Selected Recommendations of the
OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to the
Board of Directors
November 17-18, 2008
St. Louis, MO

SUMMARY

Elizabeth A. Pomfret, MD, PhD, Chair
W. Kenneth Washburn, MD, Vice-Chair

Action Items for Board Consideration

- The Board of Directors is asked to approve the continuation of the Region 1, Region 8, Region 10, Hawaii, LifeGift, and New York (Region 9) Statewide liver alternative allocation systems. (Item 1, Page 3)

- The Board of Directors is asked to approve the recommendation to discontinue the Florida Statewide, Ohio Statewide, and Tennessee Statewide liver alternative allocation systems. (Item 1, Page 4)

Other Significant Items

- None

This page is intentionally left blank.

Selected Recommendations of the
OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to the
Board of Directors
November 17-18, 2008
St. Louis, MO

Elizabeth A. Pomfret, MD, PhD, Chair
W. Kenneth Washburn, MD, Vice-Chair

The following report represents the selected recommendations of the Liver and Intestinal Organ Transplantation Committee to the Board of Directors.

In early 2008, the OPTN initiated a new process for the review of all existing alternative allocation systems (AAS) and to consider any future AAS applications. The institutions with an existing AAS, except those that cover kidney only, received a notification **(Exhibit A)** from the OPTN/UNOS President outlining the new process. The institutions were provided with a new application and all other information needed to complete the application. In order to facilitate the review of the existing liver and intestine AASs, the Committee formed a subcommittee to review the applications prior to the full Committee meeting scheduled for July 29, 2008.

1. **AAS Review Subcommittee Report.** Ken Washburn, MD, provided the background information and process used for the AAS review. This included the development of a standardized application form that clearly outlines the informational requisites of an evidence-based and experimental AAS, enables the OPTN to better comply with the Final Rule, and increases the reliability of reviews of alternative allocation systems. The new process complies with requirements of the OPTN Final Rule, which defines the scope of the OPTN's authority. These requirements define an AAS as an "experimental policy" to test methods of improving organ allocation. According to the Final Rule, an AAS can only be established or continued if:

   - it is accompanied by a research design including objective measurable goals, data collection, and an analysis plan; and
   - it is time-limited, so that variances with demonstrated value may be evaluated as a potential nationwide policy.

   Members of the subcommittee were assigned to review three AASs each, with each AAS being reviewed by two members. The subcommittee then met by conference call on July 17, 2008, to further discuss the agreements and make recommendations to the full Committee. It was noted that the Region 5 Liver AAS and the Florida Statewide Intestine AAS were voluntarily discontinuing and the appropriate documentation would be submitted to the Regional Administration department.

   Subcommittee recommendations:

   Region 1 – **(Exhibit B)** This agreement is a good example of broader sharing and the subcommittee recommends the continuation of this agreement.

   Region 8 – **(Exhibit C)** This agreement is consistent with broader sharing and in line with the Final Rule's requirements defining an AAS as an "experimental policy" to test methods of improving organ allocation. The subcommittee recommends the continuation of this agreement so additional data can be collected and evaluated since it was implemented just over one year ago.

New York Alternative System for Liver (Region 9 Sharing Agreement) – **(Exhibit D)** This differs from the Florida agreement because the state of New York makes up most of Region 9 (except for a small portion of Vermont that doesn't have a liver program) and is similar to what the Committee is currently evaluating as national policy. The subcommittee recommends the continuation of this agreement.

Region 10 – **(Exhibit E)** The subcommittee endorses the concept but the application is incomplete because the region did not submit data to support this agreement. Additional information will be needed before this agreement can be properly evaluated.

Hawaii – **(Exhibit F)** The question was raised about whether it is appropriate to keep livers in Hawaii for MELD/PELD candidates if there are Status 1 candidates in Region 6. There was agreement that some form of Status 1 sharing should be discussed with Region 6 with the acknowledgment that geographical barriers might exist. This agreement may not meet the requirements but is a unique situation due to geography and the subcommittee recommends that it be continued.

LifeGift of Houston – **(Exhibit G)** Since this agreement has been in place, only one split liver transplant has been performed. The subcommittee agreed that this is a good concept but it cannot be evaluated as national policy without more data. It was noted that this agreement fulfills the criteria as "experimental" and helps expand the donor pool. The subcommittee recommends the continuation of this agreement at the local level.

The full Committee agreed with the recommendations of the subcommittee by a vote of 21 in favor, 0 opposed, and 0 abstentions, and submits the following for consideration to the Board of Directors:

> ***RESOLVED, that the Region 1, Region 8, Region 10, Hawaii, LifeGift, and New York (Region 9) Statewide liver alternative allocation systems be continued and re-evaluated in three years.**[1]

The Resource Assessment and Impact Summary is included as **Exhibit N**.

The subcommittee also determined that the following three alternative systems did not meet the requirements as outlined in the Final Rule:

Florida Statewide – **(Exhibit H)** The concern with this agreement is that it creates another level of allocation between local and regional for MELD/PELD candidates. This agreement essentially creates a system where no Florida donor livers leave the state of Florida – whereas if you are in another state within Region 3 and a liver is not allocated locally to a MELD/PELD candidate, it gets offered out regionally. It was also noted that according to the agreement, there was no input or agreement from the rest of the region when this system was put into place. (It does impact the rest of the region) They also did not clearly define objective measurable goals and the data submitted did not seem to support what they were trying to accomplish. This agreement seems to

[1] Although the vote was unanimous, due to the structure of the combined resolution several committee members may have had perceived conflicts of interests regarding individual alternative allocation systems within the combined resolution. However, if these actions had been taken individually, or if each committee member who had a perceived conflict of interests had abstained in the combined resolution, the Committee would have reached the same conclusion.

impede "regional sharing," which is something the Committee is currently evaluating. The application also states that data should be reviewed in 4 years; however, the subcommittee opined that there should already be 17 years of data to review. It was noted that although this is being submitted as a system of "broader sharing," it is actually restrictive because if there are no local MELD/PELD candidates, the liver should be offered regionally instead of statewide. The subcommittee did not support the continuation of this agreement. The Resource Assessment and Impact Summary is included as **Exhibit I**.

***Ohio Statewide* – (Exhibit J)** This agreement is similar to Florida's in that it creates another level of allocation between local and regional and could potentially disadvantage programs located in Region 10. This was not supported by two organizations in Ohio who have both indicated that they do not wish to participate in the agreement. The subcommittee opined that this agreement restricts broader sharing and has exceeded the duration of an "experiment." The subcommittee does not support the continuation of this agreement. The Resource Assessment and Impact Summary is included as **Exhibit K**.

***Tennessee Statewide* – (Exhibit L)** This agreement is somewhat similar to the Florida and Ohio agreements where livers are offered statewide before the Region. While there are only 2 OPOs within the state, this system still potentially advantages programs within the state and potentially disadvantages other programs within Region 11 even though it creates a broader "local DSA." One of the programs in the state of Tennessee as well as the remainder of programs within Region 11 have not agreed to the continuation of this system. The subcommittee does not support the continuation of this agreement. The Resource Assessment and Impact Summary is included as **Exhibit M**.

Following the discussions at the July 29, 2008, Committee meeting, the decision was made to have the subcommittee members review the applications again before the full Committee conference call in early August. The subcommittee members completed their review and at the conference call on August 6, 2008, upheld their recommendation that these three alternative allocation systems should not be continued. All of these systems have been in place for over 13 years (Florida since 1991, Tennessee since 1993, and Ohio since 1995) and can no longer be considered either "time limited" or "experimental". Additionally, none of them have applicability as a nationwide policy. Committee vote: 13 in favor, 0 opposed, 0 abstentions.

The Committee submits the following for consideration to the Board of Directors:

> ***RESOLVED, that the Florida Statewide liver alternative allocation system shall be discontinued, effective pending distribution of appropriate notice and programming in UNet^{sm}.**
>
> ***RESOLVED, that the Ohio Statewide liver alternative allocation system shall be discontinued, effective pending distribution of appropriate notice and programming in UNet^{sm}.**
>
> ***RESOLVED, that the Tennessee Statewide liver alternative allocation system shall be discontinued, effective pending distribution of appropriate notice and programming in UNet^{sm}.**

LIVER & INTESTINAL COMMITTEE

JULY 1, 2008 - DECEMBER 31, 2008

	MONTH	JULY	AUGUST
	DAY	29	6
NAME	COMMITTEE POSITION	In Person	Teleconference
Elizabeth Pomfret MD, PhD	Chair	X	X
W. Kenneth Washburn MD	Vice Chair	X	X
Heung Bae Kim MD	Regional Rep.	X	
David Reich MD, FACS	Regional Rep.	X	X
Nigel Girgrah M.D., Ph.D.	Regional Rep.	X	
Luis Mieles MD	Regional Rep.	X	X
David Douglas MD	Regional Rep.	X	X
John Ham MD	Regional Rep.	X	
Julie Heimbach MD	Regional Rep.	X	X
Surendra Shenoy MD, PhD	Regional Rep.	X	X
Thomas Schiano MD	Regional Rep.	X	X
Shawn Pelletier M.D.	Regional Rep.	X	
James Eason MD	Regional Rep.	X	X
Scott Biggins M.D.	At Large	X	X
Patricia Carroll PA-C, CPTC	At Large	X	
Richard Johnson Ph.D.	At Large	X	X
Steven Lobritto MD	At Large	X	X
Lisa McMurdo RN, MPH	At Large	X	
Don Rockey MD	At Large		X
Jerry Rosenberg MD, PhD	At Large	X	
Janel Tedesco ACNP, CCTC	At Large	X	X
Kerri Wahl M.D.	At Large	X	X
Bernard Kozlovsky MD, MS	Ex Officio	X	X
Monica Lin Ph.D.	Ex Officio	X	X
Mary Guidinger MS	SRTR Liaison	X	X
Robert Merion MD	SRTR Liaison	X	X
Douglas Schaubel Ph.D.	SRTR Liaison	X	X
Robert Hunter MPA	Committee Liaison	X	X
Erick Edwards Ph.D.	Support Staff	X	X
Joel Newman	Communication	X	
Karl J. McCleary, PhD	PMR Director	X	