



Organ donation after circulatory death – legal in South Africa and in alignment with Chapter 8 of the National Health Act and Regulations relating to organ and tissue donation

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Organ donation after a circulatory determination of death is possible in selected patients where consent is given to support donation and the patient has been legally declared dead by two doctors. The National Health Act (61 of 2003) and regulations provide strict controls for the certification of death and the donation of organs and tissues after death. Although the National Health Act expressly recognises that brain death is death, it does not prescribe the medical standards of testing for the determination of brain death (neurological determination of death), circulatory death (circulatory determination of death) or for determination of death based on somatic criteria. However, in all cases of organ donation, including after circulatory death, the National Health Act mandates that two doctors certify the death, with one doctor possessing more than 5 years of experience. Additionally, both doctors must be independent from the transplant team. The standard for such determination, as for brain death, aligns with accepted medical standards. The Critical Care Society of Southern Africa has published South African (SA) Guidelines on Death Determination that outline rigorous standards for death determination in hospital settings by either a neurological or circulatory method. Legislation and the Health Professions Council of SA's (HPCSA) professional guidance direct clinicians on obtaining informed consent for donation either from the patient or in cases of incapacity from their surrogate decision maker. Collectively, the legislation, regulations and professional guidelines in SA provide a robust ethical framework that supports organ donation after circulatory death.

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Death is a medical occurrence that has social, legal, religious and cultural consequences requiring common clinical standards for its diagnosis and legal regulation. In cases of organ donation, it is legally and ethically required that the determination of death is independent of organ transplant teams who are considered to have a conflict of interest. Donation after circulatory death (DCD) refers to the recovery of organs for transplantation that occurs after the certification of death by circulatory criteria and not neurological criteria. In cases of circulatory death, the loss of neurological function is secondary to the complete loss of circulatory output. Given the time pressures of organ recovery in DCD, institutional and professional processes that guide DCD must be ethically and legally appropriate.^[1]

Death determination

The National Health Act^[2] does not specify the *manner* of death determination needed in cases of organ donation. 'Death' is defined as 'brain death' in section 1 of the Act. Regulation 9 of the Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes^[3] ensures that the determination of death in cases of organ donation remains autonomous and independent from the transplant team, who can be perceived to have a conflict of interest. It furthermore sets a rigorous standard by mandating that

two doctors make the death determination, one of whom should be senior and have been practising as a medical practitioner for at least 5 years after the date on which she or he was registered as a medical practitioner. South African (SA) law holds medical practitioners to standards of reasonable competence.^[4] In the donation context, this would require doctors to perform a determination of death in alignment with medical guidelines and accepted professional practice.^[5]

There are benefits of allowing best medical practice to be the standard of death determination, as scientific advances can be incorporated into best practice quicker than legislative processes and regulations. Despite aiming to clarify the determination of death, legal requirements often complicate the determination of death. In Uganda, the Uganda Human Organ Donation and Transplant Act provides in section 53 that an independent medical team, consisting of a neurosurgeon, neurologist and anaesthetist/intensivist, separate from the treating clinical team, must certify brain death.^[6] In Turkey, an ancillary test, such as an electroencephalogram (EEG), which only has a sensitivity and specificity of 70% in confirming brain death, is a mandatory part of the assessment. It was also only in 2014 that Turkey amended its regulatory requirement for certifying neurological determination of death (brain death) to be certified by

a committee of four doctors (comprising a cardiologist, neurologist, neurosurgeon, anaesthesiologist and a reanimation specialist) to be certified by only two doctors.^[7]

The development of a recent international consensus paper on brain death determination with standardised terminology and minimum standards for testing, based on the review of the literature and expert opinion of a large multidisciplinary, international panel, has been welcomed.^[8] Previously, there was a degree of variability in certain aspects of brain death testing around the world.^[9,10] A World Health Organisation expert technical review addressed standards for circulatory determination of death in 2014.^[11] These standards are included in the South African Death Determination Guidelines and specify a period of 5 minutes of no spontaneous circulatory or respiratory effort before a determination of death can be made.^[5]

In all cases of death determination, the treating clinical team must exclude reversible causes and establish that it is permanent. In the setting of a circulatory determination of death, a period of 5 minutes from the point of complete loss of circulatory output is sufficient to establish permanence, in the setting where it is either inappropriate to do cardiopulmonary resuscitation or a decision has been made to stop doing cardiopulmonary resuscitation.^[5] In a large meta-analysis, the longest period for a patient's heart to auto-resuscitate with no outside resuscitative efforts was 4 minutes 20 seconds.^[12]

A brain-based definition of death is still true after a circulatory determination of death, as brain function is lost, will not resume spontaneously and will not be restored through intervention in those cases. There is a period of complete absence of any form of consciousness (wakefulness) and of any neurological activity (including brainstem reflexes and independent respiration) as part of a circulatory determination of death with any such finding precluding certification of death by circulatory criteria.^[13]

Medical guidance must ensure compliance with domestic legislation and alignment with local resources and technical expertise. The South African Death Determination guidelines have incorporated these international guidance documents into the SA context and supply checklists and education resources for clinicians involved in death determination.^[5] These help to ensure that the testing process is standardised and performed with the necessary scientific rigour as per the local context.

Public trust

At its core, organ donation depends on public trust in the medical processes and ethical checks and balances. Public trust in organ donation after circulatory death is supported through other mechanisms in SA, beyond the rigour and independence of the death certification. These are informed consent from patients and next-of-kin, forensic pathology authorisation in cases of an unnatural cause of death, and medical manager authorisation.

Informed consent: Consent plays a central role in medical ethics and is an integral part of the four fundamental principles of medical ethics that include beneficence, nonmaleficence, autonomy and justice.^[14,15] Respect for patient autonomy is regarded as a primary element of good medical care.^[14] Where informed consent for donation of organs and tissues has not already been given or where the deceased has not prohibited donation while alive, the next of kin may consent to donation as representative of the patient's wishes in this regard. The National Health Act dictates in section 62(2) the order

of preference for those surrogate decision-makers who may consent to donation on behalf of a person after death, namely the spouse, partner, major child, parent, guardian, major brother or major sister of that person.

Forensic pathology authorisation: The National Health Act (section 66(1)(c)) and the Inquests Act^[16] (section 3) mandate that all deaths deemed to be unnatural must be referred for a (forensic) medico-legal autopsy. The cause of death is unfortunately, frequently the result of trauma, interpersonal violence or suicide in cases of organ donation.^[17] Forensic pathology approval is required for each organ or tissue donated in these cases, and the recovery team writes a report that is added to the Forensic Pathology Services request form. The inquest and SAPS process are therefore not undermined by a decision to donate organs. In controlled donation after circulatory death, there is planned withdrawal of life-sustaining therapy (WLST). This is only possible in patients where ongoing care is non-beneficial (futile) and a decision to withdraw intensive organ support such as mechanical ventilation, is agreed to in principle prior to an organ donation consent request. De-escalation of invasive medical devices as part of this process is permitted as per palliative care practices, which must be documented in the patient's folder.

Medical manager authorisation: Written medical manager authorisation is required in accordance with section 58 of the National Health Act for all living donor transplants. All transplant teams in SA apply the same standard to deceased donors as part of their processes. This is beneficial for several reasons, one of which is that it makes the institution accountable for the donation activity and ensures that management is always aware of when such activity is taking place.

Discussion

Organ donation is a reflection of good end-of-life care, counselling and bereavement support. It is important that our healthcare system, both public and private, offers patients and their families the option to support donation in all appropriate cases. Organ donation is shown to offer solace to bereaved families at an emotional and stressful time because of the level of counselling required prior to a request and independent of the answer to the donation request.^[18,19]

Donation after circulatory death helps to expand the organ donor pool and requires a high standard of end-of-life care to be provided. Donors after circulatory death constitute the majority of tissue donors in SA and the world.^[20] Legally, organ, tissue and corneal donation is not exclusively required to be performed after a neurological determination of death. The National Health Act and supporting regulations, along with the professional guidelines offer a framework to support donation after circulatory death without the need for specific legislation or legislative amendments. More widespread institutional protocols and National Department of Health guidance would assist in more widespread uptake and support of this method of organ donation.

Organ donation is also a reflection of the social contract we have in our society. The dead donor rule, which is an ethical rule that requires organ donors to be pronounced dead before organs are removed,^[21,22] is a fundamental underpinning of this contract and organ donation. Death must have occurred prior to any organ recovery surgery. As discussed above, its independence from organ and tissue recovery teams is a legal prerequisite and in cases of organ donation, a higher degree of rigour is required in terms of the regulations of the National

Health Act. This is appropriate given the sensitivity of organ donation and its proximity to the death determination.

An equally integral step in the organ donor pathway is informed consent. Organ and tissue recovery may not take place without informed consent from the patient or the patient's next-of-kin. People listed in the organ donor registry in SA are not considered to have given legally binding informed consent. Their willingness to be identified as a donor is no more than an 'expression of intent' during the informed consent process. 'What would this person have wanted to come of this situation?' is a sensitive way to make a request to a grieving family for consent to donation. Even in countries with presumed consent, such as Spain, the family is routinely approached with a refusal rate of 11.6%. In two countries, Brazil and Chile, legislative change from an opt-in to an opt-out consent approach resulted in a decrease in public support and donation rates that necessitated a legislative reversal.^[23,24]

High-performing organ donation systems integrate donation after circulatory death into their organ donation pathways to expand the donor pool and offer patients and their families more ways to support organ donation at the end of life.^[25,26] This is something SA should consider more broadly as donation after circulatory death is legally permitted within the remit of the SA health legislation and guidelines, and would expand the donor pool and improve access to transplantation. Organ donation after circulatory death has been practised ethically and successfully for kidney transplantation in SA on a small scale at two centres since 2007.^[27] The vast majority of all tissue and corneal donors are donors after circulatory death.

Ultimately, the true benefit of donation after circulatory death is the associated advancement of end-of-life counselling related to such programmes and the necessary educational engagement around good end-of-life care that is needed for the success of such programmes. The necessary role player and stakeholder engagement for such a programme filters through into all areas of the healthcare system by supporting patients and families at the end of life and thereby making the consideration of organ and tissue donation more frequent and an expected standard of care. The National Health Act and regulations, professional guidance from the Critical Care Society of Southern Africa on death determination as well as the HPCSA guidance on consent, supports organ donation after both circulatory death and brain death.

Conclusion

Organ donation after circulatory death is aligned with the current ethico-legal framework governing organ donation in SA, provided that informed consent is obtained and that the determination of death is done in accordance with accepted medical standards by two doctors independent from the transplant team, with one of them having more than 5 years of experience. Additionally, in cases where a medico-legal autopsy is required prior to organ recovery, authorisation from the relevant forensic pathology services is required.

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