

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

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* Formerly Scottish Transplant Group

Introduction

1.1 Successful organ 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 2008¹ 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, acknowledging that Scottish donation rates were previously the lowest in the UK (although they have improved in recent years). 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 See Taskforce Report at: <https://www.gov.uk/government/publications/working-together-to-save-lives>

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.

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), having previously been known as heart beating donation.

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. DCD donation was previously known as non-heart beating donation or donation following cardiac death.

Donation after Brain-Stem Death (DBD)

1.9 The irreversible cessation of brain-stem function, whether induced by intracranial 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 2006³, which provides that the surgeon proposing to retrieve body parts for the purpose of transplantation must be satisfied that life is extinct.

Donation after Circulatory Death (DCD)

1.10 Donation following Circulatory Death takes place after death has been diagnosed following a monitored period of cessation of heart function in the donor. DCD programmes in Scotland come within Maastricht Category III – awaiting cardiac arrest i.e. where the patient is expected to die following withdrawal of life-sustaining treatment. Kidneys, liver, pancreas and lungs from DCD donors can be successfully transplanted, with graft survival results similar to those organs retrieved from DBD donors. A number of UK hospitals are now also successfully undertaking DCD heart transplants.

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

³ See http://www.legislation.gov.uk/asp/2006/4/pdfs/asp_20060004_en.pdf

The Law

1.11 Once death has been confirmed, 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. The Scottish Government has indicated that it will introduce legislation into the Scottish Parliament to enable a deemed authorisation system of organ donation (often referred to as an ‘opt out’ system). However, the change in legislation is not expected to 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.

NHS Organ Donor Register

1.13 Any adult or child aged 12 and over who is able to make their own decisions can give authorisation for their organs or tissue to be donated after death for the purpose of transplantation. Signing up to the NHS Organ Donor Register (ODR) counts as a form of authorisation under the Human Tissue (Scotland) Act 2006. Many people who have not put their names on the ODR still carry an organ donor card, and this, too, is a form of self-authorisation.

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 and the need to establish that the death has not been caused, or contributed to, by the retrieval operation.
- The PF may object to removal of organs and/or tissue in a case which is likely to result in a charge of homicide 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 transplantation of organs and/or tissue in cases of 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 PF⁴. Similarly, if the death of a brain-stem dead donor needs to be reported to the PF, the death must be reported before any organ donation can take place.

DBD

2.2 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 death is confirmed, seeking a decision at the earliest possible moment.

2.3 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.

2.4 The PF will then 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 when death occurs. The PF may also wish to discuss the circumstances with the doctor in charge, the Specialist Nurse for Organ Donation (SNOD) or the on-call pathologist.

2.5 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.

2.6 It will be necessary to take steps to ensure it can be established that the death has not been caused, or contributed to, by the retrieval procedure.

2.7 If there is uncertainty as to whether the retrieval operation could affect evidence, the PF shall ask the SNOD to put him or her in touch with the senior transplant surgeon on the organ retrieval team to discuss the operation plans and co-operate with any requirement for pathological investigation.

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

2.9 The following is the procedure adopted in hospitals:

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: <http://www.copfs.gov.uk/publications/deaths>

- 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.

2.10 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

2.11 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 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.

2.12 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, 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 can be pronounced. The SNOD will have checked whether the person had joined the NHS Organ Donor Register, or otherwise given self-authorisation during his or her lifetime for the donation of organs and/or tissue after death. If such self-authorisation does not exist, there can be discussion with the nearest relative to obtain authorisation for donation. The circumstances will have been discussed with the PF in appropriate cases. The retrieval team will have been alerted and will be present to preserve or retrieve organs and/or tissue.

2.13 It is for Emergency Medicine or Critical Care teams to identify all potential patients for DCD donation and contact the SNOD and/or Tissue Donor Coordinator (TDC).

- The 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 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.

Paediatric and Neonatal Donation

2.14 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 age⁵. 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.

2.15 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 that is likely to lead to it being impossible to confirm the cause of death at post-mortem examination. The PF will nonetheless consider the individual circumstances in each case.

How to contact the Procurator Fiscal

2.16 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 unexplained⁶.

2.17 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.

2.18 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.

2.19 The death should be reported to the SFIU team in whose area the significant event leading to the death occurred. Annex 1 contains a map showing each SFIU area and a list of contacts for each team.

2.20 Information for bereaved relatives on the role of PF in the investigation of deaths can be found on the COPFS website⁷.

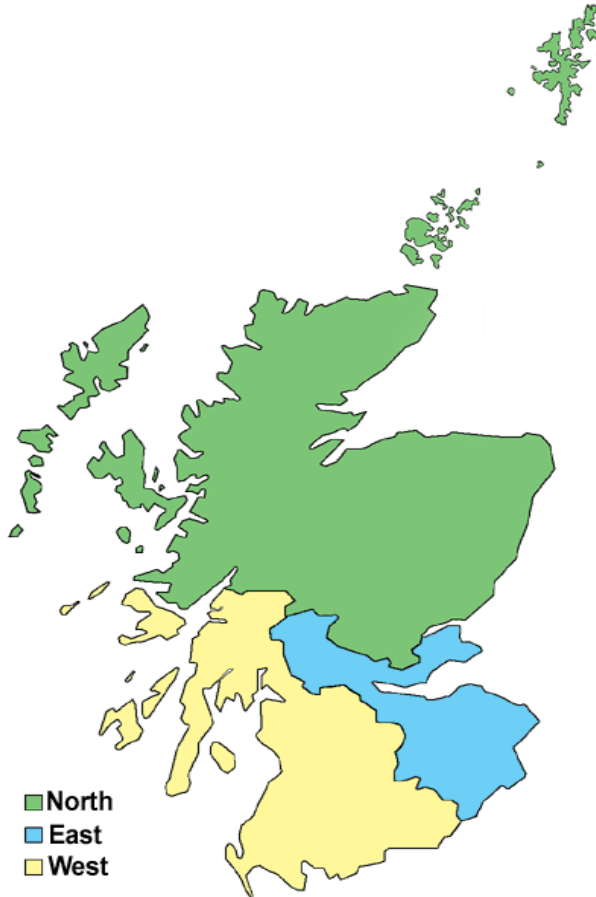
⁵ Corrected gestational age is the age corrected to allow for delivery prior to term e.g. a child who was born at a gestational age of 30 weeks who is now 6 weeks old would have a corrected (gestational) age of 36 weeks.

⁶ 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: <http://www.copfs.gov.uk/publications/deaths>

⁷ 'The role of the Procurator Fiscal in the investigation of deaths' - available via <http://www.crownoffice.gov.uk/publications/deaths>

SCOTTISH FATALITIES INVESTIGATION UNIT TEAMS AND CONTACT DETAILS

Map showing each SFIU area:



SFIU NORTH

Telephone: 0300 020 2387

Email: SFIUNorth@copfs.gov.uk

SFIU EAST

Telephone: 0300 020 3702

Email: SFIUEast@copfs.gov.uk

SFIU WEST

Telephone: 0300 020 1798

Email: SFIUWest@copfs.gov.uk

References

1. Organs for Transplants: A report from the Organ Donation Taskforce
<https://www.gov.uk/government/publications/working-together-to-save-lives>
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. 'The role of the Procurator Fiscal in the investigation of deaths' - available via
<http://www.crownoffice.gov.uk/publications/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

Taking Organ Transplantation to 2020 - a UK strategy for organ donation and transplantation
<http://www.nhsbt.nhs.uk/to2020/>

A Donation and Transplantation Plan for Scotland 2013-2020 – a Scotland-specific plan to accompany the UK strategy
<http://www.scotland.gov.uk/Publications/2013/07/7461>

Scottish Government Health Directorate Guidance on Legal Issues Relevant to Donation Following Cardiac Death (CMO Letters (2010)11)
[www.sehd.scot.nhs.uk/cmo/CMO\(2010\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf)

Scottish Government Health Directorate Guidance on Legal Issues Relevant to Donation Following Cardiac Death (CMO Letter (2012)08)
[www.sehd.scot.nhs.uk/cmo/CMO\(2012\)08.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2012)08.pdf)



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