

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Summary
June 13, 2014
Conference Call

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Discussions of the full committee on June 13, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Adding serum sodium to the MELD score (MELD-Na)

The Model for End-stage Liver Disease (MELD) score was implemented in 2002 to reduce death on the liver waiting list, and is assigned to candidates age 12 and older. While the MELD score is well-accepted and has been proven to achieve this goal, it has not been modified since implementation. The MELD score and the serum sodium (Na) concentration are important predictors of survival among candidates for liver transplantation.

The proposal to add serum sodium to the MELD score calculation which was circulated for public comment from March through June of 2013, will be forwarded to the board for consideration at the June 23 and 24, 2014 meeting. If the MELD-Na policy is implemented, approximately 34% of candidates will have a different MELD score upon implementation, which accounts for 15% of active candidates. Of those, approximately 14% will move to a higher recertification category. The Committee reviewed potential options for handling potential downgrades on implementation day, as there is less time allowed in the higher recertification categories.

Three options were presented (assuming that laboratory values have not already expired at the time of MELD-Na implementation):

1. Use the recertification schedule applicable to the patient's MELD score, pair MELD recertification date at the time of implementation with the new MELD-NA value;
2. Use the recertification schedule applicable to new MELD-Na score, downgrade to previous lower MELD score if insufficient time remaining; or
3. Use the recertification schedule applicable to new MELD-Na score, if due to expire soon (TBD), reset due date to some "grace period" TBD.

The Committee suggested and agreed upon a fourth option:

4. All candidates would be converted to a new MELD-Na score upon implementation, and the recertification date would be based upon the schedule

for the new score. The Committee agreed that this was the preferred choice and IT staff confirmed that this would not be difficult to implement.

2. Redesigning Liver Distribution

Dr. Mulligan presented the Committee with an update on a concept paper and questionnaire which has been under development by the Redesigning Liver Distribution Steering Committee. This document presents the concept of Redistricting as a method to reduce the variation in access to liver transplantation. This concept document along with a supplemental questionnaire is anticipated for release on June 16, 2014 with the intent of seeking feedback from the transplant community, other stakeholders and the public regarding the next steps to consider regarding increasing equity and access to liver transplantation. A media briefing has been scheduled to accompany the release of the document in which Dr. Mulligan will present a brief overview of the document and its purpose.

Feedback from the questionnaire will be used to develop the agenda for a national public forum, which is tentatively scheduled for September 16, 2014 in Chicago, Illinois. The forum will provide a platform for further discussion on the concepts in the paper, seek additional input from interested stakeholders and build upon ideas for a potential policy proposal. A full committee meeting will be held on September 17, 2014.

Implemented Committee Projects

3. Share 15/35/National Liver-Intestine

The Committee reviewed the 9-month analyses of the Share 15/35/National Liver-Intestine policies implemented in June 2013. Data was provided over 2 eras:

- September 21, 2012 – June 17, 2013
- June 18, 2013 – March 15, 2014

Each era consisted of 270 days and focused on:

- Transplants by MELD/PELD, age, CIT, distance;
- Waiting List Snapshot Data; and
- DSA imports/exports

It was emphasized that it is still a little too soon for proper reporting and analysis of post-transplant outcomes. The general trends reported in the 6 month analysis appear to be holding. Nationally, transplants have increased and discards have decreased. Regions 1, 4 and 10 have experienced an increase in discards; however, there has also been an increase in transplants in those regions. The number of intestinal transplants seems to have normalized since the spike that occurred just after implementation. The Committee will continue to monitor the effects of the Share 15/35/National Liver-Intestine policies.

Review of Public Comment Proposals

4. Proposal to Cap the Hepatocellular Carcinoma (HCC) Exception Score at 34

Public comment revealed general opposition focused on:

- Distaste for Share 35 and therefore anything concerning Share 35;

- HCC patient dropout rates, HCC patients within Milan criteria and without extra-hepatic spread waiting more than a year for transplant should be deemed high priority; and
- The best way to ensure regional equity is to continue to focus on holding local donation rates and holding OPOs accountable for procurement rates.

General support focused on:

- Prioritizing individuals who reached MELD scores higher than 34 purely based on progressive hepatocellular dysfunction vs. HCC exception points; and
- Prioritizing those with the highest chance of death

5. Proposal to Delay HCC Exception Score Assignment

Public comment revealed general opposition focused on several themes:

- Lack of data, limiting access to patients when liver transplantation is appropriate and a proven cure for HCC;
- Need for policy focused on OPO accountability;
- Six month delay is too long (recommend 3 months);
- Disadvantages minorities and the poor who do not have the same access to healthcare and were not diagnosed early;
- Why penalize high performing centers/OPOs due to the poor performance of others;
- Patients will be dissatisfied having to live with cancer for a longer time;
- Centers may “game the system” and list earlier to “get 6 months under their belt” ; and
- Patients should be observed for lifestyle and demonstrated healthcare management.

General support focused on:

- Other non-HCC patients may still be disadvantaged; and
- The need for a mechanism to override the system for ablated tumors.

6. Proposed Membership and Personnel Requirements for Intestinal Transplant Programs

Public comment revealed general opposition focused on:

- Timeframe for experience currency of 5 years
- Declining number of intestinal transplant programs
- Could deny access to several patients
- Concerns over the 120 day application period were also expressed.

General support focused on:

- Further separation and attention to intestinal programs
- Minimum standards are past due.

The Committee agreed to reconvene the Intestinal Subcommittee sometime in July (prior to the Membership and Professional Standards Committee meeting in August) to review this feedback and consider revising the requirements set forth in this proposal. The Committee agreed that it would be inappropriate to forward this proposal to the Board in November without substantial rework.

Other Significant Items

7. A Committee member presented the Pediatric Committee's proposed bylaws for Pediatric Transplantation and Training Experience, which focused on developing separate program requirements for pediatric programs where currently no criteria exist.

The Committee asked clarifying questions in regards to the definition of a child versus an adolescent and expressed an interest in considering other aspects than age such as size/weight. A suggestion was made to reference to the Kidney Committee's current pediatric policy.

Some concerns were raised in regards to whether these considerations will limit access for pediatric patients. It is the Committee's hope that if broader distribution is accepted and implemented, these concerns will be alleviated. Feedback will be delivered to the Pediatric Committee.

Upcoming Meeting(s)

- The next in-person meeting is tentatively scheduled for September 17th, 2014 in Chicago, Illinois. Additional Committee conference calls may be scheduled in the interim.