Staff Summary
Life Alliance Organ Recovery Agency (FLMP)
recovered organs prior to asystole, despite family wishes

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Please review the summary of potential policy violations and corrective action plans submitted to determine if a policy violation exists, to determine if the corrective action plan addresses the problem, and to identify an appropriate recommended action. Please provide a basis for your decision in the comments section.

Staff Summary: An individual called to report this event to UNOS Member Quality staff. A brain dead patient was authorized as a DCD donor because the family wanted to be in the OR when the heart stopped. Despite this, the OPO began recovery prior to cardiac asystole after communicating to staff that the case was not a DCD case because the patient had already been declared brain dead. As a corrective action, the OPO stated it would no longer recover brain dead patients as DCD donors. If a family did not authorize brain dead recovery, the OPO would shut down the case.

The MPSC reviewed the case at its July 2019 meeting and requested an informal discussion with the OPO. The Committee was concerned by the lack of a root cause analysis (RCA) and the decision to no longer permit brain dead patients to be DCD donors.

The informal discussion occurred on September 25, 2019, and included OPO staff who were involved in the case as well as OPO leadership. The OPO presented a timeline of the case, its rationale for recovering the donor's organs before cardiac standstill and the decision to not conduct a formal RCA. The subcommittee was concerned about the OPO's decision to decline brain dead donors when only DCD recovery is authorized by the family; and the decision to proceed with organ recovery prior to asystole in this case. The reviewers did not recommend an action, but requested the OPO complete a formal RCA of this case. The subcommittee also recommended FLMP review its policies regarding DCD recoveries for brain-dead donors; develop a protocol for management of DCD donors when the family wants to be present at withdrawal of care; and review and consider revising internal OPO policies for when an RCA should be conducted.

FLMP submitted its response in October 2019. Reviewers had significant concerns about the submission, including FLMP's continued assertion that the root cause of this issue was the emotional state of the donor's mother. Reviewers also believed the OPO's RCA policies and procedures were unclear and needed significant improvement. Because of these concerns, the MPSC considered recommending the adverse action of Probation for FLMP, and requested the OPO submit its DCD and brain death recovery policies; donor management and authorization policies; OPO staff authorization training; and its quality systems policies.

The OPO submitted this documentation in January 2020, and participated in an interview on February 26, 2020. The MPSC still had concerns regarding the FLMP's Quality Assurance and Performance Improvement (QAPI) program and its culture and leadership. The Committee was also concerned by FLMP's decision to re-approach the donor's mother after the recovery to gain documentation of authorization for brain-death recovery, and believed this may have caused additional, unnecessary

emotional injury to the donor family. Based on its review, the MPSC issued a Letter of Warning to FLMP for violation of Policy 2.15.H (Organ Recovery). The MPSC also requested that FLMP submit the following:

- Most recent QAPI plan;
- Most recent QAPI metrics;
- Examples of recent RCAs FLMP has conducted; and
- QAPI meeting minutes.

FLMP submitted this documentation on June 1, 2020.

Relevant Policies:
2.15.H Organ Recovery: "Organ recovery will only proceed after circulatory death is determined, inclusive of a waiting period of circulatory cessation to ensure no auto-resuscitation occurs."

Member Timeline of Events

Date	Event
2013 - 2015	UNOS received 23 complaints or self-reports involving FLMP. Many issues were not policy violations, but indicated relationship problems with transplant hospitals that indicated the potential for lost donors and organ allocation issues.
April 2015	HRSA directed an investigation of the OPO to look for potential policy violations or risks to patient health or public safety.
June 2015	Peer visit of OPO, including interviews with hospitals in the DSA. The peer team reported the general culture of the DSA was contentious and adversarial.
July 2015	MPSC reviewed information and peer report and considered recommending Member Not in Good Standing (MNGS).
August 2015	FLMP participated in an interview with the MPSC; MPSC recommended MNGS and did not believe that the OPO's CAP adequately addresses peer review findings.
October 2015	FLMP participated in a hearing with the MPSC; MPSC recommended that the Board declare FLMP a MNGS.
December 2015	The MPSC approved FLMP's CAP and requested monthly update submissions, including: • Reports of progress on and any updates to its corrective action plan; • The written communications plan for the DSA; • Reports from consultants and any follow-up actions based on those reports; • Minutes of Board of Governors meetings; • Minutes and attendance records of Transplant Provider Council meetings; • Updates on the recruitment of the Executive Director, Quality Director, and COO, including which position is intended to be filled first; and • CMS survey reports and any corrective action plans in response; • A performance dashboard including measurements of consent, conversion, donors, observed versus expected, organs transplanted per donor, organs transplanted per transplant center, and any other appropriate measures; • Reports of any allocations out of sequence; • Quarterly meetings and feedback from transplant centers; • A log of discussions or consultations elevated to an AOC/Leadership call; • A review of the OPO bylaws with external legal counsel; and

	• Address diversity of Board including other transplant centers as well as general public/donor family representation.
March 2016	The MPSC reviewed FLMP's first submission for January. The MPSC asked for additional information about two documents and requested that FLMP's performance dashboard be cumulative.
July 2016	The MPSC reviewed FLMP's February, March, April, May, and June submissions. The work group expressed some concerns about the pace of change and the organization of the submissions, and asked for more information because they felt that the OPO was not showing follow-through yet. The MPSC also reviewed two instances in which the OPO reported donor cultures late to transplanting hospitals and the OPTN. The MPSC considered issuing a Letter of Reprimand, and requested that the OPO attend the MPSC's October meeting to provide a presentation and update on their progress during the period of Member Not in Good Standing.
July – August 2016	During the MPSC's review of FLMP, UNOS received anonymous complaints from someone who appeared to have organizational information, possibly an employee. The themes of the emails were staff turnover, training issues, and a toxic work environment. Based on the volume and seriousness of these concerns, UNOS staff brought the information to HRSA and the MPSC Chair. After discussion, HRSA directed the OPTN to conduct another HRSA-directed peer visit of the OPO to investigate progress during the OPO's period as Member Not in Good Standing and evaluate changes in the organization's general culture.
October 2016	The MPSC reviewed the new peer visit report which found that the OPO is making progress, although the progress seems slow. The team identified QAPI and leadership as the biggest challenges for the OPO moving forward. The MPSC also reviewed FLMP's July, August, and September submissions and continued to have concerns about the OPO's progress. FLMP participated in an informal discussion with the MPSC to discuss their progress during this time of review. The MPSC informed the OPO that the committee was concerned about the speed of progress, and that the OPO should expect to present to each MPSC meeting until the committee feels they are making sufficient progress.
March 2017	The MPSC reviewed FLMP's October, November, December, and January submissions. FLMP participated in an informal discussion with the MPSC. The MPSC recommended that FLMP's priorities should remain networking leadership development, implementing and monitoring the new quality plan, and continuing to foster good relationships with hospitals in the DSA. The MPSC was generally pleased with the OPO's recent progress, and requested monthly updates including: • The results of the employee survey mentioned during the informal discussion; • Any report from the strategic consultant or changes made in response to suggestions; • A summary of how FLMP is incorporating leadership development information learned through visits to other OPOs; and • Board meeting minutes reviewing the quality plan or any other strategic initiatives.
July 2017	The MPSC reviewed FLMP's February, March, April, May, and June submissions. FLMP again participated in an informal discussion with the MPSC. The MPSC appreciated FLMP's presentation, and felt that the OPO has made significant progress. FLMP leadership is addressing the MPSC's concerns, and the committee

	applauded the visits and changes that FLMP has made. The MPSC believed that FLMP made sufficient progress that the OPO no longer needed to submit information monthly, and was not required to present information on its progress at the October 2017 MPSC meeting.
October 2017	The MPSC reviewed FLMP's September submission, as well as the OPO's request for release from MNGS. The MPSC felt that FLMP has made tremendous progress, and is on the right track to move forward and continue improving the organization. The MPSC acknowledged the hard work and dedication that FLMP has put forth by improving relationships with the transplant hospitals in its DSA, recruiting a new CEO, Medical Directors, Director of Quality, and Director of Operations; improving staff engagement; improving quality assurance processes and monitoring; and working with other OPOs to increase knowledge and inspire process improvements. The MPSC recommended that the Board of Directors release Life Alliance Organ Recovery Agency from the adverse action of Member Not in Good Standing and restore its membership privileges.
July 2016	Letter of Reprimand for two issues of delayed reporting of cultures.
July 2017	Notice of Uncontested Violation for a blood tube labeling error.
December 2017	Released from Member Not in Good Standing.
February 2019	Notice of Noncompliance for bypassing a transplant center when allocating a kidney, requiring the OPO to withdraw a primary offer.
February 2019	Notice of Noncompliance for allocating a liver-kidney to a candidate that was not eligible for SLK.
February 2020	Notice of Noncompliance for allocating three donor's hearts and/or lungs out of sequence. The MPSC was concerned FLMP appeared to unnecessarily expedite the recovery OR for these donors.

Survey information: A routine on site survey of the OPO occurred on June 26, 2018. The OPO had a clinical score of 99 percent and a few administrative errors. The MPSC reviewed the results of the survey at its meeting in February 2019 and closed the review with no action.

OPO Volumes

Year	Donors Recovered	Organs Recovered
2017	182	583
2018	149	536
2019	157	585
2020	106*	347*

*As of July 8, 2020

Items for consideration: The MPSC will need to determine next steps for this OPO. Options include continuing to monitor or releasing the OPO from monitoring. The MPSC can recommend higher actions, and more than one action, if needed.

Supporting Documents: Subcommittee Documents: OPO 65441O Monitoring

Reviewer Comments

Reviewer One: "My vote is to continue monitoring to assess if there has been a true change in culture of this OPO having had multiple infractions in the past. Due to many concerns, this OPO had a February 2020 interview and letter of warning provided by the MPSC. I have reviewed the material requested from the MPSC to the OPO which included the most recent QAPI plan, most recent QAPI metrics, examples of recent RCAs conducted and QAPI meeting minutes. The QAPI plan was well organized and very detailed to have final approval by their Board of Governors on June 17, 2020. The RCA example appeared acceptable with detailed discussion and corrective action plans and containment strategy included. Finally, the minutes of the QAPI team meetings were provided."

Reviewer Two: "...it appears that OPO 654410 has met the requirements that the MPSC requested during the interview. I am disappointed that the documents have some errors but I do think it meets the MPSC's requests."

Reviewer Three: "I think the response is adequate for the time being. I would like to see continued monitoring of the RCA and QAPI process, though I'm not sure how best to assess this, perhaps by assigning any reported events from this OPO to a specific team within MPSC."

Reviewer Four: "The QAPI plan looks good on paper but does looks like it was pieced together from other sources and not created specially to meet the needs of the organization. Certainly we all borrow and cut and paste at times, why reinvent the wheel, but this goes beyond that level. The QAPI minutes do not show the process improvement, responsibility assignments and follow through that I am used to seeing when a Quality work group comes together. As was noted it seems more a round table report of activity than a process improvement road map.

I am concerned by the long history and continued culture issues. I honestly do not have a good recommendation. The MSPC put a lot of time and effort into coaching and helping and it doesn't seem to have moved things forward as much as we would like... Is there some sort of Peer mentoring that can be recommended? Maybe a more hands on approach from an OPO with a highly functioning highly efficient Quality department can assist more than the MSPC has been able to?"

Reviewer Five: "My general thoughts after reviewing FLMP's documentation:

- I continue to have concerns that they "get it". After countless hours spent reading documents about this OPO over five-plus years, participating in a number of interviews, formal discussion, informal discussions, and a hearing, I still do not have a sense that they understand their issues in the realms of policy violation, safe and appropriate operations, or quality.
- I continue to have concerns that they submit significant amounts of verbiage that looks like the equivalent of stock photos. In other words, they buy and read books then transcribe the lingo into a policy document but when issues arise, their application of the policy indicates they don't fully understand their own policies.

- I continue to be concerned that they frequently do not provide everything we ask of them nor do they proactively provide much of what they should if they had a true grasp of the issues. In most cases, they are like a witness being led by the questioning lawyer: 'You have a QAPI plan? Please provide it.' Then it arrives.
- The MSPC has, since 2015 at least, provided them with countless hours of consulting and guidance at who knows what cost. Yet they are still before the MPSC, not because they have failures or errors (every OPO and transplant center does), but because of their reaction or lack there-of.
- Their overall quality culture, and for that matter, the core organizational culture are still lacking, in my opinion. Mention is made in these documents that staff are uncomfortable asking questions.

With regard to their submissions, they are so-so at best. In order:

1. Their QAPI Plan is generic. Buzz words, jargon, and aggrandizing language about the importance of their work and the consequences of not doing it well but the plan is weak. It continues to feel as if they read the book but don't know what it says. We didn't like the last version and the new one is not really any better; just more buzz words and jargon. The definitions are an extensive list of terms one could find in a quality text book; where's the meat of how they apply this and true, real-world examples of where they've used QAPI to PI?
2. QAPI metrics: First two pages provided are pretty standard dashboards. Pluses here are they are tracking conversion rate, yield, ethnicity, and rule-out reasons. Minuses (in my opinion) are no tie to O vs. E which is a performance metric for both OPTN and CMS, or authorization rates for the non- "designated" (I assume registered donors), as this is a key metric to move. Overall, the first two pages aren't bad but they're hard to look at; I'm giving them some benefit of the doubt as they're obviously screenshots of interactive dashboards. The rest of the material isn't very helpful; one chart isn't even labelled so while I assume it's a rolling 12 month total donor graphic, it doesn't really say and just illustrates the comments under QAPI (#1) ...do they understand what they're doing or is are they just generating stuff? After that, it's infographics we'd put in newsletters or on our website but definitely not QAPI data reports.
3. RCAs: I don't remember asking them to resubmit an RCA for the case we already reviewed; we've seen this before and it didn't pass muster. The second RCA (EBV result) documents a process but reinforces that (a) staff and leadership culture is still an issue and (b) the findings are pretty generic ("human error", "better training", etc.). The staff still appear to be afraid to ask questions; this has been an issue dating back five-plus years per their file.
4. QAPI Minutes: Not the best. In no particular order my concerns are:
    a. Without the laundry list of documents from Laycee, which is largely informational, there is only about 1 to 1.5 pages here for a pretty big group.
    b. This looks largely like a roundtable...I see a lot of what people are working on but not much review of issues, etc.
    c. There is no occurrence data here; maybe it was a good week/month but I'd expect to see some discussion of the data on the dashboards and what processes they're monitoring, evaluating, or developing a PDSA on.
    d. Overall, this appears to be a huddle so everyone knows what is going on, which is good, but for all of the jargon and pages of text in the QAPI plan, I see very little reference to it in the meetings.

In conclusion, as I roll off the MPSC, I am troubled that this member has been under scrutiny since at least 2015 and remains under scrutiny. It is further troubling that this level of scrutiny is not superficial nor has

it been for unconnected issues but rather that it is a continuation of the same themes: lack of a quality culture, lack of understanding, lack of progress, and ineffective leadership/governance. Finally, it is troubling that after all the effort the MPSC has put into educating, leading, and sometimes guiding this member, they are still in this state. My recommendation is continued high-level monitoring, further sanctions to hopefully get their attention (although MNGS obviously didn't work), and further communication with the Secretary as there is something clearly broken here that five-plus years of significant intervention and oversight have been unable to address."

Reviewer Six: "I am surprised that they did not go back and update their QAPI plan as a result of comments and feedback that has been provided by the MPSC members with respect to their quality systems. Common themes appear to continue after discussions with them, those of culture, clarity of procedures and execution of quality systems. With the letter of warning they received, I am not sure the next steps to be taken. They still need monitoring and help – although they don't appear to think they do.

1. QAPI Plan – this continues to be very generic, same version as they sent previously, with all the right buzz words. But in the information that was submitted along with it, there is still unclear information presented – so do they understand what the buzz words mean or should look like? I did see reference to Poka Yoke being done, what does that look like, the details are not provided to us – not sure why.

2. Dashboard/Metrics – they have provided a generic dashboard with several routine items included, interesting that there is not an authorization measurement, nor are there any apparent goals indicated on the document they submitted. Accompanying it is a graph entitled "2020 Pace with Prior Year". When you look at that graph, there are no labels, what are we measuring? It doesn't match the number of organ donors, so if this is the type of metric they are sending out, how does anyone know what it is – a very basic item when doing metrics, you should define what you are reporting. We asked for 'most recent' examples, and yet they sent graphics from 2019, seems odd to include that, would have preferred seeing what else they measure and use to measure their own performance and more importantly, opportunities for improvement. Again the QAPI plan states they do this, but where and what is the data that is used?

3. Recent RCAs - I was surprised to see the one regarding the BD vs. DCD case, so I did not really review that one again. We had already provided comments to them about what was and was not done on that one. The November 25, 2019 letter sent by the MPSC to the OPO clearly stated that we felt their RCA procedure was lacking in detail, and needed significant work, it does not appear that they have made any changes since the two RCAs are very similar in how they were performed and how their findings are presented., but there still remains a culture issue – there is mention several times about people may not be comfortable asking questions and/or assuming a senior clinical person should be asking questions which is concerning. Comments regarding the EVB RCA:

    a. The problem statement already has a solution indicated, not a good way to start an RCA. Elements that impact the actions being taken during this event, such as were folks up all night, what else was going on, connectivity issues, etc.

    b. There was a good discussion with one with the AOCs and how she did things, which was then determined to be implemented for all AOCs to obtain the required source documents and be prepared before the call. The possible solution of hard stops in

iTransplant was also a very good aspect that could help in these types of verifications, blinded entries from source documents by two people works well.

c. There still appears to be a culture issue after all this time. Mentioned in this RCA is the comment about folks being uncomfortable with asking questions, or assuming that a senior staff member and/or clinical member should be the one to ask questions which is very concerning to me. The end result of this is an empowerment training being created by the Executive Director, I am not sure how this training is going to make an impact based upon the history of culture present at this OPO.

d. In one section it states that the verification call occurred on 3/5 at 2034, at which time [redacted] (an AOC) was reading the serology results and read the EBV incorrectly as negative. The result was changed by [redacted] on 3/5 at 2019 prior to the call according to the time line provided. Essentially [redacted] changed a result which according to the RCA is verified by the AOCs (it may have been him who entered it originally?). [redacted] indicated that he saw the positive result which when [redacted] read was changed to negative, which should have triggered someone to ask a question as to why? Why didn't he? The culture aspect creeps into this one.

e. Use of the source document for serology verification is referred to as a best practice, this should be in their procedure for things like HLA, serologies, ABO and subtype. These are basic steps that have to be right and should have a quality process check in place to make sure they are right. The use of source documents is included in their work instruction for (SOP CO-6) for Donor Blood Type Determination, but not in their Policy and Procedure CO-38 which it should also reflect the use of source documents.

f. Root Cause for the EBV event was indicated as Multiple Human errors, failure to follow existing procedures, and staff afraid to question another staff member or assume they have more knowledge than they do (again existing culture). The RCA is a lot better than the previous RCA, I would have clearly indicated rapid recovery as well, that can change lots of things – there isn't too much info given about the environmental influences on this one. Their procedures definitely need to include the verification process using source documents and read out loud – the referenced procedure/guidance in the RCA is not in the packet they previously provided.

4. QAPI Meeting Minutes – this was not what I was expecting to see for QAPI. The minutes that were provided appear to be more of a huddle within the quality group, going over daily/weekly activities, with very high level details provided. I was looking more for how they manage and discuss things such as NCRs, audit findings, comments and actions taken, process improvement initiatives, etc. We are only seeing these types of activities mentioned at high level in their quality plan or in these minutes, but they have not provided details of these types of activities to demonstrate what they are doing."