Membership and Professional Standards Committee (MPSC)
Life Alliance Organ Recovery Agency (FLMP)
Interview Summary
February 26, 2020

MPSC Members Present: [redacted]

UNOS Staff Present: [redacted]

Life Alliance Organ Recovery Agency Representatives Present: [redacted]

Interview Summary:

The MPSC vice Chair convened the informal discussion pursuant to Appendix L, Section L.9 of the Bylaws to determine whether the Membership and Professional Standards Committee would consider recommending FLMP for Probation for recovering organs prior to asystole, despite family authorization, in potential violation of Policy 2.15.H. The vice Chair stated the interview was being conducted under confidential medical peer review, and the entire interview 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. The representative from FLMP's Board of Directors introduced himself and thanked the MPSC for the opportunity to meet with the Committee. He acknowledged that FLMP violated Policy 2.15.H under extraordinary circumstances. He asserted that Probation is not appropriate given the circumstances and that FLMP will provide their reasoning during their presentation.

The Executive Director began FLMP's presentation by thanking the vice Chair of the MPSC and the Committee, and provided an outline of their presentation. He also stated FLMP strongly believes Probation is not warranted for this case.

He began with a timeline of the case and explained he would be numbering the days starting with the donor's first brain death declaration. This was a 41-year-old donor admitted on November 19, 2018, after a motor vehicle accident that resulted in drowning and cardiac arrest. The first brain death note was at

10:29, a few days after her admission on day one (November 24, 2018). On day three (November 26, 2018) at 15:34, the hospital advised FLMP it was waiting for the family to withdraw life support. Soon after, OPO staff arrived onsite to await the family's arrival. At 22:05 the same day, FLMP conducted its pre-approach huddle with the hospital to determine the best way to discuss donation with the family. The OPO engaged the family soon thereafter. FLMP discussed the medical advantages of brain death over donation after cardiac death (DCD) recovery with the donor's next of kin (her mother) and family. The donor's mother decided to proceed with organ donation but only after cardiac death.

On day four, at 06:00, the patient was officially declared brain dead. On the same day at 19:55, conversations occurred between FLMP and the donor's mother regarding the donation process. The mother expressed her understanding of brain death, but also stated she wanted to proceed with DCD donation so she could witness asystole. On day five at 00:24, FLMP conducted the pre-allocation huddle and DCD organ offers began. At 12:11, FLMP conducted a pre-OR huddle with the plan to conduct a DCD recovery. The on-site coordinator conducted a huddle with the surgical recovery team and informed them the donor was brain dead but the recovery would follow DCD protocols per the donor mother's instructions. OPO staff administered heparin and extubated the donor. At that time, the mother became increasingly emotional and asked to be escorted from the OR. Before leaving the OR, she asked that recovery continue in the standard manner, i.e brain death recovery. The OPO honored the mother's instructions.

Next, the Executive Director read a written statement to the MPSC from the donor's mother. He stated FLMP obtained the letter as part of the OPO's ongoing family care and as a result of FLMP's informal discussion with the MPSC. He noted the statement, which was signed by the mother, was in Spanish, and FLMP had translated it. He told the Committee he had copies available for them, and then read the statement. The mother attested she understood FLMP wished to supplement the documentation of her daughter's medical record, including her request that FLMP continue with standard organ recovery despite her initial consent for donation after cardiac death. She stated she originally wanted to witness cardiac standstill, but changed her mind while in the operating room. She therefore instructed FLMP to proceed with recovery immediately. The mother stated she understood this was documentation of verbal consent after the fact; and her statement was requested to complete the medical record.

The Executive Director asserted FLMP honored the mother's instructions. He stated FLMP did not stop the recovery and reintubate the donor in order to re-run matches due to the high probability that they would lose consent for donation. The recovery OR had already been rescheduled several times, which had caused increased anxiety for the donor's mother. Because of the mother's verbal instructions, the OPO felt obligated to proceed with brain death recovery.

The Executive Director stated FLMP reached out to other OPOs for guidance and reviewed their own policies and procedures after this event. He also said he appreciated the informal discussion with the MPSC, and the Committee's recommendations. FLMP leadership and front-line staff had multiple discussions about this case, conducted a root cause analysis, and worked with a third-party quality consultant to conduct a tracer audit. The results of this audit aligned with FLMP's findings and existing plan to review their policies and DCD checklists.

The Director of Quality stated as a result of these internal and external reviews, FLMP determined one of the chief causes of this event was failure of imagination. The OPO had DCD recovery policies in place, but they did not foresee the events that occurred. They did not have a formal policy to address DCD recovery for brain dead donors. With staff input, the OPO wrote and implemented a formal policy for DCD recovery

of brain dead donors. The revised policies cover a wide array of circumstances. Under the new policies, OPO staff will seek authorization for both types of recoveries in these types of cases. The OPO revised its quality systems policies to reflect the learnings and containment strategies from its after-action reviews, and FLMP continues to work with other OPOs to collect best practices for these types of cases. The OPO is also working with a newly formed southeast region quality group, and they are using these interactions as a tool to exchange ideas for process improvements with their colleagues.

The Director of Operations added CMS conducted a complaint survey regarding this case in December 2019. CMS reviewed the case record, interviewed staff and reviewed FLMP's policies. CMS approved FLMP's corrective measures and found the OPO compliant.

One of FLMP's organ procurement managers added that staff was trained on the new policies and procedures, and participated in role-playing exercises on obtaining consent for DCD recovery of brain dead donors. In addition, OPO leadership conducted a question and answer session with staff regarding the new policies and procedures. The second organ procurement manager stated FLMP trained donor family advocates on how to talk with donor families about DCD recovery for brain dead donors, and Gift of Life will be conducting DCD authorization training at FLMP.

FLMP's Board Representative affirmed FLMP staff and its Board have taken all necessary steps to ensure there will be no recurrence of this type of event. He referred to the OPTN Bylaws description of Probation and stated he did not believe this adverse action was appropriate in this case.

The Executive Director continued by stating there is no ongoing failure on the part of FLMP to comply with OPTN obligations, and there is no severe risk to public health or patient safety. Because FLMP has taken all the necessary steps to respond to this event, Probation is not warranted and does not fit with the spirit or letter of the OPTN Bylaws. He summarized by stating donation is family driven and in this case, the donor's mother changed her mind. FLMP supported the mother and were sensible and sensitive to the family's needs. They honored her instructions, and then promptly addressed the issues that arose as a result through policy and process revisions and staff training. He asserted there is no ongoing risk of a recurrence of this type of event, and this case did not rise to the level of severity of an ABO error or similar event. He added the OPO was bound to follow the mother's verbal consent, and noted she later provided written consent via her signed statement. These cases are rare, the OPO learned from this experience, and there was no loss of organs. FLMP has addressed all of the Committee's concerns, and he requested the MPSC not place FLMP under Probation. He then thanked the MPSC and stated FLMP was happy to answer any questions.

The Vice Chair thanked FLMP for its presentation and additional information. An MPSC member thanked FLMP and acknowledged the difficulty of this situation. She then asked about the OPO's procedure for obtaining consent from Spanish-speaking individuals. A FLMP organ procurement manager responded the majority of their donor family advocates are bilingual, and speak Spanish. The manager confirmed Spanish-speaking staff were in the OR and heard the mother's statement.

Another Committee member asked how the mother knew DCD recovery of brain dead donors was an option. FLMPs' Executive Director explained the mother told their team this was her only daughter and the only way she would give authorization was if she could be in the room when her daughter's heart stopped. She was adamant regarding this in the days leading up to the recovery OR. The Committee member asked if the mother could only accept her daughter's death if she witnessed cardiac standstill. FLMP staff stated this was correct.

Another MSPC member stated he believed FLMP's root cause analysis (RCA) policies lacked criteria and process descriptions, and asked the participants to walk the Committee through their RCA process. The Director of Quality replied they use the Five Whys methodology. She stated by the time the OPO conducted the RCA for this case, they already had numerous discussions about it, including an after action review. Typically, they ask all involved staff to provide their version of the event and answer questions. Staff also provide written statements in order to provide more detail. The OPO continues to review and discuss the case until they believe they have determined the root cause.

Another Committee member thanked FLMP for their thorough presentation and response to the MPSC's requests after the informal discussion. He asked if the OPO requests DCD and brain death authorization for DCD donors, in case the donor later converts to brain death. The Executive Director replied they only ask for DCD recovery authorization, but staff discusses the possibility of conversion with the family. He added FLMP is open to recommendations, but their staff have observed once they family is given the opportunity to be with their loved one upon withdrawal of care, they are unlikely to consider brain death recovery. If the donor later converts to brain death, FLMP will obtain the appropriate authorization. The Committee member then asked if FLMP routinely offers families the opportunity to be present for withdrawal of care, or if they only offer this if the family requests it. The director replied they offer this routinely, and their donor hospitals strongly support it. Next, the MPSC member asked how the OPO prepared for this specific recovery during their OR huddle. The director responded they conducted a huddle with donor hospital staff and the recovery surgical staff. The OPO provided clear instructions so everyone understood their role, and communicated this was a brain dead donor but the recovery was to be conducted as DCD. The Committee member asked how the OR participants believed this case went, in retrospect, and how CMS learned about the event. The director replied he did not know how CMS learned about the case, but FLMP welcomed their investigation. After further questioning by the Committee member, the Executive Director added those present in the OR were comfortable with the decision to proceed with brain death donation.

A Committee member thanked FLMP for their presentation and additional information, and noted it was evident the OPO was striving to carry out the family's wishes. She then asked about the OPO's new hard stop process, and how it will work if the family changes its mind during a DCD recovery. The Executive Director replied FLMP will now obtain authorization for both DCD and brain death recovery for its DCD donors; however, if the family verbally changes its instructions there will be a hard stop and two FLMP staff members will document the instructions. The MPSC member then asked if the recovery team was in the OR to hear the mother's new instructions. The director stated this was correct. The Committee member commented the recovery teams were likely caught off guard by this last minute change, but the director stated OPO staff explained the family's last minute verbal instructions.

Next, an MPSC member asked about the donor mother's signed statement, noting it was very a very specific concern only for OPO staff, and the mother should not have been concerned about the documentation. The director responded the OPO routinely maintains regular contact with donor families, but after the MPSC expressed concerns about the verbal authorization during FLMP's informal discussion, FLMP believed it was necessary to obtain this documentation and asked the mother for the statement. The Committee member stated it was insensitive for FLMP to re-approach the donor's mother, and they should not have involved the mother in this internal matter.

Another MPSC member asked what type of training the OPO provides for its staff to help them address rapidly changing situations such as in this event. He also asked what organ recovery staff should do if they

are not comfortable making decisions in these types of cases. The Executive Director replied staff understand there is no ambiguity regarding following donor family instructions. After additional questions from the MPSC, an organ procurement manager added staff receive training on approaching families and assessing family dynamics, and participate in role playing activities.

A Committee member asked how FLMP helps families during DCD cases when the donor fails to progress and organ procurement does not appear feasible; and how staff will handle future cases involving last minute verbal instructions from families. The director replied if the patient is unable to donate, OPO staff, hospital social workers and hospice representatives will be immediately available for the family. OPO staff will remain available as long as the family needs them. The most important consideration for the OPO is the patient's dignity in dying, whether or not they are able to donate. An organ procurement manager added donor family advocates are trained and able at any point to talk with the family and educate and support them if at any time the donor converts to brain death.

Another Committee member asked FLMP for details about several of their processes, including their RCA and quality processes. She asked how the OPO decides when an RCA is required. The Quality Director said all staff are empowered to request RCAs, after action reviews, or any other type of review they believe is necessary at any time. There are also certain sentinel events that automatically trigger a review, such as organ loss or rescinded consent. The MPSC member asked if this process is included in FLMP's policies. The director reported it is covered in their policies under occurrence reporting. The Committee member then asked about FLMP's DCD and brain death policies, noting that their policies state the OPO will only proceed with DCD recovery if the donor hospital supports it. She asked if there are cases when a hospital does not support DCD recovery. The director explained they work with a hospital that does not allow DCD recovery for religious reasons. In these cases, the OPO will move the donor to another hospital. The Committee member then asked if FLMP requested the statement from the donor mother because they had a verbal change in authorization from her, or if it was because the MPSC requested clarification on the authorization. The director responded the OPO did not require written authorization because they had no doubts about the mother's intent. However, during the informal discussion with the MPSC, Committee members expressed concern about the mother's intent; therefore FLMP went back to the mother to obtain a written statement.

A Committee member then asked if there was a declaring or pronouncing physician in the OR for this case. The Executive Director replied this was not needed because the donor had already been declared brain dead by neurological criteria. The anesthesia team was available to document cardiac standstill for this case, along with hospital staff. The Committee member remarked the OPO could have avoided any confusion by obtaining brain death recovery authorization prior to the OR, or taking the time to obtain written authorization immediately after the mother left the OR and gave verbal instructions to continue via standard recovery.

Another MPSC member asked if FLMP offers all families of DCD donors the opportunity to be present for withdrawal of care. The Executive Director responded they do. The Committee member asked if the OPO was reconsidering this practice in light of this event. He also noted there are many challenges the family and OPO staff could face if the family is present at withdrawal, and that there may be better ways for the family to experience their loved one's end of life. The Executive Director responded if the family wants to be present upon withdrawal he believes it is important to honor this wish. The Committee member clarified he understood this if the family requests to be present, but questions offering it to the family. The director said OPO staff educates the family about the stress of the OR and how it differs from the ICU. An organ procurement manager added FLMP offers the family many other ways to honor their loved one,

including the Walk of Honor and providing a separate space outside the recovery OR where the family can say their final goodbyes. FLMP's Board Representative stated he understood the MPSC member's concerns and noted he agrees sometimes families are encouraged to be present in environments that may not be best for them, and he agrees the OPO should have further conversations about this.

A Committee member asked what conversations the OPO had with the donor's mother that lead them to believe she meant proceed with brain death donation when she expressed her wish for "standard" donation, since most non-clinical people don't understand the difference between DCD and brain death recovery. She also asked why the OPO rushed to recovery instead of waiting for asystole. The Executive Director stated it was clear to OPO staff, and it is recorded in their documentation, that the mother understood brain death donation as "standard" donation and her verbal request meant she wanted the OPO to begin recovery immediately. The Committee member commented there was a possibility FLMP could breed mistrust by changing the recovery type without written authorization, especially considering at least one person was concerned enough about this case to report it to the OPTN. The Executive Director said there is no question donation is based on public trust, and any event that shakes public trust impacts the entire transplant system, not just for this patient's family or the OPO. He said if FLMP had disregarded the mother's verbal request, there would have been a significant impact on the family's trust in the organ donation system. The Director of Quality added that to her knowledge, no one expressed to OPO staff that they were upset with how the OR was handled.

An MPSC member asked why there was a three day delay between the two brain death declarations. The director stated he believed this was due to hospital processes. An organ procurement manager added the donor was too unstable for an apnea test, so they had to conduct an EEG. It took several days for medical staff to read and confirm the results. The Committee member then asked about the decision to change the OPO's policies to prohibit DCD recovery of brain dead donors. The Executive Director explained this decision was made initially so the OPO could re-evaluate its processes. He stated he asked the MPSC, FLMP's Board and the OPO community for guidance, and then reversed the decision. The Board Representative expressed FLMP's Board was extremely concerned and recommended the OPO cease these types of recoveries out of an abundance of caution while FLMP reassessed its policies and training and consulted with OPOs around the country. Once they reviewed their data, they decided to begin these types of recoveries again. The Executive Director stated there were no brain dead donors that were not recovered due to this pause, and the OPO has not had any brain death recoveries for DCD donors since this event.

A Committee member then asked why it was necessary to obtain the letter from the mother when there were probably many people who could have corroborated her statement. The director stated because the MPSC believed there were questions about the intent of the mother's statement, FLMP decided their best option was to obtain the statement from the donor's mother. The same Committee member then asked about the OPO's current policies regarding changes in verbal consent. The director confirmed that under their new policies, if a family changes consent verbally they have processes to document it.

A Committee member then remarked the MPSC understands FLMP was doing its best to accommodate the family. He then asked how FLMP will talk with the families in the future. Will they continue to offer the family the option to be in the OR? How will staff be trained for these conversations? The Executive Director stated these decisions need to be made on a case-by-case basis. He stated FLMP consulted ten other OPOs and none of them had a policy to address these cases. The director also stressed it is important to offer equitable choices to all families, regardless of how OPO staff interprets their situation. He also stated he welcomed feedback and suggestions from the MPSC. The Committee member agreed most

OPOs would not have policies to address this specific type of case. He then asked if FLMP routinely conducts an on-site huddle to discuss family dynamics and the best way to support them. The director replied they have multiple hard stops throughout the donor management process that include OPO and hospital staff. An organ procurement manager added that leadership on call and staff are encouraged to participate on the pre-approach huddle to weigh in on family dynamics and the best way to proceed.

Next an MPSC member asked if this type of case happened today, how the OPO would handle it. The Executive Director stated they would honor the family's request and also ask them to sign both DCD and BD authorizations. The OPO would ask the family to provide consent for verbal instructions in case there are any last minute changes in the family's wishes.

A Committee member asked FLMP to comment on this donor hospital's volume and how many DCD recoveries have occurred since this case. She stated she is concerned because about the integrity of the donation system and the fact that someone was concerned enough to report the incident. The Executive Director replied the hospital involved is not one of their larger volume donor hospitals, but they have managed numerous brain dead and DCD donations there. He noted it is the role of the OPO to minimize any long-term impact to the integrity of the system, and this is why FLMP initially decided to pause brain death recoveries as DCD.

An MPSC member thanked FLMP for appearing before the Committee. She stated she was relieved to learn the OPO's initial decision to decline brain dead donors when the family requested DCD recovery was temporary, as the Committee understood from the documentation this was a long-term decision. She then asked about FLMP's RCA procedures. She noted that in their revised procedure there is no definition of root cause or a clear road map about how to conduct an RCA, or how to determine when they have found the root cause. The Director of Quality replied this is only their policy for RCAs, and there is another document that explains how to conduct an RCA. The director added she did not believe the process for conducting an RCA was in their policies, but she believes it is described in their Quality Assurance and Performance Improvement (QAPI) plan. The Committee member asked if all FLMP staff have access to the QAPI plan, and the Director of Quality confirmed this.

Another Committee member asked if policies aren't used to outline how or when to conduct an RCA, how do staff know this information? The Director of Quality responded this information is housed in documents in Q-Pulse. It is also part of onboarding training and periodic retraining. She reiterated any employee can ask for an RCA to be conducted at any time. The MPSC member then asked if the documents in Q-Pulse are policies or work instructions, and the director responded both. The same Committee member then asked the director to describe how staff are educated and informed about quality processes. The Quality Director responded all staff must read and sign off on the QAPI plan, which explains their processes for quality reviews. The MPSC member recommended FLMP review and revise their quality systems to make them clearer and easier for staff to understand.

The MPSC vice Chair concluded the interview by thanking the FLMP participants for their presentation and the discussion. He explained that the MPSC will deliberate on this matter and UNOS Staff will send a summary of the proceedings to the Member.