Pre-mortem intervention in donation after circulatory death: A framework for ethically, legally and scientifically appropriate action

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Introduction

Donation after Circulatory Death (DCD) organ transplants are potentially life-saving and for potential recipients are preferable to remaining on the waiting list; however, they could have better outcomes. The quality of DCD organs, and thus recipient outcomes, can potentially be improved by pre-mortem interventions such as systemic heparinisation to reduce thrombosis, insertion of vascular cannulae to expedite cooling of the organs and systemic treatment of the donor with drugs that reduce the detrimental impact of ischaemia.

The benefits of pre-mortem interventions in DCD donation vary depending on the type of intervention, and in some instances are not well-established. Some may result in only modest improvements, but other emerging interventions, such as drugs that ameliorate ischaemic injury, have the potential to save lives. Pre-mortem interventions are commonplace in some US states and include systemic heparinisation, arterial cannulation and opiate analgesia. Contrastingly, there has been long-standing inertia within the UK medical profession, health service and government for facilitating pre-mortem interventions to improve transplant outcomes.

Aims and Methods

We aimed to identify a framework that would enable evaluation and adoption of proposals for pre-mortem interventions in an ethically, legally and scientifically appropriate manner.

Using a multi-disciplinary panel of legal, clinical and other experts, we reviewed existing professional guidelines and the legal framework relevant to pre-mortem interventions in organ donation

Recommendations

We propose 5 steps to significantly change transplantation practices whilst remaining legally compliant, ethically sound and evidence-based.

Step 1: Understanding and communication of current guidelines

The first step is to communicate widely to transplant clinicians the important points in the Guidelines from the Academy of Medical Royal Colleges and Department of Health. These attempt to summarise the legal position, indicating that pre-mortem interventions in incapacitated potential DCD donors are permissible if they are in the donor's best interest. Broadly speaking this reflects the law governing care and treatment of incapacitated adults in England and Wales under section 5 of the Mental Capacity Act 2005 (MCA). Since pre-mortem interventions in DCD donors aim to improve recipient transplant outcomes, it is important to consider carefully whether, and in what circumstances, pre-mortem interventions are lawful.

Step 2: Re-drafting Department of Health guidelines

The second step is to re-draft Department of Health Guidelines published in 2009. These state that systemic heparinisation puts a donor "at risk of serious harm" and "is unlikely to ever be in the [DCD donor's] best interests". To assess whether a pre-mortem intervention is in the donor's best interests, it is important to consider that effective altruism is a positive benefit for some donors. The risks an intervention poses to the donor or their family must be weighed against these benefits. We suggest the Department of Health Guidelines use more open-textured phrasing so that clinicians can reach a best interest analysis favouring pre-mortem interventions if appropriate.

Step 3: Supporting high quality research

A third step is for government and professional guidelines to support much-needed high quality research studies to gather data to improve the reliability of analyses of a donor's best interests and the risks and benefits of pre-mortem interventions. Existing evidence is mostly incomplete or inconclusive. For example, it is increasingly accepted that pre-mortem heparinisation improves transplant outcomes, but neither the magnitude of the benefit nor the risk of unintended haemorrhage are precisely known.

Pre-mortem interventions are also devoid of benefit if circulatory arrest does not take place after withdrawal of treatment within a timeframe that is compatible with organ donation and they are harmful if they prevent a patient from recovering. Reliable data are thus required to identify which physiological parameters, such as blood pressure, can predict if a potential DCD donor will suffer circulatory arrest soon after withdrawal of treatment, and the rare instances of unexpected recovery after life support is withdrawn.

Such data are critical to compare risks and benefits of 'early' pre-mortem interventions (which commence before withdrawal of supportive treatment), and 'late' interventions (that take place after withdrawal of treatment and when donor physiological parameters have reached a threshold that makes rapid circulatory arrest inevitable and recovery impossible).

The perspectives of the donor family, including their desires to help other families, grief reactions, and cultural and religious beliefs, are also central to the risk-benefit analysis for pre-mortem interventions and warrant further research.

Step 4: Better Implementation of the Mental Capacity Act

We propose the establishment of a specialist review panel for organ donation research with input from clinicians, ethicists, patients, NHSBT and Department of Health, and lawyers, including those familiar with the Court of Protection. Its role would be to assess research proposals for pre-mortem interventions. The rationale for this panel is that approval from RECs is a legal pre-requisite for research with incapacitated adults pursuant to section 30(1)(a), but RECs have limited time, resources and expertise to make good decisions about DCD pre-mortem intervention research.

We also propose sensible and careful interpretation of section 31(2) of the MCA. It states that research with incapacitated adults must be connected with an impairing condition of the mind or brain, or its treatment. A narrow interpretation could prohibit all organ transplantation research with incapacitated adults which would be highly problematic for donors and recipients. We recommend that this phrasing (particularly the word 'connected') be broadly interpreted. Sections 31(4) and 32 of the MCA provide appropriate safeguards for a broad interpretation.

Step 5: Consideration of the role of Court of Protection

The fifth step is to consider the role of the Court of Protection (CoP) with respect to pre-mortem interventions. The CoP has Practice Directions to guide legal parties. Practice Direction 9e states that doctors "should" seek a declaration of lawfulness from the CoP before carrying out "serious medical treatment" in the incapacitated patient's best interests, where the benefits are finely balanced with the risks. Here, a medical procedure "for the purposes of donation to another person" is listed as a possible example of a serious medical treatment. The word "should" could mean 'it is recommended' or it could indicate a legal requirement [20]. Requiring a CoP declaration for all pre-mortem intervention would be highly problematic for transplant clinicians who operate within short and sudden time frames. But an application to the CoP might be useful as a 'test case'. The decision would not be definitive for future cases (donors' circumstances differ) but it could reduce legal uncertainty by providing a basis for analogous reasoning.

Conclusions

We commend the work that is already underway through a collaboration of NHSBT, the British Transplantation Society, Department of Health and other organizations. We hope our recommendations help build on that work to provide a path for decisive and timely action. We also encourage further multidisciplinary interactions with not only clinicians, but also with people on the organ donor register, donor families, recipients, ethicists, psychologists, anthropologists, and lawyers. Together, in a coordinated and ethically-conscientious way, we can hopefully reduce the burden of death on the transplant waiting list.