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Dear Sirs,

Response to Consultation: Give and Take? Human bodies in medicine and research.

Thank you for your invitation to offer my views on several of the questions posited by the Working Party. I submit my response in which I focus exclusively on ethical issues related to the current practice of cadaveric organ procurement and transplantation:

In the following, I will address one of the most critical issues affecting the ethical validity of the current practice of organ procurement: the requirement to fully disclose all relevant information regarding the organ donation process, thus enabling individuals to give truly informed consent.

Requiring consent is consistent with one of the cornerstones of medicine and bioethics: respect for a person's autonomy. Among other things, the process of obtaining consent must include the provision of an appropriate quantity and quality of information so as to allow a person to make an informed decision. Obtaining consent is considered one of the guiding principles that provide moral validation of organ transplant programs.

The critical information for a person considering consent for cadaveric organ donation pertains to the full disclosure of:

1) The existing controversies regarding the current practice of death determination in the context of organ procurement
2) Presumed implied permissibility of ante- and peri-mortem interventions associated with organ procurement
3) The implications of organ donation for the donor's end-of-life trajectory

Ad 1: *The existing controversies regarding the current practice of death determination in the context of organ procurement (Definition of death*):

The determination of death in the context of both heart-beating donation (HBD) and non-HBD (also known as donation after cardiac death or donation after circulatory death) organ procurement has been scrutinized in the medical and ethics literature. Despite the claim universally brought forward that brain death has come to be accepted in almost all developed countries as death of the human being itself, and that the current circulatory criteria suffice to determine cardiac death, no coherent argument has been offered to substantiate claims that these criteria for death should be considered death. In regard to brain death, I have argued, as many

other commentators have, that brain death does not disrupt somatic integrative unity and coordinated biological functioning of a living organism. In fact, in its 2008 White Paper, the President's Council on Bioethics rejected all previously advanced rationales for a neurological standard of death [1]. The Council, in its effort to salvage the neurological criteria for death, proposed to replace the term brain death with total brain failure and a completely new rationale, i.e., a more comprehensive account of *wholeness* to support the notion that following total brain failure the body is no longer an organismic whole, and therefore, is no longer alive. However, Shewmon concluded that "the new solution does not put the problem to rest" [2]. In one of his earlier works, Shewmon concluded that (a) if there is a live human body, there is ipso facto a live human person, and (b) unconsciousness per se, even if irreversible, is ontologically a cognitive disability, not death [3].

The concept of brainstem death in which death is considered synonymous with apneic coma, received an equal if not a greater amount of scientific and philosophical critique. Joffe summarized it well stating: "it does not state a concept of death; rather it states a criterion of something. Worse it is a conflation of a concept/definition of death, and a criterion of death: it is only restating the criterion, and not stating a concept/definition of death that this criterion meets" [4].

Critics have not only critiqued the concept/definition of brain(stem) death. They also increasingly questioned the scientific validity of the clinical guidelines [5] that are presumed to demonstrate that all brain functions have ceased irreversibly. Wijdicks et al concluded in their recently published update on the 1995 guidelines that "[D]espite the paucity of evidence, much of the framework necessary for the development of 'accepted medical standards' for the declaration of brain death is based on straightforward principles. These principles can be derived from the definition of brain death provided by the UDDA" [6]. The literature on clinical testing and its pitfalls in brain death determination remains meager. Many studies have concentrated on the validity of new ancillary (confirmatory) tests. We found the literature on these tests unsupportive in many instances. Brain death remains a clinical assessment, and no laboratory test can refute or prove this condition [7]. Nevertheless, clinical testing is limited to assessing functions mediated by the brainstem only [8].

Defining death by neurological criteria has additional conceptual implications. The reduction of any definition of death to exclusively neurological terms ignores the anthropologic, cultural, and religious dimensions that many people value highly [9].

With even the Presidents' Council conceding that "there is still reason to wonder if our knowledge of their condition is adequate for labeling them as dead" [1], it would not only be appropriate but morally mandatory to disclose to the

families of patients declared brain dead or brain stem dead the existence of an ongoing controversy over whether their loved one is either dead or in irreversible coma.

Similar concerns about the determination of death have been raised in the context of NHBD. Cardiac mechanical asystole (or absent arterial pulse) lasting anywhere from 75 seconds to 5 minutes is the U.S. circulatory standard of declaring death in donation after cardiac death [10]. However, it has been argued that the recovery of viable organs useful for transplantation in DCD is incompatible with the so-called Dead-Donor-Rule. The circulatory standard of mechanical asystole (lack of arterial pulse) fails to meet the criterion of *irreversible* cessation of circulation and respiration in NHBD [11]. It is also important to point out that NHBD donors may have normal brain function before mechanical asystole and declaration of death [12]. Regardless of the possibility for autoresuscitation, the fact that brain electrical activity and clinical undetected integrated brainstem functions can return despite circulatory arrest and that recovered hearts in NHBD have normal native mechanical and electrical functions after transplantation, exemplify that the irreversibility criterion has not been fulfilled. Others have argued that irreversibility is not required in the determination of circulatory and respiratory death: "brain functions must be shown to have irreversibly ceased, the more commonly applied medical tests for death that show cessation of circulation and respiration require showing only that they have ceased permanently" [13]. Though the term "permanence" only prognosticates "irreversibility," it is nevertheless argued that permanence is an appropriate surrogate for irreversibility. Others have maintained that "when a DCD donor is declared dead, it is not known that he has suffered irreversible loss of circulatory and respiratory functions" [14].

Miller and colleagues concluded that "scholars have argued cogently that donors of vital organs, including those diagnosed as 'brain dead' and those declared dead according to cardiopulmonary criteria, are not in fact dead at the time that vital organs are being procured…[leaving] the current practice of organ transplantation based on the 'moral fiction' that donors are dead when vital organs are procured" [15]. "[C]oncerns about the legal details of declaring death in someone who will never again be the person he or she was should be weighed against the value of giving a full and healthy life to someone who will die without a transplant" [16]. As it stands, "the considerable debate over the determination of death in the medical and scientific literature has not informed the public of the fact that our current determinations of death do not adequately establish that a person has died" [17].

Conclusion (1):
Considering the growing scientific scrutiny on the validity of death determination, the donation consenting process should comply with the moral and legal requirements of disclosure of all information necessary for a person to make a well-informed, autonomous decision about willingness to donate organs.

Ad 2: *Presumed implied permissibility of ante- and peri-mortem interventions associated with organ procurement*
Consent to donate is always presumed to include consent for all perimortem interventions deemed necessary to maximize the chances of successful return of the native function of the transplanted organ. Antemortem interventions could harm the patient. Anticoagulants (eg, heparin) expand intracranial haemorrhage and hasten the death of potential donors with acute ischaemic or haemorrhagic strokes. Large volumes of crystalloid fluids are infused to maintain organ perfusion, while exacerbating cerebral oedema and accelerating the onset of brain stem herniation and infarction in potential donors. Vasodilators are infused for organ preservation, causing hypotension and early onset of cardiorespiratory arrest after discontinuation of mechanical ventilation [18]. Normally consent can be presumed if interventions have the intention of healing and preserving the life of the patient. In the context of organ procurement, the presumption of consent is made on the basis of benefiting someone else.

Ad 3: *The implications of organ donation for the donor's end-of-life trajectory*
The impact of donor management and procurement protocols on end-of-life (EOL) care and the potential trade-off are not disclosed. Yet, the process of obtaining donation consent and subsequent donor management protocols for NHBOD deviate from more than 60% of the Robert Wood Johnson Foundation quality indicators recommended for optimal EOL care [19]. It has been shown that the disclosure on organ procurement organizations' web sites and in online consent forms lacks pertinent information required for informed enrollment for deceased organ donation. Instead, the information content of these web sites is concentrated on providing positive reinforcement to consent and on promoting organ donation[20].

Conclusion (2, 3):
The implied permissibility of ante- and peri-mortem interventions in the context of organ procurement can only be presumed if and only if sufficient information has been provided to individuals deciding on becoming an organ donor or having to make donation decisions as surrogates. Currently, the consenting process does not meet this criterion. Similarly, as information on the end-of-life trajectory changes secondary to organ procurement is not properly disclosed, the moral validity of the consenting process must be very much called into question.

I hope that the foregoing thoughts will contribute to your deliberations.

With regards.

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