject to child protection concerns or Procurator Fiscal involvement, then the following key professionals must be notified:

Lead Paediatrician for Child Protection
Investigating Police Officer
Procurator Fiscal
Forensic Pathologist

There may still be a possibility to consider donation even in these cases and a referral should be made to the SN.

5.4 Many parents and families take a great deal of comfort from knowing that through donating their child's organs or tissue, other people's lives were saved or enhanced. Even if donation is not possible, it may be reassuring for families to know that this option was explored.

6 TISSUE DONATION

6.1 Families of all deceased patients in NHS Lothian should be offered the option of tissue donation as part of normal end of life care.

6.2 There is an unmet clinical demand for some tissue in Scotland. One Tissue Donor has the potential to help 11 people regain a normal life after illness or injury.

6.3 Tissue Donor Co-ordinators have a presence within the hospitals' across Lothian within the Emergency Departments at the Royal Infirmary of Edinburgh and St John's. Their remit is to provide education for clinical staff and furnish them with the skills to approach suddenly bereaved families to offer tissue donation as part of the end of life care pathway.

6.4 There are also close links with the ITU.s at the RIE, St Johns and Western General Hospitals through SN-collaboration in departmental education of clinical staff to identify potential donors of tissues as part of the organ donation programme as well as for those patients that die where organ donation is not possible.

6.5 This close relationship with the SN's and collaboration in donor identification and assessment ensures the potential for both organs and tissues are maximised for the patients that become organ donors. There is a Tissue Donor Co-ordinator on call in Scotland 24/7 and they are happy to provide donation advice to Healthcare Professionals.

6.6 To refer a tissue only donor-see appendix 5.

7 SERVICE IMPROVEMENT AND AUDIT

7.1 An ongoing audit of all deaths within Critical Care areas and ED departments which will be used to identify any areas of the service that require improvement. Local data forms part of the national data set to allow comparison of activity. Operating theatre responsibilities are as described in the theatres SOP appendix 4.

7.2 Compliments and complaints can be reported in the first instance to the embedded SN and Clinical lead in Organ donation (CL-OD). The process for formal reporting of complaints can be found in NHS Lothian Complaints Management Policy or the NHS Blood and Transplant Incident Submission System on the ODT Microsite.

8 MEDIA POLICY

8.1 NHS Lothian will continue to support National Organ Donation Campaign activity through digital channels and press.

8.2 Families involved in organ donation may choose to share their circumstances/story on social media or through traditional media. This is their decision and staff should not respond directly to any requests for comment from the media. The NHS Lothian communications and public team are happy to support families who would like to share their story more widely and can provide advice on the best way to do this.

9 SPIRITUAL CARE

9.1 Spiritual Care is one form of additional support offered to patients, visitors and staff when people are facing the (sometimes) challenging consequences or repercussions of illness or sudden trauma.

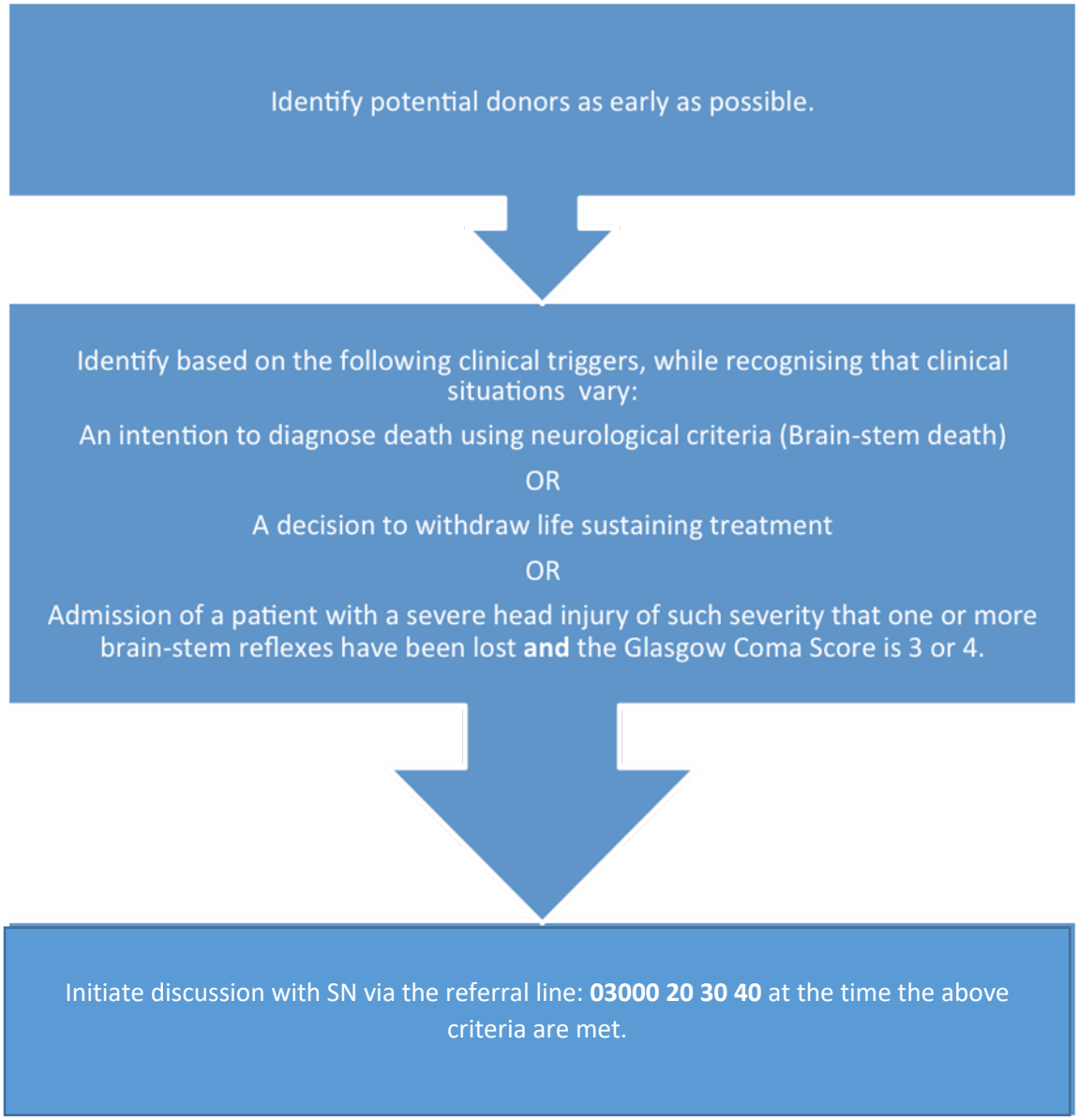
9.2 Research[1] suggests that the opportunity for patients and family members to 'talk about what is on their, with someone who is not a member of the clinical staff, can be of significant benefit. Staff themselves, may also appreciate the chance to talk through cases that have been particularly demanding, in terms of energy, clinical or ethical judgment, as well as personal resonance; not to mention, communicating with a range of people in complex and highly emotional situations.

9.3 With their considerable experience of being with people who are dying or, who are dealing with life-threatening conditions or, maybe asking some of the fundamental questions about life's meaning and purpose, what it means to be human and to face one's own mortality, the Spiritual Care Team in NHS Lothian is well equipped to offer this kind of support, around the time when organ donation is being considered.

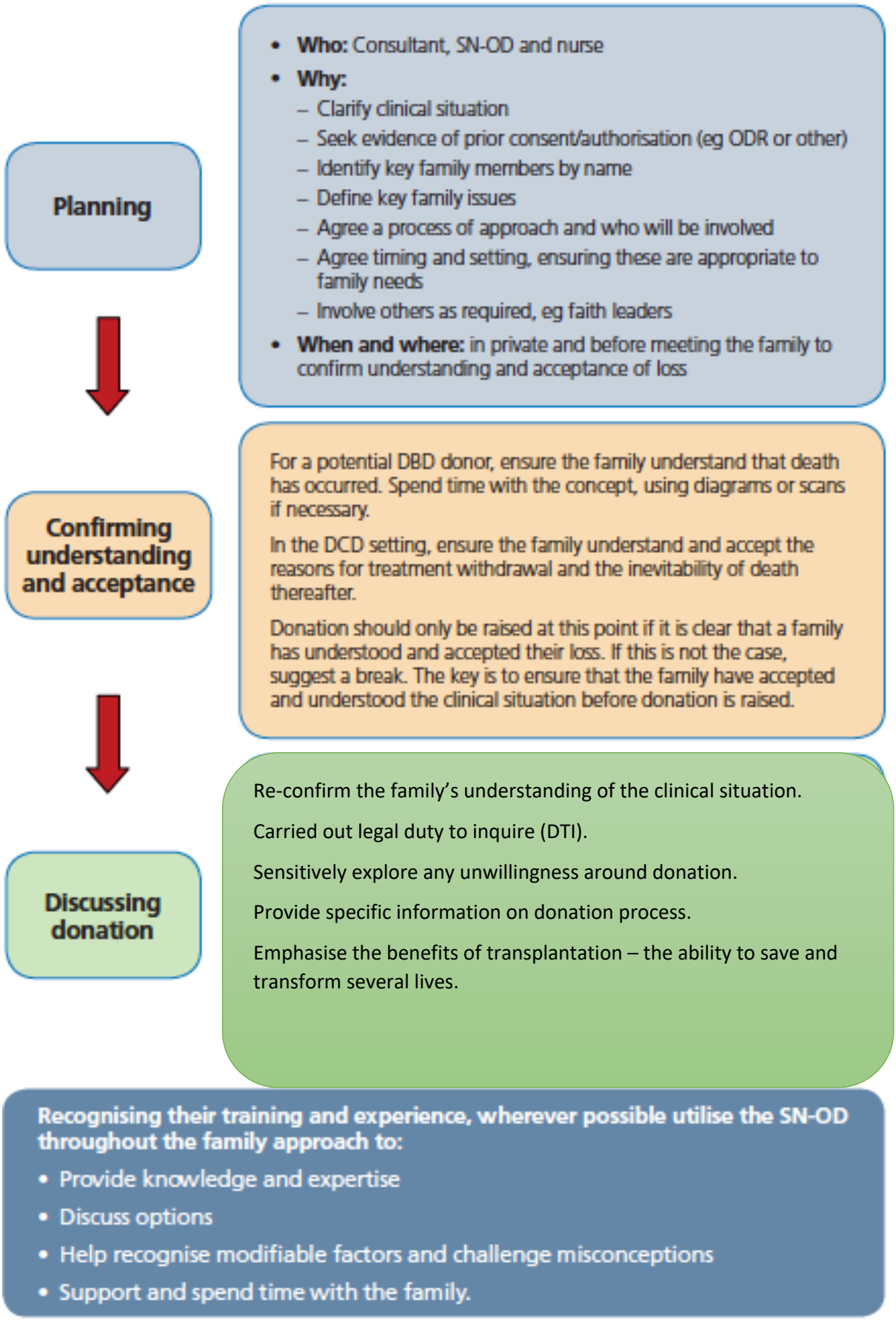
9.4 Some people will wish to explore their concerns in the context of their own cultural or faith background and, may involve prayers or ritual of one kind or another. Other people will value the opportunity for similar conversations and ritual, without reference to belief. Chaplains are experienced in being able to offer non-judgmental, supportive listening to all; as well as help create a safe place for difficult but honest conversation.

9.5 The Spiritual Care Service (or Chaplaincy) offers 24/7 support and, can be contacted during office hours on 0131 242 1990 and, out of hours through Switchboard.

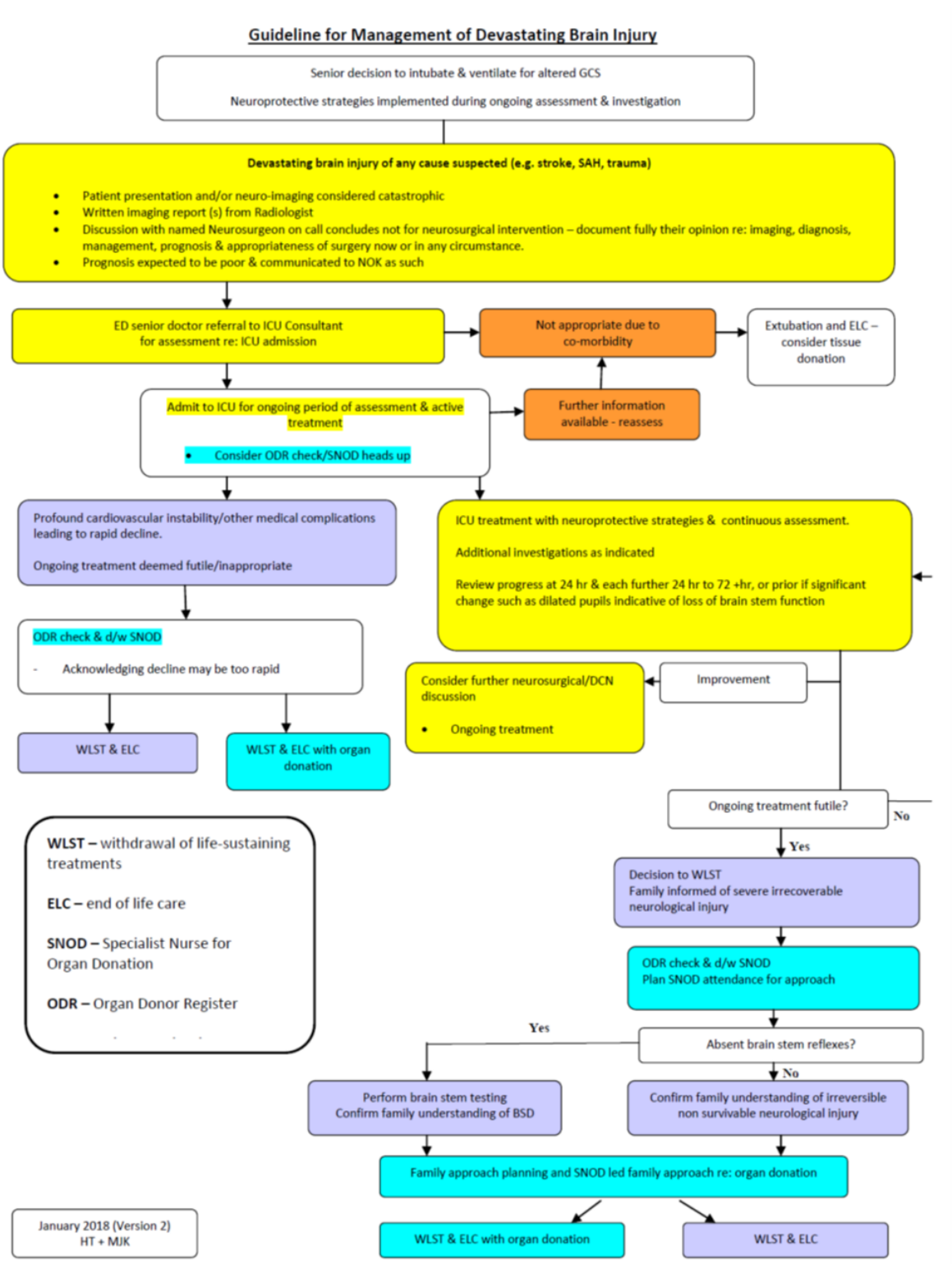
Appendix 1


Identify potential donors as early as possible.
Identify based on the following clinical triggers, while recognising that clinical situations vary:
An intention to diagnose death using neurological criteria (Brain-stem death)
OR
A decision to withdraw life sustaining treatment
OR
Admission of a patient with a severe head injury of such severity that one or more brain-stem reflexes have been lost and the Glasgow Coma Score is 3 or 4.
Initiate discussion with SN via the referral line: 03000 20 30 40 at the time the above criteria are met.

Appendix 2


Planning
• Who: Consultant, SN-OD and nurse
• Why:
– Clarify clinical situation
– Seek evidence of prior consent/authorisation (eg ODR or other)
– Identify key family members by name
– Define key family issues
– Agree a process of approach and who will be involved
– Agree timing and setting, ensuring these are appropriate to family needs
– Involve others as required, eg faith leaders
• When and where: in private and before meeting the family to confirm understanding and acceptance of loss
Confirming understanding and acceptance
For a potential DBD donor, ensure the family understand that death has occurred. Spend time with the concept, using diagrams or scans if necessary.
In the DCD setting, ensure the family understand and accept the reasons for treatment withdrawal and the inevitability of death thereafter.
Donation should only be raised at this point if it is clear that a family has understood and accepted their loss. If this is not the case, suggest a break. The key is to ensure that the family have accepted and understood the clinical situation before donation is raised.
Discussing donation
Re-confirm the family's understanding of the clinical situation.
Carried out legal duty to inquire (DTI).
Sensitively explore any unwillingness around donation.
Provide specific information on donation process.
Emphasise the benefits of transplantation – the ability to save and transform several lives.
Recognising their training and experience, wherever possible utilise the SN-OD throughout the family approach to:
• Provide knowledge and expertise
• Discuss options
• Help recognise modifiable factors and challenge misconceptions
• Support and spend time with the family.

Appendix 3


Guideline for Management of Devastating Brain Injury
Senior decision to intubate & ventilate for altered GCS
Neuroprotective strategies implemented during ongoing assessment & investigation
Devastating brain injury of any cause suspected (e.g. stroke, SAH, trauma)
Patient presentation and/or neuro-imaging considered catastrophic
Written imaging report (s) from Radiologist
Discussion with named Neurosurgeon on call concludes not for neurosurgical intervention – document fully their opinion re: imaging, diagnosis, management, prognosis & appropriateness of surgery now or in any circumstance.
Prognosis expected to be poor & communicated to NOK as such
ED senior doctor referral to ICU Consultant for assessment re: ICU admission
Not appropriate due to co-morbidity
Extubation and ELC – consider tissue donation
Admit to ICU for ongoing period of assessment & active treatment
Consider ODR check/SNOD heads up
Further information available - reassess
Profound cardiovascular instability/other medical complications leading to rapid decline.
Ongoing treatment deemed futile/inappropriate
ICU treatment with neuroprotective strategies & continuous assessment.
Additional investigations as indicated
Review progress at 24 hr & each further 24 hr to 72 +hr, or prior if significant change such as dilated pupils indicative of loss of brain stem function
ODR check & d/w SNOD
Acknowledging decline may be too rapid
Improvement
Consider further neurosurgical/DCN discussion
Ongoing treatment
WLST & ELC
WLST & ELC with organ donation
Ongoing treatment futile?
No
Yes
Decision to WLST
Family informed of severe irrecoverable neurological injury
ODR check & d/w SNOD
Plan SNOD attendance for approach
Absent brain stem reflexes?
Yes
No
Perform brain stem testing
Confirm family understanding of BSD
Confirm family understanding of irreversible non survivable neurological injury
Family approach planning and SNOD led family approach re: organ donation
WLST & ELC with organ donation
WLST & ELC
WLST – withdrawal of life-sustaining treatments
ELC – end of life care
SNOD – Specialist Nurse for Organ Donation
ODR – Organ Donor Register
January 2018 (Version 2)
HT + MJK

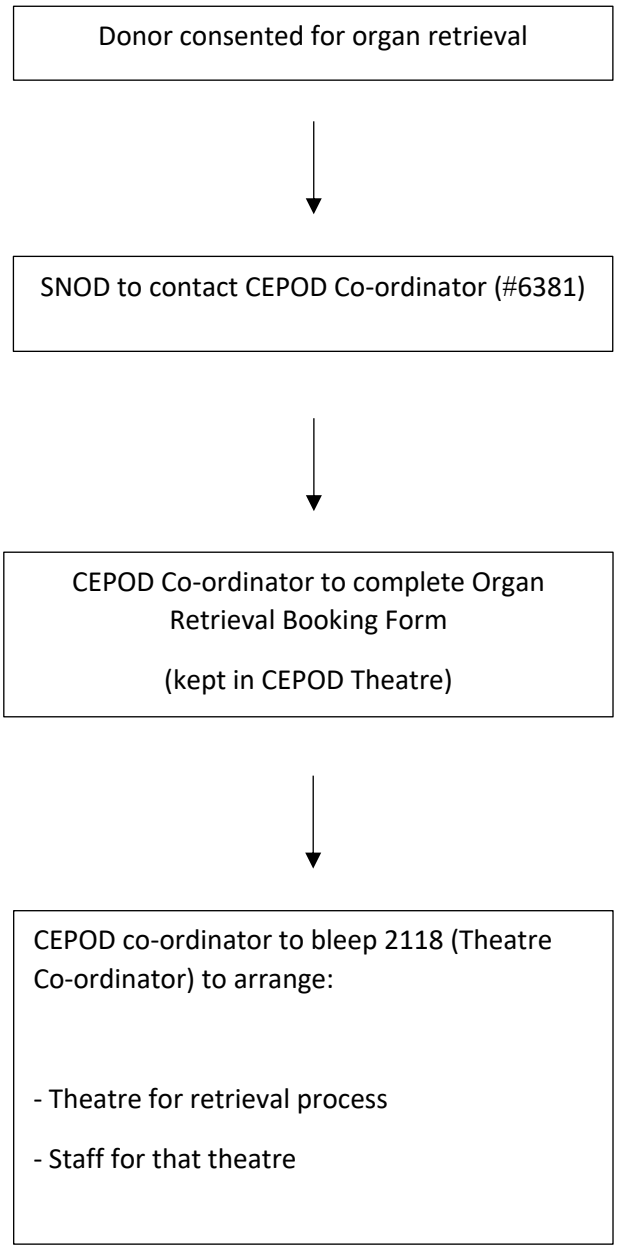
Appendix 4

Retrieval of Organs in RIE Theatres:

Standard Operating Procedure (SOP)

The aim of the following SOP is to optimise theatre usage, foster good communication between theatre and National Organ Retrieval teams (be they local or from another location), and ensure appropriate and fair staff allocation.

Booking Process



Logistics and Timing

1. All communication relating to the case should be directly with the SN.

2. Theatre allocation should be based on workload and staffing levels. Any theatre and associated staff can be utilised if available. This includes DCN theatres, although the time to theatre is very important in DCD cases and therefore DCN theatres should not be used for these patients if at all possible.

3. In the case of DBD donation, If Theatre 17 is to be used, all pre-existing booked cases categorised Priority C (within 6 hours), or more urgent, should take priority over the retrieval. Priority C patients are awaiting laparotomy for bowel perforation or intra-abdominal sepsis, for example.

    - On rare occasions, the donor's physiological condition may necessitate a more expedited process in order to preserve organ function.
    - Similarly, on rare occasions the recipient's condition may require a change in urgency. This would include a heart transplant recipient who is already under anaesthetic in another location.

4. In DCD donation, the wait for asystole may be up to 3 hours and the donor may be moved to theatre at any point within this time frame. After arrival in theatre, the donor will likely be placed on NRP for 2 hours before retrieval begins. The allocated theatre must be able to accommodate this.

5. If retrieval is out of normal working hours and CEPOD theatre is already in use as per point 3, then a second theatre team may be required to attend.

    - If organs from retrieval are to be transplanted locally, then the RIE Transplant Theatre Team would not normally be asked to assist in the retrieval process. The second on-call CEPOD team may therefore need to be contacted.

    - If organs from the retrieval are to be transplanted elsewhere, then the Transplant Theatre Team can contribute to staffing either the retrieval theatre or the CEPOD theatre, guided by clinical need.

6. Efforts to keep extraneous noise in theatre are appreciated. Necessary activities such as telephone calls to facilitate organ placement should be done in the scrub area or if possible, outside the operating theatre.

7. Last offices should be carried out by the SNOD and host theatre team once the time-critical step of organs being dispatched to the receiving centres has been completed.

Notes

<u>Definitions</u>

DBD: Donation after Brainstem Death. Previously referred to as “heart beating” donation. Retrieval of organs from patients whose death is confirmed by neurological criteria, in cases of severe brain injury. This can only be applied to patients who are on mechanical ventilation, usually in ICU.

DCD: Donation after Circulatory Death. Previously referred to as “non-heart beating” donation. Retrieval of organs from patients whose death is confirmed by cardiorespiratory criteria after planned withdrawal of treatment (eg mechanical ventilation or inotropes).

NRP: Normothermic regional perfusion. A technique similar to ECMO (though slightly less complex) to oxygenate donor organs in situ following DCD death. NRP helps to preserve organ function by restoring a circulation to the abdominal organs. Almost all donors undergoing DCD retrieval in Lothian will be placed on NRP for up to 2 hours.

Timing

One of the aims of organ retrieval is to minimise *warm ischaemic time,* i.e. the time between onset of inadequate organ perfusion and the start of protective cold perfusion *in situ*. After withdrawal of treatment, sustained systolic blood pressure <50mmHg is deemed to be the onset of warm ischaemic time.

Warm ischaemia is minimised in DBD retrieval, however, in DCD retrieval, organs will be subjected to warm ischaemia for a period of time before asystole and the subsequent transfer to theatre. The retrieval process is therefore time sensitive in nature. Some organs are more time-critical than others. The table below illustrates these in the context of a standard DCD retrieval. Note that when using NRP, these times are largely irrelevant as organ viability tests will guide utilisation.

Organ	Warm Ischaemic Time
Liver	<30 minutes
Pancreas	<30 minutes
Lungs	<1 hour
Kidneys	<2 hours

The progress to asystole after withdrawal of treatment is inherently unpredictable. There may be significant time between treatment withdrawal and onset of warm ischaemic time. The organ-specific limits of this time period, after which retrieval may not be beneficial, are shown below. Again, when using NRP, these times are less largely irrelevant and organ viability tests will guide utilisation.

Organ	Threshold time for warm ischaemia onset
Liver	1 hour
Pancreas	1 hour
Kidneys	Retrieval re-evaluated at 2 hours

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Oniscu GC, Randle LV, Muiesan P, Butler AJ, Currie IS, Perera MT, Forsythe JL, Watson CJ.

In situ normothermic regional perfusion for controlled donation after circulatory death--the United Kingdom experience. Am J Transplant. 2014 Dec;14(12):2846-54.

APPENDIX 5

TISSUE and EYE DONATION

ANY DEATH UNDER 95 YRS OF AGE

Donation of certain tissues may be possible.

Unless the deceased is known to be

HIV, Hep B or Hep C Positive

Or

Suffers from Dementia

Please call the

Tissue Donor Co-ordinator on

Radio Page No 07659 107 029

for

Organ Donor Registration status and advice on progressing Tissue and Eye Donation

AGE RANGE CRITERIA

HEART VALVES

Up to 70 years of age

TENDONS

Ages 17 – 60 years of age

SKIN

Adult – 70 years of age

EYES

Ages 3 – 95 years of age

Where there is progression – further information will be required by the Tissue Donor Co-ordinator:

Circumstances of the death and past medical history if available

Patient Details

Family Contact Details

Post Mortem Blood Samples - obtained using SNBTS standard tubes or NON Heparinised tubes

Procurators Fiscal Status

Requirement to ensure donor's body is refrigerated within 6 hours of death