Action Items Proposed by the Thoracic Organ Transplantation Committee

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Meeting of the Board of Directors
Richmond, Virginia

OPTN

Proposal to Require Provision of Human Leukocyte Antigen (HLA) Type for Adult and Pediatric Thoracic Organs *if Requested*

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Problem

- Knowledge of donor HLA type allows for a sensitized candidate to receive the most suitable thoracic organ offer

- Policy does not require OPOs to provide deceased donor HLA type for thoracic organs

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Effort to Build Consensus – Survey

- Consulted leadership of the following OPTN/UNOS Committees:
  - Histocompatibility, Operations and Safety, and OPO
- Conducted a survey of the OPO executive directors
  - Of the 58 OPO executive directors surveyed, 34 responded (59% response rate)
- Conducted a survey of the histocompatibility laboratory directors
  - Of the 135 laboratory directors surveyed, 73 responded (54% response rate).

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Impact of the Proposed Policy as Expressed by OPOs and Laboratories

■ General opinion of histocompatibility laboratory directors

- Requiring HLA typing of thoracic donors would benefit sensitized thoracic candidates as well as enable virtual crossmatching.

- Majority in favor of requiring HLA typing for thoracic organs

■ General opinion of OPO executive directors

- 20 executive directors (59% of the respondents) commented that requiring HLA typing of thoracic organs would either have no impact or minimal impact to the operation of their OPO

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Current OPO Practice in the Provision of HLA Type

- In the first four months of 2010, approximately 70% of thoracic matches had HLA type available in UNet[SM] prior to the match being run

- Because the current proposal is related to the time of final acceptance, which is later in the offering process than the time of match run, it is likely that HLA type is available even more frequently at the time of final acceptance

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Policy Options Considered

- Leave Policy 3.7.13 as is

- Require that HLA type be available for each thoracic organ at the time of the match run

- Require HLA type for each thoracic organ at the time of provisional organ acceptance

- Require HLA type for each thoracic organ, if requested, before final organ acceptance

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Proposed Policy

- OPOs must provide HLA type for a thoracic organ, if requested by the transplant center that received the organ offer, prior to the organ's final acceptance

- HLA type that must be provided if requested: HLA-A, -B, -Bw4, -Bw6, -Cw, -DR, and HLA-DQ antigens

  - HLA-DP type, if requested, must also be provided but only if the OPO's affiliated laboratory is able to provide it

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Monitoring Policy Compliance

■ A complaint to the OPTN Contractor about not receiving requested HLA-type will

- Result in the OPTN Contractor investigating the matter
  - Review of relevant documentation

  - Request of a corrective action plan if warranted by the review

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Proposed Policy Language

- **3.7.12.1 Essential Information for Thoracic Offers**. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer: [...]

  (xii) Human leukocyte antigen (HLA) type if requested by the transplant center.

  If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ's final acceptance: HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

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Public Comment Cycle

- Proposal distributed on October 1, 2010

- Comment cycle ended on February 5, 2011

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Comments Received - Overall

Public Comment Response Tally					
Type	Response Total	In Favor	In Favor as Amended	Opposed	No Comment
Individual Comments	36	29 (80.6%)	0 (0%)	3 (8.3%)	4 (11.1%)
Regional Comments	7	6 (85.7%)	1 (14.3%)	0 (0%)	0 (0%)
Committee Comments	14	4 (28.6%)	2 (14.3%)	1 (7.1%)	7* (50.0%)

10 regions approved the proposal as written, except Region 4 which recommended amendments. Pages 29-42 in your Board book include all comments submitted and the regions' votes.

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Comments from Associations

■ ASTS – in favor of the proposal

■ ASHI – in favor of the proposal

■ NATCO – not in favor of the proposal

General Concerns from the Public

- Proposed policy:
  - Could delay the recovery of thoracic organs
  - Does not go far enough – it should require the collection of HLA type for all thoracic organs recovered
  - Goes too far – require OPOs to have HLA type for thoracic organs when performing a match run
  - Should be automated

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Committee's Post-Public Comment Consideration

- It is existing practice for OPOs and transplant centers to communicate about a medically unstable donor or a donor whose family wishes to expedite the organ recovery process
    - The proposed HLA policy is unrelated to this practice
- The proposed policy requires OPOs to provide HLA typing prior to the organ's final acceptance and only if requested by the transplant center.
- The Committee would like to see this policy automated in the future

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Proposed Implementation

- Method – Manual
  - Will include the development of a guidance document for the OPO and transplant programs
- Cost – $6,275 (effort is small)
- Does not require additional data collection or programming in UNet^{SM}
- Not anticipated to impact the Chrysalis project

OPTN

Resolution

- ****RESOLVED, that Policy 3.7.12.1 (Essential Information for Thoracic Offers) shall be modified as set forth below, effective August 27, 2011**

Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNet^{SM}

OPTN

Problem

- Policy 3.7.3 (Adult Candidate Status) is not clear that inpatient status is a requirement for requesting a Status 1A-exception

- Language in Status 1A criterion (b) does not state that an entry of an "other" mechanical circulatory support device complication is possible

- Only two of the four inotropes that qualify for single, high-dose usage are listed in the status justification forms in UNet^{SM}

OPTN

Policy Solution

- Proposed policy language states that a clinician may:

  - Report an "other" mechanical circulatory support complication

  - Request a "general" Status 1A-exception only for inpatient candidates

  - Present all four inotropes that qualify for single, high-dose usage in UNet^{SM}

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Public Comment Cycle

- Proposal distributed on October 1, 2010

- Comment cycle ended on February 5, 2011

Comments Received - Overall

Public Comment Response Tally					
Type	Response Total	In Favor	In Favor as Amended	Opposed	No Comment
Individual Comments	22	17 (77.3%)	0 (0%)	0 (0%)	5 (22.7%)
Regional Comments	0	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Committee Comments	12	4 (33.3%)	0 (0%)	0 (0%)	8* (66.7%)

All regions approved the proposal as written.
Pages 102-106 in your Board book include all comments submitted and the regions' votes.

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Changes to Policy Language after Public Comment

- Includes Board-approved, interim policy for outpatient candidates implanted with total artificial hearts

- Includes that the Committee and the Membership and Professional Standards Committee can review Status 1A-general exception cases

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Proposed Implementation

- Programming needed to add two inotropes and their high-dose values when used alone to meet policy
  - Modify existing text

- Cost – $7,744 (effort is small)
- Implementation will occur after Chrysalis

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Resolution

- ****RESOLVED, that Policy 3.7.3 (Adult Candidate Status) shall be modified as set forth below, effective August 27, 2011, with the exception of the proposed changes in criterion (d), which will be effective pending programming**

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Questions?

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Problem

- Policy 3.7.13 references an incorrect title for Policy 3.7.3 and an incorrect medical urgency status – Status 1

- UNOS audits programs randomly and forwards potential non-compliance events to the Membership and Professional Standards Committee

- OPTN does not routinely monitor Policy 3.7.3 as described in Policy 3.7.13

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Solution

- Delete the policy
- Public comment is not necessary
  - Deletion does not affect allocation
  - Deletion does not affect program behavior
  - Policy change does not require programming

Resolution

- ****RESOLVED, that Policy 3.7.13 (Status 1 Listing Verification) be modified as set forth below, and the subsequent policies be renumbered as follows, effective August 27, 2011**

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Questions?