Liver and Intestinal Organ Transplantation Committee

Report to the Board of Directors

November 14-15, 2011
Atlanta, GA

Kim M. Olthoff, MD, Chair
David C. Mulligan, MD, Vice-Chair

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Items to be Submitted for Board Consideration

- Proposal for Improved Imaging Criteria for HCC Exceptions
- Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates
- Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation

Proposal for Improved Imaging Criteria for HCC Exceptions

Affected/Proposed Policy: 3.6.4.4
(Liver Candidates with
Hepatocellular Carcinoma (HCC))

Liver and Intestinal Organ Transplantation Committee

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Background and Summary

- Current: Patients with HCC are eligible for additional priority through automatic MELD/PELD exceptions
- Current: HCC exceptions based on diagnostic criteria that rely on imaging characteristics
- Proposal: HCC lesions to be classified according to more precise imaging criteria to gain automatic priority. Why?

Background and Summary

- **Why?** Recommendation from the November 2008 HCC Consensus Conference, because:
  - high priority received by patients with HCC
  - Accurate radiographic diagnosis of HCC requires specific radiographic criteria

Background and Summary

- Policy developed with extensive input of radiologists (input from 30 large centers) plus surgeons and hepatologists
- Survey of all U.S. liver transplant programs in October 2010 indicated strong support for this proposal

October 2010 Imaging Survey - Results

- 77 responses
- I would support changes to the HCC exception policy to more clearly define the imaging characteristics of HCC 88% 'yes'
- I would support a policy requiring images used for HCC exception documentation to be performed at the transplant center OR be reviewed by a multi-disciplinary team at the transplant center 92% 'yes'

October 2010 Imaging Study - Results

- The imaging specifications outlined in the Tables 4 and 5 are similar to what we are currently using at our transplant center 91% 'yes'
- Approximately what percentage of images used for HCC exceptions are obtained at a facility outside your transplant center? <25% (68%), 25-50% (25%), 51-75% (8%), 76-99% (0%), 100% (0%)

HCC Policy 3.6.4.5 proposal: Summary

- New imaging classification system for liver nodules (OPTN Class 0-5)
- Only Class 5 lesions potentially eligible for automatic exception
- Nodules <1cm indeterminate, will not be considered
- Imaging studies must meet proposed minimum technical and imaging protocol requirements
- Studies must be performed at the center or interpreted by transplant center radiologist

Highlights of Proposal

- Only patients within Milan criteria (Stage T2) eligible for an automatic HCC exception (no change from current)
- T2 defined as:
  - 1 lesion >= 2 cm and <= 5cm, OR 2-3 lesions, all >= 1cm and <= 3cm in size.
- Lesions less than 1cm are indeterminate, and will not count towards the overall staging of HCC for automatic priority (previously undefined)
- Candidates with no tumor but AFP>500 no longer receive automatic priority (currently MELD 18)

Highlights of Proposal

- New imaging classification system for liver nodules
  - (OPTN Class 0-5)
- Class 5 lesions meet all diagnostic criteria for HCC
  - More stringent imaging criteria for smaller lesions (1-2 cm) than larger lesions (2-5cm)
  - Candidates will still be required to have more than one (may have 2 or 3) smaller lesions to meet T2 criteria (no change)

Highlights of Proposal

- Liver imaging with multiphase contrast enhanced imaging (CT or MRI) must be performed or interpreted at a transplant center and should meet proposed minimum technical standards
- Lesions between 1-2 cm must:
  - be hypervascular on arterial phase imaging
  - demonstrate portal vein/delayed phase washout **and** pseudocapsule enhancement

  If both wash-out and pseudocapsule enhancement are absent, must demonstrate growth (defined on next slide) on serial imaging. Biopsy can also be performed.

Highlights of Proposal

- Lesions between 2-5 cm must:
  - be hypervascular on arterial phase imaging
  - demonstrate portal vein/delayed phase washout or pseudocapsule enhancement.

If neither wash-out or pseudocapsule enhancement, lesion must demonstrate growth (define) on serial imaging, or biopsy may be performed.

Growth defined as: maximum diameter increase in the absence of ablative therapy)by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart.

Examples

A candidate would be eligible for additional priority with:

- Two 1.5 cm (5A) lesions
- One 1.5 cm (5A) lesion and one 2.5 cm (5B) lesion
- One 3.5 cm (5B) lesion
- Two 2.1 cm (5B) lesions

*current policy. Radiographic definition of HCC is the only change. See flowchart in Public Comment document

Additional Information

Additional Data Collection:

This proposal does not require additional data collection in Tiedi[SM]

Expected Implementation Plan:

UNOS Information Technology (IT) staff will need to reprogram UNet[SM] to modify the MELD/PELD exception applications for candidates with HCC.

Public Comments

- Public Comments: 69% with an opinion (n=26) in support.
- Regions 1, 2, 3, 5, 6, 7, 8,9, 10, 11 in support
- Patient Affairs Committee, ASTS and NATCO in support
- Compromise made with LI-RAD Group

Proposed Policy Changes

- Modify 3.6.4.4 (Liver Candidates with
- Hepatocellular Carcinoma (HCC))
- Please see Resolution 7 on Page 32

Questions?

Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates

Affected/Proposed Policy: 3.6 (Adult Donor Liver Allocation Algorithm)

Liver and Intestinal Organ Transplantation Committee

Background and Summary

- Death rates for adult candidates needing a combined liver-intestine transplant are ~ 3 times higher than for liver alone (Shown in multiple published papers)
- A numerically small patient population with high waiting list mortality due to the need for two organs (LI/IN) with donor organ size and quality constraints
  - Approximately 60-70 adults are waiting for a combined liver-intestine transplant during any given year
- The proposal is intended to reduce the death rate by providing broader access to donor organs

Proposal for Liver-Intestine Distribution (Adult donors)

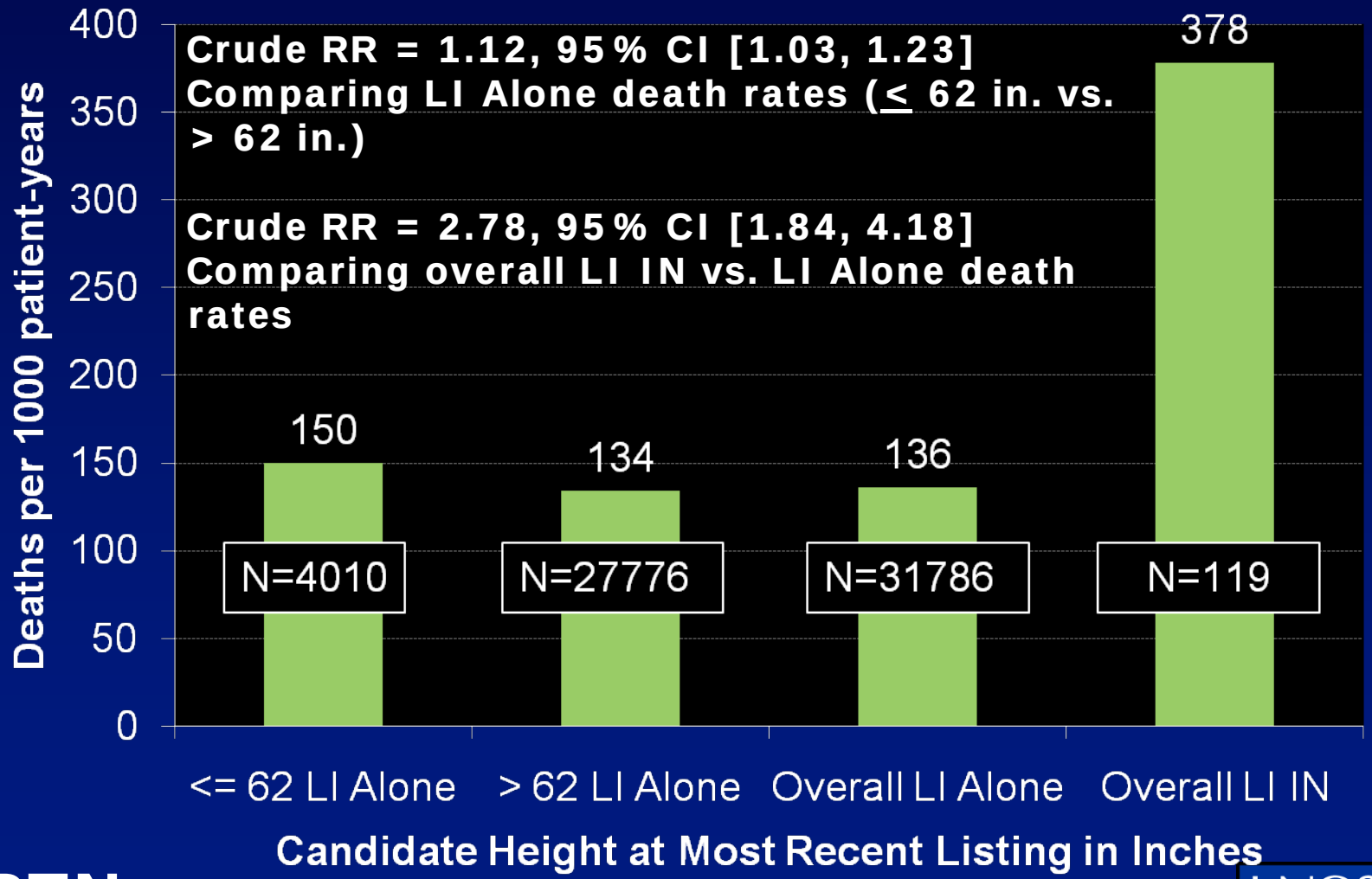
- Combined Local and Regional Status 1A Candidates
- Combined Local and Regional Status 1B Candidates
- *Local Candidates with MELD/PELD Scores >=29*
- *National Liver-Intestine Candidates*
- Local Candidates with MELD/PELD Scores *15-28*
- Regional Candidates with MELD/PELD Scores >=15
- Local Candidates with MELD/PELD Scores < 15
- Regional Candidates with MELD/PELD Scores < 15

Concerns Identified

The policy change will adversely impact small statured adults/females awaiting a liver alone.

- The mortality risk for these candidates is much lower than liver-intestine candidates
- Small adults have alternatives (living donors, or deceased donors with partial or suboptimal grafts)
- These options not available to or suitable for liver-intestine candidates

Liver Waiting List Death Rates: Adult Liver Candidates, 2008-2009*



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*Candidates on the waiting list at any point during 2008-2009

Concerns - 2

Why not just give these patients a MELD of 40?

- These patients need broader access to organs beyond the local list due to major size and quality constraints
- Simply increasing the MELD score will not improve geographic access

Concerns - 3

Why not a regional share?

- Candidates need for two organs from relatively ideal donors requires broader access
- A national share would dilute the impact on any one region, especially regions with large national liver-intestine programs
  - Based on a waiting list snapshot from 11/30/2010, 83% of adult liver-intestine candidates listed in three regions

Concerns - 4

Why was the local MELD/PELD threshold of 29 selected?

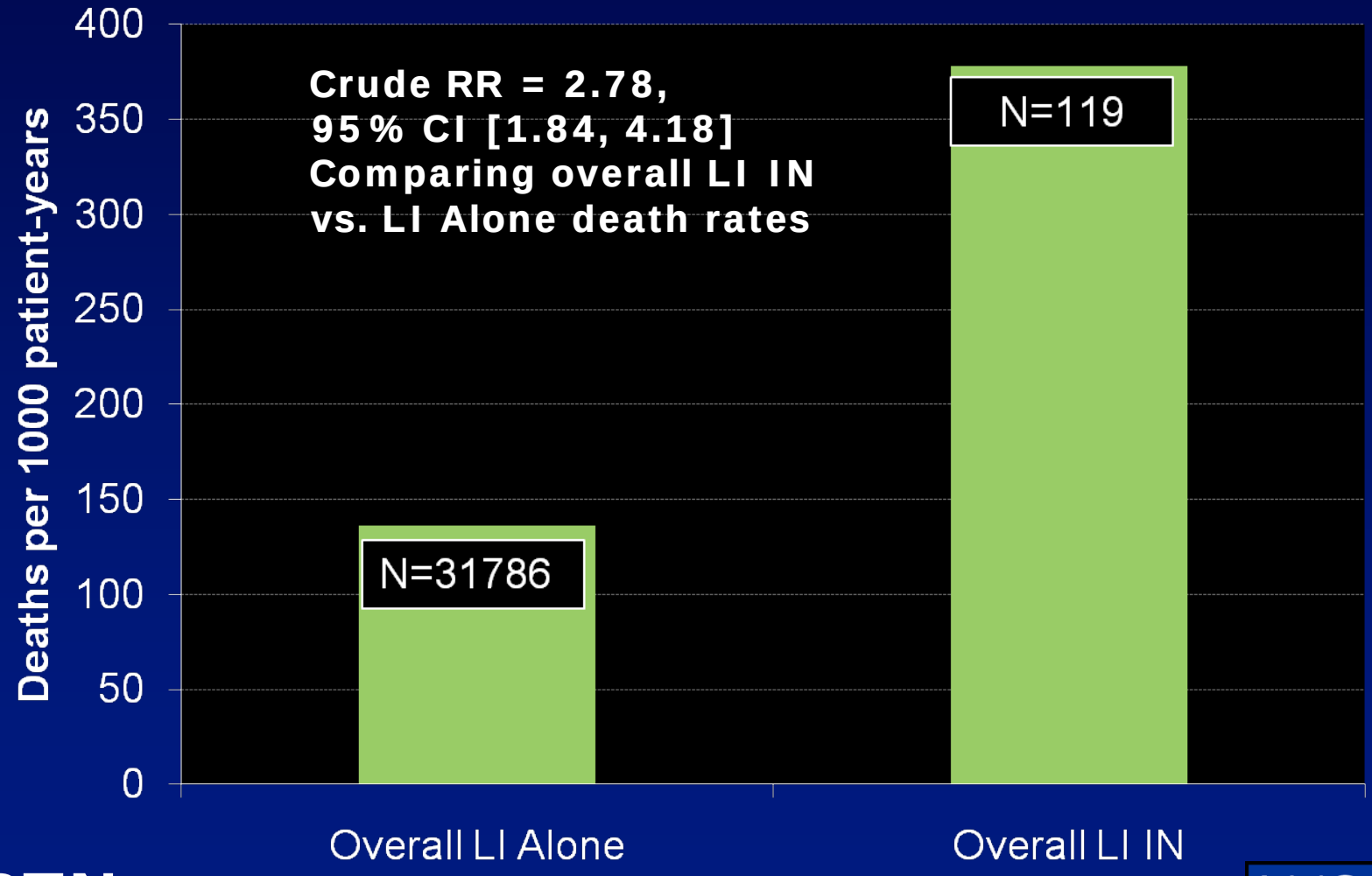
- High enough to provide some level of priority above the HCC/other exceptions
- Threshold used in the Region 8 “Share 29” AAS
- On a snapshot on 11/30/2010, only 2.3% of candidates were waiting at MELD 29+
- Still protects local access to donors for the sickest patients.

Concerns - 5

What about patients with portal mesenteric thrombosis who may need a liver-intestine?

- Short-gut syndrome (SGS) most frequent reason for candidate listing
- Need standardized criteria for liver-intestine transplantation for portal mesenteric thrombosis
  - Less than 2.7% of all new liver-intestine registrations
- Proposal restricted to candidates with SGS

Liver Waiting List Death Rates: Adult Liver Candidates, 2008-2009*



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*Candidates on the waiting list at any point during 2008-2009

Additional Information

Additional Data Collection:

This proposal does not require additional data collection in Tiedi[SM]

Expected Implementation Plan:

Additional programming in UNet[SM] will be required to modify the allocation algorithm for adult deceased donor livers.

Public Comment

- Public Comments: 83% with an opinion (n=18) in support
- Regions 1,4,5,6, and 11 in support; Region 2 supported with amendments.
- Organ Availability and Pediatric Committees supported; Patient Affairs Committee did not
- ASTS and NATCO indicated their support

Proposed Policy Changes

- Modify Policy 3.6 (Adult Donor Liver Allocation Algorithm)
- Please see Resolution 8 on Page 42

Questions?

Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation

Affected/Proposed Policy: New Policy 3.6.12 Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation

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Split Liver CAS Summary - 1

- The CAS is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients rather than transplanting the entire organ in one recipient
- Patterned after Board-approved Region 2 and OneLegacy AASs
- Board asked Committee to develop a CAS
- This would only apply to OPOs or Regions that apply for the CAS

Split Liver CAS Summary - 2

- If a candidate who has been determined to be suitable for a segmental liver transplant is offered a liver via the match run the candidate's transplant center may transplant the right lobe into that patient.
- The center may then transplant the left lobe/segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

Supporting Evidence

- Outcomes for recipients of split liver grafts for pediatric/adult splits are similar to that of whole liver transplantation.
- Adult/adult SLT is showing promising results in single center studies
- Individual center data on adult/adult SLT are summarized in the full proposal

Rationale - 1

- Current national policy for splitting requires a center who splits a liver to offer the remaining segment to the DSA list
- Splitting is technically challenging; may increase morbidity and mortality
  - →Splitting surgeons prefer to perform surgery
- Currently no benefit to centers to split

Rationale - 2

- Despite the fact that a majority of liver candidates indicate a willingness to accept a segmental liver transplant only 137 split liver transplants have occurred on average each year between 2003 and 2009

Plan for Evaluating the Proposal

- Each participating Region or DSA will meet to review the results of the first 10 segmental liver transplants performed as a result of this CAS, and each 10 thereafter.
- If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the CAS exceeds 3 of 20 grafts, an automatic hold will be placed on the procedure at that program until the results and surgical practices can be reviewed by the transplant program

Plan for Evaluating the Proposal

- The Committee will assess whether the CAS' achieved its purpose, to include: candidate waiting time, the number of transplants performed, and post-transplant graft survival, stratified by the appropriate candidate/recipient populations
- The Committee anticipates that the CAS will be in place for a minimum of 3 years, at which point the results will be evaluated and communicated to the Board.

Additional Data Collection

This proposal does not require additional data collection in Tiedi[SM]

Implementation

This proposal will not require programming in UNet[SM].

Public Comment

- Public Comments: 100% with an opinion (n=17) in support
- All Regions in support
- OPO, Patient Affairs, and Transplant Coordinators Committees in support; Pediatric Committee did not support
- ASTS and NATCO in support

Proposed Policy Changes

- New Policy 3.6.12 (Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation), replacing Policy 3.6.12 (Transition of Currently Listed Candidates)
- Please see Resolution 9 on Page 43

Questions?

Liver and Intestinal Organ Transplantation Committee

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Committee Update

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Board-Approved Committee Strategic Priorities for 2011-2012

- Further development of policies to reduce geographic disparities in waiting list mortality
- Ongoing review of MELD/PELD Exceptions
- Additional Priority for DCD Recipients That Require Retransplant
- Facilitated placement / reduced discards
- Enhancements to the MELD score / Liver Allocation
- Ongoing review of Status 1A/B Cases not meeting criteria
- Allocation of livers for hepatocyte transplants
- Intestinal Surgeon/Physician Criteria

Two Items Distributed for Public Comment Fall 2011

- Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National”
- Proposal For Regional Distribution of Livers for Critically Ill Candidates (Share 35R)

Fall 2011 Proposals (cont'd)

- Webinar, October 20, 2011
  - 114 LiveMeeting registrations
  - 124 different phone lines

  = 247 total listeners
- Positive Feedback
- Committee to Consider Comments 3/15/2012
- Possible Recommendation to Board, 6/2012

Current Major Committee Initiatives

- MELD Enhancements/Exceptions Subcommittee
  - Possible addition of sodium to MELD score
  - Review of Exceptions
  - Consider National Review Board?
- Liver Utilization Subcommittee
  - Reducing discards
  - “Facilitated Placement”

Current Major Committee Initiatives

- HCC Subcommittee
  - Allocation Score
  - Downstaging
- Status 1 Review Subcommittee