

Dear Colleague,

GUIDANCE ON LEGAL ISSUES RELEVANT TO DONATION FOLLOWING CARDIAC DEATH

I am writing to draw to your attention the guidance for NHSScotland which the Scottish Government Health Directorates have developed to clarify the legal issues relevant to organ donation following cardiac death.

As you know, the UK-wide Organ Donation Taskforce produced its first report in January 2008, 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 has the strong support of the Cabinet Secretary for Health and Wellbeing, especially as Scottish donation rates have generally been the lowest in the UK.

The main element in recommendation 3 of the Taskforce's first report was:

“Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice.”

The issues which recommendation 3 particularly had in mind are those associated with Donation following Cardiac Death (DCD), previously known as Non-Heart Beating Donation (NHBD). As a result of the development of DCD programmes in Scotland, we have seen a year on year increase in numbers of this type of donation, from 6 DCD donors in 2006-07 to

**From the Chief Medical Officer
Dr Harry Burns MPH
FRCS(Glas) FRCP(Ed) FFPH**

Enquiries to:

Ms P Niven
Healthcare Planning Division
St Andrew's House
EDINBURGH EH1 3DG

Tel: 0131-244 2343
Fax: 0131-244 2989
Pamela.niven@scotland.gsi.gov.uk

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Addresses

For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
President and Members, Scottish
Intensive Care Society
Members of Scottish Branch of British
Association of Critical Care Nurses
Clinical Leads for Organ Donation in
Scotland
Chairs of NHS Board Organ Donation
Committees
Donor Transplant Co-ordinators in
Scotland
NHS Boards' Palliative Care Executive
Leads
Hospital Chaplains

For Information
Directors of Public Health, NHS
Boards

21 in 2008-09. The increasingly important contribution which DCD has been making to the number of organ donors in Scotland has served to underline the importance of resolving the legal, ethical and professional issues associated with the process.

Potential DCD donors almost invariably lack the capacity to make their own treatment decisions because they will have had a catastrophic brain injury and are likely to be unconscious. This can pose legal, ethical and professional issues to clinicians who, in these circumstances, are guided by the provisions of the Adults with Incapacity (Scotland) Act 2000 ('the AWI Act'). The provisions of the AWI Act apply to decisions taken on the person's behalf until their death.

The guidance we are now issuing, a copy of which is attached to this letter, parallels that issued in November 2009 for the rest of the UK. In essence, it applies the principles of the AWI Act to organ donation, a context which the AWI Act did not contemplate specifically, as there were no DCD programmes in Scotland at the time the legislation was developed. Perhaps the most significant aspect of the guidance is its recognition that the AWI test of whether an intervention will benefit the adult can be interpreted as covering actions of an unselfish nature, such as a wish to donate organs after their death.

The guidance cannot of course cover all the eventualities likely to arise in such a complex and sensitive field, but I fully expect it to prove helpful in enabling all the clinicians concerned to work within a clear and unambiguous framework of good practice. I hope, therefore, that it will lead to an expansion in the number of DCD programmes across Scotland. Further clarification is likely to be provided through the consensus event on DCD which the UK Health Departments and NHSBT are organising on 7 June, and through the work of the UK Donation Ethics Committee set up as part of the implementation of recommendation 3 from the Organ Donation Taskforce's first report.

Yours sincerely

Harry Burns

HARRY BURNS

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Summary

- The UK Organ Donation Taskforce report of January 2008, setting out ways to increase donation rates, included a recommendation that *“urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice.”* This reflects concerns about donation following cardiac death (DCD, previously known as non heartbeating donation (NHBD)), where a conflict of interest may be felt between the duty of care of the doctor to the dying patient who is a potential donor after death and the steps necessary to make donation following cardiac death possible. This note sets out the Scottish Government’s view of the legal position in relation to interventions taken prior to death to facilitate NHBD. In doing so, it aims to assist in resolving these issues, and it is hoped that all those working in this area will be able to build on this information in drawing up more detailed and systematic clinical advice and guidance. The need for the guidance is intensified by the increasingly prominent role played by DCD programmes in improving Scotland’s organ donation rate.
- DCD takes place when death has been established following the irreversible cessation of the heart, and is also known as donation following cardiac death. There are a number of steps that can take place before the person dies, such as testing the person’s blood for tissue typing and virology screening or optimising their critical care physiology, which can maximise the chances of a successful organ donation.
- People who are potential DCD donors almost invariably will lack the capacity to make their own treatment decisions because they will have had a catastrophic brain injury and are likely to be unconscious. This means the Adults with Incapacity (Scotland) Act 2000 (AWI) will apply to decisions taken on behalf of the person until their death.

Background and clinical context

1. It is clear that any decision about the futility of further treatment, and whether or not such treatment should be withdrawn, must be made purely in the interests of the person and independent of any consideration of possible organ donation. It is important to give the family time to come to terms with the probable death of a loved one, and to be able to consider fully all end of life options, including donation.
2. Donation following cardiac death takes place when death has been established following irreversible cessation of the heart (ie following cardio-respiratory arrest). The Academy of Medical Royal Colleges issued guidance on the diagnosis of death in 2008 <http://www.aomrc.org.uk/aomrc/admin/reports/docs/DofD-final.pdf>
3. There are a number of steps that can be taken before a person has died, which can optimise the chances of a successful donation and transplant. These steps fall into the broad categories of actions to check the person’s wishes about donation and their suitability to be a donor, maintaining treatment and the timing of its withdrawal to coordinate with organ retrieval and introducing new treatment or activities that improve the chances of a successful organ transplant. There has been some discussion within the clinical community about the legal basis for such actions, which is why the UK Organ Donation Taskforce saw a need for advice on the law in this area.

4. This guidance has been drawn up in tandem with the guidance on the subject developed by the Department of Health in England for use in England and Wales and published in November 2009 at:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825 The aim has been to promote uniformity of approach across the UK so far as can be achieved in the light of the different legal systems involved.

The law

5. The Adults with Incapacity (Scotland) Act 2000 requires that any interventions in relation to an incapacitated adult observe certain general principles. These are that the intervention will benefit the adult, and that such benefit cannot reasonably be achieved without the intervention. The intervention should always be the least necessary to achieve the end. In determining whether an intervention is to be made, account shall be taken of:

- the present and past wishes of the adult so far as they can be ascertained by any means of communication;
- the views of various individuals in so far as it is reasonable and practicable to take account of their views. Those individuals are the nearest relative, named person and primary carer of the adult, any guardian or continuing or welfare attorney, any person whom the sheriff has directed be consulted or any other person with an interest;
- In relation to medical treatment, there are additional criteria over and above the general principles described above which must be met. Part 5 of the 2000 Act allows medical treatment certificates to be issued to give healthcare professionals the authority to do what is reasonable in the circumstances to safeguard or promote the physical or mental health of the adult.

The concept of 'benefit' is discussed further in paragraph 19 below.

6. It is essential to be clear that up until the point at which life is pronounced extinct, the relevant legislation is the Adults with Incapacity (Scotland) Act 2000. Once death has been confirmed, the relevant provisions of the Human Tissue (Scotland) Act 2006 (HTSA) are those which must guide the next steps when organ donation is to take place.

7. The 2006 Act is based on the concept of authorisation. As explained in paragraph 8 of the Guide to the Implications of the Human Tissue (Scotland) Act 2006, issued as HDL(2006)46 on 20 July 2006, '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.

8. This emphasis on the autonomy of the individual is also one of the underlying principles of the AWI legislation, and therefore underlines the importance which should be attached to making sure that where people's wishes are known, the practical arrangements which are put in place should be designed to ensure those wishes are fulfilled.

End of life decisions

9. Potential DCD donors are people who are likely to have had a catastrophic brain injury and are therefore likely to be unconscious and lack capacity. They will usually (but not always) be in critical care, with relatives close by. A clinician will make treatment decisions following an assessment of the person's best interests, which means considering all aspects of the person's condition, consulting their family and considering the person's previously expressed wishes. At some stage, a clinician may reach the view that there is no prospect

of recovery and further active treatment would therefore be futile and not in the person's best interests, in which case a decision may be made to withdraw treatment.

10. Guidance on end of life decisions and withdrawing treatment is available in the GMC's *Withholding and withdrawing life-prolonging treatments: Good practice in decision making*.

11. Where the dying person could be a potential donor after their death, and the decision is made to withdraw treatment, decisions may also be made about the person's care and treatment in relation to donation when it has become clear death is inevitable. Issues about the timing and location of withdrawal of treatment are dealt with in paragraphs 25-28.

12. Clinicians would also need to be satisfied that any exchange of information relating to the potential donor complies with the law relating to confidentiality and data protection.

13. In terms of the potential involvement of the Procurator Fiscal (PF) in DCD, a Protocol has been drawn up between the Crown Office and Procurator Fiscal Service and the Scottish Transplant Group with regard to organ and tissue donation. The most important points are:

- where there is reason to believe that the death may be reported to the PF, no parts of a body will be removed without his or her prior consent (Human Tissue Act 2006 Section 5). Annex A details which deaths, or prospective deaths, must be reported to the PF;
- the PF may object to removal of organs in a case which is likely to result in a charge of homicide or where, in the time available, insufficient enquiry is able to be carried out to allow an informed decision. There are procedures available which will allow the PF not to object to transplantation of organs in cases of homicide but early discussion with the PF is essential;
- the PF will normally permit removal of organs 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.

Assessing a person's wishes in relation to organ donation

14. In deciding whether actions to enhance the chances of a successful donation would be for the person's benefit, it will be important first of all to assess what their wishes and preferences were in relation to organ donation. There are a number of ways that such wishes and preferences can be established in relation to organ donation.

15. Some people will have indicated their wish to be an organ donor by joining the NHS Organ Donor Register (ODR) or by carrying an organ donor card. Others may have discussed their wishes with family or friends or by indicating this in some other way. All of these count as authorisations under the 2006 Act. Clinicians should, therefore, consult the ODR and talk to the person's family and friends to find out if the person had expressed any wishes about donation to them. Under the HTSA, where authorisation has been given, the nearest relatives have no legal right to overrule those wishes. Where no formal authorisation has been given by the potential donor, authorisation for organ donation may be given by the person's nearest relative, as defined through the hierarchy set out in the 2006 Act, assuming that the relative has no actual knowledge that the person was unwilling to be a donor. In considering whether to give authorisation, the nearest relative is expected to act on the basis of what they believe the deceased's wishes would have been.

Actions for which medical treatment certificate not necessary

16. A number of actions which clinicians may wish to carry out prior to the patient's death in the context of DCD are matters for which a medical treatment certificate in terms of Part 5 is unlikely to be necessary.

17. Such actions include:

- Alerting the transplant team of a potential donor and asking the donor transplant co-ordinator to speak to the patient's relatives about donation;
- Seeking details from the family members of the patient's medical history relevant to donation;
- Testing either blood samples already taken as part of the patient's care or new samples for tissue typing and virology as an aid to the donation process;
- Moving the patient to a different location to facilitate organ retrieval after death.

18. While these actions are unlikely to require a certificate under Part 5, clinicians will need to ensure that they comply with the general AWI principles, including the concept of the patient's benefit. In assessing benefit and compliance with the general principles, there are a number of factors which require to be taken into account including:

- the person's past and present wishes and feelings, including in particular any relevant written statements;
- the beliefs or values that would be likely to influence the person's decision if they had the capacity to make it;
- any other factors they would be likely to consider if they were able to do so; and
- the views of nearest relative, named person and primary carer of the adult, any guardian or continuing or welfare attorney, any person whom the sheriff has directed be consulted or any other person with an interest.

19. The concept of 'benefit' is likely to be wider than the person's immediate medical situation. It can reasonably be interpreted as permitting something which the adult could reasonably be expected to have chosen to do if capable, even though of a gratuitous or unselfish nature.

20. It is therefore important to take account of whether such actions would benefit the person by:

- maximising the chance of fulfilling the donor's wishes about what happens to them after death;
- enhancing the donor's chances of performing an altruistic act of donation; and
- promoting the prospects of positive memories of the donor after death.

21. Other aspects must also be considered, such as the risk of harm to the person by worsening their medical condition or shortening their life, or any distress an action may cause the person or their family and friends. Clinicians will need to consider the weight that should be given to the information they have about the person's wishes and values. As indicated in paragraph 7, where the person has given authorisation under the 2006 Act, the expectation is that those wishes should be fulfilled after death. If the person was registered on the NHS Organ Donor Register, or the family agree to DCD as the end of life pathway they wish their loved one to follow, these would count as forms of authorisation under the 2006 Act once the person was dead. Specific actions may be involved in order to enable

those wishes to be fulfilled. The key issue is the timing of the withdrawal of treatment, which is dealt with in paragraphs 25-28 below.

22. If, having considered and weighed up all of the factors relevant to the person's situation and consulted their family and friends, it is decided that a particular action or actions that will facilitate DCD is for the person's benefit, then it may be carried out. Equally, if it is decided that an action is not for the person's benefit, then it should not be carried out.

23. There may be times when it is not possible to obtain information about the person's values and preferences, for example if the person's family or friends are not able to give any advice on this aspect. In such cases a clinician would need a compelling reason to consider that actions to facilitate DCD were for that person's benefit.

24. Clearly, if the person has indicated that they do not want to be an organ donor after their death then no further actions towards organ donation can or should be taken.

Timing and location of withdrawal of treatment

25. Decisions about the timing of withdrawal of treatment must also comply with the AWI principles, including being for the person's benefit. It is generally understood and accepted that there are a number of reasons for flexibility in timing, for example to allow family members to be present or to make sure the relevant healthcare professionals are available to oversee the process. In practice, the timing of withdrawal of treatment is a matter of discussion and agreement between the person's family and clinicians. An important aspect of timing may be the need to allow time for absent family members and friends to be present when withdrawal happens. This recognises that a person has an interest in the manner in which they die and in how they are remembered.

26. There will almost invariably be a lapse of time between reaching agreement on the withdrawal of treatment and the actual moment at which treatment is withdrawn, for the reasons given in the previous paragraph. During that period, maintenance of the patient would of course be reasonable, so as not to cause distress to the relatives. That maintenance would include adjustment of cardio-respiratory support, including maintaining the patient's blood pressure, and generally making sure the patient's condition remains stable.

27. Since it is necessary to begin organ retrieval very soon after death has been declared, this means in practice that the surgical retrieval team must be ready in an operating theatre before cardio-respiratory support is withdrawn. Because it commonly takes some hours for arrangements for retrieval to be completed, this requires withdrawal of cardio-respiratory support to be delayed if DCD is to be possible. For similar reasons, local circumstances may necessitate moving the patient to a different location within the hospital, close to or within the operating theatre complex, ahead of withdrawal of treatment.

28. Again, it will be necessary for clinicians to assess whether such actions are for the benefit of the potential donor. If the person wanted to donate, then in many cases because these steps facilitate donation they may be considered to be in that person's best interests. The decision-maker must therefore consider whether this is something the person wanted to happen, whether the actions would cause any distress or harm to the person, or whether there was any material risk of such an occurrence when determining if such steps would be in their best interests.

Interventions for which medical treatment certificate would be necessary

29. Clinicians should seek legal advice in relation to any kind of DCD intervention which is likely to fall within the provisions for medical treatment under Part 5 of AWI. These are likely to include at least the following:

- full cardio-respiratory resuscitation in response to a rapid deterioration in the patient's condition, in the event of cardiac arrest in the period after the decision to withdraw treatment but before donation;
- Continuing treatment, other than the maintenance of stability of the patient in the interval of time between agreement on the withdrawal of treatment and the actual moment at which treatment is withdrawn, as described in paragraph 25;
- Instigating treatment intended solely for the preservation of organs for donation, such as the insertion of femoral cannulae or systemic heparinisation.

30. It is important to emphasise that interventions such as the insertion of femoral cannulae or systemic heparinisation are not undertaken in Scotland at present. Legal advice would therefore need to be sought if such interventions were contemplated. Legal advice would also be needed in relation to any new, novel additional or treatments or actions not discussed above for which a medical treatment certificate is or may be necessary.

31. For all interventions mentioned above, individual decisions will depend on the specific situation of the person concerned, given the variety of situations that could arise. NHS Boards and health professionals must always be able to satisfy themselves that an individual's decisions are made in compliance with the law.

32. There is a role here for the Clinical Leads for Organ Donation and the NHS Board organ donation committees to promote consistency of practice across Scotland as a whole, for example by sharing any legal advice that becomes available in relation to individual cases. The UK Donation Ethics Committee may also produce relevant advice.

Annex

The following deaths must be reported to the Procurator Fiscal.

(i) Sudden deaths

- (a) any death where there is evidence or suspicion of homicide;
- (b) any death by drowning;
- (c) any death by burning or scalding or as a result of fire or explosion;
- (d) any death caused by an accident involving the use of a vehicle including an aircraft, a ship or a train;
- (e) any death resulting from an accident in the course of work, including voluntary or charitable work;
- (f) any death where the circumstances indicate the possibility of suicide;
- (g) any death following an abortion or attempted abortion whether legal or illegal;
- (h) any death of a person subject to legal custody, including any death of such a person outwith a Police station or prison (for example during prisoner transport or in hospital);
- (i) any death occurring in health premises in the community including a GP's surgery, health centre, dental surgery or similar facility;
- (j) any death due to violent, suspicious or unexplained circumstances.

(ii) Deaths related to neglect or complaint

- (a) any death where the circumstances seem to indicate fault or neglect on the part of another person;
- (b) any death, if not already reported, where a complaint is received by a Health Board or NHS Trust and the complaint is about the medical treatment given to the deceased with a suggestion that the medical treatment may have contributed to the death of the patient.

(iii) Deaths of children

- (a) any death of a newborn child whose body is found;
- (b) any death which may be characterized as sudden unexplained death in infancy (SUDI) or the like;
- (c) any death of a child from suffocation including overlaying;
- (d) any death of a child in foster care;
- (e) any death of a child in the care of a Local Authority;
- (f) any death of a child on a Local Authority "at risk" register.

(iv) Public Health

- (a) any death caused by an industrial disease or industrial poisoning;
- (b) any death due to a disease, infectious disease or syndrome which poses an acute, serious public health risk including:
 - any form of food poisoning
 - Hepatitis A, Hepatitis B (with or without delta-agent co-infection (Hepatitis D)), Hepatitis C and Hepatitis E

- any hospital acquired infection
 - Legionnaires Disease
- (v) Deaths associated with medical or dental care
- (a) any death which was unexpected having regard to the clinical condition of the deceased prior to his or her receiving medical care;
 - (b) any death which is clinically unexplained;
 - (c) any death which appears to be attributable to a therapeutic or diagnostic hazard
 - (d) any death which is apparently associated with lack of medical care;
 - (e) any death which occurs during the administration of a general or local anaesthetic;
 - (f) any death which may be associated with the administration of an anaesthetic;
 - (g) any death caused by the withdrawal of life sustaining treatment to a patient in a persistent vegetative state (This is to be distinguished from the removal from a life-support machine of a person who is brain stem dead and cannot breathe unaided.);
 - (h) any death occurring as a result directly or indirectly of an infection acquired while under medical or dental care while on NHS premises, including hospitals, GP's surgeries, health centres and dental surgeries.

These categories should not be regarded as exhaustive.

- (vi) Any drug-related death (This category includes death as a result of ingestion of any drug where the death does not fall into any category above.)
- (vii) Any death not falling into any of the foregoing categories where the cause remains uncertified or where the circumstances of the death may cause public anxiety.