Action Items
Thoracic Organ Transplantation Committee

Mark L. Barr, MD – Chairman

Meeting of the Board of Directors

November 14-15, 2011

Atlanta, Georgia

Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Non-Contrast Computed Tomography (CT) Scan if Requested by Transplant Programs, And to Modify Language in 3.7.12.3 for Currency and Readability

Problems the Proposal Seeks to Address

- Deceased donor lungs may have emphysema, contusions, or infiltrates or malignant nodules, which may not be visible on a chest x-ray
- Some transplant programs have experienced difficulty in receiving CT scans requested from OPOs
- Transplant programs ask for CT scans based on perceived risk factors for occult lung disease
  - In exercising their responsibility, transplant programs will not ask for CT scans on all donor lungs offered

CT Scan Policy Options Considered

- Leave Policy 3.7.12.4 as is
- Provide guidance through an educational material
- Require the provision of a non-contrast CT scan of the chest if requested
- Encourage, through policy, the provision of information requested by a transplant program, but not change practices without evidence

Proposed CT Scan Policy Language

- **3.7.12.4 Desirable Information for Lung Offers**. With each lung offer, the Host OPO ~~or donor center~~ is encouraged to provide the ~~recipient center~~ transplant center with the following information:
  - Mycology smear; ~~and~~
  - Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested~~.~~; and,
  - Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

Proposed CT Scan Policy

- **Encourages** OPOs to provide the result of a non-contrast CT scan of the chest if requested by a transplant program (receiving a lung offer)
- **Encourages** OPOs and transplant programs to document communications with each other about, and provision and receipt of, CT scan results

Public Comment Feedback

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider/ No Opinion
Individual	20	14 (70.0%)	0 (0%)	2 (10.0%)	4 (20.0%)
Regional	11	9 (81.8%)	0 (0%)	2 (18.2%)	0 (0%)
Committee	19	8 (42.1%)	0 (0%)	1 (5.3%)	11 (57.9%)

Post-Public Comment Consideration

- Committee will issue a guidance document, as part of the policy notice, to avert abuse of CT scan requests or denials

Resolution 14

- **RESOLVED, that OPTN/UNOS Policies 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) are amended as set forth below, effective February 1, 2012:

Questions?

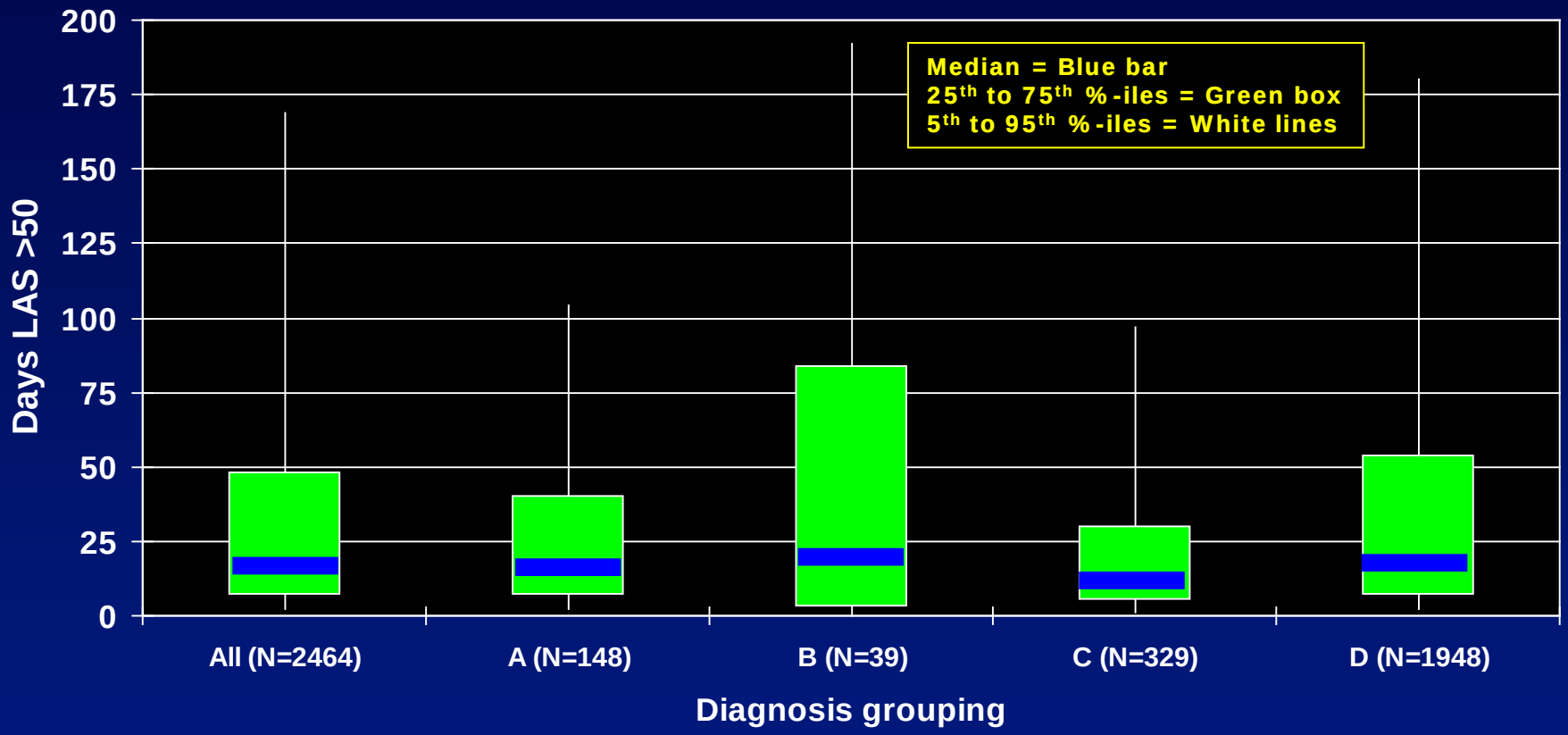
Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at Least Fifty, And to Modify Policy 3.7.6.3 for Currency and Readability

Problems that the Proposal Seeks to Address

- Candidates with LAS of 50 or higher (high-LAS) are a sicker waiting list population whose scores could be affected by therapeutic interventions they receive
  - Without requiring more frequent updates in UNet^{SM}, the actual score – higher or lower – is unknown
- Some high-LAS candidates may receive transplants due to a high score that does not reflect their current clinical profile

DAYS* WITH LAS > 50

Overall and by Diagnosis Group



Interpretation: The median time a registration had an LAS > 50 was 18 days. The central 50% of registrations (25th to 75th %-iles) ranged from 7 to 48 days. So only 25% of registrations in the high LAS group had an LAS > 50 for longer than 48 days.

OPTN

*There may be multiple periods during which the LAS remained above 50 for each registration ever having LAS>50. Only the longest period (consecutive days) per registration is tabulated in this figure.

UNOS DONATE LIFE

Variables Proposed for 14-Day Update Policy

- Need for assisted ventilation
- Supplemental oxygen
  - Need for it and amount required
- PCO_2 (but only if the test is performed)

What the Thoracic Committee Suggests that Transplant Programs Do

- Create a mechanism to identify high-LAS candidates
  - For example, the transplant program can create a custom report in WaitList[SM] to identify candidates and their LASs

If the Board approves this proposed policy, the policy notice will include suggestions to the lung transplant community on identifying high-LAS candidates

Monitoring and Compliance

- For a high-LAS candidate, the lung transplant program must record and maintain documentation in the patient's medical records that it:
  - Assessed the three variables in question in WaitList[SM]
  - Reported any change in the proposed three variables in question in WaitList[SM]
  - Document the date of each assessment and related data gathered in the patient's medical record

Proposed 14-Day Update Policy

- A program must update three key variables in UNet^{SM} no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet^{SM}. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.

Public Comment Feedback

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider/ No Opinion
Individual	18	11 (61.1%)	0 (0%)	1 (5.56%)	6 (33.3%)
Regional	11	10 (90.9%)	1 (9.1%)	0 (0%)	0 (0%)
Committee	19	5 (26.3%)	0 (0%)	1 (5.3%)	13 (68.4%)

Post-Public Comment Consideration

- Committee plans to automate this policy when it automates the revisions to the LAS system
- Committee recognizes that the proposed policy may create a burden for transplant programs to remember to review their candidate's records and maintain documentation

Resolution 15

- **RESOLVED, that OPTN/UNOS Policy 3.7.6.3.1 (Candidate Variables in UNet℠ upon Implementation of Lung Allocation Scores Described in Policy 3.7.6) is repealed and OPTN/UNOS Policies 3.7.6.3 (Candidate Variables in UNet℠) and 3.7.6.3.2 (Updating Candidate Variables), are amended as set forth below, effective February 1, 2012:

Questions?

Proposal to Extend for One Year the Interim Policy for Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH)

Background

- Some candidates implanted with TAHs can now be discharged from the hospital
- Outpatient candidates with TAHs are a new patient population and their medical urgency status was not adequately addressed in policy
- Board of Directors approved the interim policy, which has been in effect since November 10, 2010

Interim Policy Language

- Status 1A
  - A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1A for 30 days at any point in time after the discharge.
- Status 1B
  - A candidate with a total artificial heart who has been discharged from the listing hospital may be listed as Status 1B at any point in time after the discharge.

Interim Policy Development Process and Implementation Timeline

- Interim policy:
  - Underwent an expedited and unusual policy development process and implementation timeline due to the outpatient candidates' urgent need for heart transplantation
  - Distributed for public comment in March, 2011
  - Will expire on December 1, 2011

Potential Policy Options

- Let the interim policy expire
  - Then, only inpatient candidates with TAH would be Status 1A
- Extend the interim policy for one year
  - Allows the Committee to continue its efforts to revise the policy for all candidates implanted with mechanical circulatory support devices

Public Comment Feedback

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider/ No Opinion
Individual	24	10 (41.7%)	0 (0%)	7 (29.2%)	7 (29.2%)
Regional	11	9 (81.8%)	0 (0%)	2 (18.2%)	0 (0%)
Committee	19	5 (26.3%)	0 (0%)	0 (0%)	13 (68.4%)

Primary Public Comment Concerns

- Outpatient candidates implanted with TAHs should remain as Status 1A until the clinical trial is complete
- Interim policy advantages candidates implanted with TAHs over candidates with VADs
  - Candidates implanted with TAHs receive time at Status 1A while inpatients, and can accrue an additional 30 days as Status 1A as outpatients

Post-Public Comment Consideration

- At this time, there is no quantitative data nor clinical rationale to change the interim policy
- So, the Committee seeks to extend the term of the interim policy for one year

Resolution 16
Lines 35-39 and 120-124

- **RESOLVED, that OPTN/UNOS Policy 3.7.3 (Adult Candidate Status) is amended as set forth below, effective February 1, 2012

Questions?

Report of the Thoracic Organ Transplantation Committee to the Board of Directors

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Committee's Current Activities (1/3)

- Revise the adult heart policy to better address the waiting list mortality of candidates implanted with mechanical circulatory support devices
  - Anticipate distributing revised policy for public comment in 2012

Committee's Current Activities (2/3)

- Revise the pediatric heart policy for medical currency
  - Currently, many pediatric candidates are listed as Status 1A, resulting in a system where waiting time prioritizes allocation
  - Working with the Pediatric Committee and the Pediatric Heart Transplant Study
  - Anticipate distributing revised policy for public comment in March, 2012

Committee's Current Activities (3/3)

- Revise the Lung Allocation Score System
  - Effort planned since its implementation
  - Revisions add new variables and modify the use of existing variables in the waiting list and post-transplant models
  - Public comment distribution in March, 2012

Extra Slides

What the Proposed Policy Requires that Transplant Programs Do (1/5)

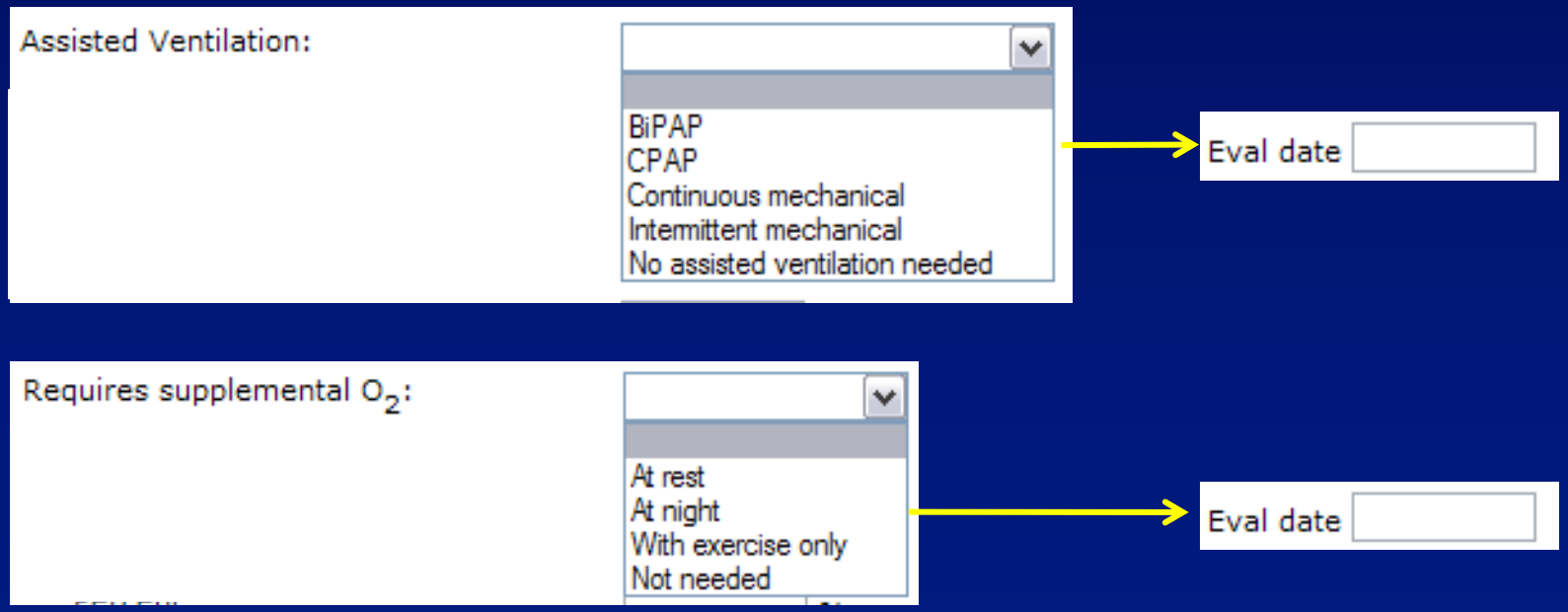
- Monitor their candidates' LAS
- Assess for each candidate whose LAS becomes 50 the clinical variables proposed
- Report for each candidate the date when the transplant program evaluated the need for assisted ventilation and supplemental oxygen

What the Proposed Policy Requires that Transplant Programs Do (2/5)

- Repeat the assessment and reporting of any change in the proposed every 14 days from the date of the previous assessment

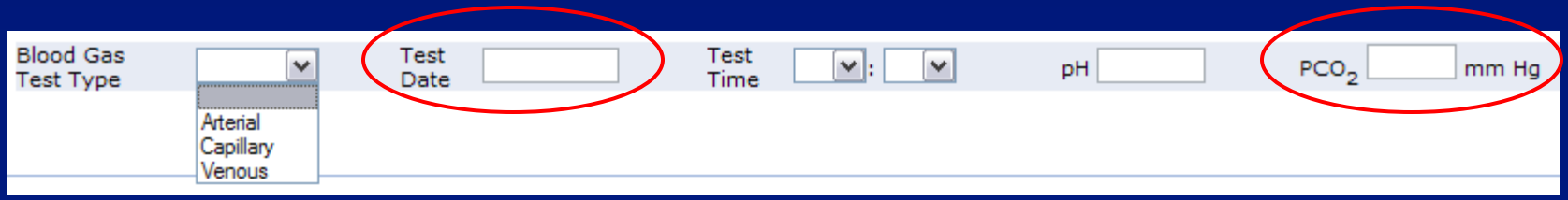
What the Proposed Policy Requires that Transplant Programs Do (3/5)

- Maintain documentation in the patient's medical record of assessment date and data entered in UNet^{SM}



What the Proposed Policy Requires that Transplant Programs Do (4/5)

- Report the date of the PCO_2 test and the value in the "Add Candidate PCO_2" page if the program repeats this test in the 14-day period under discussion, or if the six-month expiration date of the value occurs during this 14-day period
  - If a PCO_2 value expires, UNet^{SM} will assign the candidate the default value of 40 mm Hg in the LAS calculation.



What the Proposed Policy Requires that Transplant Programs Do (5/5)

- Follow the six-month data update schedule for candidates whose scores are less than 50 (Policy 3.7.6.3.2 (Updating Candidate Variables))
- Resume the six-month data update schedule for candidates whose scores become less than 50