Membership and Professional Standards Committee (MPSC)
Life Alliance Organ Recovery Agency (FLMP)
Informal Discussion Summary
September 25, 2019

MPSC Members Present: [redacted]

UNOS Staff Present: [redacted]

Life Alliance Organ Recovery Agency Representatives Present: [redacted]

Informal Discussion Summary:

The Subcommittee Chair convened the informal discussion pursuant to Appendix L, Section L.8 of the Bylaws to review FLMP's decision to no longer permit brain dead patients to be DCD (donation after cardiac death) donors. This decision was made as a corrective action after FLMP recovered organs prior to asystole, despite family authorization for DCD recovery. The Chair stated that the informal discussion was being conducted under confidential medical peer review, and the entire informal discussion and review process, including all related documents and information, are protected by applicable peer review statutes.

Participants from FLMP made their introductions and began their presentation. FLMP thanked the MPSC for the opportunity to participate in the informal discussion. The Executive Director began by explaining the terms "DCD" and "withdrawal" would be used interchangeably in their presentation. He then continued with a timeline of the case. The donor was a 41-year-old female admitted to the hospital on November 19, 2018, after a motor vehicle accident that resulted in submersion of the vehicle and subsequent cardiac arrest. On November 24 at 10:29, a physician wrote the first brain death note. On November 26 at 15:34, the hospital advised FLMP they were waiting for the donor's family to withdraw life support. OPO staff went to the hospital to wait for the family to arrive. At 22:05 that evening, the OPO conducted a pre-approach huddle, and later engaged with the family. OPO staff explained brain death and DCD donation to the family, who decided to proceed with DCD donation. On November 27 at 6:00, a second physician issued another brain death note and the donor was legally declared brain dead. At 19:55, OPO staff again discussed brain death and donation with the legal next of kin (the donor's mother). The family expressed they wanted to proceed with DCD recovery and witness cardiac standstill. On November 28 at 00:24, OPO staff conducted their pre-allocation huddle and began making electronic offers for the lungs, liver and kidneys as a DCD donor pursuant to family wishes.

FLMP's Donor Management Coordinator who was on-site that night continued with the timeline of the case. She explained the donor's mother was emotionally distraught and, although she understood brain death would allow FLMP to optimize the gift of donation, she was adamant that she witness her

daughter's last heartbeat for emotional closure. If she was not able to be in attendance for withdrawal of care, she would rescind authorization.

The Executive Director continued with the timeline of events. On November 28 at 12:11, the OPO held their pre-recovery huddle. Staff planned to proceed with DCD recovery upon cardiac standstill, even though the donor was brain dead. Hospital staff would document cardiac standstill.

FLMP's Administrator on Call (AOC) explained she conducted the pre-recovery huddle with the surgical recovery team. She stated she advised OPO staff this was a brain dead donor who would be recovered as a DCD donor per the family's wishes. The Donor Management Coordinator continued by explaining he huddled with the surgeons and informed them this was a brain dead donor who would be recovered as a DCD donor. Immediately after extubation, the donor's mother became extremely emotional and asked to leave the room. She also requested that organ recovery continue.

The Executive Director said that although the donor's mother was initially insistent on witnessing cardiac standstill, she changed her mind, authorized recovery, and left the OR. FLMP's Donor Family Advocate, who was providing support for the donor's mother, added that after a moment of honor for the donor, support was withdrawn. At that time, the mother became emotional, asked to leave the OR, and requested the OPO continue recovery.

The Executive Director stated FLMP supported the family with compassion, and were sensitive to their change of mind. The OPO proceeded with brain death recovery after starting as a DCD recovery. This was done to limit ischemic time and to honor the family's wishes. FLMP did not consider stopping the recovery process, re-intubating the donor, or rerunning the matches due to the high probability of the donor's mother rescinding authorization.

The Executive Director explained that OPO leadership met to discuss this case upon receiving an inquiry from the Organ Procurement and Transplantation Network (OPTN). They held a debriefing with the team who managed the case, and then leadership met again. FLMP's Director of Quality explained they did not conduct a root cause analysis because everyone agreed the root cause was the emotional and fragile state of the donor's mother. The Executive Director added the team then discussed their plan to handle these cases in the future, including a debate about potential loss of organs if they stopped recovering brain dead donors as DCD. He stated OPOs provide a public service, and a transparent relationship with regulators, and by extension, the public, is essential to ensuring the public trust. He remarked on negative press regarding organ donation, and said a distorted narrative regarding this case could have led to a sensational story and a damaging impact on organ donation. He was concerned the public would perceive FLMP was recovering organs from donors who were not yet dead, or believe the OPO was not respecting the donor's dignity or the wishes of the family. He added the OPO has only had three cases of brain dead donors recovered as DCD in the past 10 years, but negative press could result in the loss of hundreds of organs. The Director of Operations stated the OPO decided to no longer pursue brain dead donors under DCD protocols, and communicated this to their staff on March 18, 2019, during a general staff meeting.

The Executive Director continued by stating donation is family driven, and in this case the mother changed her mind upon witnessing extubation. FLMP team members supported the family, were sensitive to their fragile state of mind, and honored their wishes. He explained the OPO considered two factors when reaching the decision to no longer recover brain dead donors as DCD: the rarity of these types of cases, and concerns about the impact on organ donation as a whole. He concluded the presentation by stating

FLMP welcomes the MPSC's guidance on how to approach these dynamic cases while balancing the family's wishes and maximizing the gift of donation.

The Subcommittee Chair thanked FLMP and asked if their existing authorization policy allows for verbal authorization from the donor's family. The Executive Director responded it does not, but the recovery in the case was done with the approval of the donor's mother. He added they will consider revising their policy to include verbal authorizations.

An MPSC member thanked FLMP for their presentation and asked if the OPO only had authorization for DCD recovery in this case, and if it was standard for the OPO to only obtain DCD authorization and then go back to the family and request brain death authorization if needed. The Executive Director replied in this case they only had authorization for DCD recovery. The OPO asked the family for brain death authorization, but they declined up until the point of extubation. At this time, the mother was too distraught and FLMP did not believe this was the appropriate time to ask for additional authorization. Staff was concerned the family would withdraw authorization entirely if they did this. The same committee member then asked if FLMP staff considered continuing with DCD procurement as originally intended after the mother left the room, and if not, who made the decision to proceed with recovery before cardiac standstill. The Executive Director stated the FLMP team on-site made the decision since the donor had already been declared brain dead. He added all of the decisions were made under fast-paced and quickly changing circumstances. The committee member then asked if the OPO considered that when the donor's mother left the room and told staff to proceed, they should have proceeded with DCD procurement to avoid any misrepresentation or confusion. The Executive Director replied he was not sure of the team's thought processes, other than minimizing ischemic time and supporting the family. The MPSC member then commented that most OPOs have encountered situations where the family wishes to have a brain dead donor recovered as DCD, and stated he believes the OPO may have overreacted in its decision to no longer recover brain dead donors as DCD. He reported concern the only root cause FLMP noted was the emotional state of the donor's mother. He asked that, given OPO staff work with emotionally distraught families regularly, if the OPO would reconsider its decision to no longer procure brain dead donors under DCD protocols. The Executive Director replied FLMP debated their corrective action plan but because organ donation is family driven, and no one can predict how families will react when grieving, they reached this decision. He also commented concerns regarding the impact on organ donation overall factored into their decision. He added in the future, FLMP would try to accommodate a family's wishes under these circumstances, but if they were to change their mind upon withdrawal, FLMP would stop the recovery. The Director commented he briefed FLMP's board of directors on this case, and would brief them again after the informal discussion.

Another subcommittee member asked if FLMP considered the effect any appearance of pain or suffering on the part of the donor may have had on the family. The Executive Director replied that because the donor was brain dead, there were no outward signs of pain or suffering. The donor management coordinators who were on-site confirmed this.

A third subcommittee member asked if there was a retroactive review of the communications between the team members and the AOC for this case. The Executive Director explained FLMP has two layers of support for each case. There is an AOC and Leadership on Call (LOC). The AOC stated she had no concerns about communication regarding this case, and had she been on site, should would have handled the case in a similar manner. The committee member then asked if there has been any discussion regarding communication and how a consensus was reached that day. The Executive Director reported the OPO discussed this in two leadership meetings, and decided if the case had been paused so staff could discuss

or escalate the case they may have lost the opportunity for donation. The committee member then asked if FLMP reached out to any other OPOs to find out how they manage the process and if there was any way FLMP could have improved their own practices. The Executive Director responded their main concern was the possibility of negative publicity and the impact it would have on donation overall.

The Subcommittee Chair then asked about the root cause analysis and the focus on the emotional state of the mother. She asked if there was any process review or discussion of other possible root causes. The Executive Director asked if she believed there was any other potential cause that lead to this unique situation. She responded by asking if any of the discussions focused on the lack of a process for how to manage these cases, regardless of the fact the volume is low. She added the cause may have been lack of training or policies on how to manage these cases. The Director responded that in retrospect, they should have asked the mother for both brain death and DCD authorizations, since FLMP's policies do not allow for verbal authorization.

The Chair then asked about the volume of these types of cases. The Director stated they have had three in the past 10 years. They have not had any more of these cases since receiving the initial inquiry from the OPTN [in February 2019]. FLMP weighed the potential loss of organs from the low number of these cases against the potential for negative publicity and its subsequent impact on organ donation and decided continuing with these types of cases would result in higher potential organ loss. The Chair then asked if the other two cases went according to FLMP's policy, and he responded they went very smoothly and followed their policy.

A committee member then asked if the OPO would consider revising their practices to continue to allow DCD recovery for brain dead donors if the family requests it. He noted their current practice of not recovering these types of donors will definitely result in the loss of donors, while negative publicity may not result in the loss of donors. The Executive Director replied that FLMP will revisit their decision and discuss it with their Board for future consideration. He added they want to honor families' wishes while minimizing any negative impact on donation. He thanked the committee for their insightful comments and stated FLMP would discuss their decision again and change their practices if needed.

The Subcommittee Chair concluded the informal discussion by thanking the FLMP participants for their presentation and discussion. She explained the MPSC will deliberate on this matter and UNOS staff will send a summary of the proceedings to the Member.