

Ensuring Safety and Reliability in DCD Protocols — A Message to the OPTN Community

Dear OPTN Members,

The OPTN, in collaboration with HRSA, is <u>issuing this message</u> to highlight a critical safety concern in donation after circulatory death (DCD) procedures, specifically the occurrence of spontaneous return of cardiac or respiratory activity ("autoresuscitation") after declaration of circulatory death and in the initial stages of organ recovery. The OPTN has received verified reports of such events. Though extremely rare, these events call for heightened vigilance and standardized practice across all organ procurement organizations (OPOs). In the coming weeks, the OPTN will be proposing new policy requirements and associated data collection in order to further improve system safety.

In the interim, in an effort to reinforce patient safety, improve trust in organ donation, and increase consistency in practice, we ask that all programs commit to the following three actions:

1. Adhere strictly to the defined waiting ('timeout') period between the cessation of circulatory/respiratory activity and incision.

Current medical evidence (Dhanani S et al, New Engl J Med 2021 384(4)345-352) and recommendations (Croome KP et al, Am J Trans 2023 23(2)171-179), as well as the majority of in-place OPO protocols support 5 minutes as the waiting time that best balances risk of autoresuscitation with risk of ischemic injury to organs. Some hospitals and OPOs by mutual agreement may have described a shorter waiting time (e.g., 2 minutes); however, given safety incidents reported to the OPTN and regulators, current medical evidence, and peer-reviewed recommendations, OPOs may wish to reassess any standard operating procedure that reflects waiting time of less than 5 minutes. Care should be taken to confirm cessation of circulatory and respiratory activity in accordance with the applicable OPTN and OPO DCD policies and hospital-OPO agreement before declaring death and proceeding with organ procurement. Ensure everyone involved (donor hospital clinicians, OPO staff, third-party procurement teams, and transplant teams) understands the required waiting period duration and what constitutes satisfactory confirmation of asystole/cessation of circulatory activity. If any uncertainty arises (e.g., signs of organ perfusion, cardiac motion, spontaneous respiration), pause and reassess. Do not advance to incision until timeout criteria are met.

2. Ensure hospital partners and OPOs share awareness of the autoresuscitation risk and have a coordinated plan should it occur.

OPOs should conduct baseline education sessions with all hospitals with DCD donor potential to raise awareness of the possibility, prevention, and management of autoresuscitation during attempted DCD organ procurement. Hospitals should be advised to update their own policies to address patient management in the unlikely event of an intraoperative discovery of autoresuscitation. Conduct pre-procedure huddles (including donor hospital treatment team(s), transplant team, and OPO procurement staff) to review roles, criteria for declaration of death, monitoring modalities, and steps to take if signs of re-animation appear. Verify that monitoring equipment, documentation

expectations, and intra-operative protocols are clearly established. Develop a contingency plan if autoresuscitation is observed post-incision. Specifically, the team should (i) pause recovery; (ii) revert to patient-care protocols driven by the patient's primary care team; (iii) notify centers, hospital, and family; (iv) document the event in real time in all medical records; and (v) immediately report the incident via the OPTN Safety Portal.

3. Report all observations of autoresuscitation promptly via the OPTN Patient Safety Reporting Portal.

Reporting incidents enables learning, identifies systemic risks, and protects patients, providers, and the public's trust. When reporting an autoresuscitation event, include in your report: the timeline (time of death declaration, observation period, incident of autoresuscitation), monitoring modalities used, clinical signs observed, and actions taken. In addition, OPTN members are encouraged to share learnings (redacted as appropriate) and best practices with each other so the community can benefit from increased knowledge and consistency in practice.

We appreciate the diligence and professionalism of all OPTN members in advancing lifesaving organ donation, procurement, and transplantation. As part of that commitment, we must ensure the highest standards of patient safety, ethical integrity, and transparency remain front-and-center.

Thank you for your cooperation and continued dedication to safe, reliable organ donation and procurement practice.

Sincerely, John Magee, MD 11/6/2025