Agreement between the Crown Office and Procurator Fiscal Service and the Scottish Donation and Transplant Group
In regard to Organ and Tissue Donation

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Scottish Government
Riaghaltas na h-Alba
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Contents

Introduction

1.1 Successful organ and tissue transplants can be lifesaving, and for many people organ and tissue transplants are the most effective form of treatment. However, many people are unable to benefit from a transplant because of a shortage of donated organs and tissue.

1.2 Recognising that unnecessary deaths occur every year in the UK, the UK Organ Donation Taskforce produced its first report in January 2008[1] with 14 recommendations designed to remove existing barriers to donation, and to make organ donation a usual part of all end-of-life care in every appropriate case. Implementation of these recommendations in Scotland had high-level Government support. Nonetheless, the number of patients waiting for transplants still significantly exceeds the number of potential donors and it is therefore important to seek to enable donation to proceed wherever this is feasible and appropriate.

1.3 One of the Taskforce's recommendations is particularly relevant to this Agreement.

> Recommendation 14: "The Department of Health and the Ministry of Justice should develop formal guidelines for coroners concerning organ donation."

1.4 In Scotland, it was considered that this recommendation had been achieved already because of the existence, since 2004, of this Agreement between the Scottish Donation and Transplant Group (SDTG) and the Crown Office and Procurator Fiscal Service. It underlines the need, however, to ensure that this Agreement is kept up-to-date.

Diagnosis and Confirmation of Death

1.5 Prior to the advent of modern Intensive Care techniques, the diagnosis of death was relatively simple. Death was diagnosed at the cessation of circulation. The advent of long-term ventilation techniques in the 1950s meant inadequate ventilation no longer immediately led to circulatory death. With the advent of these techniques, case series of patients with profound irreversible apnoeic coma began to be described.

1.6 The current UK consensus is that "Death entails the irreversible loss of those essential characteristics which are necessary to the existence of a living human person and, thus, the definition of death should be regarded as the irreversible loss of the capacity for consciousness, combined with irreversible loss of the capacity to breathe." *(A Code of Practice for the diagnosis and confirmation of death. Academy of the Royal Medical Colleges 2008)*[2].

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[1] See Taskforce Report at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4245/organsfortransplantstheorgandonortaskforce1streport.pdf

[2] See http://www.aomrc.org.uk/publications/reports-guidance/ukdec-reports-and-guidance/code-practice-diagnosis-confirmation-death/

1.7 In the past, organ donation largely depended on donors being pronounced dead following brain-stem death testing while still on mechanical ventilation in an intensive care unit. This is termed Donation after Brain-Stem Death (DBD), sometimes referred to as donation after death diagnosed using neurological criteria (DNC).

1.8 However, more recently, partly because of a shortage of organs from DBD donors, there has been a significant increase in the number of Donation after Circulatory Death (DCD) donors in the UK.

Donation after Brain-Stem Death (DBD)

1.9 The irreversible cessation of brain-stem function, whether induced by intra-cranial events or the result of extra-cranial phenomena, such as hypoxia, will produce this clinical state, and irreversible cessation of the integrative function of the brain-stem therefore equates with the death of the individual and allows the medical practitioner to diagnose death. For organ and/or tissue retrieval to be legal and acceptable, the certification of brain-stem death must be sufficiently rigorous to give those close to the deceased total confidence that death has occurred before any procedures relating to organ and/or tissue donation are commenced. Certification of brain-stem death must be completed by two senior doctors who are independent of the transplant teams and can only take place after rigorous preconditions are met. Further protection is given by the terms of section 11(4) of the Human Tissue (Scotland) Act 2006[3], which provides that the surgeon proposing to retrieve body parts for the purpose of transplantation or another registered medical practitioner must be satisfied that life is extinct.

Donation after Circulatory Death (DCD)

1.10 Donation following Circulatory Death takes place after a monitored period of cessation of heart function in the donor. DCD programmes in Scotland come within Maastricht Category III or IV, wherein the heart is expected to stop following withdrawal of life-sustaining treatment in patients who are not (Maastricht III) or who are (Maastricht IV) brainstem dead. The great majority of such DCD donors are Maastricht Category III. Kidneys, liver, pancreas, islets, lungs, tissues and now also hearts from DCD donors can be successfully transplanted. With some exceptions, results from DCD organs are generally poorer than DBD organs. New techniques are now being developed in DCD organ retrieval, with results similar to those in organs retrieved from DBD donors.

[3] See https://www.legislation.gov.uk/asp/2006/4/section/11

The Law

1.11 Once death has been confirmed or is anticipated following withdrawal of treatment, the relevant provisions of the Human Tissue (Scotland) Act 2006 apply and must guide the next steps when organ and/or tissue donation is to take place.

1.12 The 2006 Act is based on the concept of authorisation. "Authorisation" is the expression of the principle that people have the right to specify, during their lifetime, their wishes about what should happen to their bodies after their death, in the expectation that those wishes will be respected.

1.13 The Human Tissue (Authorisation) (Scotland) Act 2019 amends the Human Tissue (Scotland) Act 2006 and enables a potential donor's authorisation to be 'deemed' under certain circumstances where the potential donor has neither self-authorised donation, for example on the NHS Organ Donor Register, nor 'opted-out'. The change in legislation will not affect the matters covered in this Agreement - in other words it will not impact on the need for the Procurator Fiscal (PF) to consent to organ and/or tissue donation proceeding in cases where a patient's death needs to be reported to the PF.

Agreement between Crown Office and Procurator Fiscal Service (COPFS) and the Scottish Donation and Transplant Group (SDTG)

1.14 This Agreement was developed in 2004 between the Crown Office and Procurator Fiscal Service (COPFS) and the Scottish Donation and Transplant Group. It describes the role of the Procurator Fiscal (PF) in relation to potential organ and/or tissue donation. It is updated regularly. The most important points are:

- Where there is reason to believe that a death may be reported to the PF, no parts of a body will be removed without the PF's prior consent (section 5 of the Human Tissue (Scotland) Act 2006).
- The PF will normally permit removal of organs and/or tissue, subject to the need to ensure that sufficient evidence is available for any subsequent criminal proceedings or Fatal Accident Inquiry.
- The PF may object to removal of organs and/or tissue in a case where there is evidence that the death has happened due to a crime having occurred or where there is insufficient time available to complete the enquiries which would allow an informed decision. In certain circumstances, the PF may be in a position to agree to the donation for transplantation of some and/or all organs and/or tissue in cases where there is evidence that the death has happened due to homicide; early discussion with the PF is essential.

1.15 This agreement provides that, where necessary, deaths will be reported to the PF and, in the case of a potential DCD donor, the PF will be advised in advance of cardio-respiratory arrest to enable the PF to make a rapid and informed decision about donation.

Terms of Agreement

General

2.1 In any case of proposed donation after circulatory death, once a decision to withdraw life-sustaining treatment has been reached, the PF should be consulted in advance of proposed treatment withdrawal if there is reason to believe that the death would need to be reported to the PF[4]. Similarly, if the death of a brain-stem dead potential donor needs to be reported to the PF, the death must be reported before any organ or tissue donation can take place.

2.2 The Specialist Nurse for Organ Donation (SNOD), Specialist Requester (SR) or Tissue Donor Coordinator (TDC) will have checked whether the person had joined the NHS Organ Donor Register, or otherwise given express authorisation during his or her lifetime, for the donation of organs and/or tissue after death. If such express authorisation does not exist, there needs to be discussion with family members or friends to establish whether authorisation can be deemed or (if the potential donor is in an excepted group) to obtain authorisation for donation from the nearest relative. A valid authorisation is required to permit donation to proceed and express, deemed, and nearest relative authorisation are all equally valid types of authorisation.

2.3 The 2019 Act permits the sharing of a person's donation decision recorded in the register, or the fact of the absence of such a recorded decision, with certain people. Aside from the potential donor's family members or others consulted about their views, this information may only be shared with certain people to carry out functions under the Act which relate to the removal and use of a body part for the purpose of transplantation. These are registered medical practitioners, retrievers or health workers carrying out enquiries about the potential donor's views.

2.4 Organs must be retrieved soon after death if they are to be viable. Medical authorities must inform the PF of any potential organ donation in appropriate cases as soon as possible after either brain-stem death is confirmed or the decision is reached to withdraw life sustaining treatment, seeking a decision at the earliest possible moment.

2.5 Corneas can be donated up to 24 hours after death, while tendons, heart valves and other tissue can be donated up to 48 hours after death.

2.6 The PF will consider whether the retrieval should proceed. In order to make an informed decision, the PF may instruct the police to make enquiries into the circumstances, so that they may decide whether to consent to the retrieval following death. The PF may also wish to discuss the circumstances with the doctor in charge, the SNOD or TDC, or the on-call pathologist.

2.7 Where no objection is made to organ and/or tissue retrieval, it is the responsibility of the PF to ensure that sufficient evidence is available for any subsequent criminal proceedings or Fatal Accident Inquiry. This includes ensuring

[4] A complete guide for reporting deaths to the Procurator Fiscal is contained within the publication entitled 'Reporting Deaths to the Procurator Fiscal' and is available via the following link: www.copfs.gov.uk/investigating-deaths/deaths

that the time of death can be confirmed followed by confirmation of the time of the retrieval operation commencing. This will ensure confirmation that the donor's death has not been caused, or contributed to, by the retrieval procedure.

2.8 If there is uncertainty as to whether, subsequent to death, the retrieval operation could affect evidence, the PF shall ask the SNOD and/or TDC to put him or her in touch with the senior retrieval surgeon on the organ retrieval team or tissue retrieval staff to discuss the operation plans and ensure cooperation with any requirement for pathological investigation.

2.9 If it is felt that discussions should be assisted by involving a pathologist, the on-call forensic pathologist should be contacted for advice.

2.10 Organ donors may also donate tissues post-organ retrieval. Such a tissue retrieval process takes place in a separate second procedure at a later time point, usually in the mortuary. The tissue retrieval staff will also be able to provide any information that may be required by the PF pathologist if there are any queries about findings at the tissue retrieval procedure.

DBD

2.11 The following is the procedure adopted in hospitals:

- The retrieval procedure will not be commenced until the brain-stem death of the potential donor has been established by two senior doctors independent of the transplant team.

- These doctors will, if required, give evidence to that effect, to provide proof that the death of the donor was not caused by the retrieval operation; and

- The retrieval surgeon will detail the operative procedure and any other findings in the patient's medical records, which will be available for the autopsy pathologist should they wish to see them. The retrieval surgeon will also be available for court purposes, if required.

2.12 The above procedure ensures that if the PF then decides that a post-mortem examination is necessary, evidence will be available to prove that the retrieval operation did not contribute to the death of the donor.

DCD

2.13 Anyone dying in hospital is a potential DCD organ and/or tissue donor unless they have a medical contraindication or there is no authorisation for donation (either deemed or from the individual or their nearest relative). The PF's consent for DCD organ donation is required **before** death occurs. This does not apply in the case of tissue donation, as tissue can be retrieved up until 48 hours (24 hours for cornea donation) after death so the PF's consent for tissue donation can be obtained either before or after death, but before the retrieval procedure starts.

2.14 In the majority of cases, patients will have been admitted to an Intensive Care

Unit and given full life support. After hours or even days of care, it may become clear that further treatment is not in the patient's overall best interests. With the agreement of the family (or occasionally the patient themselves), a decision may then be taken to withdraw all life-sustaining treatment. Once life-sustaining treatment has been withdrawn, cardio-respiratory arrest will occur after an interval, following which death will be pronounced. The circumstances will have been discussed with the PF in appropriate cases. The retrieval team will have been alerted and will be present/available to preserve or retrieve organs and/or tissue.

2.15 It is for Emergency Medicine or Critical Care teams to identify all potential patients for DCD donation and contact the SR, SNOD or TDC.

- The SR/SNOD will confirm that there are no medical contraindications to donation. This will assist the decision as to whether the death should be reported to the PF in advance;

- Because of the need to commence organ preservation or donation immediately after death in the case of DCD, it is essential to discuss the circumstances with the PF in advance whenever the death has to be reported to the PF. It is also good practice to do this in the case of tissue donation. In general, a PF, after suitable enquiry, will be able to give a view as to whether or not consent will be given to organ or tissue retrieval after death, assuming there is no change in relevant circumstances. Medical authorities must inform the PF of any proposed retrieval operation in appropriate cases as soon as possible;

- Thereafter, the case will proceed to donation if consent is given by the PF in terms of section 5 of the Human Tissue (Scotland) Act 2006.

- As for DBD donors, the retrieval surgeon (or team in the case of tissue donation) will detail the operative procedure and any other findings in the patient's medical records, which will be available for the autopsy pathologist should they wish to see them. The retrieval surgeon or team will also be available for court purposes, if required.

Paediatric and Neonatal Donation

2.16 It is also possible for organ and/or tissue donation to occur from children and even babies from the age of at least 36 weeks corrected gestational age[5]. Like adults, children and babies can potentially be either DCD or DBD donors and the procedures to be followed in seeking consent from the PF for paediatric or neonatal donation to proceed are the same as those set out above for adult potential donors.

2.17 However, in some cases, particularly in the case of neonates, it may be more likely that a death needs to be reported to the PF as the cause of the baby's death/ anticipated death is unclear. In such cases, it may not be possible for the PF to consent to donation proceeding where it is considered likely that the retrieval procedure may make it impossible to confirm the cause of death at post-mortem

[5] Corrected gestational age is the age corrected to allow for delivery prior to term e.g. a child who was born at a gestational age of 30 weeks who is now 6 weeks old would have a corrected (gestational) age of 36 weeks.

examination, depending on the details of the individual case. The PF will nonetheless consider the individual circumstances in each case.

How to contact the Procurator Fiscal

2.18 The Scottish Fatalities Investigation Unit (SFIU) is a specialist unit within the Crown Office and Procurator Fiscal Service (COPFS). SFIU has responsibility for receiving reports of deaths occurring in Scotland which are sudden, suspicious, accidental or unexplained.

2.19 There are three SFIU teams in Scotland based in the North, East and West. Each team comprises of a number of legal and administrative staff.

2.20 The SFIU North team has staff located in Dundee, Aberdeen and Inverness. The SFIU East team is based in the Procurator Fiscal's office in Edinburgh and the SFIU West team is based in the Procurator Fiscal's office in Glasgow.

2.21 The death should be reported to the SFIU team in whose area the significant event leading to the death occurred. Annex 1 provides contacts for each team. Please note that where a death or expected death needs to be reported out of normal office hours, the homicide out of hours Procurator Fiscal should be contacted. SNODs/SRs can provide the relevant contact details.

2.22 Information for bereaved relatives on the role of PF in the investigation of deaths can be found on the COPFS website[6].

[6] 'The role of the Procurator Fiscal in the investigation of deaths' - available via www.copfs.gov.uk/investigating-deaths/deaths

Annex 1

Scottish Fatalities Investigation Unit teams and contact details

SFIU NORTH (for NHS Grampian, NHS Highland (except Argyll and Bute), NHS Tayside, NHS Orkney, NHS Shetland and NHS Western Isles)

Telephone: 0300 020 2387

Email: SFIUNorth@copfs.gov.uk

SFIU EAST (for NHS Lothian, NHS Borders, NHS Fife, NHS Forth Valley)

Telephone: 0300 020 3702
Email: SFIUEast@copfs.gov.uk

SFIU WEST (for NHS Greater Glasgow and Clyde, NHS Lanarkshire, NHS Ayrshire and Arran and NHS Dumfries and Galloway, plus Argyll and Bute)

Telephone: 0300 020 1798
Email: SFIUWest@copfs.gov.uk

References

1. Organs for Transplants: A report from the Organ Donation Taskforce
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4245/organsfortransplantstheorgandonortaskforce1streport.pdf

2. A Code of Practice for the diagnosis and confirmation of death. Academy of Royal Medical Colleges
http://www.aomrc.org.uk/publications/reports-guidance/ukdec-reports-and-guidance/code-practice-diagnosis-confirmation-death/

3. Human Tissue (Scotland) Act 2006
www.legislation.gov.uk/asp/2006/4/contents

4. Human Tissue (Authorisation)(Scotland) Act 2019
https://www.legislation.gov.uk/asp/2019/11/contents

5. 'Reporting deaths to the Procurator Fiscal - Information and Guidance for Medical Practitioners' - available via www.copfs.gov.uk/investigating-deaths/deaths

Useful Links

An Ethical Framework for Controlled Donation after Circulatory Death: UK Donation Ethics Committee
http://aomrc.org.uk/wp-content/uploads/2016/04/Ethical_framework_donation_circulatory_death_1211-3.pdf

Donation and Transplantation Plan for Scotland: 2021 – 2026
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