

**OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, VA**

**Carl L. Berg, M.D., Chair
Jonathan M. Chen, M.D., Vice Chair**

Contents

Action Items	2
1. Membership Status Changes and Application Issues	2
2. Proposed Patient Notification of Functional Inactivity Due To Lack of Transplant Activity ..	2
3. Proposal to Revise the Current Method for Flagging Transplant Programs Post-transplant Performance Review	3
Committee Projects	3
4. Data Submission and Accuracy in Reporting	3
5. Bylaw Proposal to Allow a Recommendation from the MPSC to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area	4
6. Transplant Hospital Definition:.....	4
7. Quality Assessment and Process Improvement Requirement (QAPI)	5
8. Composite Pre-Transplant Metric (CPM)	6
9. Reassess Currency Requirements for Primary Surgeons and Primary Physicians	6
10. Develop a Process to Ensure Ongoing Compliance with Membership Requirements	7
11. Limit Paper Documentation	7
12. Developing a System to Review and Share Safety Event Data	7
Committee Projects Pending Implementation	8
Implemented Committee Projects	8
13. Changes to the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity	8
Review of Public Comment Proposals	8
14. Clarify Requirements for Blood Type Verification & Align with CMS Regulation where Possible	8
15. Require Reporting of Aborted Living Donor Organ Recovery Procedures	8
Other Committee Work	8
16. Shipping Kidneys on Cassettes	8
17. Site Survey Innovation Project	9
18. Member and Applicant Related Report of Committee Actions	9
Meeting Summaries	10

**Report to the Board of Directors
June 23-24, 2014
Richmond, VA**

**Carl L. Berg, M.D., Chair
Jonathan M. Chen, M.D., Vice Chair**

This report reflects the work of the OPTN/UNOS Membership and Professional Standards Committee during December 2013 through April 2014.

Action Items

1. Membership Status Changes and Application Issues

Public Comment: n/a

The Committee is charged with determining that member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee reviewed the applications and status changes listed below and will make recommendations to the board to take the following actions:

New Members

- Fully approve 5 new histocompatibility laboratories; and
- Fully approve 11 medical/scientific, public organizations, and individual members for two year terms

Existing Members

- Fully approve 2 transplant programs;
- Approve 2 previously inactive programs/living donor components in existing member hospitals for active status;
- Grant full approval to 3 existing transplant programs and 2 existing living donor components that were conditionally approved; and
- Grant 12-month conditional approval status to 1 program and 3 existing living donor components that are conditionally approved.

2. Proposed Patient Notification of Functional Inactivity Due To Lack of Transplant Activity

Public Comment: September 6, 2013 – December 6, 2013

The Committee developed a proposal that would require a program to notify all candidates and potential candidates of a program's functional inactivity. The bylaws currently define functional inactivity as a lack of transplant activity for a defined period. The proposal also specifies the information that must be contained in the notification. In addition, revisions are proposed to remove confusing language and eliminate duplication in the bylaws regarding functional inactivity, voluntary inactivation and waiting list inactivity.

The Committee considered feedback from public comment on the proposal and revised the proposal to remove the definition of potential candidate that was inconsistent with the definition in Bylaws, Appendix M and to remove the definitions of functional inactivity and long-term inactivity from Bylaws, Appendix M.

The Committee recommends the following resolution for consideration by the Board of Directors, by a vote of 32 For, 0 Against, and 0 Abstentions:

RESOLVED, that Bylaws, Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs, Sections 9 and 10; Appendix K Transplant Program Inactivity, Withdrawal, and Termination, Sections 1 and 3; and Appendix M Definitions are modified as set forth in Exhibit A, effective September 1, 2014.

3. Proposal to Revise the Current Method for Flagging Transplant Programs Post-transplant Performance Review

Public Comment: September 6, 2013 –December 6, 2013

The Committee developed a proposal to better identify those transplant programs that may be underperforming in the area of patient and graft survival. The bylaw proposal adopts the new Bayesian methodology that will be utilized by the SRTR in the production of the public transplant program performance metrics and establishes new thresholds that are more efficient at identifying small and medium volume programs for review by the MPSC. In doing so, the transplant programs most in need of MPSC review and assistance in improving outcomes will be identified.

The Committee recommends the following resolution for consideration by the Board of Directors, by a vote of 32 For, 3 Against, and 1 Abstention:

RESOLVED, that Bylaws Appendix D. Membership Requirements for Transplant Hospitals and Transplant Programs, Section D.10 A. and Appendix M. Definitions are modified as set in Exhibit B, effective January 1, 2015.

Committee Projects

4. Data Submission and Accuracy in Reporting

Public Comment: March – June, 2014

Board Consideration: November 2014 (estimated)

As part of its role to monitor compliance and patient safety, the Committee sometimes reviews reports of inaccurate data submission and/or data falsification. Policy 18 (Data Submission Requirements) requires members to submit data, and the Committee has always agreed that the obligation to submit accurate data is implied within the policy. However, members who have submitted inaccurate data and have been cited for violations of Policy 18 have stated that they believed they only had to submit data in order to comply with the Policy. Additionally, while certain policies explicitly require members to maintain documentation in patients' records or to submit source documentation for auditing, Policy 18 does not state that members must maintain or provide documentation to verify the accuracy of their data submissions. Members have

suggested that they are therefore not required to maintain or submit documentation to verify the accuracy of their data submissions under the Policy. This proposal change modifies Policy 18 to state explicitly that members must submit accurate data and that members are responsible for providing documentation to verify the accuracy of their data.

The proposal was distributed for Public Comment on March 14, 2014, and the majority of comments received so far support the proposal. Opposition to the proposal can generally be explained as either misinterpreting the proposal as a requirement for source documentation rather than supporting documentation or as a belief that the current policy sufficiently grants the OPTN the ability to require supporting documentation. The Transplant Coordinators Committee also suggested that an unintended consequence of the proposal may be that member would submit less or no data to avoid any potential violations of the policy. The Committee will consider all of the public comments received when it meets in July and finalize the proposal. The plan is to present this proposed bylaw change to the Board during its November 2014 meeting.

5. Bylaw Proposal to Allow a Recommendation from the MPSC to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area

Public Comment: March – June, 2014

Board Consideration: November 2014 (estimated)

The proposed bylaw language makes available a mechanism by which the Committee can recommend to the Board of Directors that it might consider designating and approving a transplant program that cannot meet key personnel qualifying criteria because the applicant is located in an acknowledged geographically isolated area. This proposed bylaw, distributed for public comment on March 14, is on the regional meetings' discussion agenda. Initial feedback indicates resistance to providing a mechanism for considering program qualification exceptions. The Committee will consider all of the public comments received when it meets in July and finalize the proposal. The plan is to present this proposed bylaw change to the Board during its November 2014 meeting.

6. Transplant Hospital Definition:

Public Comment: Fall, 2014 (Estimated)

Board Consideration: June, 2015 (Estimated)

During its December 2012 meeting, the Committee tasked a new working group with addressing the definition of a transplant hospital and transplant program in order to work on the issue of health care systems operating multiple transplant programs in multiple hospitals under a single OPTN program approval. Issues to consider include single program data submission, performance outcomes, compliance with OPTN obligations, and patient safety monitoring.

The basis for these discussions is the definition of a transplant hospital found the OPTN Final Rule at Sec. 121.2, which defines a transplant hospital as "a hospital in which organ transplants are performed." This description is carried over to the OPTN bylaws in Article 1.2 (Transplant Hospital Members), which states "a *transplant hospital member is*

any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.”

The work group has been reporting its progress to the full Committee during each of its meetings. During its March 2014 meeting, the Committee received an update regarding the work group's efforts to develop a better definition of a transplant hospital member in the bylaws. During its February 24, teleconference meeting the work group agreed to the following:

- A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.
- A transplant hospital member cannot transplant the same organ type in more than one defined facility
- A transplant hospital member with distinct adult and pediatric services transplanting in physically separated facilities cannot do so as a single member

Suggestions made by the committee during its discussion will be further reviewed by the working group and incorporated into a draft definition.

The goal is for the Committee to consider proposed bylaws language when it meets in July. If the Committee approves the proposal, it will be distributed for public comment in the fall 2014 release. The Board of Directors could consider it for approval during its June 2015 meeting.

7. Quality Assessment and Process Improvement Requirement (QAPI)

Public Comment: Fall, 2014 (Estimated)

Board Consideration: June 2015 (Estimated)

During its reviews, the Committee has observed that members who are having difficulty with compliance or performance often do not have well developed quality assurance performance improvement (QAPI) programs. The Committee concluded that there appears to be a correlation between underperformance in the areas of compliance and outcomes, and the lack of a robust QAPI program. Currently, the OPTN bylaws and policies do not contain a requirement for a QAPI program. As a result, the Committee does not have a basis for taking action when there is a finding that a member's QAPI program is inadequate. The Committee requested that an OPTN QAPI requirement be developed.

During its December meeting, the Committee reviewed sample language as well as the language contained in the CMS Conditions of Participation and the CMS QAPI Resource Guide for Transplant Surveyors. The Committee is looking for a balance between a requirement that is over-detailed that may limit a member's ability to develop a QAPI program that can work at its facility and a requirement that is too general and that will not provide sufficient guidance as to what is expected. At the March 2014 meeting, the Committee reviewed and approved proposed bylaw language for a requirement for a QAPI program for transplant hospitals and organ procurement organizations by a vote of 38 For, 0 Against, 0 Abstentions.

The Committee will review monitoring options for this proposal at its July 2014 meeting. Proposed bylaw language will be provided to the Histocompatibility Committee to consider in its efforts to rewrite the bylaws regarding membership requirements for histocompatibility labs.

8. Composite Pre-Transplant Metric (CPM)

Public Comment: Fall, 2014 (Estimated)

Board Consideration: June 2015 (Estimated)

At the December meeting, staff presented an overview of the progress made over the last 4 years regarding CPM. The CPM is an aggregate observed/expected (O/E) ratio that is a weighted average of transplant rates, waiting list mortality rates, organ acceptance rates, and offer acceptance rates. Currently, it can be provided on a program-specific basis for kidney and liver programs only. Some of the component metrics for the CPM have not yet been developed for organs other than liver and kidney. Once these metrics are available, a work group of the MPSC, with assistance from the SRTR and UNOS Research, will assess whether the CPM or another approach for pre-transplant evaluation is appropriate for those organs. Higher values of CPM (>1.5) may be indicative of a program with waiting list management issues. Based on data from 2011, CPM would have flagged an additional 15 programs that were not already under review for post-transplant outcomes. Although the CPM Work Group had recommended that staff send out an “awareness” survey to members about CPM, the Committee did not support an additional survey, citing the poor response from members on a prior survey submitted in 2011-2012 and the extensive awareness and educational efforts over the last three years. Additional educational efforts will be considered during 2014. There was consensus that the Committee should proceed with public comment on this metric, since this is one of the best mechanisms for soliciting critical feedback from the transplant community. Concerns raised just prior to the March meeting regarding the component metrics will be referred for consideration by the CPM Work Group with a goal of providing proposed bylaw language for consideration by the Committee at a June 17, conference call.

9. Reassess Currency Requirements for Primary Surgeons and Primary Physicians

Public Comment: Spring, 2015 (Estimated)

Board Consideration: November, 2015 (Estimated)

During the March MPSC meeting, the Committee was informed that the Joint Society Policy Steering Group is asking to provide input on the primary surgeon and physician qualification topics and concepts the MPSC work group is addressing. A joint societies working group will be formed with representatives from AST, ASTS, and NATCO. This group will also include three MPSC Members as non-voting members. Once the working group recommendations are agreed on, they will be forwarded to the MPSC primary qualifications work group for further discussion. This effort includes multiple issues relating to the qualification of primary surgeon and primary physicians including the consideration of “foreign board equivalent”, procurement requirements for the primary physicians, specific volume requirements for primary transplant surgeon and physician experience.

10. Develop a Process to Ensure Ongoing Compliance with Membership Requirements

Public Comment: n/a

Board Consideration: n/a

Committee leadership discussed the intent of developing a process to ensure ongoing compliance with membership requirements, a project assigned to the Committee by the Board based on the 2012 OPTN Strategic Plan. MPSC evaluations occur for numerous routine activities during which noncompliance with membership requirements would be discovered (e.g. performance reviews, compliance reviews, changes in key personnel, staffing audits). This concept was considered in 2008 and data showed that over 90% of members experienced some type of routine MPSC interaction once every three years. In absence of evidence that a problem exists, and based on higher priority projects including reevaluation of existing membership requirements, the Committee will not be proceeding with this project.

11. Limit Paper Documentation

The Committee previously requested that the OPO Committee review whether policy should allow for the electronic transfer of medical chart information. The Committee reviewed the OPO Committee's response, in which the OPO Committee stated that it is supportive of a move towards a mostly electronic system and, as an intermediate step, limiting the amount of paper information to those critically important items. The OPO Committee and the Operations and Safety Committee are working on a project together to address this and other issues and will keep the MPSC informed of the project's progress. For more information, see the **OPO Committee's report to the Board**.

12. Developing a System to Review and Share Safety Event Data

In response to an initiative identified in the Strategic Plan the Committee considered a path forward on how it Committee could share safety events, lessons learned, and prevention strategies to give members ideas and tools that they can use within their own settings to prevent safety situations and avoid repeating past mistakes, while at the same time protecting and maintaining peer confidentiality.

The Committee suggested that the following safety topics be developed into some type of communication or educational opportunity for members:

- Strategies for appropriately reviewing documentation for and reporting donor hemodilution status.
- Clarifying and emphasizing the importance of psychosocial evaluations for living donors.

These topics will be referred to the Operations and Safety Committee and others as appropriate for further evaluation. Operations and Safety has a Patient Safety Advisory Group to develop strategies that can be turned into communication and education efforts. For more information, see the **Operations and Safety Committee report to the Board**.

Committee Projects Pending Implementation

None

Implemented Committee Projects

13. Changes to the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity

Public Comment: September 21, 2012

Board Approval: June, 2012

Implemented: January 2014

Part of this proposal approved by the Board in June 2012 modified the Bylaws to indicate specifically how and when transplant program staff must notify patients when they inactivate their waiting list in UNetSM. The Bylaw revision also changed the review cohort for waiting list inactivity from, "...a rolling 365-day period" to "...any calendar year." The monitoring of waiting list inactivity was changed from peer review three times a year to an annual review by Department of Evaluation and Quality staff. In order to efficiently and smoothly transition to the new monitoring process, the implementation of this portion of the bylaw modification was delayed until the beginning of the calendar year, January 1, 2014. Review under the new monitoring plan will not occur until early 2015 in order to examine periods of waiting list inactivity for a full year.

Review of Public Comment Proposals

The Committee reviewed 2 of the 17 proposals released in March – June, 2014.

14. Clarify Requirements for Blood Type Verification & Align with CMS Regulation where Possible

The Committee did recommend any changes to the proposal.

15. Require Reporting of Aborted Living Donor Organ Recovery Procedures

The Committee supported the proposal and offered the following suggestions:

- Clarify in Table 18-4 that "receives anesthesia" means induction of general anesthesia.
- Recommend reporting when the recipient surgery is aborted due to an adverse event and that in turn results in the donor surgery also being aborted.

Other Committee Work

16. Shipping Kidneys on Cassettes

The Committee previously requested that the OPO and Kidney Transplantation Committees review the practice of shipping kidneys on cassettes and consider whether the practice should be allowed. The Committee reviewed the OPO Committee's response, in which the OPO Committee suggested that the practice should not be allowed. The OPO Committee stated that the kidney should be removed from the cassette and packaged in a triple sterile barrier according to Policy 5.2 (External

Packaging Specifications). The Committee will discuss this issue again after it receives a response from the Kidney Transplantation Committee.

17. Site Survey Innovation Project

The UNOS Site Survey team is conducting a comprehensive review of its processes with the overarching goal of enhancing its relevance to members in their efforts to meet OPTN obligations by improving the consistency, transparency and relevance of our routine, site-specific compliance review activities. The scope of this project is member-specific site survey activities.

The Committee provided feedback to staff on this project and steps are being developed to make the suggested improvements. The Committee will be involved in these discussions, and its guidance will be required regarding the composition and use of scorecards in assessing compliance and how to assess and utilize submitted member CAPs (corrective action plans). Identified process changes will be incorporated into the OPTN evaluation plan.

18. Member and Applicant Related Report of Committee Actions

The Committee reviewed and approved the following:

- 146 Applications for changes in transplant program personnel
- 5 application for a change in primary laboratory director.

The Committee also received notice of the following membership changes:

- 9 programs and 1 living donor components inactivated
- 9 programs, 3 living donor components, and 1 laboratory withdrew from membership
- 11 OPO Key Personnel Changes

During the December 2013 meeting, the Committee conducted one interview and one informal discussion with member transplant hospitals. The interview and informal discussion were convened as provided for in Bylaws Appendix L (Reviews, Actions, and Due Process) of the Bylaws.

Live Donor Adverse Events Reporting

As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data) and Policy 12.8.5 (Reporting of Non-utilized Living Donor Organs) transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. Transplant programs also must report instances when a recovered live donor organ is transplanted into a recipient other than the intended recipient within 72 hours.

In December 2013, The Committee reviewed three reported cases: one living donor death, one non-utilized organ, and one redirected kidney. The Committee issued two Notices of Uncontested Violation for late reporting and closed the third issue with no action. In addition, the Committee heard three voluntary reports of living donor deaths (those beyond 2 years after donation). In March 2014, the Committee reviewed eight reported cases: six living donor deaths, one non-utilized liver segment, and one organ

OPTN/UNOS Membership & Professional Standards Committee

failure in a donor. The Committee issued two Notices of Uncontested Violation for late reporting, closed five issues with no action, and recommended a peer visit and is considering an action up to and including Probation for one issue. That program will be offered an interview at the Committee's July meeting. The Committee is not recommending any further action to the Board at this time for any of the issues.

Meeting Summaries

The committee held meetings on the following dates:

- December 10-12, 2013
- March 25-27, 2014

Meetings summaries are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=8>

Proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity

Table of Contents

Proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity.....2

Sponsoring Committee: Membership and Professional Standards Committee2

Summary and Goals of the Proposal:2

Background and Significance of the Proposal:2

Supporting Evidence and/or Modeling:5

Expected Impact on Living Donors or Living Donation:6

Expected Impact on Specific Patient Populations:.....7

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:7

Plan for Evaluating the Proposal:.....7

Additional Data Collection:7

Expected Implementation Plan:7

Communication and Education Plan:8

Compliance Monitoring:8

Policy or Bylaw Proposal:9

Public Comment Responses..... 15

 1. Public Comment Distribution 15

 2. Primary Public Comment Concerns/Questions 15

 3. Regional Public Comment Responses..... 18

 4. Committee Public Comment Responses23

 5. Individual Public Comment Responses.....27

Post Public Comment Consideration:35

Title: Proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity**Sponsoring Committee: Membership and Professional Standards Committee****Summary and Goals of the Proposal:**

The purpose of this proposal is to provide, through a requirement for patient notification, candidates and potential candidates with information about the program's activity levels that will allow the patient to make informed decisions about whether to move to another more active program or multiply list at another program. In addition, the proposed Bylaw revision may provide an incentive for a low volume program to develop ways to increase transplant activity thereby positively impacting the program personnel's experience and currency. In the alternative, it may spur a functionally inactive program to examine whether there is sufficient need in the community to justify the maintenance of the functionally inactive program resulting in the inactivation or withdrawal of a low volume program with the resultant referral of candidates to a higher volume program.

Background and Significance of the Proposal:

As part of its role to monitor compliance and patient safety, the MPSC conducts reviews of functionally inactive programs that have not performed a transplant during a defined period. The Bylaws define functional inactivity as a lack of transplant activity for the following periods:

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas or Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

In July of 2011, the Performance Analysis and Improvement subcommittee (PAIS) of the MPSC expressed concerns that the level of transplant activity at some programs that are repeatedly identified for functional inactivity are too low for a program to remain current with both surgical skills and programmatic administrative competence. Table 1 notes the number of programs and organ type of newly identified functionally inactive programs for each MPSC meeting cycle over the last three and one-half years and the number of those programs previously reviewed by the MPSC for functional inactivity:

Table 1. Number of Programs Identified as Functionally Inactive due to lack of transplant activity and the number previously reviewed.

Meeting Date	Newly Identified					Previously Reviewed				
	PA/KP	KI	LU	HR	LI	PA/KP	KI	LU	HR	LI
Apr 2013	9	1				2				
Dec 2012	4			1		3			1	
Jul 2012	6					5				
Mar 2012	7	1	2	1		5		2		
Dec 2011	7	1				5				
July 2011	4			1	1	2			1	
Mar 2011	5					4				
Oct 2010	2			1						
Jul 2010	3					2				
Mar 2010	3			1		3			1	

PA/KP = Pancreas/Kidney and Pancreas; KI – Kidney; LU = Lung; HR = Heart; LI = Liver

As illustrated in the above table, the majority of the programs reviewed for multiple periods of functional inactivity are pancreas programs. In response to this concern, the PAIS requested that the Pancreas Transplantation Committee discuss modifying the pancreas functional inactivity threshold and provide any additional insights regarding inactivity in pancreas programs, such as factors to consider when reviewing these programs, or other relevant data.

The Pancreas Transplantation Committee recommended that the MPSC and PAIS consider the following changes to the pancreas program functional inactivity requirements:

- If a program performs fewer than two pancreas transplants in the six-month period, then the program will receive a warning notification, but patients do not need to be notified.
- If the program receives such a warning, it has 6 months to perform at least four pancreas transplants. If they do not perform a total of four pancreas transplants in the one-year period, then the program must then notify its patients of its inactivity.
- The MPSC should consider citing the program for functional inactivity at the one-year mark if the program has not performed four transplants.

At its meeting in July 2012, the PAIS considered the recommendations of the Pancreas Transplantation Committee and created a focused work group of PAIS members to discuss the recommendations and potential impact on other organ program requirements.

At its December 2012 meeting, the PAIS held extensive discussions regarding the functional inactivity review, the purpose of this review, and additional information that might be helpful to the work group to identify a path forward. The subcommittee made the decision to not focus on the thresholds contained in the Bylaws as the suggested revision for changes to the pancreas thresholds did not address the concerns related to functional inactivity and in fact, would result in more programs being identified. The subcommittee observed that it was apparent that the purpose of these reviews is the evaluation of patient access to transplants but it is also closely related to quality. In addition, the subcommittee members noted that there is overall concern regarding the experience of transplant surgeons at lower volume facilities and if they are remaining current. Subcommittee members also discussed information that would assist the

reviewers in evaluating the program. The work group was asked to consider revisions to the questionnaire utilized by the PAIS to collect information to review functionally inactive programs and if there was a way to incentivize the programs to increase their volumes.

At its meeting in March 2013, the work group reviewed data analysis that UNOS Research presented through maps indicating the location and volume of the pancreas, heart, and lung programs noting those programs that were functionally inactive. The SRTR presented an analysis of data on the effect of volume on transplant rate and mortality on the waiting list for pancreas and kidney/pancreas candidates. The analysis demonstrated that in low volume programs, the candidates on the waiting list were less likely to undergo a transplant but were not more likely to die on the waiting list. Based on consideration of the data presented, the suggestions of the Pancreas Transplantation Committee and the charge from the PAIS, the work group recommended that the Bylaws be revised to require that functionally inactive programs provide notification to candidates and potential candidates of the program's inactivity and remind the patients of their ability to multiply list. The group recognized that this is inherent in the pre-transplant educational requirements, but also noted that not all programs advocate this and awareness of programmatic inactivity may come at a time disparate from when a patient receives that education.

The MPSC reviewed the work group's recommendations at its April 2013 meeting and approved the recommendation for the addition of a patient notification requirement for all functionally inactive programs to the Bylaws. Patient notification would be required within 30 days of MPSC notification to the program that it has been identified as functionally inactive.

The notification requirement will provide candidates and potential candidates with information about the program's activity levels that will allow the patient to make informed decisions about whether to move to another more active program or multiply list at another program. A requirement to notify patients will impose an additional administrative and resource burden on functionally inactive programs. However, this additional burden may provide an incentive for a low volume program to examine whether there is sufficient need in the community to justify the maintenance of the functionally inactive program or may spur the program to implement productive program growth initiatives. Over the course of 2012, 30 transplant programs met notification thresholds for functional inactivity due to lack of transplant activity, which affected approximately 500 candidates. Of those 30 programs, 27 had 30 or fewer candidates on the waiting list. The other three programs had waiting lists of 38, 46 and 76 candidates. Data is not available on the number of patients that were under evaluation during 2012.

This proposal addresses patient notification of a program's lack of transplant activity as distinguished from another current proposal to notify patients when the patient's waiting list status is inactive.

Revisions are proposed to remove confusing language and eliminate duplication in the Bylaws regarding functional inactivity, voluntary inactivation and waiting list inactivity. The proposal removes the provision regarding the inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days from the section addressing functional inactivity and references it in Appendix K.1. (Transplant Program Inactivity) as one of the instances when a program should inactivate. Appendix K.3. (Long-term Inactive Transplant Program Status) already references this as a reason to voluntarily inactivate so it was duplicative to have it in the functional inactivity provision. In addition, this language was inserted in Appendix K.1. (Transplant Program Inactivity) because Appendix K.3. (Long-term

Inactive Transplant Program Status) contains primarily instructions on the mechanics of inactivation.

The phrase referencing inability to perform transplants contained in Appendix D.10.B. (Patient Notification Requirements for Waiting List Inactivation) is removed because it is not specific and inability to perform transplants could, and often should, result in more review by the MSPC than the typical waiting list inactivity resulting in patient notification. Finally, the paragraph referencing the requirements for voluntary inactivation requirements is removed from Appendix D.9 (Review of Transplant Program Functional Activity) because the requirements are addressed in Appendix K (Transplant Program Inactivity, Withdrawal, and Termination) so this provision is duplicative and could result in inconsistent provisions if revisions were made in one place and not the other.

Supporting Evidence and/or Modeling:

Proximity and Access

As part of its review of functional inactivity based on lack of transplant activity, the PAIS requested information about the location of very low volume programs and their proximity to other programs for the same organ. Very low volume was defined as fewer than 5 transplants in a two year period for pancreas programs, fewer than 8 transplants during a two year period for heart programs and fewer than 4 transplants during a two year period for lung programs.

Of 118 pancreas programs that were active as of July 1, 2010, 20 programs (16.9%) performed fewer than 5 transplants during the period from July 1, 2010 to June 30, 2012. According to the OPTN bylaws, at least one pancreas transplant must be performed every 6 months in order to remain functionally active. Table 2 provides data regarding the number of pancreas programs in proximity to the pancreas programs identified as very low volume.

Table 2. Number of Pancreas Programs in Proximity to Pancreas Programs with very low volume.

Distance	Number of other Pancreas Programs									
	0	1-5	6-10	11-15	16-20	21-25	26-30	31-35	36-40	>40
<100 miles	5	11	3	1	0	0	0	0	0	0
Within 250 miles	0	2	7	5	6	0	0	0	0	0
Within 500 miles	0	1	0	3	2	2	5	3	1	3

Of 115 heart programs that were active as of July 1, 2010, 5 programs (4.4%) performed fewer than 8 transplants during the period from July 1, 2010 to June 30, 2012. According to the OPTN bylaws, at least one heart transplant must be performed every 3 months in order to remain functionally active. Of these 5 heart programs, 1 has 8 heart programs and 4 have between 2 and 4 heart programs within 100 miles; and 2 have 5 to 10 heart programs and 3 have 11 to 19 heart programs within 250 miles. The MPSC concluded that in many instances, alternative programs were available in close proximity to functionally inactive programs. Accordingly, in many instances, access would not be significantly affected if a functionally inactive program was to inactivate or withdraw.

Of 57 lung programs that were active as of July 1, 2010, 1 program (1.8%) performed fewer than 4 transplants during the period from July 1, 2010 to June 30, 2012. According to the OPTN bylaws, at least one lung transplant must be performed every 6 months in order to remain functionally active. The one lung program has 3 lung programs within 100 miles, 7 programs within 250 miles and 17 programs within 500 miles.

Outcomes

As part of the Pancreas Transplantation Committee's review of functional inactivity, the SRTR performed an analysis of whether pancreas transplant outcomes differ for small versus large volume programs. The SRTR's analysis utilized several methods to analyze the data. The conclusions of the report were inconclusive. Specifically, the conclusion stated:

Results from the tabular analyses are inconclusive, largely because they lack power to detect differences. There is a sufficiently low flagging rate that a tabular analysis cannot discern whether centers that are flagged are different from those that are not. The funnel plots do not convey a clear message, either. Not all small or inactive centers perform worse than other centers, though more often than not those beyond the 95% or 99th confidence intervals are in the lower 50th percentile of size. There is a clear ordering of small to larger as the expected number of graft failures increases, but this is due to the fact that more transplants means more possible failures. The funnel plot approach and flagging in general use observed-versus –expected events per center to look at whether any one center differs significantly from the nation. Again, this comparison is hindered by low power to identify differences in performance. Any particular center would have to differ greatly from the average of all other centers in order to stand out.

The Kaplan-Meier curves suggest a difference in graft survival in pancreas-alone transplant recipients by program size and inactivity, but not for simultaneous kidney-pancreas graft survival. Program size and inactivity are calculated based on total pancreas transplants per program, but since most programs perform more SPK transplants than PA-alone transplants, periods of inactivity or low volume may have a differential effect on outcomes for the two procedure types. Causation has not been established, nor is it clear whether program size, inactivity or both contribute to the survival disparities seen above. Future directions for analysis include using program volume and measures of program inactivity as predictors for survival in Cox PH models. Inactivity could be measured on a programmatic (total periods of inactivity in a given time window) or a per-transplant basis (time since last pancreas transplants was performed at that center). Overall, smaller-volume centers are much more likely to experience a period of functional inactivity than larger volume centers. Observed-versus-expected outcomes do not lead to the conclusion that all small-volume or inactive centers have worse outcomes than larger-volume or programs with no functional inactivity. However, the observed-versus-expected approach is not designed to look for a difference in performance between two types of centers (e.g. small versus large, or inactive versus active); rather, it is designed to assess whether any particular center stands out as worse than the rest.

In addition, the MPSC requested that an analysis be conducted focusing on pretransplant metrics to determine whether access to pancreas transplant was restricted for candidates waiting at small-volume pancreas programs. The SRTR's analysis concluded that there is no evidence to suggest that candidates at small-volume pancreas programs experience higher wait-list mortality than candidates at medium- or large-volume pancreas programs. However, as expected, the transplant rates for pancreas candidates were positively associated with program volume on both the KP and PA-alone waiting lists.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

This proposal impacts potential candidates and candidates at programs that have periods of functional inactivity. This proposal would require that transplant programs inform all potential candidates and candidates of periods of inactivity and remind those patients of the ability to multiply list at other programs. Over the course of 2012, 30 transplant programs met notification thresholds for functional inactivity due to lack of transplant activity, which affected approximately 500 candidates. Of those 30 programs, 27 had 30 or fewer candidates on the waiting list. The other three programs had waiting lists of 38, 46 and 76 candidates. Data is not available on the number of patients that were under evaluation during 2012.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal addresses the OPTN key goals of increasing the number of transplants, promoting transplant safety, and increasing access to transplants. Requirements regarding notification of candidates may spur functionally inactive programs to focus on growth of the program resulting in increased transplants or may cause the program to realistically evaluate the need for the program. If a program makes a decision to inactivate or withdraw, the patients on the waiting list may be referred to higher volume programs that could result in a shorter waiting time to transplant. Transplant safety is promoted when a functionally inactive program either increases transplants or inactivates or withdraws decreasing concerns about program personnel experience and currency. However, inactivation or withdrawal of programs could result in decreased access to transplant.

Plan for Evaluating the Proposal:

The MPSC will continue to monitor the number and organ type of programs that experience periods of functional inactivity and assess any trends identified. The MPSC will evaluate the responses to its inquiries to programs identified as functionally inactive based on lack of transplant activity. The MPSC will also review the effect that the requirement to notify patients of functional activity may have on the number of functionally inactive programs and the number of programs that inactivate or withdraw. Where data is available, the MPSC will continue to evaluate the effect of low volume on patient and graft survival.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will be considered by the Board of Directors in June 2014. If approved, the changes will be effective September 1, 2014.

There are currently no requirements for notification of functional inactivity based on lack of transplant activity. If this proposal is approved, transplant programs must provide a representative copy of the notification and a list of all patients that received the notification to the MPSC. Notifications must contain all of the required elements and must be sent within the timeframe outlined in the proposal details section above. The MPSC will continue to monitor transplant program compliance with the notification requirements contained in the proposal.

This proposal will not require programming in UNetSM.

Communication and Education Plan:

Notification of the Bylaw revision would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Transplant Pro/Member Communications archive article
- Presentation at Regional meetings

The new patient notification requirement will be incorporated into the OPTN Evaluation Plan, and education could accompany efforts to notify members of periodic updates to the plan.

Compliance Monitoring:

The MPSC Performance Analysis and Improvement Subcommittee will continue to monitor compliance with bylaw requirements as part of its existing review of functional inactivity. UNOS will review a list of all programs that are identified for lack of transplant activity for the specific periods defined in the Bylaws (This is an existing report). In addition to the current requests for information regarding the program, the program personnel's ability to maintain currency and the factors involved in the lack of transplant activity, UNOS will request confirmation that candidates were notified of the period(s) of functional inactivity, in compliance with the proposed content and timing requirements. The program will be required to submit a representative copy of the notification and the list of patients that received the notification to the MPSC.

Policy or Bylaw Proposal:

At a meeting of the OPTN/UNOS Board of Directors convened on June 23, 2014 in Richmond, VA, the following resolution is offered.

A resolution to provide, through a requirement for patient notification, candidates and potential candidates with information about the program’s activity levels when the program meets the thresholds for functional inactivity contained in the bylaws.

Sponsoring Committee: Membership and Professional Standards Committee

RESOLVED, that Bylaws, Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs, Sections 9 and 10; Appendix K Transplant Program Inactivity, Withdrawal, and Termination, Sections 1 and 3; and Appendix M Definitions are modified as set forth below, effective September 1, 2014.

Appendix D.9 Review of Transplant Program Functional Activity

A. Functional Inactivity

Each transplant program must remain functionally active by performing a minimum number of transplants. Transplant program functional activity will be reviewed periodically by the MPSC. Any program identified as functionally inactive will have the opportunity to explain its inactivity in a report to the MPSC. For purposes of these Bylaws, functional inactivity is defined as ~~any of the following:~~ the failure to perform a transplant during the periods defined in the table below:

- ~~1. The inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days.~~
- ~~2. The failure to perform a transplant during the periods defined in the table below:~~

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and or Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

~~Given their experimental and evolving nature, functional inactivity thresholds and waiting list notification requirements for functional inactivity have not been established for pancreatic islet and intestinal transplant programs.~~

B. Notification Requirements for Transplant Program Functional Inactivity

If a transplant program is notified by the MPSC that the program has been identified as functionally inactive, the transplant program must provide written notice to

1. Potential candidates
2. All candidates registered on the waiting list.

44 Written notice must be provided within 30 days of the date of the MPSC notification to
 45 the program and must include *all* of the following:

- 46
- 47 1. The dates identified in the MPSC notification during which no transplants were
 48 performed.
- 49 2. The reason no transplants were performed.
- 50 3. The options available to the candidates, including multiple listing or transfer of
 51 accrued waiting time to another transplant hospital
- 52 4. A copy of the OPTN Contractor's Patient Information Letter

53

54 **B.C. Review of Member Functional Inactivity**

55

56 As part of its review of a program's functional inactivity, tThe MPSC may also require, at
 57 its discretion, that the member participate in an informal discussion regarding a
 58 performance review. The informal discussion may be with the MPSC, a subcommittee,
 59 or a work group, as determined by the MPSC. The informal discussion will be conducted
 60 according to the principles of confidential medical peer review, as described in *Appendix*
 61 *L: Reviews, Actions, and Due Process* of these Bylaws. The discussion is not an
 62 adverse action or an element of due process. A member who participates in an informal
 63 discussion with the MPSC is entitled to receive a summary of the discussion.

64

65 ~~A functionally inactive transplant program should voluntarily inactivate for a period of up~~
 66 ~~to 12 months by providing written notice to the Executive Director. If the transplant~~
 67 ~~program expects to be inactive for more than 12 months, the member should relinquish~~
 68 ~~designated transplant program status as required in these Bylaws.~~

69

70 The MPSC may recommend that a program inactivate or withdraw its designated
 71 transplant program status due to the program's functional inactivity. If the program fails
 72 to inactivate or withdraw its designated transplant program status when the MPSC
 73 recommends it do so, the MPSC may recommend that the Board of Directors take
 74 appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of
 75 these Bylaws. Additionally, the Board of Directors may notify the Secretary of HHS of the
 76 program's inactivity.

77

78 **D.10 Additional Transplant Program Requirements**

79 **B. Patient Notification Requirements for Waiting List Inactivation**

80

81 A transplant program must provide written notice to candidates if it does *either or both* of
 82 the following:

- 83
- 84 1. Inactivates its waiting list ~~or is unable to perform transplants~~ for 15 or more
 85 consecutive days.
- 86 2. Inactivates its waiting list ~~or is unable to perform transplants~~ for 28 or more
 87 cumulative days during any calendar year.

88

89 A ~~t~~ransplant ~~p~~rogram must provide written notice *each* time it reaches either of the
 90 inactive waiting list thresholds listed above. Written notice must include *all* of the
 91 following:

- 92
- 93 1. The reason for the inactivity
 - 94 2. The expected length of time that the waiting list will be inactive
 - 95 3. The explanation that during the period of inactivity, organs cannot be accepted on
 96 the candidate’s behalf at this transplant program
 - 97 4. The options available to the candidate during this period, including multiple listing or
 98 transferring of accrued waiting time to another Transplant Hospital
 - 99 5. How the candidates will be notified when the waiting list is reactivated or if the
 100 expected length of inactivation is extended
 - 101 6. A copy of the UNOS OPTN Contractor’s Patient Information Letter

102

103 **Note:** If written notice is required because a ~~t~~ransplant ~~p~~rogram exceeded the inactive
 104 waiting list threshold due to *cumulative* periods of inactivation, then the written notice must
 105 also include the dates of each instance of waiting list inactivation.

106

107 Written notice must be provided within the periods defined in the table below:

For...	Written Notice Must be Provided...
Periods of waiting list inactivation scheduled at least 30 days in advance	30 days before inactivity begins.
Periods of waiting list inactivation scheduled less than 30 days in advance	No more than 7 days following the initial date of waiting list inactivation.
Any periods of waiting list inactivation related to a cumulative period of inactivation	No more than 7 days following the last date of the inactive period that caused the transplant program to exceed the inactive waiting list threshold.

109

110 **Appendix K: Transplant Program Inactivity, Withdrawal, and Termination**

111

112 This appendix defines transplant program inactivity, withdrawal, and termination, and outlines
 113 what members must do to be in compliance with OPTN obligations during these periods.

114

115 **K.1 Transplant Program Inactivity**

116 Transplant programs must remain active in transplantation to maintain membership in
 117 the OPTN. There are two types of member inactivity:

- 118
- 119 1. Short-term Inactivity
 - 120 2. Long-term Inactivity

121

122 A member may voluntarily inactivate a transplant program, on a short-term or long-term
 123 basis, for reasons including but not limited to:

- 125 ▪ The inability to meet functional activity requirements.
- 126 ▪ The inability to serve potential candidates, candidates, recipients, potential living
- 127 donors, or living donors for a period of 15 or more consecutive days.
- 128 ▪ Temporarily lacking required physician or surgeon coverage.
- 129 ▪ A substantial change in operations that requires an interruption in transplantation.

130
131 For more information about the functional activity requirements for transplant programs,
132 see *Section D.9 Review of Transplant Program Functional Inactivity* of these Bylaws.

133
134 **A. Program Component Cessation**

135 Programs that cease performing a specific type of transplant (e.g. the living donor
136 component of a transplant program, or cessation of only pediatric or only adult
137 transplants in a transplant program that performs both), must notify every patient
138 affected by the cessation, including:

- 139
- 140 ▪ Potential candidates, including those currently in the referral or evaluation process
- 141 ▪ All candidates registered on the waiting list
- 142 ▪ Potential living donors, including those currently in the referral process, in the
- 143 evaluation process, or awaiting donation

144
145 For more information about the notification content and timing requirements, see
146 *Appendix K, Sections K.3-4:* of these Bylaws.

147 **K.3 Long-term Inactive Transplant Program Status**

148 Long-term inactivity occurs when a transplant program is inactive for 15 or more
149 consecutive days., ~~resulting in an inactive UNetSM waiting list status and an inactive~~
150 ~~membership status.~~

151
152 Members should voluntarily inactivate a transplant program that is not able to serve
153 potential candidates, candidates, living donors, or recipients for 15 or more consecutive
154 days. Voluntary inactivation may extend for a period of up to 12 months.

155
156 Long term inactivation results in an inactive waiting list status and an inactive
157 membership status.

158 **A. Notice to the OPTN Contractor of Long-term Inactive Status**

159 When a member will voluntarily inactivate a transplant program for 15 or more
160 consecutive days, it must provide written notice, including the reasons for
161 inactivation, to the OPTN Executive Director.

162 **B. Notice to the Patients of Long-term Inactive Status**

163 When a member intends to inactivate a transplant program for 15 or more
164 consecutive days, it must provide written notice to the transplant program’s
165 potential candidates, candidates, recipients, and living donors currently being

166 treated by the transplant program. Written notice should be provided at least 30
 167 days prior to the planned inactivation date by a method that can be tracked and
 168 that provides proof of receipt, such as:

- 169
- 170 ■ Commercial overnight delivery service
 - 171 ■ Secure electronic communication
 - 172 ■ Registered or certified mail, return receipt requested

173

174 Written notice must be provided no later than 7 days after inactivation and
 175 include *all* of the following:

- 176
- 177 1. The reasons for inactivating the transplant program.
 - 178 2. Explanation that although the patient is still on the waiting list, the candidate
 179 cannot receive an organ offer through this program while it is inactive.
 - 180 3. Options for potential candidates, candidates, recipients, and living donors to
 181 transfer to another transplant program.
 - 182 4. The phone number of the inactive program’s administrative office that can
 183 help with transferring to another transplant program.

184

185 The member must provide to the OPTN Contractor a sample of each type of
 186 patient notice it sends to potential candidates, candidates, recipients, and living
 187 donors along with a list of patients who received the notice.

188

189 If a natural disaster adversely affects the function of a transplant program, the
 190 patient notification requirements will be applied reasonably and flexibly.

191

192 **Appendix M: Definitions**

193 **F**

194

195 **Functional Inactivity**

196 Functional inactivity is when a transplant program meets ~~any or all~~ of the following:

- 197 ~~1. The inability to serve potential candidates, candidates, recipients, or living donors for a period~~
 198 ~~of 15 or more consecutive days.~~
 199 ~~2. An inactive waiting list for 15 or more consecutive days, or 28 or more cumulative days over~~
 200 ~~any 365 consecutive day period.~~
 201 ~~3. The failure to perform a transplant during the periods defined in the table below:~~

Program Type	Inactive Period
Kidney, Liver or Heart	3 consecutive months
Pancreas and Lung	6 consecutive months
Stand-alone pediatric transplant programs	12 consecutive months

204 **L**

205 **Long-term Inactivity**

206 ~~A transplant program that is inactive for 15 or more consecutive days. Long-term inactivity~~
207 ~~results in an inactive UNetsm waiting list status and an inactive membership status.~~

208

209

#

Public Comment Responses

1. Public Comment Distribution

Date of distribution: 9/6/2013

Public comment end date: 12/6/2013

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	42	28 (66.7%)		14 (33.3%)	12
Regional	11	7 (63.6%)	1 (9.1%)	3 (27.3%)	0
Committee	18	8 (88.9%)		1 (11.1%)	8

2. Primary Public Comment Concerns/Questions

Initially, the MPSC would like to thank all of the regions, committees, organizations and individuals that took the time to carefully review and provide thoughtful comments on this proposal. Many of the comments received expressed common concerns that will be addressed in this section on primary concerns and questions. All comments received have been included within the document. However, if the concerns raised in the comment have been addressed in this initial response, no individual response will be noted. Any unique concerns will be addressed below the related comment.

Basis for and process of functional inactivity review

Some commenters questioned the need for review of programs for functional inactivity. The bylaws require, as a condition of membership, that all institutional members (including transplant hospitals) be active in the field of transplantation. These bylaws also stipulate that a transplant hospital, once approved as a member, must continuously meet membership requirements or elect to inactivate (for a period of up to 12 months), or terminate, any program that does not continue to meet the standards. The PAIS is concerned that such programs may not meet requirements for being active in the field of organ transplantation.

Definition of potential candidate

A number of commenters expressed concerns about confusion over the definition of “potential candidate.” The proposal includes patients in the referral process as a “potential candidate” which is in conflict with the definition of “potential candidate” in Appendix M Definitions. Appendix M defines “potential candidate” as “an individual who is under evaluation for transplant by the transplant program.” The proposal has been amended to strike “referral” from the proposal.

Penalizing start-up programs

Several responses expressed concern about the identification of newly approved or reactivated programs for functional inactivity. Newly approved or reactivated programs are not currently and will not be sent an inquiry by the Committee until one year after approval or reactivation. The patient notification letters are only required if the program receives an inquiry from the Committee.

Requiring more isolated pancreas may not be best for patient

Some commenters noted a concern with requiring isolated pancreas transplants and not included kidney/pancreas transplants. When reviewing pancreas program functional inactivity, the Committee considers both pancreas alone transplants and simultaneous kidney/pancreas transplants. A pancreas program will not be identified for functional inactivity if the program performs either a pancreas alone or kidney/pancreas transplant during the six month period under review.

Pancreas Program Problem

With regards to the comments that this is a pancreas program problem, the commenters are correct in noting that the majority of programs identified as functionally inactive are pancreas programs. However, other organ programs are identified and reviewed for functional inactivity. The Committee believes that all functionally inactive programs should be subject to the same requirements.

Thresholds arbitrary

Although many of the commenters expressed concerns about the thresholds, this is not the focus of this proposal. The revision in the current proposal simply requires that a program notify its candidates and patients under evaluation when the program has been identified as functionally inactive for not performing transplants. The MPSC will consider these comments and suggestions during its continued evaluation of the effectiveness of the functional inactivity reviews.

A number of responders commented that the thresholds for identification of programs as functionally inactive were arbitrary with no data to support the current thresholds. In addition, some commenters suggested that the performance of pancreas islet transplants should be considered in determining functional inactivity for pancreas programs; and performance of kidney transplants at a member hospital should be sufficient to maintain currency for pancreas transplant. The Committee is not proposing revision of the thresholds for functional inactivity in this proposal.

While reviewing functional inactivity in pancreas programs, the MPSC requested and received input from the Pancreas Transplantation Committee on revision to the functional inactivity threshold for pancreas programs. After reviewing the recommendations of the Pancreas Transplantation Committee, the Committee decided not to change the thresholds contained in the Bylaws as the suggested revision for changes to the pancreas thresholds did not address the concerns related to functional inactivity and in fact, would have resulted in more

programs being identified. The Pancreas Transplantation Committee did not recommend inclusion of pancreas islet transplants or kidney transplants in the determination of whether a pancreas program is functionally inactive.

Also, as noted in the public comment document, there are only a small number of programs that are identified as functionally inactive. Due to the time periods for submitting data, the reports on functional inactivity usually end several months before the MPSC/PAIS meeting. However, a member is not referred to the MPSC if a transplant occurs at that program prior to the meeting of the MPSC/PAIS. Because no inquiry is sent if a transplant is performed prior to the meeting, there is no significant lag time between the period of functional inactivity and the date the MPSC letter is received by a program identified as functionally inactive. In addition, generally, those programs that receive a letter from the MPSC have not performed a transplant for much longer than the published thresholds in the bylaws. For example, a PAIS meeting was held on July 30, 2013. The reports identifying pancreas or lung programs that were functionally inactive considered data from October 1, 2012 through March 31, 2013. However, if a newly identified program performed a transplant between March 31, 2013 and July 30, 2013, an initial inquiry would not be sent to that program. Therefore, a pancreas or lung program would not have received an inquiry from the MPSC unless that program had not performed a transplant in at least the previous nine months. For kidney, heart and liver, it would have been a period of at least six months. Following the July 2013 MPSC meeting, three newly identified pancreas programs received an initial functional inactivity survey. These programs had not performed a transplant for either 10 or 12 months and the programs' waiting lists included one, ten or fourteen active candidates. For the seven pancreas programs that continued under review, no transplants had been performed for periods between 12 months and 27 months and the programs waiting lists contained between 1 and 5 active candidates. Accordingly, the burden imposed by this proposal on programs is quite small.

Limiting patient access due to program closing or failure to take into account waiting list size or organ availability

Some commenters expressed concern that small volume programs will be closed and access to transplant will be limited if this proposal is approved. The Committee's proposal does not include a revision of the bylaws to close functionally inactive pancreas programs. In fact, the Committee chose to focus on issues of patient access and informed decision making through the route of requiring patient notification of functional inactivity instead of focusing on options available to the Committee to request inactivation or withdrawal of a program. The proposal is intended to provide patients with information about the activity levels of the program at which the patient is listed thereby contributing to transparency in the process. Therefore, since the thresholds and the process for review by the Committee is not changed by this proposal, there should not be an increase in the number of programs that close. However, if the Committee considers requesting that a program inactivate or withdraw, a factor generally considered in this decision is the availability of alternatives for the program's patients.

As noted in the public comment document, an ancillary effect of the patient notification for a small number of the programs could be a decision by the program to close the program.

However, the Committee does not expect the number of program’s closing due to functional inactivity to significantly increase. Additionally, the Committee would like to note that the number of programs identified as functionally inactive is very small compared to the total number of programs performing transplants. As noted before, the main focus of the proposal is to enhance patient access to transplant by ensuring that programs inform their patients about the program’s activity levels thereby allowing the patients to make informed decisions about their transplant care.

No candidates on the waiting list or no offers received

The purpose of this proposal is to provide patients with information about the lack of transplant activity of the program. If a program does not have any potential candidates or candidates on its waiting list, the program would not be required to do anything under this proposal. The proposal requires that the program provide the patients with the reasons why a transplant has not been performed. Therefore, if a program has not received organ offers or if it has received very few, the program would inform the patients that no organs were available to the program during that time period or the program has not received many offers.

Relationship between outcomes and functional inactivity

Some comments suggested that functional inactivity or small volume does not necessarily result in concerning outcomes. On the other hand, some commenters suggested that inactivity and outcome reviews are circular in that an outcome review would cause a program’s volumes to decrease to a level that the program may be identified as functionally inactive and a functional inactivity review would cause programs to take risks that may lead to poor outcomes. As noted earlier, the existence of reviews for functional inactivity and the thresholds utilized for those reviews are not at issue in this proposal. During the Pancreas Transplantation Committee’s review of functional inactivity in pancreas programs, it reviewed data regarding low volume pancreas programs and found that the results were not definitive on whether low volume affects outcomes. This led to a focus by the Committee on patient access and patient notification. In addition, when possible, the Committee considers a program’s outcomes when reviewing periods of functional inactivity. In fact, if identified for both, the cases are combined for review by the MPSC. Unfortunately, the Committee does not currently receive outcomes data on pancreas programs. Beginning in January 2014, the Committee will be receiving data on pancreas patient survival. The Pancreas Transplantation Committee has not yet provided a definition for pancreas graft failure. Therefore, the Committee’s consideration of a pancreas programs graft survival will be delayed.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1				Choose an item.
1	9/30/2013	12 yes, 3 no, 0 abstentions		In person
2	10/25/2013	0 yes, 32 no, 1 abstention		In person
3	12/6/2013	16 yes, 0 no, 1 abstention		In person

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
4	12/6/2013	17 yes, 1 no, 0 abstentions		In person
5	12/12/2013	32 yes, 0 no, 0 abstentions		In person
6	10/04/2013	33 yes, 29 no, 0 abstentions		In person
7	11/22/2013	0 yes, 22 no, 0 abstentions	21 yes, 0 no, 1 abstentions	In person
8	12/6/2013	1 yes, 15 no, 2 abstentions		In person
9	10/23/2013	22 yes, 0 no, 0 abstentions		In person
10	10/18/2013	4 yes, 13 no, 4 abstentions		In person
11	12/6/2013	20 yes, 0 no, 0 abstentions		In person

Region 1:

The region approved the proposal but commented on the analysis that was performed to determine the number of programs located in proximity to a program identified as very low volume. The analysis didn't provide information regarding the volume or outcomes of the centers located nearby. The nearby centers could be low volume with no better transplant rate or outcomes.

In addition, the definition of a potential candidate in the bylaws is vague and should be revised.

Committee Response:

The Committee appreciates Region 1's support of the proposal.

The Committee acknowledges that it is possible that centers nearby to functionally inactive programs may also be low volume but the notice is to inform the patient about the hospital for which the patient is listed and not to encourage a transfer per se. Although the Committee acknowledges that a transfer may be a result.

A response to the region's other comment is included in the Primary Concerns above.

Region 2:

Region 2 did not approve this proposal. During the discussion members had the following concerns:

- The inactive periods used to flag inactivity are arbitrary across organs.
- The problem is with pancreas programs and does not apply to all organs.
- This would be a problem for start-up centers.
- Some small volume centers have better outcomes than large volume centers. Doing more transplants does not make your outcomes better.

Committee Response:

Responses to the region's comments are included in the Primary Concerns above.

Region 3:

The region had no comments.

Committee Response:

The Committee appreciates Region 3's support of the proposal.

Region 4:

The region approved this proposal, but would like for the MPSC to clearly define a potential candidate. The current definition is open to wide interpretation.

Committee Response:

The Committee appreciates Region 4's support of the proposal. A response to the region's comment is included in the Primary Concerns above.

Region 5:

The region had no comments.

Committee Response:

The Committee appreciates Region 5's support of the proposal.

Region 6: Although the proposal was approved, the vote was split. Those who opposed the proposal had the following comments/concerns:

- This is primarily a problem with the pancreas programs. Because of improvements in diabetic care, there are fewer patients in need of an isolated pancreas transplant. The waiting list for pancreas is driven more by the number of people who need to be transplanted than by the number of available pancreas.
- Requiring centers do more isolated pancreas transplants in order to stay active would create a situation where what is good for the center (doing more pancreas transplants) is in conflict with what is good for the patient.
- Closing small volume pancreas programs will disadvantage the few people in a local area who need a transplant and can't afford to travel to a larger center.
- A majority of the expertise needed to do a PA transplant is found in transplanting kidneys. If you have an active kidney program, key personnel will have the experience needed to do a pancreas transplant.
- Committee should consider flagging pancreas programs separately from other organ programs.

There was general consensus that the language in Appendix D.9, B, 1, "Potential candidates" was too vague and needs to be defined as anyone who is currently going through the evaluation process.

Committee Response:

The Committee appreciates Region 6's support of the proposal.

Responses to the region's comments are included in the Primary Concerns above.

Region 7:

The region opposed this proposal (0 yes, 22 no, 0 abstentions) but passed an amendment version (21 yes, 0 no, 1 abstentions) with additional comments to the committee.

Regional Amendment: Strike the word referral on page 111 when referring to what patient populations require notification.

Regional Comments:

- The region would request that pancreas and pancreas islet numbers be considered as one. Regional programs asserted that it is often a decision of program to use this organ in one way or the other – the use of either is reflective of an active program.
- Concerned that if this is in place prior to the programming of the new pancreas allocation system, it is feasible that pancreas candidates will have to wait longer due to OPO allocation practices. This is not something the transplant center can actively change and, potentially, this should be put into place until the new allocation system has been implemented.
- The region was very concerned that this notification does not take into consideration outcome measures. The region feels strongly that the committee needs to start incorporating outcome measures as part of notification requirements. If a transplant program performs 5 transplants in the last three years and has poor outcomes and a second performs 4 (1 not in the last year) with outstanding outcomes, only the second would have to notify their patients. Notification requirements need to consider both outcome and activity measures.

Committee Response:

The Committee appreciates Region 7's support of the proposal as amended. The Committee has made the amendment suggested by the region in a post-public comment amended proposal.

In response to the region's suggestion that the proposed revision should be put on hold until after the new pancreas allocation system is implemented, the Committee believes that providing information to patient's about the activity level of the program at which the patient is listed should not be delayed until the new pancreas allocation system can be implemented.

Responses to the region's other comments are included in the Primary Concerns above.

Region 8:

The MAC rep brought forward the committees concerns which were supported by the region. These included lag time from actual inactivity until the time patients are notified. A program could have increased activity during the lag time resulting in candidates receiving incorrect information and disadvantaging the program. 100 miles is too far for candidates from some economically challenged areas. Requiring the centers to notify candidates could result in programs closing creating a lack of access to a population and programs w/low volume do not have poor outcomes or provide poor care. There was also concern voiced that the two proposals working together may have unintended consequences. One proposal flags programs for poor outcomes which possibly discourages centers from being aggressive and doing more transplants. The other flags programs for doing too few transplants encouraging them to do more transplants and be more aggressive. Lastly, there was agreement that this is not going to fix the problem and the MPSC needs to find a different way to address this issue.

Committee Response:

In response to the concern that 100 miles is too far for some candidates, many of the programs identified as functionally inactive have programs that are much closer than 100 miles. The 100 mile distance was used only as a round figure to demonstrate that there are often alternatives for patients in the area surrounding functionally inactive programs. The intent of the MPSC is not to close programs.

In addition, the MPSC has investigated alternative avenues to address the problem of functional inactivity. Those efforts are discussed in the Primary Concerns section above.

Responses to the region's other comments are included in the Primary Concerns above.

Region 9:

The region had no comments.

Committee Response:

The Committee appreciates Region 9's support of the proposal.

Region 10:

- The proposal does not correlate inactivity to the size of a waitlist. There is a difference in a transplant program that has 200 patients listed and is inactive and program that has 10 waitlisted patients. The requirement also does not take into consideration that in smaller DSAs the offer pool may be such that there has not been a good offer for one of these 10 patients in the preceding 12 months. These factors need to be considered by the MPSC prior to a center having to notify patients. The region would be more comfortable if notification was based off a transplant rate equation taking into consideration the size of the waitlist and the number of offers the center has received for these candidates in the preceding 12 months.
- The region is aware that the center provides information about the cause of the inactivity as part of the notification, but felt any notification about inactivity shows the transplant program in a negative light. For several of the scenarios the region discussed, this would not be an accurate reflection of the program (new program, transplanted entire waitlist, waiting for the best possible organ, etc.).
- Strongly concerned that this requirement does not take into consideration any outcome measures. A candidate may be better served at a transplant program that waits 13 months for the best offer with a high graft survival then to accept a suboptimal offer at 6 months.
- The region was also concerned that this does not have a provision for centers that have transplanted their entire list and are now listing new patients. These centers will certainly have periods of inactivity as they repopulate their list and this inactivity is not the result of negligence or inattentiveness on the part of the transplant program.

Committee Response:

Responses to the region's comments are included in the Primary Concerns above.

Region 11:

Region 11 approved this proposal but had the following comment:

- There are some programs that do not have another program within 100 miles and that would affect patient access to transplant services.

Committee Response:

The Committee appreciates Region 11's support of the proposal.

A response to the region's comment is included in the Primary Concerns above.

4. Committee Public Comment Responses**Ad Hoc Disease Transmission Advisory Committee:**

Upon review, the Committee determined that it had no specific comment regarding this proposal.

Ad Hoc International Relations Committee:

The Committee did not consider this proposal.

Ethics Committee:

There has been reported concern in the community about how the notification would work. After review and discussion of this issue, the Committee had general approval of the proposal but did want to comment that the letters should include a statement that clarifies that "there are reasons that are reasonable and reasons that are not reasonable for inactivity at a program" and that these letters should include that context.

Committee Response:

The Committee appreciates the Ethics Committee's support of the proposal and takes note of its suggestion. The MPSC does not believe it is possible to create a list of reasons that are reasonable and unreasonable for use by programs in the letter. The MPSC, when reviewing a program's response to the MPSC inquiry, considers the reasonableness of a program's reasons for functional inactivity. This review, however, occurs after the program would be required to notify its patients of the period of functional inactivity.

Liver and Intestinal Organ Transplantation Committee:

The Committee reviewed this proposal during its November 21, 2013 conference call. This proposal would require centers determined to be functionally inactive to send notification to all candidates and potential candidates within 30 days of receipt of letter from MPSC. Programs that have not performed a transplant during a defined period are considered functionally inactive; these periods are 3 months for kidney, liver and heart programs, 6 months for lung and pancreas programs and 1 year for stand-alone pediatric programs. It was noted that a program will not be referred to the MPSC for review for functional inactivity during the first year following interim approval of the program or interim approval of a reactivation. The majority of programs identified as functionally inactive are pancreas programs. One Committee member expressed concern that some patients will not have the ability to transfer to a nearby program if a center is inactivated. The Committee had no other comments.

Committee Response:

The MPSC thanks the Liver and Intestinal Organ Transplantation Committee for its consideration of the proposal.

Living Donor Committee:

The Living Donor Committee considered and supports this policy proposal. The Committee opined that functional inactivity should be reported publicly, so transplant candidates can determine if a center is functionally inactive or has a history of periods of functional inactivity.

Committee Response:

The Committee appreciates the Living Donor Committee's support of the proposal and takes note of the Living Donor Committee's suggestion that functional inactivity should be reported publicly. Both waiting list activity and transplant activity information for programs can be found in the Transplant Program Reports on the Scientific Registry of Transplant Recipients (SRTR)'s public website.

Minority Affairs Committee:

The committee was presented with a review of the proposal by the Assistant Director for Membership at UNOS. During discussion, the committee voiced specific concerns that the requirements in the proposal could potentially force the closure of smaller, less active transplant programs. The committee comments addressed overall concerns with regard to the following:

- Lack of distinction between the reasons for transplant inactivity within a transplant program
- Reduced/inequitable patient access which may result from the patient notification and potential high volume transplant center relocation
- Potential for negative candidate/patient perception
- Potential for negative media exposure
- Administrative burden on transplant program

The committee discussed several scenarios in which both the transplant center and the patient could be adversely impacted by the proposal. The committee believes that the proposal does not account for programs which are conducting transplants with good survival; however, there may be periods of time when the program is receiving offers; however, the organs are being accepted by other transplant centers. The transplant center may be completing the required number of transplants (14-15 a year); however, it could still be penalized for having 3 months of inactivity during the year. It was also commented that there may be lulls in transplantation due to decreased donor activity. The committee also believes that the proposed change would have a detrimental impact on socioeconomically disadvantaged patients within a certain geographic area for whom it may pose a hardship to travel 100 miles to a higher volume transplant center. It was noted that this may effectively deprive specific patient populations of the opportunity for a transplant due to logistical concerns. Members also expressed concern that the notification requirement would be perceived to be negative to both current and potential transplant candidates and could potentially result in negative exposure in the media.

The concerns expressed by the committee were addressed by the presenter. She noted that the only penalty in the proposal is the requirement to notify candidates or potential candidates of periods of transplant inactivity. Transplant centers are not being required to advise patients to relocate or transfer to another center. Further, there will be a lag of approximately two months reporting between the time when a transplant center has crossed the threshold of functional inactivity defined in the proposal and its subsequent review by the MPSC. Therefore, it is likely that a program will not be reviewed for approximately 5-6 months following the time it is identified as functionally inactive by the MPSC. The committee may use this extended time to attempt to address the problem. She also noted that unlike CMS, the OPTN is not requiring a specific minimum number of transplants to be conducted during a specific reporting time frame. The proposal only addresses functional inactivity during 3, 6 and 12 month reporting intervals for not conducting a transplant.

Committee discussion continued to frame the proposal as advancing toward the slippery slope of forced program closures. The prevailing sentiment from the committee was that the patient notification requirement would negatively impact patient and public perception and lower the standing of the transplant program. Concern was also expressed regarding the cutoff times for program review. It was acknowledged that the timeframes incorporate a grace period resulting from implicit inefficiency in the MPSC reporting process. It was noted that the grace period would not be honored forever. Members suggested that there should be longer, harder, more realistic intervals for review. Members suggested that the proposal should also appreciate the burden the requirement would impose on transplant programs, particularly when attempting to outline the rationale explaining why transplants were not performed during the time period in the patient notification letter. It was suggested that rather than improving patient safety, the proposal may actually negatively impact patient safety through reduced access to transplantation.

A member of the committee also suggested that a “potential” candidate in the proposal be more narrowly defined. For example, in the member’s transplant center, the number of patients undergoing the transplant evaluation process could equal 2000 or more. It was suggested that the definition of potential candidates to be notified should be narrowed to include only waitlisted patients or patients’ waitlisted on hold.

The presenter noted that she would take the committee’s concerns and comments regarding the proposal back to the MPSC Committee.

The committee disapproved the proposal based on the concerns noted above with the following vote:

Committee vote: 10 Oppose, 2 Support, 4 Abstentions

Committee Response:

Responses to the Minority Affairs Committee’s comments are included in the Primary Concerns above.

Operations and Safety Committee:

The Operations and Safety Committee considered this proposal at their December 3, 2013 conference call meeting.

The Committee voted to support this proposal (12 in favor, 0 opposed, 0 abstentions).

Committee Response:

The Committee appreciates the Operations and Safety Committee’s support of the proposal.

Pancreas Transplantation Committee:

The purpose of proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity proposal is to provide, through a requirement for patient notification, candidates and potential candidates with information about the program’s activity levels that will allow the patient to make informed decisions about whether to move to another more active program or multiple-list at another program. In addition, the proposed Bylaw revision may provide an incentive for a low volume program to develop ways to increase transplant activity thereby positively impacting the program personnel’s experience and currency. In the alternative, it may spur a functionally inactive program to examine whether there is sufficient need in the community to justify the maintenance of the functionally inactive program resulting in the inactivation or withdrawal of a low volume program with the resultant referral of candidates to a higher volume program.

It was asked if MPSC is going to apply the definition for small volume programs to the definition for functional inactivity? A MPSC representative explained that the MPSC reviewed Committee's recommendations for functional inactivity and decided to not change the definition for functional inactivity, which means for pancreas programs functional inactivity remains at no transplants in 6 months.

It was suggested MPSC provide a slide that states what the Committee will be voting on. It was suggested for MPSC to show both the current Bylaw language and the proposed change to the Bylaws in a slide.

It was asked if part of the proposal includes who will be notified; in other words, what is the definition of an active patient. A MPSC representative explained if a program is functionally inactive then the program must send a letter to all candidates and potential candidates explaining the programs' functionally inactive status. It was noted the definition for candidate and potential candidate is unclear. A MPSC representative directed the member to the Bylaws Glossary which defines potential candidate: any individual who is under evaluation for transplant by the transplant program.

Most members support this proposal; however, several members are uncomfortable with the "potential candidate" definition and may not support the proposal based on how programs' define "potential candidates".

Several members expressed a concern about how this proposal may falsely label small volume programs that have a lack of transplants for reasons outside the programs' control (i.e. low patient population, etc.) It was noted 6 months is not a long time period for a small volume program and the patient notification letter may give the patient a misperception about the programs' competency. It is more important for a program to notify its patients of the patient's waiting time rather than a programs' functional inactivity status. It was noted this proposal may generate more paperwork and administrative burdens for small volume programs.

The Committee voted on the proposed Patient Notification of Functional Inactivity Due to Lack of Transplant Activity. (12-Support, 1-Oppose, 0- Abstain)

Committee Response:

The Committee appreciates the Operations and Safety Committee's support of the proposal.

Responses to the Pancreas Transplantation Committee's comments are included in the Primary Concerns above.

Pediatric Transplantation Committee:

The Committee raised concerns about some of the functional inactivity thresholds currently in the Bylaws; however, understanding the proposed Bylaws changes do not address functional inactivity case volumes, the Committee unanimously supported a motion to support the proposal as written (10 support, 0 oppose, 0 abstentions).

Committee Response:

The Committee appreciates the Pediatric Transplantation Committee's support of the proposal.

A response to the Pediatric Transplantation Committee's comment is included in the Primary Concerns above.

Policy Oversight Committee (POC):

The Committee did not consider this proposal.

Thoracic Organ Transplantation Committee:

The Committee did not voice concerns or questions about the proposed policy, and voted in favor of it: 20-supported; 0-opposed; and 0-abstained.

Committee Response:

The Committee appreciates the Thoracic Organ Transplantation Committee's support of the proposal.

Transplant Administrators Committee:

The Committee voted to approve the proposal as written (14 support, 1 oppose, 0 abstentions). It was noted that notifying all candidates is excessive.

Committee Response:

The Committee appreciates the Transplant Administrators Committee's support of the proposal.

Transplant Coordinators Committee:

The Committee voted to approve the proposal as written (12 support, 3 oppose, 0 abstentions).

Committee Response:

The Committee appreciates the Transplant Coordinators Committee's support of the proposal.

5. Individual Public Comment Responses**Comment 1:**

vote: Oppose

Date Posted: 09/10/2013

I am submitting this again as I am not sure my last comment was transmitted. We are a low volume pancreas program. the main limitation is the lack of transplantable pancreases available to us from our OPO. the OPO is relatively small, ~40 donors/year, of which the great majority are ECD or DCD. In addition, there is another pancreas program affiliated with our OPO. Despite or low volumes our outcomes are good. In fact our last graft failure was at a time when we were under scrutiny by UNOS for not performing a pancreas transplant within 9 months. This contributed to our decision to use a less than optimal pancreas for transplant, which thrombosed immediately. The closest pancreas center to us is 3-4 hours away, there are no other local pancreas transplant programs. Flight access into Albany is very limited, thus most import offers have excessive cold-ischemia time, which as you know is critical for a good outcome. We already notify all our listed patient of the average wait time for a pancreas ~3 years, and tell them of the closest pancreas transplant programs as other options (again, all of which are at least 3 hours away).

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. Responses to the commenter's concerns are included in the Primary Concerns above.

Comment 2:*vote: Oppose**Date Posted: 11/26/2013*

I am opposed to Proposal #6. I do not know how implementing such a proposal will increase the amount of transplants in Region 10. In our area, we compete with two other hospitals for the same organs. The only way to increase transplantation is by increasing the donor pool. There is also a hope that accessibility will be increased if such a proposal goes through. I believe that this will in fact decrease accessibility as the majority of our patients have Medicaid or Medicare. These patients have limited resources to come to our local hospital, and if you told them they would have to travel further, I do not believe that they would be able to do this. This problem would escalate, and these patients would no longer have an option for transplantation, thus decreasing the amount of transplants performed. I believe that the only way to know if a center is meeting criteria is to look at their yearly data and survival rate, rather than a period of time that they have not transplanted, to determine the validity in them maintaining a center. This proposal cannot go through for so many reasons. Closing the doors on such centers could close the door on a patients potential of receiving a life saving organ.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. Responses to the commenter's concerns are included in the Primary Concerns above.

Comment 3:*vote: Oppose**Date Posted: 11/20/2013*

I am writing to communicate my opposition to Proposal #6 regarding patient inactivity of transplant programs. I believe this proposal would ultimately be detrimental to the transplant patient population of Metro Detroit and the surrounding region. The heart transplant program at Henry Ford Hospital is one of the premiere programs in the region. I believe putting a requirement on how often patients are transplanted would not improve the quality of patient care in the area. Thank you for your consideration.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. Responses to the commenter's concerns are included in the Primary Concerns above.

Comment 4:*vote: Oppose**Date Posted: 12/05/2013*

I believe that 3 months is too short of a period to notify patients of inactivity. The program that I am currently involved in has had a period of inactivity for 3 months but then has gone through 4 transplants in 6 weeks. I feel that 6 months of inactivity would be more reasonable and would still allow pt's be see other programs and multi list.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. A response to the commenter's concerns is included in the Primary Concerns above.

Comment 5:*vote: Oppose**Date Posted: 11/20/2013*

IF IMPLEMENTED THIS POLICY WOULD BENEFIT LARGE PROGRAMS AND DRIVE SMALLER PROGRAMS OUT OF THE TRANSPLANT MARKET GIVING FEWER OPTIONS TO PATIENTS. THIS POLICY WOULD BE UNFAIR TO PATIENTS.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. A responses to the commenters concern is included in the Primary Concerns above.

Comment 6:*vote: Oppose**Date Posted: 10/25/2013*

Our organization xxxx is opposed to this proposal as written. Smaller programs may have longer waiting times to transplant because they list fewer patients than larger programs. For example, let's say a pancreas program in a DSA lists one or two patients every 6 months and a larger volume program lists 5-6 programs during every 6 month period. Assume the average wait time for a pancreas in that DSA is 8 months. Well, the larger program will transplant, on average, several patients every 6 months and will be OK under your proposal. The smaller program will probably transplant one patient every 8 months. Their patient won't wait any longer than if they listed at the larger program. If the results at the smaller program are good, the patient gets the same result. Under your proposal the smaller program would have to send that patient that they listed a letter after 6 months saying that they hadn't done a transplant in six months and should consider transferring to the larger program and you will likely kill that program. If the larger program is at some distance from the smaller program you will also be impacting that patient's access to a transplant. In addition you state that this proposal will keep surgeons and programs proficient and current. If this is so why does a liver or heart (adult) program have to do a transplant every 3 months, while a lung or pancreas surgeon only needs to do one every 6 months and a pediatric surgeon only once per year to all stay proficient and current. These numbers are arbitrary and not based on any meaningful data of which I am aware.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. A response to the commenter's concerns is included in the Primary Concerns above.

Comment 7:*vote: Oppose**Date Posted: 11/06/2013*

The proposal does not take into account that smaller programs will list fewer patients at any given time period than a larger volume program. Suppose a pancreas program lists a patient about every 6 months and a larger program in the same DSA lists 3-4 patients during that same 6 months. If the average waiting time in that DSA to get a pancreas is 8 months, the larger program will likely transplant one of their patients during that time. However, the patient listed at the smaller program will likely get a transplant at around 8 months. That patient would not have gotten transplanted any more quickly at the larger program. However, your proposal would require the smaller program to send that patient a letter at 6 months saying that they hadnt done a transplant in 6 months and to consider switching to a larger volume program. If the outcome results at the

smaller program are good, this policy serves no purpose. If enough patients drift off that programs list, they may close. If the larger center is far from the smaller center, you may impact the ability of patients' access to a transplant. Also, the proposal states that the surgeons and center need to stay proficient and current. Then why must an adult heart or liver program do at least one transplant every 3 months to stay proficient, while an adult lung program only needs to do one every 6 months and a pediatric program can allegedly stay proficient doing only one a year? These numbers seem arbitrary and are not based on any meaningful data of which I am aware. Thank you for your time.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. A response to the commenter's concerns is included in the Primary Concerns above.

Comment 8:

vote: Oppose

Date Posted: 11/21/2013

The proposal may hurt moderate size programs and it really doesn't help in improving quality at all. I truly believe that the proposal has theoretical value but a lot of potential bad effect. Should never see the light.

Committee Response:

The MPSC thanks the commenter for the response to the proposal.

Comment 9: ASTS

Vote: Opposed

Date Posted: 12/08/2013

ASTS does not support this proposal and appreciates the opportunity to comment on the proposed policy change that would require notification of listed patients when a defined period of transplant inactivity occurs at a given center. The intent is specifically to make patients aware of the program's inactivity and the availability of more active centers. The threshold of inactivity varies by organ: for heart, liver and kidney it is no transplants in 3 months and for pancreas and lung, 6 months. Recent UNOS analysis of a 3-year period (2010-2013) found that inactivity triggers are most often met in pancreas, with an average of 17 programs/year meeting an inactivity threshold, versus 1.6 for heart, 1 for kidney, .6 for lung, and .3 for liver. Thus, while the policy would apply to all organs, the discussion below is focused on pancreas as an illustrative example.

The proposal under consideration rests on the premises that such notification will: 1) encourage transfer of patients from lower to higher volume programs where they will receive superior care and/or 2) be a punitive measure that will spur low volume programs to become more aggressive and increase their transplant rate and volume. ASTS objects to the proposed policy based on the fact that neither premise is supported by data suggesting there will be a benefit to the patients involved and the fact that the policy could have negative consequences for patients and the field of pancreas transplantation in general.

Regarding the assumption that patient outcome will be improved by being transplanted at a high versus a low volume center, the OPTN/UNOS pancreas committee reviewed data on both post-transplant survival and the waitlist mortality at high and low volume programs, and in neither case was there a significant difference in outcome between low and high volume centers. If there is no expected benefit to the patients, we question why such a policy would be put forward to the OPTN

board for consideration. Furthermore, a patient electing to transfer to a higher volume center with a higher transplant rate, while not gaining appreciable benefit, will suffer the confusion and inconvenience of transferring their care to another center that is likely farther away and detached from their existing network of care providers. This is particularly problematic for SPK patients who constitute the majority of pancreas recipients and who benefit from maintaining their ESRD care at a closer location.

We also contest the suggestion that the punitive nature of notifying patients of program inactivity will encourage more aggressive utilization. Surgeons and programs practice in a manner compatible with their abilities and risk aversion tolerance. To attempt to dictate patient care by forcing programs to accept organs and/or recipients that would otherwise have been declined may yield poorer outcomes for patients and programs and potentially lead to closure of what was previously a well-functioning low volume program. At a time when the field is already contracting with a >30% reduction in pancreas transplants in the last decade, unnecessary (with necessity defined by outcome) program closures will be the inevitable result of this proposal. This will likely reduce overall patient access to optimal care and lead to a further decline in total pancreas transplant volumes. For example, small centers evaluating diabetic patients for kidney transplantation who have lost their pancreas program may merely elect to list the patient for renal transplant rather than refer the patient to another center offering combined kidney-pancreas transplantation. In other cases, potential SPK candidates may prefer to stay at their current center to receive a kidney alone rather than confront the obstacles of relisting for SPK elsewhere (such as logistics, re-evaluation testing, added travel, etc).

We also question the claim in the background of the public comment proposal that the current levels of “inactivity are too low for a program to remain current with both surgical skills and programmatic administrative competence.” This assertion fails to consider the fact that most pancreas centers also perform renal transplantation and that there are largely overlapping skill sets in pancreas and kidney transplantation surgically, medically, and administratively. Thus a program performing only a handful of pancreas transplants per year may in part remain current through an active kidney transplant program.

Other problems with the current proposal include: 1) that it fails to consider the correlation of regional variation in organ availability with the distribution of low volume centers, as well as how regional variations in wait time affect program inactivity, and 2) whether the planned changes in pancreas and kidney allocation that simultaneously prioritize pancreas transplantation and eliminate regional variances will affect the likelihood of program inactivity.

Low volume center conservatism in organ and recipient selection is likely multifactorial but almost certainly is motivated in part by an attempt to maintain excellent results. This notion was also evident in the minutes of the pancreas committee deliberations on the matter: “Committee members hypothesized that a relatively low number of quality donors in a given DSA could be a factor in this trend, compounded by a hesitancy to use less ideal organs knowing that a single poor outcome would result in a quality review of that program. This is not as much of a concern at higher volume centers because a single poor outcome will not have the same magnitude of impact on their actual versus expected outcomes metric.” We agree with this point and suggest that in the case of low volume activity, that OPTN/UNOS and SRTR analyses routinely consider a larger window of activity to relieve the performance pressure for low volume programs to minimize the chances of a single graft loss. This might serve to stimulate more liberal donor and recipient selection.

Finally, given that 70% of pancreas transplant programs perform 10 or fewer transplants/year, we suggest that UNOS reconsider the merits of their focus on yearly program volume for transplants of organs such as pancreas for which there exists a high percentage of low volume programs and no data to suggest that low volume in itself is a measure of program quality and patient outcome.

Committee Response:

The MPSC appreciates the thoughtful comments provided by the ASTS and has addressed the concerns expressed in the Primary Concerns section above.

Comment 10: AST

vote: Oppose

Date Posted: 12/06/2013

It should first be noted that the title of this proposal doesn't make sense. It would seem to be more appropriately stated as either "Transplant Functional Inactivity" or "Lack of Transplant Activity".

The AST understands that transplant volume is important for surgical and medical competence as well as administrative capacity. However, we wonder whether heart programs should be grouped with the intestine and lung programs as having 6 months defined inactivity, rather than 3 months, particularly because a program that does 15-20 heart transplants annually (as many programs do) may well have a period of 3 months of inactivity. Considering 3 months of inactivity for a heart program may be onerous to these programs, but not improve transplant quality. It also needs to be kept in mind that too short a duration to define functional inactivity may result in centers using riskier donors which could lead to worse outcomes. Safeguards need to be put in place to ensure that volume requirements do not result in compromised outcomes. The thresholds noted for the other organs to define functional inactivity appear appropriate (i.e., 3 months for a kidney or liver program, 6 months for a lung or pancreas program, and 12 months for a standalone pediatric program).

The following additional concerns are raised:

1. The majority of programs reviewed for periods of functional inactivity by the MPSC are pancreas programs. There is concern that programs that have an islet transplant program as well as a pancreas transplant program may be disadvantaged if patients are referred for islet transplantation rather than a pancreas transplant. This needs to be addressed or at least monitored.
2. The AST is concerned that access to transplantation could be significantly affected if a functionally inactive program was to inactivate or withdraw. Having a service available 70% of the time in a rural area is more beneficial than not having the service available at all. The AST respectfully disagrees with the PAIS (and MPSC) on the definition of "close proximity" to alternative programs. A 100 to 250 mile drive to an alternative program could severely disadvantage patient access to transplantation. An unintended consequence of reporting inactivity is that it may lead to patients being listed elsewhere, leading to even lower volumes. It is possible that this proposal would in effect drive out of business already struggling transplant programs, even if they have good outcomes, which seems to unfairly provide a competitive advantage to larger programs without any clear reason beyond sheer politics. In addition, knowledge is just one component. Many candidates do not have the financial resources to multi-list or move to another center. The AST encourages the MPSC to continue to evaluate the effect of low volume on patient and graft survival before enacting any changes to existing requirements.

3. Will functionally inactive centers be responsible for helping their patients move to another center?
4. We wonder if in addition to evaluating transplant activity within certain time periods, there should also be consideration of waitlist duration and deaths on the waitlist for candidates who have waited a long time. If a center does a transplant every 3 months and has a waitlist of 60 patients, this might suggest that the center is not adequately serving the patients on the waitlist and that they may be better served at a higher volume center. Centers should be required to let patients know of their long waitlist times if they are flagged as a center that has a long waitlist time.
5. Some guidance should be given as to reactivation of a program. Depending on the cause of the program inactivity, once temporary factors have been addressed, the program should have some guidance in this document or reference to another set of guidelines on the reactivation process.
6. In D.10, there is nothing stating that the MPSC will be reviewing periods of waitlist inactivity; thus it is implied that the transplant program will be responsible for self-review. Even in the absence of nefarious intentions, programs may not be keeping running balances of inactive days (speaking to the 28 cumulative days over 365 consecutive days point). As there may be little incentive for such programs to notify patients, shouldn't the running number of inactive days also be tracked and the program notified if they reach this threshold?
7. From the intestine transplant perspective this proposal carries a great threat. Multivisceral transplantation may occur at volumes of 3-10/year in even a robust intestine program. Pancreas transplants may vary depending on the number of multiviscerals each year. An intestine program not able to do multiviscerals becomes meaningless. So, programs would be punished for wishing to do multivisceral transplants for carcinoid involving the pancreas or for severe mesenteric thrombosis unless there is an independent pancreas transplant program deemed active. Some centers have all these elements, but it may be problematic to deem a certain organ system inactive which could lead to the shutting down of related programs which could affect a center's ability to offer transplant for multiple organs when needed.
8. That the proposal will affect stand alone pediatric transplant programs that do not do a transplant within 12 months is clear. What is not clear is whether this is across the board for all pediatric organs and what the impact on pediatric programs integrated into larger adult programs will be. In order to support the proposal, more information on the effect on pediatric programs/candidates is necessary. The AST would support that pediatric patients transplanted in the context of larger adult programs be afforded the same advantage regarding notification of functional inactivity as the adults in the program. However, the impact of this policy proposal on children is unclear as those programs with functional inactivity may enter into a circular situation where a low volume program that is serving perhaps a geographic need is functionally inactive, the listed patients are notified, they multiple list at another program, get transplanted at another program and it becomes impossible for their home program to increase its volume due to the exodus of patients. The argument that this is not necessarily bad is that the patients were perhaps transplanted sooner, their morbidity and/or mortality on the list are decreased, and a low volume program that should close is put in a situation where it must close. This is only true if there are other transplant options for the listed patients that are reasonable and within geographic reach. For this reason the AST suggests that the proposal include plans to review the impact on pediatric programs and whether closure of any pediatric programs puts children at a disadvantage with regard to opportunities for listing and transplant within reasonable geographic limitations.

Although the AST supports transparency to transplant candidates and recipients as to program volumes and outcomes, the proposal cannot be supported in its current form without further clarification of the issues outlined above.

Committee Response:

The MPSC appreciates the thoughtful comments provided by the AST and has addressed many of the concerns expressed in the Primary Concerns above.

The AST asks if a functionally inactive program will be required to help patients transfer to another program. The current proposal only requires programs to notify candidates and potential candidates of periods of inactivity.

With regard to the suggestion that the MPSC should consider length of time a candidate remains on the waiting list and deaths on the waiting list, the MPSC is currently considering a pre-transplant metric and review of program pre-transplant performance. The MPSC expects that a proposal to implement pre-transplant performance reviews will go out for public comment in Fall 2014.

In response to the comment regarding waiting list inactivity, the only change to that section in the proposal is a minor revisions to fix a duplicative inconsistent provision. However, in response, waiting list inactivity information is available to each program through UNetsm.

With regard to the AST's comment regarding multi-visceral transplants, the concerns expressed will not be an issue unless the pancreas program at the member hospital closes. Please see the discussion in the Primary Concerns above regarding the closing of programs.

The AST further asks about pediatric patients within a combined adult and pediatric program. As noted before, the current proposal does not address the previously determined thresholds for identification of functional inactivity. However, the MPSC will consider the AST's comment during its continuing process improvement reviews.

Comment 11:

vote: Support

Date Posted: 09/06/2013

I support fully, we had to do extensive research in deciding where to have my transplant the activity numbers where not readily available to us. Also found out how much competition there is between hospitals and states for the transplants. My home state was not happy in me leaving the state to be transplanted (no pun intended, lol) As they are trying to build their transplant program.

Committee Response:

The Committee appreciates the commenter's support for the proposal.

Comment 12:

vote: Support

Date Posted: 12/06/2013

NATCO supports this proposal as written.

Committee Response:

The Committee appreciates NATCO's support for the proposal.

Comment 13:*vote: Support**Date Posted: 11/30/2013*

The American Nephrology Nurses' Association supports this proposal without revisions.

Committee Response:

The Committee appreciates the American Nephrology Nurses' Association's support for the proposal.

Comment 14:*vote: Support**Date Posted: 12/04/2013*

The National Kidney Foundation supports this proposal that will ensure that kidney patients on the transplant waiting list at a center that has not performed any kidney transplants in a three month period be notified within 30 days after the transplant center has received its notification of inactivity from the Membership and Professional Standards Committee. This will help ensure that patients receive more timely notification and information about their options, such as listing with a more active program or joining multiple lists, so they can make better informed decisions.

Committee Response:

The Committee appreciates the National Kidney Foundation's support for the proposal.

Post Public Comment Consideration:

After considering responses received during public comment, as well as consideration of the existing requirements, the MPSC, on March 26, 2014, recommended removing the defining phrase following "potential candidates." The definition of "potential candidates" contained in Appendix M, Definitions of the bylaws will apply. In addition, the MPSC recommended removing definitions of "functional inactivity" and "long-term inactivity" from Appendix M, Definitions since these definitions simply restate the language contained in the bylaw and are duplicative. The Committee supported sending these bylaw modification recommendations to the Board of Directors for its consideration: 32 support, 1 opposed, and 2 abstained.

Proposal to Revise the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews

Table of Contents

Title: Proposal to Revise the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews..... 2

Sponsoring Committee: Membership and Professional Standards Committee (MPSC) 2

Summary and Goals of the Proposal:..... 2

Background and Significance of the Proposal: 2

Supporting Evidence and/or Modeling:..... 4

Understanding the Problem..... 4

Description of Flagging Methods 5

Current flag 5

Comparison of Flagging Methods using Historical Data 7

Analysis of True and False Positives..... 8

SRTR Simulation Analyses 9

Deriving the Optimal Flagging Criteria..... 10

Expected Impact on Living Donors or Living Donation: 12

Expected Impact on Specific Patient Populations:..... 12

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule: 12

Plan for Evaluating the Proposal: 12

Additional Data Collection: 12

Expected Implementation Plan:..... 12

Communication and Education Plan: 13

Compliance Monitoring: 13

Policy or Bylaw Proposal:..... 15

Public Comment Responses 17

 1. Public Comment Distribution..... 17

 2. Primary Public Comment Concerns/Questions 17

 3. Regional Public Comment Responses..... 25

 4. Committee Public Comment Responses..... 30

 5. Individual Public Comment Responses..... 34

Post Public Comment Consideration:..... 45

Title: Proposal to Revise the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews

Sponsoring Committee: Membership and Professional Standards Committee (MPSC)

Summary and Goals of the Proposal:

The purpose of this proposal is to better identify those transplant programs that may be underperforming in the area of patient and graft survival. The Bylaw proposal adopts the new Bayesian methodology that will be utilized by the SRTR in the production of the public transplant program performance metrics and establishes new flagging thresholds that maximize the true positive flags while minimizing false positive flags. In doing so, the transplant programs most in need of MPSC review and assistance in improving outcomes will be flagged.

Background and Significance of the Proposal:

As part of its role to monitor compliance and patient safety, the MPSC conducts reviews of transplant program post-transplant outcomes to identify underperforming programs and work with those programs to implement performance improvement measures. The principal tool utilized by the MPSC to identify programs that may merit closer review is performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR). Using data analysis provided by the SRTR and UNOS staff, the MPSC develops thresholds for flagging those programs that may warrant closer review by the Committee. As part of its efforts to periodically review and evaluate the flagging threshold, the MPSC, in collaboration with the SRTR, has spent several years reviewing alternative flagging mechanisms and thresholds to reduce the number of false positive flags and maximize the number of true positive flags. In addition, the MPSC noted during this evaluation period that the current flagging mechanism seemed to be fairly efficient at flagging the large transplant programs that were underperforming but was not as successful in identifying medium and small programs. In fact, a separate methodology has been utilized to identify small volume programs for review.

At the July 2007 MPSC Data Subcommittee (currently Performance Analysis and Improvement Subcommittee (PAIS)) meeting, the SRTR presented information regarding modifications to the current criteria utilized for flagging programs with lower than expected outcomes for patient or graft survival. The Data Subcommittee reviewed the SRTR's proposed modifications to flagging programs in detail during a January 2008 conference call and requested that the SRTR conduct the outcome analysis retrospectively over several cohorts to show programs that would have been flagged if the proposed methodology were implemented. In addition, the subcommittee requested that UNOS staff research and provide historical information about each program that is flagged using the proposed modifications and report back to the subcommittee. During the December 2009 meeting, the MPSC reviewed the retrospective analysis and recommended before adoption that the SRTR conduct a simulation analysis. The modified flagging method, while capturing some of the small volume programs, did not capture all small volume programs that were considered "true positives." As such, the MPSC wanted to identify a hybrid flagging model that would utilize the modified flagging methodology with some sort of small volume flag.

Over several meeting cycles, the MPSC reviewed results from the retrospective analyses and SRTR simulations regarding small volume triggers. The Committee requested additional investigation into small and medium volume programs; this review was conducted by the PAIS and reported to the MPSC during its March 2011 meeting. The Committee recommended a study

of the modifications to the flagging methodology to determine if changes should be made to the thresholds and methodology. This study was conducted and the results were reported at subsequent Committee meetings.

During the March 2012 meeting, the Committee recommended adopting the proposed modified flagging methodology as the sole flagging method. During the July 2012 meeting, the PAIS and the full Committee reviewed proposed bylaw language for the modified flagging methodology. The Committee approved the language and planned to distribute these modifications for public comment during the spring 2013 cycle.

During the December 2012 meeting, the SRTR presented a different approach to the flagging criteria for the MPSC to consider. This new approach uses a Bayesian methodology that the SRTR will be implementing for all public program-specific reports in January 2015. The Bayesian approach was a key recommendation of the SRTR/OPTN Consensus Conference of Program Evaluation¹ and was supported by the 2012 COPSS²-CMS report on “Statistical Issues on Assessing Hospital Performance.” The Committee discussed this approach in comparison to the modified flagging methodology that was approved for public comment during the July 2012 meeting. As a demonstration of this new approach, the SRTR generated a Bayesian Example flagging system that would offer similar performance to the modified flag by identifying more medium volume programs and fewer small volume programs. The Bayes Example flag was based on the distribution of the hazard ratio³, similar to the O/E ratio on which the current and modified flags were based. At the conclusion of the discussions, the Committee rescinded its previous recommendation to send out the modified flagging criteria for public comment, and requested additional analysis to compare the current flagging methodology, the modified flagging criteria, and the Bayesian methodology should the MPSC recommend adopting the Bayesian approach.

At the April 2013 MPSC meeting, staff from both the OPTN and the SRTR contractor gave a joint presentation on post-transplant outcomes flagging using the Bayesian methodology compared to the previous modified flag and the current method. The analysis presented included a review of historical data using the July 2012 and July 2008 PSR cohorts and SRTR simulations. The SRTR conducted an analysis using simulated data and calculated the flagging rates for 57,915 possible Bayesian flagging algorithms. Based on this analysis, optimal flagging thresholds led to the Bayesian Proposed flag in which programs are identified as underperformers if:

- 1) The probability is greater than 75% that the hazard ratio is greater than 1.2, or
- 2) The probability is greater than 10% that the hazard ratio is greater than 2.5.

The above thresholds produced the highest true positive rate while holding the false positive rate to approximately 5% for small, medium and large transplant programs. The MPSC voted to approve these new flagging thresholds but based on a concern that some small volume programs (performing fewer than 10 transplants within the two and a half year evaluation period) with lower than expected performance may still be missed, the Committee agreed to continue to monitor

¹ Report of a Consensus Conference on Transplant Program Quality and Surveillance, AMERICAN JOURNAL OF TRANSPLANTATION, Volume 12, Issue 8, August 2012, Pages: 1988–1996, B. L. Kasiske, M. A. McBride, D. L. Cornell, R. S. Gaston, M. L. Henry, F. D. Irwin, A. K. Israni, N. W. Metzler, K. W. Murphy, A. I. Reed, J. P. Roberts, N. Salkowski, J. J. Snyder and S. C. Sweet
Article first published online : 8 JUN 2012, DOI: 10.1111/j.1600-6143.2012.04130.x

² Committee of Presidents of Statistical Societies

³ In this context, the hazard ratio is a relative comparison of the risk of graft failure or mortality at a given program relative to what would be expected if the program was performing as expected based on national performance, after adjustment for donor and recipient characteristics.

small volume programs per the current method for a period until such time it is agreed that this “safety net” can be safely discontinued. The MPSC will review whether the separate small volume flagging process can be discontinued one year after the implementation of the Bayesian methodology.

The proposed new flagging methodology will result in better identification of those programs that truly need review and assistance to improve their patient and graft survival. The data utilized in the analysis for the new flagging methodology does not change from that currently collected. In addition, the use of this new methodology should result in a decreased unnecessary burden on transplant programs since it will result in fewer false positive flags; and therefore, fewer inquiries to programs that do not require in-depth review of performance by the MPSC. Transplant programs will require education to understand the new Bayesian methodology. However, this education would be required regardless of whether the MPSC utilizes this methodology to flag for performance review because the SRTR will be utilizing the Bayesian methodology for its public performance metrics. In fact, the adoption of this proposal would ensure that consistent methods are utilized for both the public website performance metrics and the performance metrics reviewed by the MPSC, thereby reducing confusion in the community.

The proposal includes the addition of language noting the MPSC’s ability to request that a member voluntarily inactivate its program or a component of the program or withdraw a program based on patient safety concerns arising from review of the program’s graft and patient survival. The inserted language parallels language currently contained in Appendix D.9.B. *Requirements of Functional Inactivity* regarding MPSC review of program functional inactivity and codifies current practice of the MPSC. The MPSC rarely requests that a program inactivate or withdraw. However, there are instances where programs have been requested to inactivate when patient safety is implicated and the MPSC has concluded that a period of inactivation to implement improvements is necessary. Codifying this option in the Bylaws provides more transparency to the process of MPSC post-transplant outcomes review. Finally, Appendix D.10.A. *Transplant Program Survival Rates* has been reorganized for better flow of the content making the provision easier to read and understand.

Supporting Evidence and/or Modeling:

Understanding the Problem

In developing criteria for identifying transplant programs that are underperformers, there are always tradeoffs. No system is perfect, and setting thresholds for performance needs to be accomplished with an overall goal in mind. A given performance threshold may capture the majority of the true underperformers, but may falsely identify many programs that are not truly underperforming (i.e., have a high false positive rate). On the other hand, a different performance threshold may reduce the number of programs that are falsely identified as underperforming, but it may also fail to identify the majority of programs that are true underperformers (i.e., have a low true positive rate, or low power). Since 2009, analyses conducted by the SRTR and the OPTN have suggested that the current flagging method has a high false positive rate (particularly among small volume programs) and is lacking power to detect performance issues at medium volume programs. A high false positive rate has negative implications both for OPTN members and for the MPSC, while maximizing the true positive rate is desired in terms of the overarching MPSC goal of process improvement. As such, the proposed Bayesian flag is expected to address these issues by reducing the overall false positive flagging rate while increasing the true positive flagging rate.

Description of Flagging Methods

In the following sections, references will be made to 4 distinct methods by which OPTN transplant programs may be identified (“flagged”) for post-transplant underperformance: the current flag, the modified flag, the Bayesian Example flag, and the Bayesian Proposed flag. The Bayesian Example flag was developed to flag a similar number of programs when compared with the modified flag and was initially considered by the MPSC. The Proposed Bayesian flag is the flagging system being considered for adoption after further study and review by the MPSC. *Neither the modified flag nor the Bayesian flags have been implemented, but all have been studied by the MPSC as potential alternatives to the current flagging algorithm.* Both the current flag and the modified flag are based on standard statistical methods (i.e., point estimate of the transplant program effect) with traditional hypothesis testing (p-values). In traditional hypothesis testing, a null hypothesis (for example, the transplant program is performing as expected) is rejected if $p < 0.05$. For details of the statistical models used in this approach and frequently asked questions about the Program Specific Reports (PSRs), visit <http://www.srtr.org>.

As its label implies, the Bayesian flags are based on a Bayesian approach to statistical modeling, as recommended in the COPSS report referenced earlier and supported by recommendations from the PSR Consensus Conference. Unlike the current/modified flag, the Bayesian flags are derived from a model-based estimate of the hazard ratio that compares the risk of graft failure/mortality at a given program to what would be expected if the program was performing as expected based on national experience. An advantage of this approach is that the likely *distribution* of the hazard ratio can be estimated, rather than a single point estimate. From this distribution, the probability of underperforming can be estimated, giving the end-user more information with which to make a decision. In other words, the Bayesian methodology provides the members of the MPSC with information about how confident we are that a program’s performance exceeds the predetermined thresholds for review. For more details on this approach, see the COPSS report available on the CMS website.

The four flagging methods are described below. The time period of analysis in all cases is 2 ½ years which is used in the current PSRs. As referenced earlier, the modified flag was the first alternative to the current flagging system that was considered. This was followed by consideration of the Bayesian *Example* flag, which led finally to the Bayesian *Proposed* flag. The Bayesian Example and the Bayesian Proposed are similar in format, but simulation studies (see below) demonstrated that the Bayesian Proposed flag was the optimal choice.

Current flag

- For programs performing fewer than 10 transplants (small volume), at least one death/graft failure
- For programs performing 10 or more transplants, all 3 conditions below must be met for the observed and the expected number of failed grafts or deaths
 - Observed – Expected > 3
 - Observed/Expected > 1.5
 - One-sided p-value < 0.05

Modified flag (irrespective of the number of transplants, at least one of the conditions must be met)

- Observed/Expected > 1.5 and one-sided p-value < 0.05
- Observed/Expected > 2.5

Bayesian Example flag (irrespective of the number of transplants, at least one of the conditions must be met).

For an illustration, see Figure 1 below. The thresholds below were chosen to provide results similar to those of the modified flag. The hazard ratio is similar in concept to the observed/expected ratio used in the current system.

- Probability(Hazard Ratio > 1.25) > 0.75
- Probability(Hazard Ratio > 2.5) > 0.10

Bayesian Proposed flag (irrespective of the number of transplants, at least one of the conditions must be met).

For an illustration, see Figure 1 below.

- Probability(Hazard Ratio > 1.2) > 0.75
- Probability(Hazard Ratio > 2.5) > 0.10

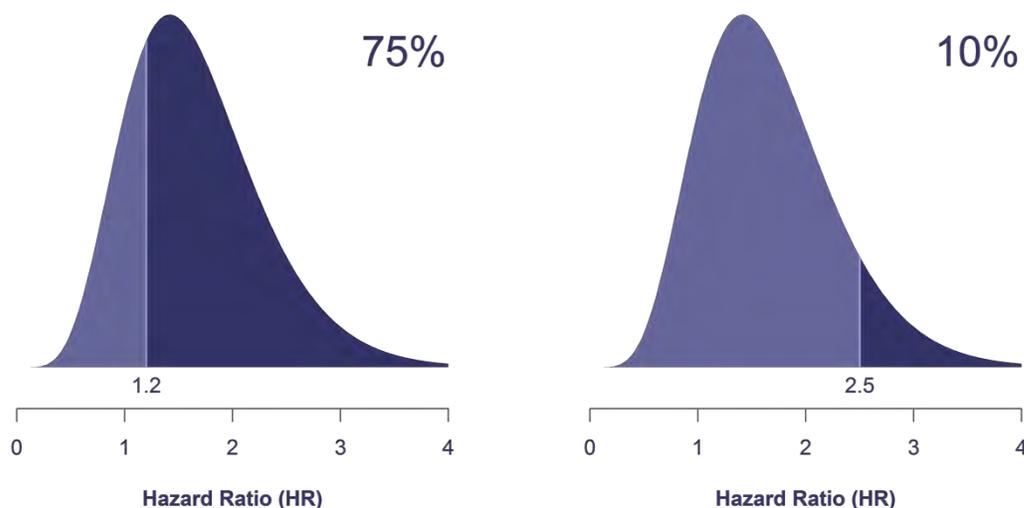


Figure 1. Depiction of Bayesian Proposed Flagging Thresholds. The darker shaded areas represent the probabilities above each flagging threshold. In this example, a program would be flagged if there is a strong probability (75%) that the program is underperforming to a moderate degree (HR > 1.2), or a non-negligible probability (10%) that the program is underperforming to an extreme degree (HR > 2.5). This second condition was added to improve the flagging performance of small volume programs that, due to limited numbers, are less likely to demonstrate a strong probability of underperformance.

Comparison of Flagging Methods using Historical Data

During the initial review by the MPSC, data from the SRTR (July 2012 PSR cohort) were used to identify the number and types of programs flagged by the current method as well as the alternative methods (modified flag and the Bayesian Example Flag) *had they been in place during that period*. This report was based on transplants from January 1, 2009 to June 30, 2011. Table 1 below shows the number of programs flagged by each method.

Table 1. Method by which Programs were Flagged in the July 2012 PSR Cohort.

Flagging Category	Number	Percent
All 3 Flags	63	48.5
Current and Modified Only	22	16.9
Modified and Bayesian Example Only	23	17.7
Current Only	17	13.1
Modified Only	3	2.3
Bayesian Example Only	2	1.5
Total	130	100.0

From Table 1, there were 102 programs flagged by the current method, and 88⁴ programs flagged by the Bayesian Example. Note that there were 39 programs flagged by the current method that were not flagged by the Bayesian Example. This includes 22 programs that were flagged by the both the current and the modified method, and 17 programs that were flagged by the current method only. Additional details about these programs are summarized below.

- Current flag (n=102 programs)
 - 61 adult programs
 - 41 pediatric programs
 - Of 102 total, 54 small volume programs
- Bayesian Example flag (n=88 programs)
 - 59 adult programs (48 also flagged by current 11 new)
 - 29 pediatric programs (15 also flagged by current, 14 new)
 - Of 88 total, 15 small volume programs
- Current flag, but not flagged by Bayesian Example (n=39 programs)
 - 13 adult programs
 - 26 pediatric programs
 - All small volume

Among those programs flagged by the Bayesian Example were 25 programs (11 adult and 14 pediatric programs) that were not flagged by the current method. In this group, transplant volumes ranged from 10 to 161. The Bayesian Example also flagged fewer small volume programs, which an adjunct study (see next section) found to have a high percentage of false positives using the current method. Of the 39 programs flagged by the current method but not flagged by the Bayesian Example, all were small volume, and most (34) had only one death or graft failure. Only 10 programs were still under review by the MPSC as of March 2013. Of these, only one program's

⁴ A simulation study (see SRTR Simulation Analyses, below) demonstrated that decreasing the first Bayesian threshold from Probability (HR > 1.25) to Probability (HR > 1.2) flagged 97 programs which is comparable to that of the current method that flagged 102 programs.

performance was of particular concern to the Committee. This program has entered into a Systems Improvement Agreement with CMS.

Analysis of True and False Positives

In the fall of 2009, the OPTN conducted a retrospective study on behalf of the MPSC to compare the performance of the current flag to that of the modified flag. A key component of the study was the ascertainment of the false positive flagging rate associated with each method. In 2012, the SRTR updated the analysis to include the Bayesian Example flag for comparison. Using data from the January 2007, July 2007 and the January 2008 PSR cohort, programs flagged were reviewed for significant actions taken by the MPSC during the ensuing one-year period. A significant action was defined as an informal discussion, peer visit, formal interview, and/or a decision to continue to monitor the program for performance. If the Committee took no significant actions and the program was released from review after the one-year period, the flag was considered to be a false positive. Otherwise, the flag was considered to be a “true” positive⁵. Of the 128 programs flagged by the current method in the January 2008 PSR cohort, 57 programs (44.5%) were found to be true positives, while 71 programs (55.5%) were found to be false positives. Table 2 and Table 3 show these flagging results for the programs in each group. Note that similar results were found in the January 2007 cohort (56% of programs flagged were false positives) and the July 2007 cohort (58% of programs flagged were false positives).

Table 2. The Number of True Positive Programs Flagged by the Modified and Bayesian Example Method. Based on the January 2008 PSR cohort, including transplants from July 1, 2005 to December 31, 2007.

Flagging Category	Number of Programs	Percent
Modified and Bayesian Example	46	80.7
Modified Only	1	1.7
Neither Method	10	17.5
TOTAL	57	100.0

From Table 2, each method flagged about the same percentage of true positives. The Bayesian Example method flagged 46/57, or 81%, while the modified flag identified 47/57, or 82%. The Bayesian Example method failed to flag 11 of the 57 true positive programs. All 11 programs were small volume programs, 9 of which had only one event.

Table 3. The Number of False Positive Programs Flagged by the Modified and Bayesian Example Method. Based on the January 2008 PSR cohort, including transplants from July 1, 2005 to December 31, 2007.

Flagging Category	Number of Programs	Percent
Modified and Bayesian Example	29	40.8
Modified Only	17	23.9
Neither Method	25	35.2
TOTAL	71	100.0

⁵ An overall true positive or false positive rate cannot be derived from these retrospective data since the actual number of programs in the cohort that were true underperformers is unknown. We know only the number flagged by either the current method or by the Bayesian Example method; it is possible that other programs would have been flagged using alternative methods.

From Table 3, the Bayesian Example method had a much lower number of false positives, incorrectly flagging 41% of the false positive programs (29/71), while the modified flag incorrectly identified 65% of the false positive programs (46/71).

In addition, of the 71 false positive programs, 60 (85%) were small volume. The Bayesian Example Flag method incorrectly flagged 18 of these 60 (30%) while the modified flag incorrectly identified 35 (58%) of these programs.

SRTR Simulation Analyses

Because the number of programs that are true underperformers is unknown in the actual data, it is useful to compare flagging algorithms using simulated data. In a computer simulation, the analyst can generate data that comports with a hypothesized distribution (e.g., HR=1, HR=2, etc.) and then study how well a system designed to detect performance outliers actually works when one knows the “truth.” Figures 2 and 3 below show the results of four such simulation analyses, where the underlying probability of graft failure/death ranged from 0.05 to 0.15 for each transplant.

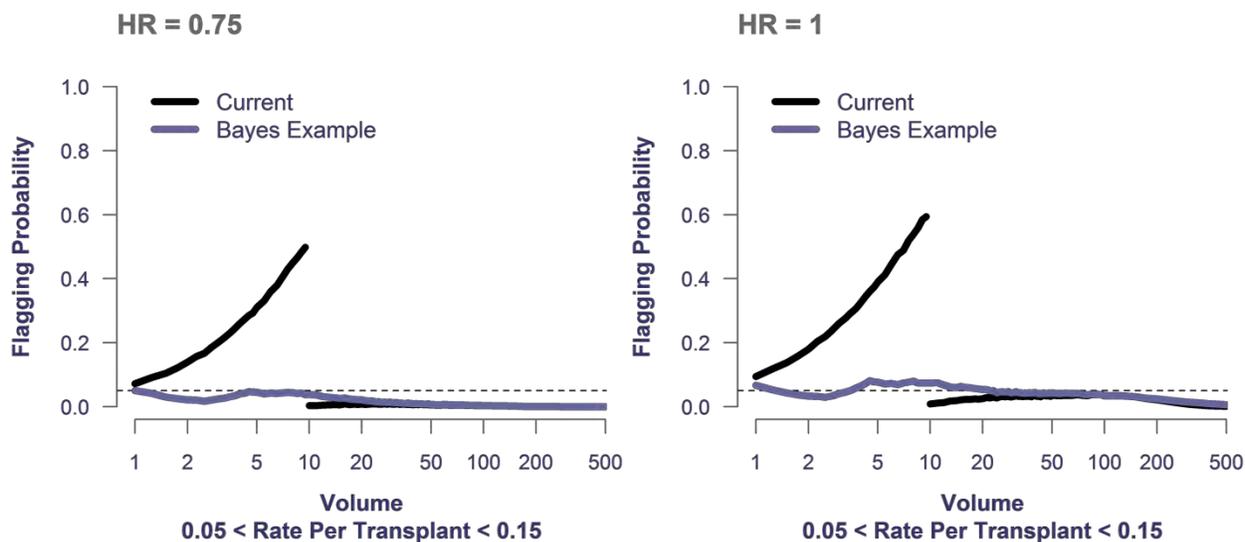


Figure 2. Simulated False Positive Flagging Rates for the Current Flag and Bayes Example Flag as a Function of Transplant Volume. Programs with HR=0.75 (number of graft failures/deaths fewer than expected) or HR=1 (number of graft failures/deaths as expected).

From Figure 2, note the high false positive rate for the current method at volumes below 10, while the Bayes Example flag maintains the desired rate of about 5% or below irrespective of volume.

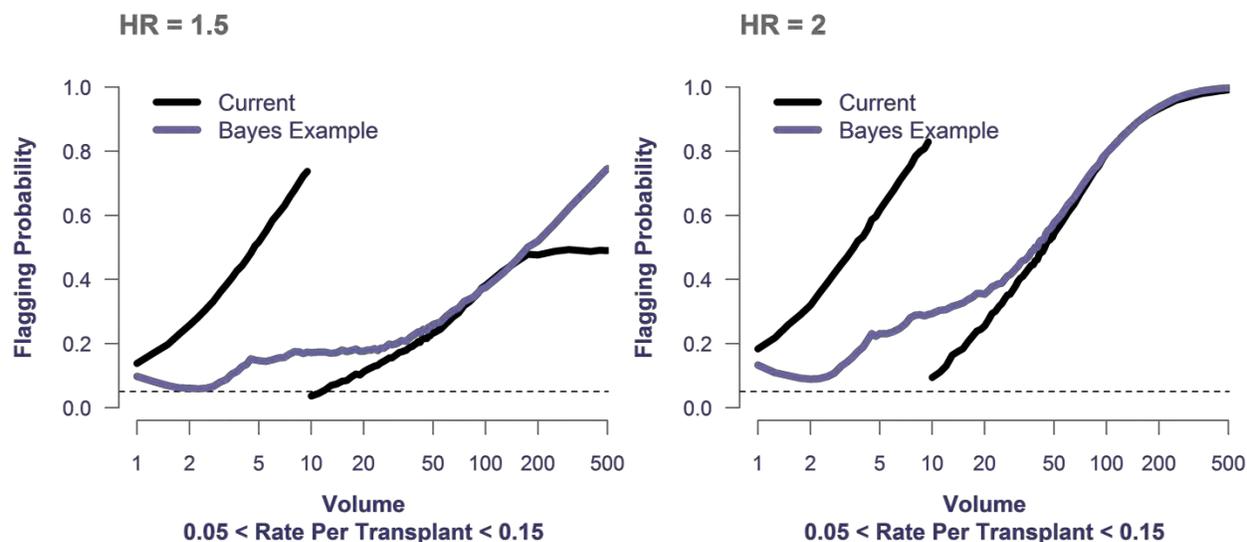


Figure 3. Simulated True Positive Flagging Rates for the Current Flag and Bayesian Example Flag as a Function of Transplant Volume. Programs with HR=1.5 or HR=1.2 (more graft failures/deaths than expected).

From Figure 3, the current method has a greater true positive flagging rate at low volumes (which is offset by a greater false positive rate in Figure 2), but the Bayes Example Flag outperforms the current flag at volumes between 10 and 50 transplants. Beyond 50 transplants, the two methods have similar true positive rates of flagging when the HR=2, but the current method flags less often when the HR=1.5.

Deriving the Optimal Flagging Criteria

The Bayesian Example flag used in preliminary deliberations described above was developed to identify similar programs that are identified by the modified flagging system. In order to identify the optimal flagging system that would maximize the ability to identify underperforming programs while holding the rate of false positives relatively low across small, medium and large programs, the SRTR performed a simulation study that compared the properties of nearly 58,000 Bayesian flagging systems. In order to compare each potential flagging systems to all others considered, the SRTR created a scoring system. A flagging system received a penalty of 5 points for every percent the false positive rate differed from 5% for each program when the simulated hazard ratio was equal to 1. A penalty of 1 point was received for every percent the true positive rate differed from 100% when the simulated hazard ratio was equal to 2.

Graft failures were then simulated in two different ways. In the first scenario, all Heart, Kidney, Liver, and Lung programs had graft failures consistent with the expected number at 1 year for adult recipients in the July 2012 PSR. This scenario was replicated 2,500 times. In the second scenario, graft failures were generated for the same programs at a rate that was twice the expected number. This scenario was also replicated 2,500 times. Flagging rates for 57,915 possible Bayesian flagging algorithms and their associated score were calculated. The results for the top five Bayesian algorithms as well as the Bayesian Example algorithm and the current flagging system appear in Table 4.

Table 4. Scoring of Potential Flagging Algorithms

System	Rank	Criteria 1		Criteria 2		Simulation Score (smaller is better)
		Hazard Ratio is greater than:	With Probability greater than:	Hazard Ratio is greater than:	With Probability greater than:	
Bayesian #1	1	1.20	0.75	2.50	0.10	283.0
Bayesian #2	2	1.20	0.75	2.25	0.15	283.1
Bayesian #3	3	1.20	0.75	2.90	0.05	283.3
Bayesian #4	4	1.25	0.70	2.50	0.10	283.4
Bayesian #5	5	1.20	0.75	2.45	0.10	283.6
Bayesian Example	2,163	1.25	0.75	2.50	0.10	303.4
Modified Flag	6,912	Modified Flag (O/E>1.5 & p<0.05, or O/E>2.5)				329.5
Current Flag	11,987	Current Flag (O/E>1.5 and p<0.05 and O-E>3)				354.9

Note that the flagging criteria for the optimal method (rank=1) shown in Table 4 is very similar to the Bayesian Example method, yet the ranks of the two methods are substantially different (rank=1 vs. rank=2,163). Compare this to the ranks of the modified flag (rank=6,912) and the current flag (rank=11,987). Based on these results, the flagging criteria that maximizes the true positive rate while holding the false positive rate near 5% is the Bayesian Proposed flag (#1) from row 1 in Table 4:

Probability (HR > 1.2) > 75% OR
Probability (HR > 2.5) > 10%

Table 5 shows the number of programs flagged by each method for the July 2012 PSR cohort.

Table 5. Programs Flagged by Selected Methods, by Volume: July 2012 PSR Cohort. The numbers following the Bayesian flags refer to the ranking in Table 4.

Volume	Programs	Total Transplants Performed	Current	Bayes Proposed	Bayes # 2	Bayes # 3	Bayes # 4	Bayes # 5	Bayes Example
[1,10)	223	799	54	15	14	19	15	19	15
[10,50)	270	7,519	22	44	44	44	47	45	43
[50,100)	126	9,139	11	19	19	19	19	19	14
[100,250)	147	23,694	11	15	15	15	13	15	12
[250,744)	61	23,977	4	4	4	4	4	4	4
Total	827	65,128	102	97	96	101	98	102	88

As shown in Table 5, the proposed algorithm (Bayesian Proposed) flags substantially fewer small volume programs than the current method, while substantially increasing the number of programs flagged in the 10-49 range as well as the 50-100 range. Beyond a volume of 100, the two methods flag a similar number of programs. The overall number of programs flagged is also similar (97 vs. 102). Note that both the simulations and the historical analysis support that many of the current small volume flags are false positives. The proposed Bayesian system should shift focus away from many false positive small volume flags toward medium volume programs that are more likely to be true positives. Furthermore, as can be seen in column 3 of Table 5, many more transplants are performed in the medium volume programs compared to the small volume programs, so this shift in focus is likely to have the potential to improve outcomes for a greater proportion of the transplant population.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

This Bylaw revision has no known impact for specific patient populations.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal addresses the OPTN key goals of improving post-transplant survival and promoting transplant patient safety through better identification of those transplant programs that are underperforming in the areas of patient and graft survival. Therefore, MPSC review and assistance in improving those outcomes will be targeted where needed.

Plan for Evaluating the Proposal:

The MPSC, in collaboration with the SRTR, will continue to monitor whether the new methodology is flagging those transplant programs that are truly underperforming in the areas of patient and graft survival. In addition, the MPSC will continue to receive reports for small volume transplant programs patient and graft survival under the current methodology in order to evaluate whether the Bayesian methodology is adequately capturing underperforming small volume transplant programs.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If approved by the Board of Directors, implementation of this proposal will be guided by the SRTR's schedule for implementing the use of the Bayesian methodology to produce transplant program performance metrics.

Since the flagging is solely a screening mechanism to identify programs that need further inquiry, the process of review by the MPSC will not change. This proposal will not require programming in UNetSM.

Communication and Education Plan:

The proposal provides details on the new flagging methodology and thresholds that will be utilized by the MPSC to determine the programs that require closer scrutiny. The MPSC plans to take this opportunity to educate the community on the process for MPSC review of transplant program performance as well as the proposed new methodology and flagging thresholds through a series of educational offerings.

In addition, notification of the policy would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Transplant Pro/Member Communications archive article
- Presentation at Regional meetings

The new flagging methodology will be incorporated into the OPTN Evaluation Plan, and education could accompany efforts to notify members of periodic updates to the plan.

Compliance Monitoring:

The proposal revises a tool used in the monitoring of patient and graft survival. Since the flagging is solely a screening mechanism to identify programs that need further inquiry, the process of review by the PAIS/MPSC will not change.

The current process of review is as follows. Once a program is identified for review, the program is sent a survey of inquiry to complete unless the program was released from review during the last two meeting cycles. This survey requests a validation of the data submitted into UNetsm and information regarding program activity such as the number of patients the program evaluated for listing during a designated time period. Additionally, the survey provides the program an opportunity to inform the PAIS of unique clinical aspects that may have influenced the observed survival rates. A synopsis of the deaths and/or graft failures that occurred within one year of transplant is also requested for review. The PAIS considers changes in key personnel, changes to processes and procedures within the transplant program, proactive and introspective reviews of program performance, as well as the cause of graft failure and/or death in determining which programs require further review.

Following review of the information submitted by the program, the PAIS may make any number of recommendations for programs under review due to outcomes. Recommendations regularly utilized by the PAIS include:

Release from reporting: the PAIS may release a program from review if satisfied that the issues that led to the lower than expected outcomes have been addressed by the program and/or the survival rates in subsequent years have improved. Programs typically must demonstrate improved one-year post transplant outcomes for two consecutive cohorts to be considered for release.

Releasing a program from reporting does not mean that the program is no longer subject to performance reviews conducted by the PAIS. Rather, the program is released from actively reporting to the PAIS at that time. A program can be introduced back into the PAIS performance

reviews if, in subsequent cohorts, it does not meet the performance thresholds established by the PAIS.

Continue to report: In its simplest form, a recommendation for continued monitoring by the PAIS is a recommendation for continued reporting for the next meeting cycle. Reports for programs continuing in monitoring include validation of UNetsm data and routine activity reports, which summarize quarterly program activities such as new referrals, evaluations, additions to wait list, and transplant activity. Programs that continue in monitoring may also be asked specific questions relating to the review including updates on personnel recruitment, creation of an action plan to formalize plans for improvement, synopses of recent deaths and/or graft failures not previously summarized for the PAIS, and copies of protocols/clinical pathways.

Additionally, programs may be asked to complete a more detailed questionnaire, the Expanded Outcomes Questionnaire. This survey instrument includes more detailed questions on program operations, and is sometimes a precursor to the recommendation for a peer visit or informal discussion.

Informal Discussion: Programs may be offered the opportunity to meet with the PAIS informally, through a teleconference. An informal discussion provides the members of the PAIS the ability to ask questions of program personnel in real time, and allows the program personnel to address issues that are sometimes hard to summarize in the paper submissions. Programs can be invited to participate in an informal discussion with the PAIS if the program has not been able to identify steps to improve patient outcomes, there has been an apparent lack of progress in implementing the site visit recommendations, or if the PAIS simply wishes to discuss particular issues with the program. An informal discussion does not constitute an adverse action.

Peer Visit: Some programs with lower than expected survival rates may be recommended to undergo a peer review site visit. Typically, programs must exhibit lower than expected outcomes over two or more cohorts before the PAIS makes this recommendation. All programs recommended for a peer visit must complete the Outcomes Expanded Questionnaire.

The peer visit team generally includes a transplant surgeon, physician, and administrator, and is supported by a UNOS staff member. Typically, the panel is on-site for two days to conduct interviews of all key personnel to the program, including ancillary support, as well as an in-depth review of the patient charts for those transplants that resulted in death or graft failure. At the conclusion of the site visit, the panel provides the center with a preliminary (verbal) summary of its findings. A formal report is submitted to the PAIS for issuance to the program.

Once a program has undergone a peer visit and received the report, the PAIS requests a plan for quality improvement be submitted in response to the recommendations contained within the report. The Committee continues to monitor the program's progress in implementing the site visit recommendations as well as changes in their subsequent one-year survival outcomes.

Policy or Bylaw Proposal:

1 At a meeting of the OPTN/UNOS Board of Directors convened on June 23, 2014 in Richmond, VA, the
 2 following resolution is offered.
 3

4 *A resolution to better identify those transplant programs that may be underperforming in the area of*
 5 *patient and graft survival.*
 6

7 Sponsoring Committee: Membership and Professional Standards Committee
 8

9 **RESOLVED, that Bylaws Appendix D. Membership Requirements for Transplant Hospitals and**
 10 **Transplant Programs, Section D.10 A. and Appendix M. Definitions are modified as set forth**
 11 **below, effective January 1, 2015.**
 12

D.10 Additional Transplant Program Requirements**A. Transplant Program ~~Survival Rates~~ Performance Reviews**

16 The MPSC will conduct reviews of transplant program performance to identify underperforming
 17 transplant programs and require the implementation of quality assessment and performance
 18 improvement measures. One measure of transplant program performance is triggered through a
 19 review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics
 20 produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to
 21 identify transplant programs that have lower than expected outcomes.
 22

23 For programs performing 10 or more transplants in a 2.5 year period, †The MPSC will review a
 24 transplant program if it has a higher hazard ratio of mortality or graft failure than would be
 25 expected low survival rate compared to the expected survival rate for that transplant program.
 26 The criteria used to identify programs with a hazard ratio that is higher than expected will include
 27 either of the following:
 28

- 29 1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
- 30 2. The probability is greater than 10% that the hazard ratio is greater than 2.5.
 31

32 For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a
 33 transplant program if the program has one or more events in a 2.5 year cohort.
 34

35 The MPSC review will be to determine if the higher hazard ratio low survival rate or events can be
 36 explained by patient mix or some other unique clinical aspect of the transplant program. If a
 37 program's performance cannot be explained by patient mix or some other unique clinical aspect
 38 of the transplant program in question, the member program, in cooperation with the MPSC, will
 39 adopt and promptly implement a plan for quality improvement. The member's failure to adopt and
 40 promptly implement a plan for quality improvement will constitute a violation of OPTN obligations.
 41

42 The MPSC may conduct a peer visit to the program at member expense and may require the
 43 member to adopt a plan for quality improvement. The MPSC may also require, at its discretion,
 44 that the member participate in an informal discussion.
 45

46 As part of this process, the MPSC may conduct a peer visit to the program at member expense.
 47 The MPSC may also require, at its discretion, that the member participate in an informal
 48 discussion. The informal discussion may be with the MPSC, a subcommittee, or a work group, as
 49 determined by the MPSC. The informal discussion will be conducted according to the principles of
 50 confidential medical peer review, as described in Appendix L of these Bylaws. The informal
 51 discussion is not an adverse action or an element of due process. A member who participates in
 52 an informal discussion with the MPSC is entitled to receive a summary of the discussion.
 53

54 The MPSC may recommend that a member inactivate a program or a component of a program or
 55 withdraw its designated transplant program status based on patient safety concerns arising from
 56 review of the program's graft and patient survival. If the program fails to inactivate or withdraw its
 57 designated transplant program status when the MPSC recommends it do so, the MPSC may
 58 recommend that the Board of Directors take appropriate action as defined in *Appendix L:*
 59 *Reviews, Actions, and Due Process* of these Bylaws.

60
 61 While the precise statistical criteria may be selected by the MPSC, the initial criteria used to
 62 identify programs with low patient or graft survival rates will include ~~all~~ of the following:

- 63 1. ~~The finding that *observed events* minus *expected events* is greater than 3.~~
- 64 2. ~~The finding that the *observed events* divided by *expected events* is greater than 1.5.~~
- 65 3. ~~There exists a one-sided *p value* less than 0.05.~~

66
 67
 68 ~~*Observed events* are deaths or graft losses as reported in UNETsm database. *Expected events*~~
 69 ~~are deaths or graft losses as calculated using organ-specific transplant models.~~

70
 71 ~~Those programs whose actual observed patient or graft survival rates fall below their expected~~
 72 ~~rates by more than a threshold will be reviewed. The absolute values of relevant parameters in~~
 73 ~~the formula may be different for different organs, and may be reviewed and modified by the~~
 74 ~~MPSC, subject to Board approval.~~

75
 76 ~~If a program's performance cannot be explained by patient mix or some other unique clinical~~
 77 ~~aspect of the transplant program in question, the member, in cooperation with the MPSC, will~~
 78 ~~adopt and promptly implement a plan for quality improvement. The member's failure to do so will~~
 79 ~~constitute a violation of OPTN obligations.~~

80 81 **Appendix M: Definitions**

82 83 **E**

84 85 **Event**

86 Any death or graft loss that occurred within one year of transplant.

87 #

Public Comment Responses

1. Public Comment Distribution

Date of distribution: 9/6/2013

Public comment end date: 12/6/2013

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	42	33 (78.6%)	0 (0%)	9 (21.4%)	8
Regional	11	8 (72.7%)	0 (0%)	3 (27.3%)	0
Committee	18	7 (87.5%)	0 (0%)	1 (12.5%)	10

2. Primary Public Comment Concerns/Questions

Initially, the MPSC would like to thank all of the regions, committees, organizations and individuals that took the time to carefully review and provide thoughtful comments on this proposal. Many of the comments received expressed common concern that will be addressed in this section on primary concerns and questions. All comments received have been included within the document. However, if the concerns raised in the comment have been addressed in this initial response, no individual response will be noted. Any unique concerns will be addressed below the related comment.

Support for the appropriateness of thresholds and 5% false positive rate

Many of the comments received expressed concerns that too many programs are and would be flagged under the new proposal. In addition, some commenters suggested that the 5% false positive rate was too high. The implications of both of these concerns are that a flag indicates that the program is an underperformer. The ASTS and other commenters suggested that the MPSC should implement a hazard ratio for peer review, separate from the hazard ratio for flagging. For purposes of the MPSC, the threshold for flagging is the hazard ratio for peer review. Unfortunately, partly based on other uses, the term “flag” has taken on a more negative meaning in the transplant community, namely that a program is bad or an underperformer. The MPSC submits that, as the thresholds were originally intended, the threshold contained in the current proposal should be viewed as the “threshold for peer review” and not a threshold for identifying a program as an underperformer.

The flag is simply a screening tool and is solely an attempt to make the number of programs that need to be evaluated and reviewed by staff and the MPSC manageable and to reduce the burden on programs that clearly are performing as expected or better on post-transplant outcomes, not to definitively identify the underperformers. Without these thresholds, the MPSC would, in order to fulfill its charge, need to review all programs, placing an undue burden on the MPSC and programs whose post-transplant outcomes are as expected or better. With that goal in mind, not all 100+ of the identified programs are reviewed by the MPSC. The data provided by the SRTR on the number of programs flagged in the July 2012 reports (102 programs) is the number of programs identified as either falling below the thresholds for large volume programs or having at

least one event in the 2.5 year cohort for small volume programs. The flags only limit the number of programs that the MPSC may review. If we continue to use the July 2012 cohort as an example, the following table provides information on the number of programs that were actually reviewed by the MPSC:

	Large Volume	Small volume	Total
Newly identified	8	2	10
Already under review	27	13	40
New component flagged, combined with component already under review	2		2
Not reviewed ¹	11	39	50
Total flagged	48	54	102
Total Reviewed	37²	15	52

¹Not reviewed:

Large volume: released in the last 2 MPSC cycles or had withdrawn or inactivated the program.

Small volume: did not meet the MPSC review criteria, had been released in the last two cycles or had withdrawn or inactivated the program.

²if you count the additional components of a program already under review.

As this data illustrates, a flag under the MPSC thresholds often does not lead to a review by the PAIS/MPSC. Only 52 of the 102 programs flagged in the July 2012 report entered review or continued under monitoring by the MPSC. Survival data in and of itself does not provide an adequate basis for determining if a program is an underperformer and needs assistance in implementing performance improvement measures. Peer review of a program's response to the MPSC inquiry and raw data about the program is the appropriate avenue to determine whether a program is truly underperforming. Following initial flagging, the PAIS sends the flagged program a survey of inquiry to complete unless the program was released from review during the last two meeting cycles. This survey requests a validation of the data submitted into UNetsm and information regarding program activity such as the number of patients the program evaluated for listing during a designated time period. Additionally, the survey provides the program an opportunity to inform the PAIS of unique clinical aspects that may have influenced the observed survival rates. A synopsis of the deaths and/or graft failures that occurred within one year of transplant is also requested for review. The PAIS considers recent raw outcome data, other SRTR analyses and MPSC metrics, recent and/or pending personnel changes, recent changes in program status, issues identified by center under review, history of previous reviews, changes to processes and procedures within the transplant program, proactive and introspective reviews of program performance, as well as the cause of graft failure and/or death in determining which programs require further review. The members of the PAIS perform an extensive and thoughtful review of the available information on a program.

Although the 5% false positive rate may seem high, in the interest of patient safety, the MPSC has chosen flagging thresholds that cast a wider net to try to ensure that those programs that are underperforming and need assistance to implement performance improvement measures are identified rather than using a narrower threshold that increases the risk of missing programs where there are serious issues with patient safety. In compliance with this premise, a false positive rate of 5% was identified. Those programs identified through flagging who in fact are not underperformers will be identified through peer review and released from review. The peers on the MPSC review raw data and submissions by an identified program to determine if a program is underperforming. Through the use of a request for information, MPSC can determine if there

are factors or unique circumstances that may not be captured by the risk adjusted model that are affecting the program's outcomes.

Small number of actions consistent with goal of performance improvement

Some of the comments noted that the small number of "actions" taken by the MPSC in outcomes reviews is evidence that too many programs are being flagged. Although "actions" is not defined in the comments, the MPSC is assuming that this would include adverse actions, other punitive actions, requests to inactivate, peer visits and informal discussions. As noted in the applicable bylaw, the goal of the MPSC process for review of program performance is not a punitive process but performance improvement. Accordingly, there is no provision in the bylaws for the MPSC to take an adverse action or any of the punitive actions noted in Appendix L of the bylaws based solely on a program's post-transplant performance. In the overwhelming majority of reviews, the process of communication between the PAIS and the program over a period of monitoring is the catalyst for the program to improve its performance through the implementation of performance improvement measures. Requests for inactivation, peer visits and informal discussions are used sparingly and only in those situations where the PAIS/MPSC determines there are significant and immediate patient safety concerns or where improvement has not been demonstrated over a significant period of monitoring. The MPSC would, therefore, suggest that the small number of "actions" is not evidence that too many programs are flagged but that the process of monitoring by the PAIS is successful at moving programs toward better self-evaluation and more effective performance improvement plans and measures without the use of more serious actions.

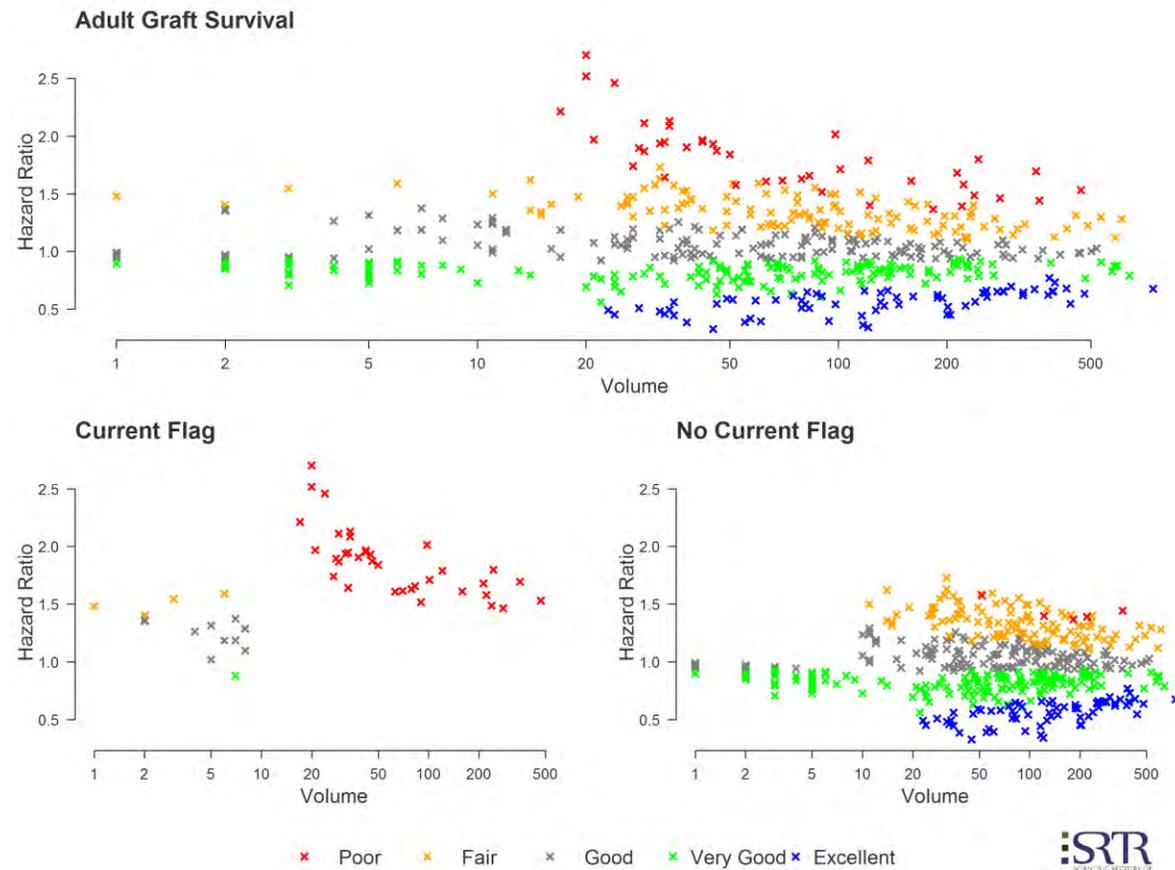
Further explanation of purpose of development of new thresholds, including new data

Although a similar number of programs would be flagged under the new thresholds, the distribution of the flags will change to better capture programs in the medium volume range (10-100 transplants over 2.5 year cohort) and to significantly decrease the number of small volume programs (1-9 transplants over 2.5 year cohort). In reviewing the two statistical models and developing the proposed new threshold, the MPSC reviewed both historical data and simulated data. Since it is impossible to accurately identify true positives without reviewing every program individually, the proposed flagging boundaries were developed based on simulated data where the true underperformers were known. The SRTR simulated the outcomes to see which flagging boundaries best captured the simulated underperforming programs while avoiding the programs that were not underperformers. The thresholds contained in the proposal are the best performing flagging boundaries, out of close to 60,000 tested, that met those goals. So although the MPSC did not determine all truly underperforming programs in developing the new proposed thresholds, the SRTR tried to provide the next best thing by creating a simulation where it was possible to know the truly underperforming programs and test the possible flagging boundaries.

Some of the commenters were concerned that more medium volume programs will be identified without clear data that demonstrates that underperforming medium volume programs are not captured by the current flagging thresholds. Because of low statistical power in the medium volume range, the current flagging system is almost certainly missing programs that are true underperformers. The committee agrees that the proposal assures that more medium sized programs will be identified because that was one of the goals that it was designed to meet. Currently, the MPSC is not meeting its charge of reviewing program performance for those medium volume programs because of the low power of the current model and thresholds to identify programs in that range.

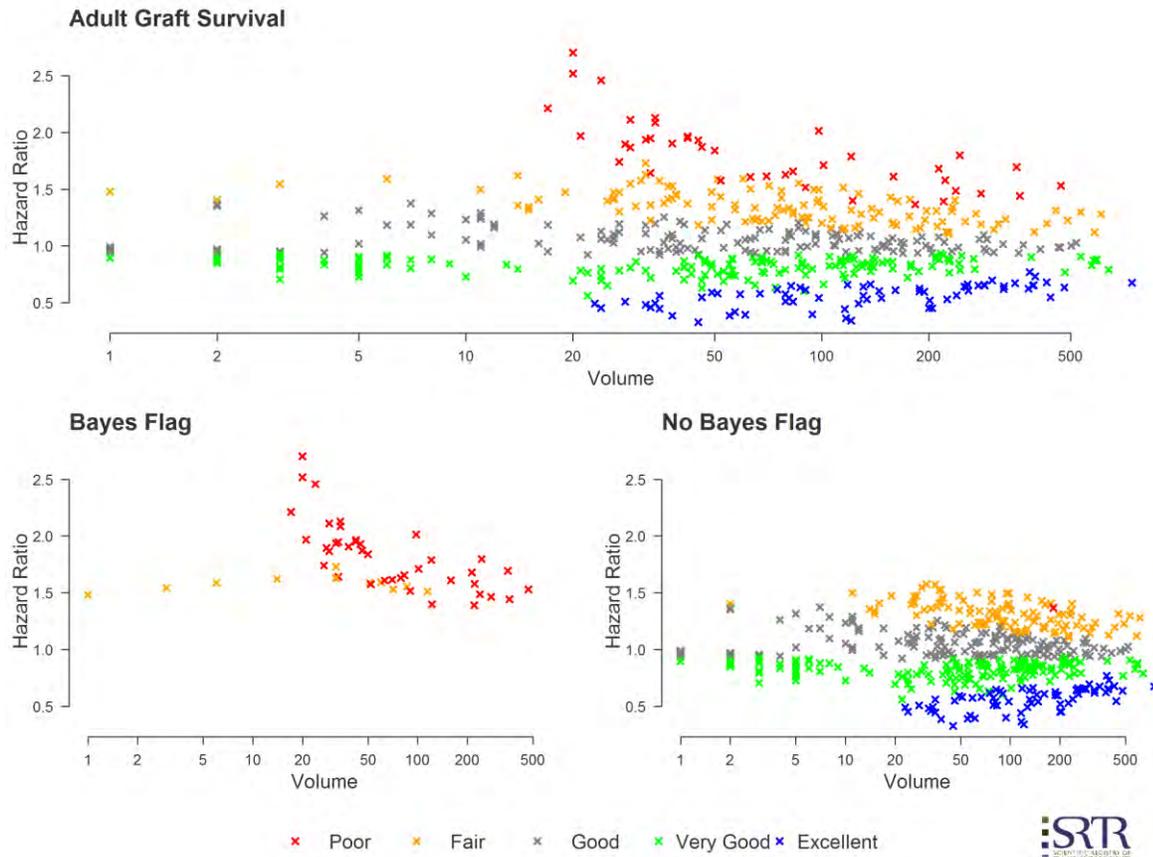
The Bayesian model and the new thresholds have higher power in that medium volume range, and therefore, should be better than the current system at capturing true underperformance. In a further analysis by the SRTR, data from the July 2012 PSR was used to create plot graphs of all programs, color coding them into five performance groups based on where the program falls approximately along the hazard ratio continuum. As an example, the following graph shows the distribution of programs for adult graft survival. The flagging results were then plotted for the current flagging system and the proposed Bayesian flagging system. The graph to the left shows those programs that are or would be flagged and the graphs to the right show programs not flagged.

Current flagging system:



- Excellent = Strong evidence of better than expected outcomes
- Very Good = Some evidence of better than expected outcomes
- Good = As expected (or little evidence to the contrary)
- Fair = Some evidence of worse than expected outcomes
- Poor = Strong evidence of worse than expected outcomes

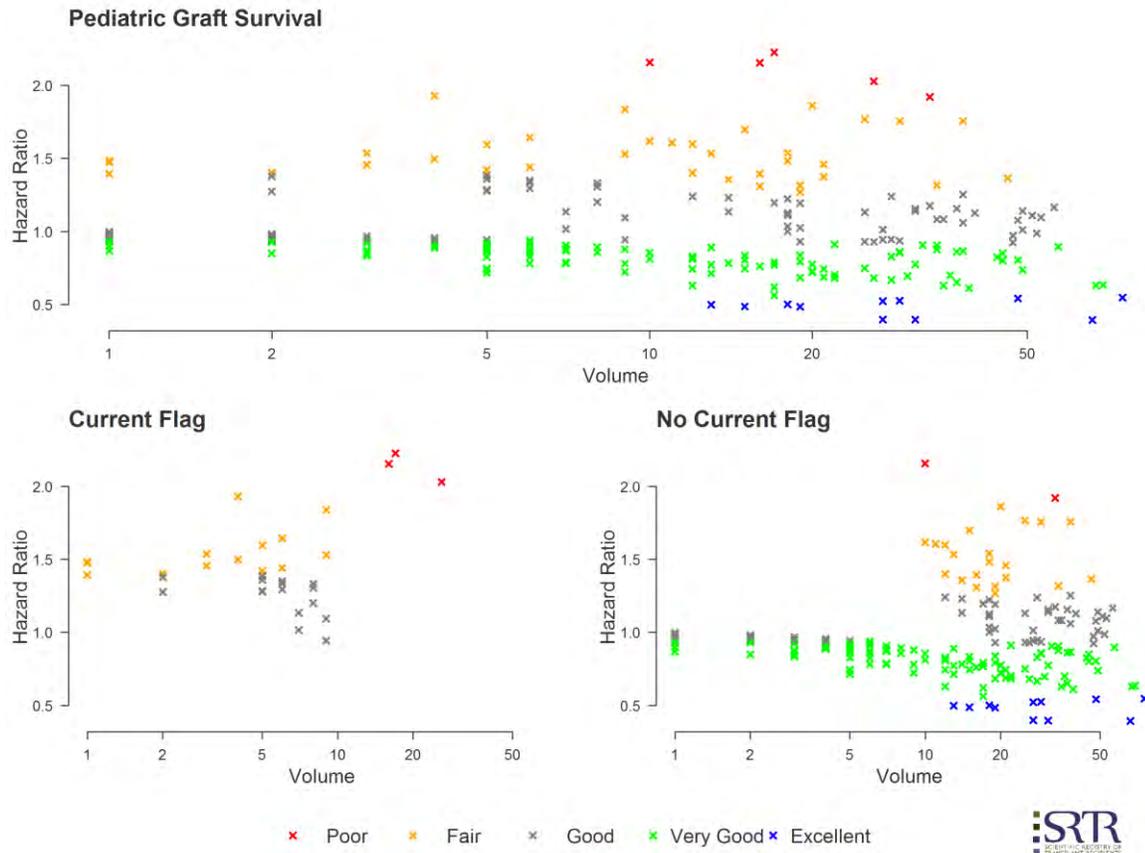
Bayesian Flagging System



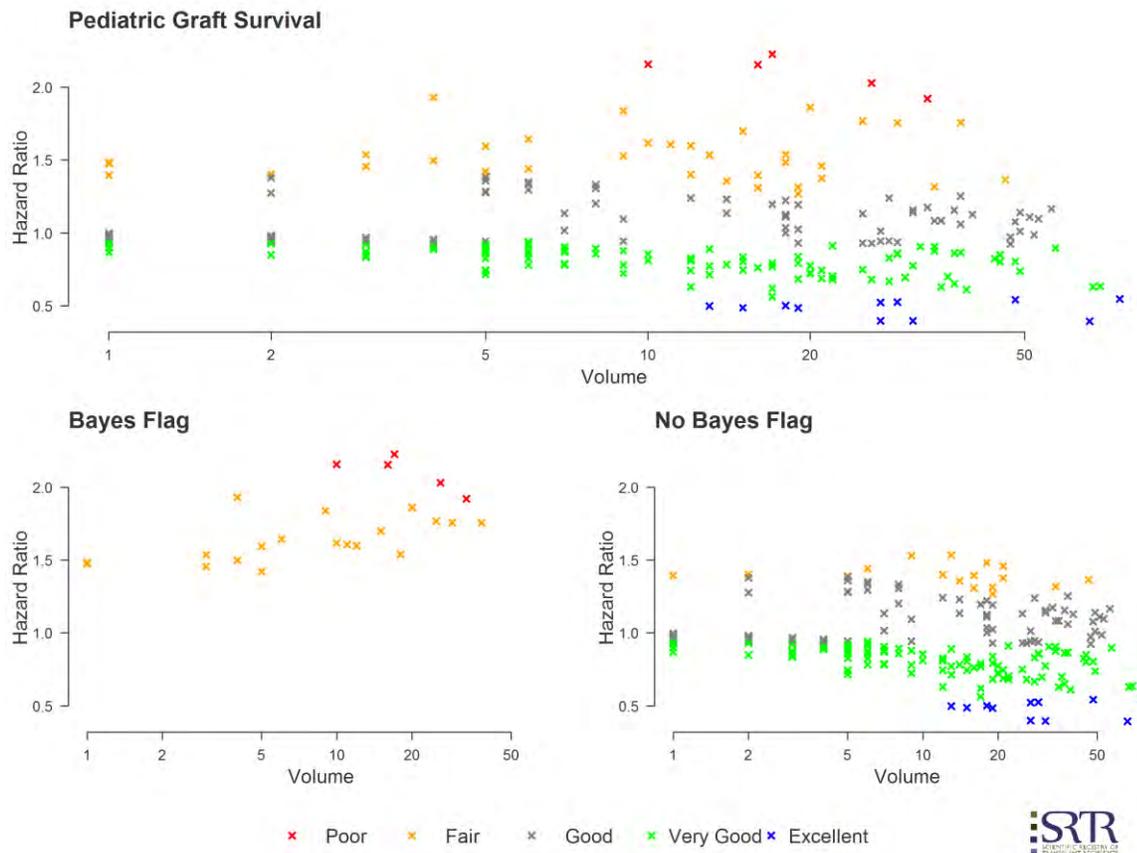
In the current system, in the low volume range, there are lots of flags. Many of the programs currently flagged in the low volume range are in the good (as expected) range and one has a very good rating (some evidence of better than expected outcomes). Some of the red (strong evidence of worse than expected outcomes) are being missed. Under the Bayesian, programs with good (grey – as expected) or very good (green - some evidence of better than expected outcomes) ratings shift over to not being flagged. The Bayesian flag has pulled over all but one red x (strong evidence of worse than expected outcomes).

Below is the same information for pediatric graft survival. The graphs are a good illustration of how the current system has very little ability to capture programs that are in the red (strong evidence of worse than expected outcomes) and high oranges (some evidence of worse than expected outcomes) in the 10-50 transplant volume range. The Bayesian model shifts all of the reds (strong evidence of worse than expected outcomes) and many of the high oranges (some evidence of worse than expected outcomes).

Current Flagging system:



Bayesian model:



As illustrated by these two examples, the current method is not capturing many pediatric components that appear to be low performers. The proposed Bayesian method and thresholds will perform better at identifying underperformers and will avoid flagging a substantial group of what would be considered average programs.

MPSC’s decision to use Bayesian methodology

To address the concerns of a few regions and commenters regarding the OPTN’s ability to make a decision to adopt or not adopt the new model and thresholds, the development of the SRTR public program specific reports and CMS’ process for identifying programs for post-transplant outcomes is separate and apart from the MPSC’s development of thresholds for review. The OPTN develops its own thresholds to meet the charge and goals of the MPSC. The MPSC would like to emphasize that the committee has been reviewing the flagging thresholds for a number of years and had identified the problems with the current thresholds long before the Bayesian methodology was being considered, namely the flagging of too many small volume programs and the failure of the thresholds to adequately flag medium volume programs. New thresholds had been developed using the current statistical model prior to being notified that the SRTR would be moving forward with the use of the Bayesian methodology for development of the public program specific reports available on the SRTR website. The MPSC, although not required by UNOS or HRSA to adopt the Bayesian methodology, decided that it would be appropriate to accommodate use of the Bayesian methodology, if possible, to avoid inconsistency and confusion for member institutions. The SRTR was able to demonstrate to the MPSC that a threshold could be developed using the Bayesian methodology that would meet the established goals of the project. The new

thresholds, as contained in this proposal, were developed through the use of extensive testing of alternative thresholds using computer simulated data.

Continued evaluation of thresholds

A number of comments requested that the MPSC monitor the results post implementation and if there continue to be too many false positives, or if there are too many “small infractions” being flagged, the Committee should adjust the thresholds. As noted in the public comment document, the MPSC, in collaboration with the SRTR, will continue to monitor whether the new methodology is identifying those transplant programs that are truly underperforming in the areas of patient and graft survival. In addition, the MPSC will continue to receive reports for small volume transplant programs patient and graft survival under the current methodology in order to evaluate whether the Bayesian methodology is adequately capturing underperforming small volume transplant programs. The MPSC will re-evaluate the use of the current methodology for small volume programs and eliminate its use if the data demonstrates that the thresholds under the Bayesian methodology will sufficiently identify underperforming small volume programs.

Approval of Bayesian methodology without approving proposed thresholds

A few regions approved the use of the Bayesian methodology but did not approve the proposed flagging thresholds contained in the proposal. Approval of the Bayesian methodology and disapproval of the proposed flagging thresholds will result in the maintenance of the current methodology and thresholds until the MPSC is able to re-evaluate the thresholds. Flagging data cannot be produced using the Bayesian methodology without the identification of thresholds for the flags using the hazard ratio.

Use of pre-transplant metrics and Quality Assurance Performance Improvement program evaluation in review

Some of the comments suggest that the MPSC should include pre-transplant metrics and/or a QAPI evaluation in its review of program performance. The MPSC agrees with these comments and is currently considering proposals to include these factors in its review of programs. A work group of the MPSC has been reviewing pre-transplant metrics for a number of years. The MPSC anticipates that a proposal to include review of pre-transplant metrics for liver and kidney programs in the OPTN bylaws will go out for public comment in the next year to eighteen months. In addition, the MPSC is currently considering proposed bylaw language for a QAPI requirement to go out for public comment in Fall 2014. The inclusion of a QAPI requirement in the OPTN bylaws would provide a basis for MPSC evaluation of a member’s QAPI program when necessary.

Public availability of flagging

Another common theme was a concern about the availability of the MPSC flagging information to the public and other entities. The flagging data used by the MPSC is available only to the MPSC and to each program on the program’s secure SRTR site. The MPSC does not provide flagging data to any other entity. The SRTR provides information on program post-transplant outcomes for the public on its public website. The MPSC does not provide input or control the information provided by the SRTR to the public.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	9/30/2013	2 votes – see below		In person
2	10/25/2013	2 votes-see below		In person
3	12/6/2013	16 yes, 1 no, 0 abstentions		In person
4	12/6/2013	2 votes – see below		In person
5	12/12/2013	0 yes, 20 no, 10 abstentions		In person
6	10/04/2013	62 yes, 0 no, 0 abstentions		In person
7	11/22/2013	21 yes, 2 no, 0 abstentions		In person
8	12/6/2013	17 yes, 2 no, 1 abstention		In person
9	10/23/2013	2 votes – see below		In person
10	10/18/2013	9 yes, 5 no, 8 abstentions		In person
11	12/6/2013	18 yes, 2 no, 0 abstentions		In person

Region 1:

Region 1 voted to approve the Bayesian methodology with a vote of 15 yes, 0 no, 3 abstentions.

With a vote of 6 yes, 7 no, 2 abstentions, Region 1 did not approve the proposed flagging thresholds for the following reasons:

1. The region thinks that too many programs are being flagged and establishing new thresholds that essentially flag the same number of programs as the current thresholds isn't an improvement.
2. The region prefers a tiered approach to flagging. Fewer centers should be flagged and they shouldn't be flagged publically. The MPSC should determine where the new baseline should be for flagging thresholds in order to flag programs that are truly underperforming.

Committee Response:

Responses to the region's comments are included in the Primary Concerns above.

Region 2:

Region 2 voted to approve the Bayesian Methodology: 34 yes, 0 no, 0 abstentions

Region 2 voted to approve the proposed thresholds: 17 yes, 13 no, 0 abstentions. The region recommended that the MPSC monitor the results post implementation. If there continue to be too many false positives, or if there are too many "small infractions" being flagged, the Committee should adjust the thresholds.

Committee Response:

The MPSC appreciates Region 2's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

Responses to the region's comments are included in the Primary Concerns above.

Region 3:

No comments.

Committee Response:

The MPSC appreciates Region 3's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

Region 4:

Region 4 voted to approve the Bayesian methodology with a vote of 15 yes, 1 no, 1 abstention.

The region proposed that the hazard ratios be reassessed and defined differently for flagging versus peer review. The region is supportive of programs being peer reviewed prior to being flagged. Vote on this amendment: 9 yes, 4 no, 3 abstentions.

Comments:

- The region is not supportive of flagging programs first and subsequently determining if the program is truly underperforming. The region would like for programs to be peer reviewed prior to flagging.
- The MPSC should establish a hazard ratio for peer review and a different hazard ratio for flagging.
- The false positive rate of 5% is too high, the MPSC needs to re-evaluate this rate and perhaps reduce it which will ultimately reduce the number of programs that are flagged.

Committee Response:

Responses to the region's comments are included in the Primary Concerns above.

Region 5:

The region opposed this proposal with the following comments:

The region opposed the change to the flagging methodology due to a lack of information as to why the MPSC chose to maintain the same overall number of programs flagged. The region felt that there was not sufficient evidence that the number of programs selected correlated to the number of programs that required MPSC review. The members are aware that although UNOS does not release these findings to third parties – these numbers are used by third parties for unintended consequences. Therefore, if the MPSC is proposing to change their flagging thresholds they should select ones that accurately represent the numbers of true positives.

The region took a second vote and approved the committee's proposal to move to the Bayesian model for flagging (23 yes, 0 no, 0 abstentions).

Committee Response:

Responses to the region's comments are included in the Primary Concerns above.

Region 6:

No comments

Committee Response:

The MPSC appreciates Region 6's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

Region 7:

The region approved this proposal with the following comments to the committee (21 yes, 2 no, 0 abstentions).

- The region was unsure if comparing the new and old thresholds for pediatric programs for one year would provide enough comparison to decide if this should be used for pediatric programs.
- The region felt that the proposal did not illustrate what the differences are between true and false positive since part of this consideration is peer reviewed and is extremely subjective. They felt that the proposal was inaccurate where it stated that the proposal would flag more "positive" centers – how can the committee be assured of this?
- They were concerned that the 10-50 groups is going to receive a majority of the scrutiny when there is no evidence that these are the "true positive" programs. This proposal only assures that more of these programs will show up in the flagging group.
- Although the region approved the proposal, they would strongly request that the committee consider the option to look at this flagging in parallel for several cycles before it decides on the final model.

Committee Response:

The MPSC appreciates Region 7's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

In response to Region 7's first comment, the MPSC will consider what is revealed by the peer review of pediatric programs in an effort to determine if the program should have been flagged in addition to reviewing which pediatric programs are flagged under the new and old thresholds.

The MPSC recognizes that peer review is, by its nature, subjective. However, steps within the process of peer review are taken to limit the effect of this subjectiveness. Each program is reviewed initially by an ad hoc subcommittee of three PAIS members. If the members of the ad hoc subcommittee do not agree on the path forward, the full PAIS, consisting currently of 17 members, reviews the case and makes a recommendation. Although there is an element of subjectivity, the committee does not know of any more definitive avenue to determine those programs that truly need to be reviewed and make improvements (true positives) and those programs that do not need to be reviewed (false positives). No statistical model exists that can evaluate all of the variables that might affect a program's outcomes. For this reason, peer review is utilized to look at any unique circumstances that may exist at a program that is not taken into account by the statistical model used for flagging.

In response to the region's final point, the MPSC has been reviewing the issues involved in the change for a number of years and has reviewed extensively historical data as well as simulated data. Therefore, the committee is reluctant to delay implementation further. As noted in the Primary Concerns, the MPSC will continue to monitor and evaluate the process post-

implementation and will be receiving reports under both methodologies for small volume programs.

Region 8:

Region 8 agreed that this method of flagging was an improvement, but that there will still be too many false positives. Some Members commented that the MPSC needs to review the false positives and determine if the thresholds can be improved to result in fewer false positives.

Committee Response:

The MPSC appreciates Region 8's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

Responses to the region's comments are included in the Primary Concerns above.

Region 9:

Region 9 voted to approve the use of the Bayesian methodology with a vote of 20 yes, 0 no, 1 abstention.

With a vote of 5 yes, 3 no, 11 abstentions, Region 9 approved the proposed flagging thresholds with the following comments:

- Several members think that too many programs are being flagged and establishing new thresholds that essentially flag the same number of programs as the current thresholds isn't an improvement.
- Reviewing post-transplant outcomes is one piece of the puzzle, but the MPSC needs to move towards adding pre-transplant metrics and incorporating cardiovascular morbidity factors.

Committee Response:

The MPSC appreciates Region 9's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

With regard to the comment regarding incorporating cardiovascular morbidity factors into the review, all programs that receive an inquiry from the MPSC are given an opportunity to provide information on the factors that are affecting that program's outcomes. The peers on the MPSC then review the program's response in conjunction with other information to determine if the program should remain under review. In addition, the SRTR is currently working with the organ-specific committees to review factors in the risk adjustment models as part of its process of periodically reviewing these models.

Responses to the region's other comments are included in the Primary Concerns above.

Region 10:

- The region was very concerned that the MPSC has not considered the cascading effect of the proposed change. Flagging information, even if not provided by UNOS to third parties, is obtained and used by these entities for punitive purposes. The region supports the use of this information by the MPSC to identify potential patient safety issues and assist programs in developing quality improvement initiatives but asserts that MPSC needs to understand that this change could potentially impact a transplant program's existence. Therefore, it is not fair to ask programs to accept a change of the current flagging methodology without providing them specific information on if it will change their program's current standing. It is reasonable that a program that has never been flagged prior but will be under this new methodology may be unaware that an issue exists.

Providing them both sets of flagging data for a period of time would allow them to address these issues prior to it being used for other, potentially punitive, purposes. The region discussed an amendment to request that this information be provided to centers for a period of time so that they can assess how this new methodology reflects their program's performance. Although strongly supported, it did not ultimately pass.

- The region commented that this change was being done without the implementation of the universally supported recommendations from the PSR workgroup concerning additional data variables to better assess expected patient/graft survival.
- The region was unclear why UNOS would move forward with implementation when it was still unclear if the flagging was appropriate for all centers (small centers will still be flagged using current methodology). Both flagging could run for several cycles to see how this will impact both medium and small volumes and then tweak the final proposal to include all programs in the final proposed methodology.
- There was concern that the submission of this proposal was a formality and that HRSA and UNOS have already made this decision for the membership.

Committee Response:

The MPSC appreciates Region 10's support of the proposal to revise the flagging methodology for post-transplant outcomes review.

In response to the region's request that programs be given access to analyses under the new Bayesian methodology and flagging thresholds, the SRTR provided the Bayesian expected survival worksheets to programs on their secure sites in November 2013. The worksheets provide information about whether a program would have been flagged under the new thresholds using the July 2012 PSR data. If this proposal is approved, the use of the Bayesian methodology and the new thresholds would be implemented with the January 2015 program specific reports.

The region also noted that this change was being proposed without implementation of the PSR work group's recommendations concerning additional data variables to better assess expected patient/graft survival. As noted in the Ad Hoc Committee on Program-Specific Reports' report to the Board of Directors, the SRTR currently evaluates each organ-specific model every three years, and the ad hoc committee noted that this interval is sufficient. The process of reevaluation of the data variables utilized in the risk adjustment model is determined by the SRTR in conjunction with HRSA with input from the organ-specific OPTN committees. It is the understanding of the MPSC that the SRTR is currently reviewing the risk adjustment models. This process is completely separate from the MPSC's evaluation of thresholds for flagging programs for post-transplant outcomes as addressed in this proposal.

Responses to the region's other comments are included in the Primary Concerns above.

Region 11:

Region 11 voted to approve this proposal and had the following question and comment:

- Has the MPSC considered developing a statistical method based on program size?
- The language in D.10 related to the MPSC recommending that a member inactivate a program is not clear with regards to whether this would be before or after due process.

- A concern was raised that the methodology will always result in a minimum number of programs flagged regardless of their absolute outcomes, i.e. the bar or threshold for flagging will be constantly raised.

Committee Response:

The MPSC appreciates Region 10’s support of the proposal to revise the flagging methodology for post-transplant outcomes review.

The current flagging process and the proposed thresholds utilize a statistical method based on program size. Two different statistical methodologies are used for small volume programs that perform nine or less transplants in two and a half years and the large volume programs. As noted in the Primary Concerns, the MPSC will continue to monitor the effectiveness of the flagging methodology.

Recommendations by the MPSC that a program inactivate a program are quite rare. In some instances, a program recognizes the need to take a time out and work on improvement efforts without a recommendation by the MPSC. In those instances where the MPSC recommends inactivation, the program is provided the option to voluntarily inactivate or the MPSC will consider an adverse action. The MPSC does not have the ability to require that a program inactivate. Due process would begin if the program does not voluntarily inactivate based on the consideration of an adverse action by the MPSC.

The MPSC recognizes that the methodology used to flag programs will result in a minimum number of programs flagged and believes that this is consistent with the goal of continuous quality improvement. In addition, since the flagging is solely a tool to decrease the number of programs the MPSC will review, programs that are not true underperformers will be released from review during the peer review process.

4. Committee Public Comment Responses

Ad Hoc Disease Transmission Advisory Committee:

Upon review, the Committee determined that it had no specific comment regarding this proposal.

Ad Hoc International Relations Committee:

The Committee did not consider this proposal.

Ethics Committee:

The Committee did not consider this proposal.

Executive Committee:

The Committee did not consider this proposal.

Finance Committee:

The Committee did not consider this proposal.

Histocompatibility Committee:

The Committee did not consider this proposal.

Kidney Transplantation Committee:

The Committee did not consider this proposal.

Liver and Intestinal Organ Transplantation Committee:

Committee members were supportive of the Bayesian methodology. There have been some concerns in the community about what the MPSC will do with those centers that are flagged, and that too many centers will still be flagged. The total number of centers that are expected to be flagged should actually decrease slightly. It was suggested that there could be some type of tiered approach that would allow the MPSC to act more quickly or with more rigor if a center was above a certain threshold. The Committee had no other comments.

Committee Response:

Responses to the Liver and Intestinal Organ Transplantation Committee's comments are included in the Primary Concerns above.

Living Donor Committee:

The Living Donor Committee considered and supports this proposal.

Committee Response:

The Committee appreciates the Living Donor Committee's support of this proposal.

Minority Affairs Committee:

After brief review and discussion, the committee determined that there was no inherent minority impact resulting from the proposal.

Operations and Safety Committee:

The Operations and Safety Committee considered this proposal at their December 3, 2013 conference call meeting. One Committee member questioned the definition and impact on medium or large programs. The presenter discussed that programs performing between 10-100 transplants (medium) would have more flags that were appropriate and that current thresholds were not efficient at identification in this range.

The Committee voted to support this proposal (12 in favor, 0 opposed, 0 abstentions).

Committee Response:

The Committee appreciates the Operations and Safety Committee's support of this proposal.

Pancreas Transplantation Committee:

The purpose of the Proposal to Revise Current Method for Flagging for Transplant Program Post-transplant Performance Reviews is to better identify those transplant programs that may be underperforming in the area of patient and graft survival. The Bylaw proposal adopts the new Bayesian methodology that will be utilized by the SRTR in production of the public transplant program performance metrics and establishes new flagging thresholds that maximize the true positive flags while minimizing false positive flags. In doing so, the transplant programs most in need of MPSC review and assistance in improving outcomes will be flagged.

It was inquired whether re-transplants are included in the volume numbers. A MPSC representative explained that pancreas re-transplants are included in the outcomes numbers for graft survival but not patient survival analysis.

It was inquired if the MPSC's proposal will flag a center that has completed 9 transplants within 2.5 years if the center has 1 event (i.e. graft failure or death). A MPSC representative explained

that small volume programs include those programs that perform 9 or less transplants within a 2.5 year period; if there is 1 event in the 2.5 year period the program will be flagged. The MPSC instituted a 2nd threshold for these programs, whereby staff review the programs outcomes to determine if at least 1 additional event occurred in years subsequent to the 2.5 year cohort prior to the referral to the MPSC.

It was noted that the 10 transplants in 2.5 years is too stringent a threshold because 70% of the pancreas programs perform less than 10 transplants per year. A MPSC representative pointed out that flagging a program doesn't mean MPSC will review the program. The number of flagged small volume programs versus the number of programs the MPSC reviews is significantly different.

It was noted that regardless of the 2.5 year cohort, what's important is the number of events versus number of transplants and the 1 in 10 events is too stringent because the technical failure rate in the first year for all types of transplants is about 10% (thrombosis is 5%, leaks about 4-6%, etc.). Most centers consider 85% graft survival at 1 year successful. It was suggested that 1.5 or 2 events would be a better value to use.

A MPSC representative explained MPSC currently does not review pancreas outcomes. However, MPSC will begin reviewing pancreas patient survival outcomes beginning with January 2014 PSRs.

It was emphasized that how MPSC addresses small volume programs may be problematic since the Committee believes the 1 out of 10 is too strict. Further, it was noted that 9 out of the 11 cases that were missed by switching to the Bayesian methodology were low volume centers and this is bothersome.

It is a concern that the Bayesian methodology has only been used in theory and not actually applied to real numbers. It was asked if there will be a time period where the current methodology and the Bayesian methodology will both be used. If so, it was asked for MPSC to provide a time-frame in which both methodologies will be used. A MPSC representative responded that the Bayesian methodology will only apply to large volume programs, which is any program that performs 10 or more transplants in a 2.5 year time period. The small volume programs will continue to be flagged based on the 1 event in a 2.5 year period. However, MPSC will be reviewing flagging data for small volume programs produced using the Bayesian methodology to compare to the flagging data produced using the current methodology. The MPSC will use this data to determine if the Bayesian methodology will adequately flag small volume programs.

It was pointed out that what constitutes "small volume" transplants for one organ may not apply to another organ. It was suggested there should be different definitions for a small volume program for each organ type. A MPSC representative emphasized that the flagging is just a screening and that a center's review is performed by a group of colleagues on MPSC, where the review includes raw data and substantive responses from the center.

It was suggested MPSC use both methodologies for a period of time and to educate the centers as to how the MPSC applies the methodologies to flag a program, and MPSC's process after MPSC flags a program. The MPSC representative explained that the SRTR will provide the Bayesian methodology data to the programs, on a secure website, when the SRTR releases the PSRs.

The Committee decided to split the vote on the proposal. The Committee first voted to support the proposal to revise current methods for flagging for transplant program post-transplant performance as it applies to medium or large volume programs. (16-Support, 0-Oppose, 1-Abstain)

The Committee subsequently voted to support the current method for flagging for transplant program post-transplant performance as it applies to small volume programs. (7-Support, 7-Oppose, 3- Abstain)

Committee Response:

Responses to the Pancreas Transplantation Committee's comments are included in the Primary Concerns above.

Patient Affairs Committee:

With minimal discussion, the Committee voted to support this proposal [15 – Support, 0 – Oppose, 0 – Abstentions]

Committee Response:

The Committee appreciates the Patient Affairs Committee's support of this proposal.

Pediatric Transplantation Committee:

The Committee voted to support a motion to approve the proposal as written (9 support, 1 oppose, 0 abstentions).

Committee Response:

The Committee appreciates the Pediatric Transplantation Committee's support of this proposal.

Policy Oversight Committee (POC):

The Committee did not consider this proposal.

Thoracic Organ Transplantation Committee:

One Committee member asked whether the methodology would be transparent, or whether it is proprietary. The SRTR explained that the methodology is very transparent.

The Committee did not voice any other concerns or questions about the proposed policy, and voted in favor of it: 20-supported; 0-opposed; and 0-abstained.

Committee Response:

The Committee appreciates the Thoracic Organ Transplantation Committee's support of this proposal.

Transplant Administrators Committee:

The Committee voted unanimously to approve the proposal as written (15 support, 0 oppose, 0 abstentions). There was some concern about effectively communicating center outcomes to patients.

Committee Response:

The Committee appreciates the Transplant Administrators Committee's support of the proposal.

Transplant Coordinators Committee:

The Committee voted unanimously to approve the proposal as written (15 support, 0 oppose, 0 abstentions).

Committee Response:

The Committee appreciates the Transplant Coordinators Committee's support of the proposal.

5. Individual Public Comment Responses**Comment 1:**

vote: Oppose

Date Posted: 12/02/2013

The rationale for changing from the current flagging model to the Bayesian Proposed model is largely instrumental: A desire to flag fewer small-volume programs which have historically resulted in a high number of false-positive flags which in turn have not reliably and reproducibly identified programs which warrant peer review and/or regulatory scrutiny. Hooray, and all to the good. No one wants their time wasted, least of all the clinical and administrative leadership of programs falsely flagged. But, a pivot to the Bayesian Proposed model merely exchanges a high number of false positive flags of small volume programs for a much higher number of flags of medium volume programs, without any evidence one way or another as to whether the higher number of flags of medium volume programs will yield a lower rate of false positives. Indeed the estimated total number of flags under the new model is quite close to the number flagged under the extant model (97 vs. 102). Despite the observation in the proposal that the Bayesian Proposed model will ...shift focus...toward medium volume programs that are more likely to be true positives, there is no evidence (certainly none offered in the proposal) that medium volume programs are surreptitiously making it under the regulatory radar under the current metric. If there were such evidence, then perhaps the shift in metric would be justified in the name of patient safety, even if accompanied by unintended/undesirable consequences (such as a drop in Center volume). But, absent such evidence, there is good reason to suppose that the new metric merely shifts the negative externalities entailed by false positives from small volume to medium volume centers. If a sufficient number of medium volume programs are flagged using the new model, it can be reasonably expected that the total number of organ transplants in the U.S. will contract even further. Prudent and attentive medium volume programs which do not flag will take heed of the increased number of similar programs which will flag under the new metric and may curb their risk tolerance (and by extension, volume) accordingly. If this is judged to be an acceptable side effect of a metric which yields better absolute patient and graft survival (even at the expense of volume, to say nothing of innovation and access to transplantation for patients with risk-unadjusted conditions), this tradeoff should be stated plainly by the relevant regulatory bodies. Indeed, if it is the case that SRTR and CMS have already decided to adopt the Bayesian Proposed metric, then to that extent the solicitation of public comment on its implementation as part of the MPSCs purview of regulatory authority is just a *fait accompli*. Ultimately, which metric is most appropriate depends on (a) which kinds of programs a regulatory body wishes to subject to increased scrutiny and (b) what that increased scrutiny practically entails from a regulatory vantage. Flagging has been conflated with poor outcomes and need for peer review to an unnerving degree. Unless and until the implications of flagging are changed by the MPSC and the Board (and CMS, and insurance companies, and Quality Improvement Organizations), figuring out which metric to use only addresses half the problem, and does so in a fashion which may materially change the collective behavior of medium volume programs in unnecessary and undesirable ways. And, insofar as this proposal only addresses half the problem, I would encourage the Board to reject this proposal as written, and send it back to the relevant committees

for reconsideration and a germane revision of other relevant policies governing what should follow from a "flag" from the standpoint of UNOS/OPTN, focusing in particular on efforts to identify false positives early and curtail further regulatory consequences therein, for the sake of the MPSC, the Centers in question, and most importantly, the patients they serve. I would also encourage the Executive Committee of the Board to take this opportunity to reach out to the Ad Hoc Committee on Program Specific Reports to engage with the other regulatory stakeholders to rethink the standards for and implications of flagging and peer review in order to generate a uniform, substantively sufficient and parsimonious regulatory approach. This would make it easier for Centers to comply with regulatory requirements, provide vast opportunities for identifying and implementing efficiencies in resources required for regulatory oversight, and refocus the attention of regulators and Centers on true positive quality concerns.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal.

Reponses to the comments are included in the Primary Concerns above.

Comment 2:

vote: Oppose

Date Posted: 11/22/2013

1. Bayes model is an acceptable mathematical tool. 2. Current MPSC metrics and the proposed thresholds for the Bayes Model flag nearly 1 of 8 transplant programs. This is far too many programs to be deemed under performers. The public interpretation of the flag is such and this conclusion should not be reached for that large a number of programs before careful peer review.

a. Perhaps the MPSC should determine how many programs have significant adverse actions a year and then ask SRTR to create flagging thresholds that are close to this number of programs. This is likely to be 12 or less programs a year based on annual significant actions by the MPSC.

b. A larger number of programs similar to the 1 of 8 or 1 of 10 programs may be under consideration for random peer review as shown in the public comment illustration, but this number of programs should NOT be flagged

c. Perhaps programs should only under at peer review based on various hazard ratios and then after MPSC peer review, the determination for the flag should be made after complete program evaluation which includes pre-transplant and QAPI/policy program performances

3. A more important type of information for program evaluation and patient information concerning their potential treatment at a transplant center would be a combination metric of pre-transplant/waitlist events, policy and QAPI evaluation, and outcome measurement. Looking at a small different in outcome may not be very important to most patients compared to their ability to receive a transplant and the programs ability to continually evaluate and improve their quality indicators.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal.

Reponses to the comments are included in the Primary Concerns above.

Comment 3:

vote: Oppose

Date Posted: 10/26/2013

I support the Bayes Model as a superior math tool that also [allows] flexibility with using various thresholds to achieve different goals. I oppose the current thresholds as stated in the policy since they simply reproduce the output of a previous model. There are no "true positives" or "true negatives" used for determination of the number of programs that the thresholds should determine. The prior model created the numbers used in this creation of the new thresholds. It is not very believable that nearly 1 out of 8 transplant programs are under performers to the extent that they should be 'flagged' due to the real life negative consequences of the 'flag'. These consequences have led to decreased utilization of donated organs, and to fewer transplant opportunities for patients with end stage organ disease. These negative consequences are far more harmful than nearly all small differences in outcomes that are 'flagged' by the thresholds suggested. The current peer review system unintentionally creates an amount of program risk aversion that harms far more transplant candidates than it helps by attempting to slightly improve outcomes. The concept is well meaning, but the application of the peer review process is severely flawed as it currently is practiced. Please differentiate the need to peer review from a public premature notification of programs as being under performers.

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal.

Responses to the comments are included in the Primary Concerns above.

Comment 4:

vote: Oppose

Date Posted: 12/06/2013

COMMENTS ON REVISED SRTR FLAGGING RULES -- John Kalbfleisch, University of Michigan, Ann Arbor, MI 48109 (December 6, 2013)

1. This review of the flagging rule for transplant centers is timely. The current rule, as described in the proposal, has worked well for larger centers, but not for smaller centers. One feature of this is that a center with 9 or fewer transplants in the 30 month period is flagged if it has one or more deaths (Observed ≥ 1). On the other hand, a center with 10 transplants is flagged only if it had 4 or more failures (Observed ≥ 4). This peculiar discontinuity is due to the criterion 'Observed - Expected > 3 ', which is part of the current rule for facilities with 10 or more transplants in a given year; this condition accounts for the low flagging rate of moderate sized facilities and other oddities of the current rule that are summarized in the proposal.
2. The simple rule 'flag if one-sided p-value $< 5\%$ ' would yield nearly the same flagging rule as the proposed Bayes rule.

As described in the proposal on pages 10 and 11, the proposed Bayes rule is obtained by choosing the probability cutoffs to achieve a false positive rate of 5% or less across all facility sizes while striving to maximize the true positive rate. Using the simple rule, 'one sided p-value $< 5\%$ ', for signaling would be much simpler, would be based on standard techniques and would accomplish this aim. Table 1 compares the proposed Bayes rule to this simple rule (p-value $< 5\%$) and shows that the simpler approach gives nearly the same thresholds or cut-offs. Further,

it gives thresholds in terms of the SMR that are always decreasing with increasing facility size, a definite improvement on the proposed Bayesian rule. (See highlighted entrees in Table 1.)

Table 1: Entries in the table give the cutoff values or thresholds in terms of number of failures (Observed) and $SMR = \text{Observed}/\text{Expected}$ for a facility with N transplants in 30 months. If $\text{Observed} \geq O^*$ or $SMR \geq SMR^*$, then the facility would be flagged. It is assumed that the one-year mortality rate is 3%

	N=10	N=20	N=25	N=50	N=100	N=200	N=400	N=800
Flagging rule	Thresholds in terms of Observed (O^*)							
p-value<5%	2	3	3	5	7	11	19	33
Bayes Proposed flag	2	2	3	4	7	11	18	34
	Thresholds in terms of SMR (SMR^*)							
p-value<5%	6.67	5.00	4.00	3.33	2.33	1.83	1.58	1.38
Bayes Proposed flag	6.67	3.33	4.00	2.67	2.33	1.83	1.50	1.42

3. The proposed Bayes approach is justified in part through reference to the ‘COPSS report’ (Ash et al., 2012) which recommended, subject to some discussion and caveats, use of a hierarchical model or empirical Bayes model for profiling of hospitals. The approach being used in this proposal is fundamentally different from that in the COPSS report; in hierarchical models, the prior distribution of hazard ratios (HRs) is estimated using the data to reflect the distribution of HRs in the population of centers, whereas the proposal here assumes the prior distribution of HRs is known in advance. This is an important distinction that should be acknowledged.
4. In fact, a key ingredient of the Bayes method is the assumed prior distribution for the HR. In the proposal, however, the prior distribution is not defined nor described. Although all the results depend on this assumed prior, there is no discussion of its form or its genesis. Is the prior a reflection of prior belief? If so, whose belief and what is the basis of that belief? The probabilities upon which the proposal is based depend on the prior distribution assumed and are not probabilities unless the prior is ‘true’. The proposal apparently assumes that the prior distribution of the HR is the same for all transplant types and I believe that a gamma distribution with mean 1 and variance 0.50 is being used.
5. The proposed Bayes rule will lead to estimates of the HRs for a given facility that depend on the assumed prior distribution and are shifted towards 1. For example, consider a center with $O=12$ deaths in the first year and an expected number of, $E=9$ deaths. The previously used $SMR=O/E$ would be $12/9=1.33$, but the Bayesian approach shrinks that value toward 1 and gives an estimated $HR= 1.27$. The degree of shrinkage depends on the expected number with greater shrinkage for smaller facilities. A facility of one-third this size with $O=4$ and $E=3$ would again have $SMR=1.33$, but $HR=1.17$. If it is planned to use these attenuated values, there would have been value to discussing them in the proposal.

References:

1. Ash AS, Fienberg SE, Louis TA, Normand ST, Stukel TA, Utts J (2012) Statistical issues in assessing hospital performance. COPSS-CMS White Paper Committee. The report can be found at: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf>

Committee Response:

The MPSC thanks the commenter for a thoughtful response to the proposal. Responses are enumerated by the reviewer's points above:

1. MPSC thanks the reviewer for these comments.
 2. It is correct that the commenter's proposed rule ("flag if the one-sided p-value < 5%") would produce a similar flagging rule. However, when constructing a screening test, it is often useful to consider the tradeoff between sensitivity and specificity. The MPSC optimization criteria did strongly favor a 5% rate of flagging average programs by mistake, but would permit an algorithm with a higher rate of incorrect flags providing the probability of flagging a truly underperforming program increased substantially. The commenter also notes that the SMR constantly decreases, but the decline is not as uniform as the commenter suggests. The SMR for flagging at $N = 12$ is 8.33, which is higher than the SMR when $N = 10$. This is because the number of observed events is discrete, so the p-value distribution for a given expected event count isn't continuous. Although many people are more familiar with frequentist procedures than Bayesian procedures, that does not necessarily imply that frequentist procedures ought to be preferred, and "simpler" flagging algorithms are not necessarily preferred. It is worthwhile to note that although the proposed flagging algorithm was developed within a Bayesian analytical framework, the proposed criteria were chosen to achieve frequentist goals.
 3. The reviewer correctly points out that the proposed Bayesian approach uses a gamma (2,2) prior distribution rather than an empirical prior. The SRTR's Technical Advisory Committee (STAC) debated the appropriate prior to use in this setting and recommended using the gamma (2,2) prior for the following reasons:
 - a. It is conservative in the sense that it overestimates the true spread of program variability in the U.S. The chosen prior has approximately double the standard deviation of the empirically derived prior. This is attractive in the context of the PSRs given that it allows data from smaller-volume programs to continue to influence the posterior distribution of the SMR, a quality that MPSC felt to be important in the context of program quality monitoring.
 - b. The chosen prior has convenient mathematical properties given that it is the conjugate prior to the Poisson distribution. This fact allows the SRTR to continue to provide simple tools to programs to allow them to perform their own analyses on the data. Use of the empirical prior would make it difficult for individual transplant programs to monitor their own data.
 4. See responses to point #3.
 5. The reviewer correctly points out that the Bayesian approach yields shrunken estimates of each program's hazard ratio, and the smaller the program the greater degree of shrinkage. MPSC notes that the posterior mean estimate of the hazard ratio is not a component of the proposed Bayesian flagging algorithm, rather the algorithm is based on the posterior distribution of the hazard ratio. The algorithm assesses whether there is "sufficient evidence" to suggest underperformance within each program rather than making a decision solely based on the mean of the posterior distribution.
-

Comment 5:

vote: Oppose

Date Posted: 12/04/2013

The National Kidney Foundation recommends this policy be modified to also include a parallel pre-transplant review process. Flagging programs for performance reviews based solely on graft and patient survival may inappropriately influence transplant centers to pick candidates and organs that are most likely to be successful. This may reduce the number of people receiving transplants that could truly benefit from them and cause organs to be unnecessarily discarded. In order to receive the complete picture of transplant centers performance, factors like patient survival on the wait list and organ wastage also need to be considered.

Committee Response:

The MPSC thanks the National Kidney Foundation for a thoughtful response to the proposal.

Reponses to the comments are included in the Primary Concerns above.

Comment 6: ASTS

vote: Opposed

Date Posted: 12/08/2013

ASTS does not support this proposal as currently written. While ASTS supports the Bayesian model as a sound method, we disagree with the hazard ratios, which were arbitrarily set to ensure the same number of programs that are currently flagged will be flagged in the new system. The proposal includes the thresholds to define flagging under the new system, which include: 1) The probability is greater than 75% that the hazard ratio is greater than 1.2, or 2) The probability is greater than 10% that the hazard ratio is greater than 2.5. It is time for us, as a community, to do better when it comes to the SRTR/OPTN flagging process. Instead of a selecting a hazard ratio that ensures 1 of 8 programs ends up flagged, the community should better define what should trigger review by the OPTN Membership and Professional Standards Committee (MPSC) and set the ratios accordingly. It is our understanding that currently, the MPSC investigates all 100+ flagged programs and typically takes action on only 12-24 of them. If the switch to the Bayesian model were accompanied by more appropriate hazard ratios, MPSC could focus its work on the true under-performers. The current flagging system is often used in a manner that decreases transplant opportunities to patients in this country and thus decreases opportunities to utilize donated organs and allow patients with end stage organ failure to live longer. Transplant centers' fear of "the flag" can result in risk aversion and is counterproductive to our collective goal to increase the effectiveness and efficiency of organ transplantation. One potential solution is to create different thresholds for 'flagging' versus 'peer review.' For example, the MPSC could use the above thresholds to peer review a yet-to-be-determined number of programs over a certain period of time, and it could set a second threshold criterion that would 'flag' a smaller number of programs that more closely approximates the smaller number of programs a year that have any significant MPSC action, including a peer visit or higher action.

Currently, MPSC peer review is interpreted as a true negative program outcome, when in reality it is just the initial trigger for closer examination of the center's waitlist activity, policy procedures, QAPI program and outcomes. This summation of total program performance is the true evaluation of the patient's experience at a given transplant center and not simply a relatively minor outcome difference. This complete look at a program from its success of getting listed patients to transplant based on available organs to the program, the center's safety in policy and QAPI initiatives, and

its outcomes is a better measure to examine transplant programs and decide if programs are adequately performing for their transplant candidates and recipients.

Committee Response:

The MPSC appreciates the thoughtful comments from the ASTS.

Responses to the comments are included in the Primary Concerns above.

Comment 7:

vote: Oppose

Date Posted: 12/18/2013

The proposed switch from a parametric probability that a center's risk-adjusted deviation in outcomes from the national average is not the result of chance to Bayesian inference of a probability that a center's true hazard ratio differs from the national average is an appropriate improvement in methodology, well-supported by evidence and the opinions of experts. Nonetheless, there are fundamental problems with this proposal which make its implementation at this time an unacceptable threat to transplant centers, to patients' rights to informed consent, and patients' rights to have centers make selection decisions in the best interest of the patient rather than their regulatory survival.

While in principle, MPSC false flagging only exposes a center to the cost of responding to the MPSC and a potential site visit; the reality is that CMS and other payors have historically taken their cues from the SRTR and MPSC. It is not realistic to suppose that adopting this new methodology will not lead to its use by payors as a bright-line test of transplant center eligibility for participation, as has happened with prior methodologies including the current PSRs and recently-developed CUSUM reports. If we as a community adopt this proposal with the best of intentions now, it will likely later be inappropriately used by payors. As written, the proposal significantly increases the number of medium-sized centers exposed to flagging, while small centers will be flagged by virtue of having a single event. While the SRTR is able to offer models which suggest the distribution of flagged programs makes sense, they are able to offer absolutely no evidence that there is a problem of false-negatives among medium-sized centers currently. These additional centers to be flagged, who may well have done nothing to earn that, risk being shut down based solely on a theoretical model inclusive of arbitrary thresholds and dubious assumptions. As we saw with the 2007 implementation of the three pronged ($O-E > 3$, $O/E > 1.5$, $p \leq 0.05$) transplant centers may become more risk averse in response to this, especially for risk factors such as peripheral vascular disease not included in the risk adjustment, not for scientific reasons, but simply because the SRTR does not have the data. This places medium-sized transplant centers and their physicians in the position of having to make decisions against the best interest of their patients to avoid having their programs shut down. This is an unacceptable betrayal of patients by the transplant regulatory system.

In addition to these problems, I consider it likely that the new methodology is very poorly understood by patients, nurses and social workers, and even transplant physicians, and the MPSC has offered no evidence otherwise. Given the regulatory requirement to share these data with the public and with potential recipients and living donors, it would undermine informed consent and patient choice to implement a methodology patients do not understand and that transplant centers are not in a position to explain.

Prior to adopting this proposal at some point in the future, the MPSC needs to establish several things:

1. Implementation of hazard ratios and probabilities that significantly reduce or eliminate the number of false positive flags, and only expand flags with hard evidence of a significant false negative problem.
2. Evidence that the physicians and nurses in transplant centers understand the new methodology well enough to explain it to patients, and that patients have the capacity to understand it, so those patients are not denied their right to informed consent.
3. Evidence that transplant centers would not be placed in a position of choosing between their own survival and the best decision for their patients, especially for diseases which have higher incidences in poor and minority populations such that this new proposal does not reduce access to care for patients in underserved groups.

Further, it should be a higher priority for the MPSC and SRTR to address data quality, composite outcomes which reflect both pre- and post-transplant outcomes (including long-term graft survival) instead of focusing only on short-term post-transplant survival, outcomes measures that reflect patient-reported outcomes and character of graft function rather than binary patient- and graft-survival results, and inclusion of important risk factors currently not collected. These should be much higher priorities than incurring the expense of making this small methodological improvement with all its potential unintended consequences.

I respectfully request the board reject this policy change until the MPSC and SRTR can satisfy the above concerns, and that they further direct the SRTR and MPSC to focus on the more pressing and significant problems with PSRs.

Committee Response:

The MPSC appreciates the commenter's thoughtful response.

The MPSC has responded to most of the concerns expressed in its Primary Concerns.

In response to the concerns about patient's understanding of this methodology, the OPTN does not require that the MPSC post-transplant outcomes data be shared with patients. The information available publicly for patients is not produced by or for the MPSC. The public information is produced by the SRTR. It is the understanding of the MPSC that the SRTR is currently working on more patient friendly representations of outcome data to include on its public website.

Comment 8: AST

vote: Oppose

Date Received: 12/06/2013

In general, the AST believes that use of the Bayesian methodology to flag underperformance in patient and graft survival appears appropriate. The conversion from the current statistical methodology to a Bayesian approach was a key recommendation of the SRTR/OPTN Consensus Conference on Assessing Hospital Performance 2012. The Bayesian methodology provides the MPSC with information about how confident they can be that a program's performance exceeds the predetermined thresholds for review. The current flagging mechanism cannot be applied to small volume programs due to the inability to achieve statistical relevance. The simulations and applications of the new system give confidence that the new methodology will perform at least as well, if not better than, current methodology, while limiting false positives. Based on the examples presented, this methodology will decrease false positive flagging of small volume centers, and will favor larger centers, however, there is potential for false negatives that must be evaluated if this new system is adopted. In addition, a drawback is that this model is less clear and harder to

reproduce. It would appear important to know what variables are going to be included in the model to establish hazards and specifically how the SRTR is going to account for severity of disease in candidates with uncommon but high risk markers, such as candidates on ECMO or with extremely high MELD or LAS scores. The available statistical functions and equations cannot hide the inherent problems with the lack of inclusion of important risks (cardiovascular or peripheral vascular disease burden, for one additional example) in the “risk adjusted” model.

The proposal remains difficult to read for anyone who is not an expert statistician and some of the language is convoluted. For example: “For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected. The criteria used to identify programs with a hazard ratio higher than expected will include *either* of the following:

- a. The probability is greater than 75% that the hazard ratio is greater than 1.2
- b. The probability is greater than 10% that the hazard ratio is greater than 2.5

If a program director does not want to be flagged, one is stuck with this question: *How do I lower the probability that my hazard ratio of mortality or graft failure is higher than expected?* The real question, of course is simpler: How do I lower mortality and graft failure in my center? Therefore, would the following be a better way to say the above: “For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has higher mortality or graft failure than would be expected for that transplant program, as determined by a validated statistical method (see Appendix X)?

An issue that is particularly relevant to small programs and to children is how conversion to this proposed Bayesian methodology will affect the ability to appropriately monitor the performance of small programs. The current method for review of small volume programs is for small programs (9 or fewer transplants in a 2 ½ yr period) that have an event (graft or patient loss within a year of transplant), to be reviewed by 3 MPSC reviewers who take into account the program’s history, volume, characteristics, and specific circumstances surrounding the event (e.g., loss of kidney due to recurrent FSGS or loss of kidney due to thrombosis, or death s/p liver failure due to cerebral edema) and make a judgment as to whether the event seemed to be random in a center that otherwise has no “red flags” or whether the event could have been predicted or prevented. The reviewers then determine whether it is advisable for the center to face some action, to be released from review, to continue to be monitored, or to provide more information. The MPSC and the reviewers realize that for events in small volume programs it has been impossible to rely on statistical significance to assist with identification of poorly performing programs. The frustration on the part of the MPSC is that many times an event cannot be categorized easily as random and unpreventable or predictable and preventable with any certainty. It is frequently left to the best judgment of the reviewers after carefully reviewing as much information as is known about the center, the center practices and the event. An argument can continue to be made that any event in a small volume program should be carefully scrutinized, whether that event is determined to be random and unpreventable or not, since a pattern of events within a program may be identified and the very act of being reviewed may be of benefit to the program. The issue is thus whether recipients transplanted in small programs, a substantial proportion of who are children, will be afforded the same level of protection with use of the proposed Bayesian analysis as is afforded in the current system. The AST would recommend that some prospective analysis be undertaken to be certain patients transplanted in small programs are still adequately protected.

Although the AST in general supports the use of the Bayesian approach to assessing transplant center performance, additional information is required concerning the above noted issues before complete support for this proposal as written can be provided.

Committee Response:

The MPSC appreciates the thoughtful comments from the AST.

The MPSC has responded to most of the concerns expressed in its Primary Concerns.

In response to the suggestion that the actual thresholds be removed from the bylaw language, the MPSC has included the thresholds in the interest of transparency. Without clear evidence that the confusion created by inclusion of the actual thresholds outweighs the interest in transparency, the MPSC will continue to include the specific thresholds in the bylaw.

Comment 9:

vote:Support

Date Posted: 09/06/2013

Anything that would help improve the information on survival rates or the facilities numbers on them to help better make a decision on the facility to be transplanted at would be an advantage.

Committee Response:

The Committee appreciates the commenter's support of the proposal.

Comment 10:

vote:Support

Date Posted: 10/08/2013

Bayesian methodology would be a welcome change. However, the new system should not seek to flag an equal number to the current system. That is based on the assumption that the flagging system is appropriate. However, as the flagging system is based on statistical outliers, it may not be appropriate to keep the same approach. At this point, several years into flagging, there has been a "migration to the middle," and it is likely not necessary to flag the same number of programs based on O/E standard deviations, especially if the actual "true" results are becoming more standardized (i.e., the variation is down).

Committee Response:

The Committee appreciates the commenter's support of the proposal.

Reponses to the comments are included in the Primary Concerns above.

Comment 11:

vote:Support

Date Posted: 10/22/2013

Concerns about impact on small centers.

Committee Response:

The Committee appreciates the commenter's support of the proposal. Without knowing more about the specific concerns of the commenter, the MPSC cannot respond to this comment.

Comment 12:

vote: Support

Date Posted: 12/06/2013

NATCO supports this proposal as written.

Committee Response:

The Committee appreciates NATCO's support of the proposal.

Comment 13:

vote: Support

Date Posted: 11/30/2013

The American Nephrology Nurses' Association supports this proposal without revisions.

Committee Response:

The Committee appreciates the American Nephrology Nurses' Association's support of the proposal.

Comment 14:

vote: Support

Date Posted: 11/27/2013

While I support the proposal, there are two related comments I would like to make: 1. As OPOs continue efforts to expand the donor pool, there will be more and more "non-conventional" organs available, such as organs from DCD donors, ECD donors, or SCD donors with added risk factors for disease transmission. Transplant programs are appropriately thoughtful and cautious about using organs that will negatively impact their O:E ratios for outcomes, so many of these non-conventional donor organs go unused. If there was a way to allow certain donor organs, carefully defined by objective criteria, to be excluded from the PSR outcomes O:E analysis, this might stimulate programs to be more innovative and have a higher tolerance for risk in using some of these organs. The outcomes for these organs could be evaluated separately, but not included in the standard PSRs. 2. In addition to the current outcome metrics of one year patient and graft survival, it would be useful to monitor program specific pre-transplant metrics such as listing rates, waitlist mortality, waiting time, organ acceptance and decline rates, etc. to provide a more complete review of program effectiveness through an intention-to-treat analysis.

Committee Response:

The Committee appreciates the commenter's support of the proposal.

In response to the first comment, the SRTR models consider many donor factors in developing a program's expected survival. In addition, during the peer review process, a program is requested to provide information on any factors or unique circumstances that may affect that program's outcomes. These factors are considered by the peers in determining if a program is an underperformer requiring assistance in developing and implementing performance improvement measures.

A response to the second comment is included in the Primary Concerns above.

Post Public Comment Consideration:

On March 26, 2014, the Membership and Professional Standards Committee reviewed the votes and comments on this bylaw proposal that were provided by the public, OPTN/UNOS committees, and OPTN/UNOS regions. Following its review, the Committee supported sending these recommendations, as detailed in the public comment proposal, to the Board of Directors for its consideration: 32 support, 3 opposed, and 1 abstained.