Ethical Guidelines for Use of NRP cDCD

Catholic health systems across the United States are increasingly encountering requests from Organ Procurement Organizations (OPOs) to utilize a new technique for organ procurement, normothermic regional perfusion in controlled donation after circulatory death (NRP cDCD). This technique involves restoring oxygenated blood flow to organs after the declaration of death by the circulatory standard with the arch and cerebral vessels often clamped in the process.

Ethicists and ethics committees have a unique opportunity to support hospital leaders in evaluating ethical considerations around whether to use NRP cDCD. Many ethicists are already engaged in this dialogue.[i] If your ministry has decided to allow NRP cDCD in some form (i.e. abdominal or thoracoabdominal NRP), or if you discovered the protocol is already used at your ministry, I offer rationale to make the case for developing ethical guidelines for use of NRP and a project management strategy to identify and implement the guidelines that best serve your ministry, diocese, patients, and staff.

WHY ETHICAL GUIDELINES?

As the Ethical and Religious Directives state, "new medical discoveries, rapid technological developments, and social change, … can either be an opportunity for genuine advancement in human culture, or … lead to policies and actions that are contrary to the true dignity and vocation of the human person."[ii] At least four reasons suggest Catholic health care should establish ethical guidelines for use of NRP cDCD:

1. *Minimize harm to donors:* Bernard Lo, discussing potential harm to donors of medications administered pre-mortem to preserve organs, cautions that "[T]he best interests of organ donors should not be compromised to retrieve organs and benefit the recipient."[iii] Since respecting the dignity of the donor prohibits doing further harm to the donor, even for the sake of the common good of the organ donor.
2. *Remove and/or manage conflicts of interest:* The dichotomy in organ donation, namely that one person's death is necessary for others to live, inherently poses conflicts of interest. Such conflicts are augmented by the business context around organ donation. Recognizing this, Lo states: "Decisions about the potential donor's care must be separate from and take priority over decisions about procurement and transplantation."[iv] The ERDs similarly encourage mitigating conflicts: "the physician who determines death should not be a member of the transplant team."[v] Managing conflicts can also prevent possible scandal from arising.
3. *Respect for the dying process:* The relative newness of NRP, the intimacy with which

it uses the donor's body, and the significant implications of analyses on the ethicality of NRP demand special attention to Catholic health care's role in caring for the seriously ill and dying. The ERDs urge Catholic health care to provide patients "with appropriate opportunities to prepare for death," (no. 55) which in organ donation could mean providing the dying patient with a compassionate space for loved ones to be present that is not the sterile, rigid environment of the Operating Room (OR).

4. *Respect the deceased:* Upholding Catholic health care's longstanding respect for the deceased, Pope Pius XII affirmed, "The human body deserves to be regarded entirely differently [from the dead body of an animal]. The body was the abode of a spiritual and immortal soul, an essential constituent of a human person whose dignity it shared. Something of this dignity still remains in the corpse."[vi] Since organs can be perfused in situ during NRP for minutes to hours, respecting the deceased might mean limiting perfusion to the minimum time necessary to confirm organ viability and arrange transfer plans.

APPLYING PROJECT MANAGEMENT FUNDAMENTALS

The Ethics Manager employed project management methodology can be used to establish ethical guidelines for use of NRP cDCD. Common in the information technology industry, project management involves developing project plans to oversee a project through five phases: *Initiation, Planning, Execution, Monitoring and Controlling,* and *Closing.*

INITIATION

Initiation: *team defines project purpose, objectives, scope, stakeholders, and constraints.*

Our purpose was to establish ethical use criteria for NRP cDCD. Objectives involved identifying the criteria, delivering education, developing an enhanced inform consent process, and integrating the criteria in the clinical process map for organ donation. The scope was for one hospital. Constraints included legal, risk, and ethical considerations, space, and resources.

Stakeholders spanned layers of subsidiarity: our hospital, the ministry market (region), and our national system. Local stakeholders included Clinical and Administrative leaders, Risk, Cardiac Surgeons, Ethics Committee Chairs, Hospitalists, Nurse Managers and Chaplains for units where donor patients receive care. Regional stakeholders included leaders in Transplant, Mission, Ethics, and Spiritual Care, Diocesan leaders, and OPO leaders. National stakeholders included leaders in Ethics and Legal, and counterpart Ethics and Transplant roles in another region using NRP.

PLANNING

Planning: *project manager builds a project plan with tasks, schedules, resources, budgets, and risk assessments.*

First, we discussed ethics and legal concerns with national stakeholders, then held multidisciplinary meetings locally to learn about the protocol, discuss clinical and ethical considerations, plan the effort, and assign tasks.

An Ethics Committee subgroup reviewed ethics literature and crafted guidelines to mitigate ethical concerns (see next section).

EXECUTION

Execution: *work the plan (one might prefer 'implementation' to this project management term).*

Enhanced informed consent language was developed by Clinical leaders, Ethicists, and Legal. A clinical process map was developed by Clinical Leaders, Ethicists, and Medical Educators. Education was developed and presented by Medical Educators and Ethicists to clinicians and staff involved in organ donation. Mission and Ethics leaders communicated with the Diocese.

MONITORING AND CONTROLLING

Monitoring and Controlling: *project performance is tracked in the project plan and monitoring practices are set for post-project administration.*

For monitoring, Ethics and Spiritual Care management were added to a monthly organ donation meeting with Clinical leaders and the OPO, and issue escalation plans were communicated.

CLOSING

Closing: *all project tasks are completed and accepted by stakeholders, project documents are shared, and a retrospective is conducted.*

Ethical use criteria were accepted and implemented before the launch date, with materials shared appropriately. Retrospective space occurs in monthly meetings.

ETHICAL GUIDELINES

This process allowed us to establish these ethical guidelines for NRP cDCD:

1. *Enhance the informed consent process.* Our informed consent language is used in verbal conversations between the OPO's Family Care Liaison and families consenting/authorizing for donation, and a Team Lead or Chaplain witnesses the conversation.
2. *Locate the dying process in the Post-Anesthesia Care Unit (PACU).* A separate PACU room provides a compassionate space for the dying process where family can be comfortably present without needing personal protective equipment, spiritual care and the Sacraments are accessible, and physicians experience less pressure to determine death. The PACU provides a visual ethical separation in addition to the separation of staff between the declaring and procuring teams.
3. *Educate all clinicians and staff involved in donation on clinical and ethical considerations.* Education involves clarifying our ethical approach for the purpose of clamping the arch and cerebral vessels.
4. *Observe the Dead Donor Rule (of course).* After death is determined in the PACU, a 5-minute hands-off period occurs, during which the donor is moved to the OR for second confirmation of death. Procurement only begins after the second confirmation.

Establishing ethical guidelines via this

process can help Catholic ministries maintain integrity to their mission, values, and ethical commitments throughout the organ donation process. ✠

KIRSTEN DEMPSEY, PHDC, MA
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ENDNOTES

i. Kelly Stuart, "Reframing the Ethics of Normothermic Regional Perfusion," *HCEUSA* (2024); Barett Turner, "Thoraco-abdominal Normothermic Regional Perfusion (TA-NRP) Resuscitates Moral Doubts about Donation after Circulatory Death (DCD)," *HCEUSA* (2024); Kyle Karches and Jason Eberl, "Distinguishing Ethical from Diagnostic Concerns About NRP-cDCD," *The American Journal of Bioethics* 24, no. 6 (2024): 69-71; Kyle Karches et al., "Dead Enough? NRP-cDCD and Remaining Questions for the Ethics of DCD Protocols," *The American Journal of Bioethics* 23, no. 2 (2023): 41-43; Matthew DeCamp et al., "POINT: Does Normothermic Regional Perfusion Violate the Ethical Principles Underlying Organ Procurement? Yes," *The American Journal of Bioethics* 162, no. 2 (2022): 288-90.

ii. United States Conference of Catholic Bishops, "Ethical and Religious Directives for Catholic Health Services: General Introduction," 6th ed., (United States Conference of Catholic Bishops, 2018), 7.

iii. Bernard Lo, *Resolving Ethical Dilemmas: A Guide for Clinicians,* 5th ed., (Wolters Kluwer: Lippincott Williams & Wilkens, 2013), 295.

iv. Bernard Lo, *Resolving Ethical Dilemmas*, 295.

v. United States Conference of Catholic Bishops, "Ethical and Religious Directives for Catholic Health Services: Part Five, no. 64," 6th ed., (United States Conference of Catholic Bishops, 2018), 22.

vi. Pope Pius XII, "Discourse of Pope Pius XII to the Association of Corneal Donors and to the Italian Union of the Blind," (Vatican Library, 1956).