Author's response to reviews

Title: Organ Procurement Organizations Internet Enrollment for Organ Donation: Abandoning Informed Consent

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Author's response to reviews: see over
The authors are indebted for the comments made on the manuscript to improve its quality. The authors attempted to address all the points raised by the reviewers on the initial draft of the manuscript.

As a result further editing has been incorporated into the revised manuscript which is highlighted in red font for clarity. Additional references were added to support some of the statements made in the text.

Again, we express our gratitude to the reviewers for their important comments.

Yours truly,

Reviewer: Marc I Lorber

Revise the manuscript to present the results more objectively
For example, they seem to have assumed that the web represents the primary focus of informed consent activities within the organ donation community. That seems unlikely to be the case; most OPOs currently still focus on the face to face consent process, including experienced professionals leading the discussion.

New paragraph has been added to discussion to clarify the anticipated change in trend for organ donation enrollment.

“Most OPOs currently still focus on the face to face consent process, including experienced professionals or organ requesters leading the discussion for organ donation. The OPOs are increasingly referring to organ donation registries which are linked to DMV driver license or Internet registration to make the intent for donation legally binding [11]. In the 2006 report, the Committee on Increasing Rates of Organ Donation of the Institute of Medicine (IOM) has encouraged the universal adoption of organ donor registries across the United States to increase the rate of donation consent [9, 12]. The organ donor registries are linked to OPOs Web sites to facilitate and expedite electronic organ donor registration. “

Also, they expressed concern that consent forms did not disclose brain and cardiac death criteria, but this has been considered improper for the donation process. Rather, it has been considered the domain of the care giving professionals involved with the potential donor during the time leading to the declaration of death. The decision is NOT of the donation team, but it is that of the care giving team. therefore, although it may be proper to provide a discussion (or a link to a discussion) describing the process, this does not seem appropriate for a donation consent form per se.

“The salient differences between the process of organ donation after cardiac or imminent death and organ donation after brain death have not been emphasized in the public domain since its integration into transplantation practice [14]. We have expressed concern that consent forms for organ donation do not disclose or distinguish between brain and cardiac death criteria and processes. It can be argued that this information is
improper to disclose at the time of registration for organ donation. The argument can be made that disclosure of types of organ donation should be the domain of the health care professionals involved with the potential donor during the time leading to the declaration of death. However, the current practice and federal guidelines designate the OPOs and affiliates rather than the health care professionals to explain and obtain consent for different types of organ donation [10, 15]. Therefore, the OPOs have the responsibility for the disclosure of information pertaining to the types of organ donation in order for the donors and families to make informed choices. The President’s Council on Bioethics have expressed concerns similar to ours that certain issues pertinent to cardiac or imminent death organ donation have not been addressed explicitly by hospitals and OPOs in their donation consent process and protocols or by those bodies that have made recommendations for reforming or expanding deceased organ donation practice [16].”

Focus the discussion section to the results presented, avoiding speculation about topics such as the definition of brain death, beneficial or non-beneficial testing, other aspects of end of life care, presumed consent or mandated choice, etc. Each of these subjects are important, but they were not the subject of this report.

“None of the Web sites disclosed how the organ preservation procedures crucial for successful procurement can interfere with certain quality indicators for end-of-life care. Interestingly, The Robert Wood Johnson Foundation Critical Care End-of-Life Peer Workgroup has developed and recommended compliance with certain quality indicators to ensure that end-of-life care is not sacrificed for the purpose of organ donation [18]. The Critical Care Peer Workgroup of the Promoting Excellence in End-of-Life Care Project has reported wide variability and frequent deficiencies in end-of-life care across the United States [19]. The workgroup reported over 70% of the surveyed intensive care units do not monitor end-life-care metrics. It is not surprising that the end-of-life care metrics have neither been measured nor reported in organ donors [20]. The President Council on Bioethics has re-affirmed that there are obligations to disclose how the organ donor’s end-of-life care will change as a result of the decision to donate and there is an ethical imperative for a true informed consent to disclose the trade-off [16].”

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

The Figures have been re-organized so that each item is labeled and has a self explanatory legend.

“The content scores for donor knowledge (Fig. 2) and informed consent (Fig. 5) were equally low for all UNOS regions. The content scores for donor consent reinforcement (Fig. 3) and donation promotion (Fig. 4) were equally high for all UNOS regions.”

Reviewer: Christopher Doig
Please confirm that the UAGA act (1968) and reference 16 is complete. I believe this act has undergone revision and is more recent than the date provided in the
The Uniform Anatomical Gift Act (UAGA) of 1968 and amended in 1987 and 2006 specified that the donor’s authorization to donate as recorded on an organ donor card, on the individual’s driver’s license, or in a donor registry is as legally binding as an advance directive regarding end-of-life care [21]. The revised UAGA in 2006 has assigned explicit priority to the donor’s intent so that the donor consent for organ donation becomes irrevocable and does not require consent or concurrence of any person after the donor's death [22]. In compliance with the UAGA legislation, the current OPO practice is to proceed with organ donation with a pre-signed organ donor card or registry without requiring family consent in nineteen jurisdictions within the United states [23, 24]. The UAGA amendment has also enabled OPOs to procure organs even with family refusal to donation if the donor has documented their intent to donate [25]. However, the application of UAGA also demands that voluntary consent of the organ donor is a transparent process.

The electronic source of reference has been changed to revised UAGA 2006 http://www.law.upenn.edu/bll/ulc/uaga/2006final.htm

There is a syntax problem with the following sentence: "The IOM has supported in principle the concept of presumed consent and proposes future legislative enactment to increase organ donors pool [12]."

“The IOM has supported the concept of presumed consent and proposes that future legislative enactment can increase organ donors pool[12].”

In your discussion regarding UAGA and subsequent revisions, there is no discussion on whether OPO's are simply proceeding with signed donor consent, or requiring consent (or assent) of families. My understanding is that the normative standard for OPO's in North America is to obtain family consent (assent). Perhaps a short sentence to clarify this point would be helpful particularly given that in other countries presumed consent or required refusal is a standard.

“In compliance with the legislative amendment, the OPO practice is to proceed with organ donation with a pre-signed organ donor card or registry without requiring family consent (assent) in nineteen jurisdictions in the United states [23]. This amendment has also enabled OPOs to procure organs even with family refusal to donation if the donor has documented their intent to donate [24].

I believe your discussion could be enhanced with a short comment on the moral propriety of IOM supporting presumed consent, yet not supporting mandated choice. I thought the IOM was an independent body. From your discussion the implicit message is that any action (for example legislation) that might decrease the organ donor pool is 'bad'. I guess either I don't understand IOM (maybe they're not independent) or more discussion must be placed on their justification for this decision.
“The IOM prefers presumed consent to increase the rate of organ donation because that type of consent does not require the development of costly public education programs necessary for the implementation of mandated choice [25]. “

You call for an independent body to take charge of the process for enrollment. I'm not sure if you mean for administering and managing a registry, for the process of consent in the ICU, or potentially both. If the process of consent in the ICU...why should this not be the sole responsibility of the ICU team? One reason against is that there might be institutional conflict that bears on the action of the members of the ICU i.e. we are a transplant hospital, we are doing enough transplants because of a lack of donors, do better or don't work here.

“Therefore, we recommend that in order to maintain transparency and public trust, an independent entity with no potential for conflict of interest should take charge of the process of enrollment for organ donation. The independent entity can take charge of the public eduction in the community and determine the ethical and legal standards required for disclosure of information before registration of organ donation consent.”

One issue not discussed in terms of content of the websites is the potential variability in practice in end-of-life care in the ICU, and the impact that might play on EOL decision making (see Cook et al JAMA 1995, NEJM 2003). I don't believe that this is mentioned in your discussion, and/or whether this information should comprise part of informed consent.

“None of the Web sites disclosed how the organ preservation procedures crucial for successful procurement can interfere with certain quality indicators for end-of-life care. Interestingly, The Robert Wood Johnson Foundation Critical Care End-of-Life Peer Workgroup has developed and recommended compliance with certain quality indicators to ensure that end-of-life care is not sacrificed for the purpose of organ donation [18]. The Critical Care Peer Workgroup of the Promoting Excellence in End-of-Life Care Project has reported wide variability and frequent deficiencies in end-of-life care across the United States [19]. The workgroup reported over 70% of the surveyed intensive care units do not monitor the quality of end-life-care. It is not surprising that the end-of-life care metrics have neither been measured nor reported in organ donors [20]. The President Council on Bioethics has re-affirmed that there are obligations to disclose how the organ donor’s end-of-life care will change as a result of the decision to donate and there is an ethical imperative for a true informed consent to disclose the trade-off” [16].