

OPTN/UNOS Organ Procurement Organization (OPO) Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, VA

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- **Imminent and Eligible Death Definitions.** The Committee is identifying ways to make the imminent and eligible (I & E) death data collection more consistent by refining the I & E definitions. They have identified organ specific criteria that will exclude a patient from being reported as an eligible death. (Item 2, Page 3)
- **U-DCD Joint Work Group.** The joint OPO/OAC Committee Work Group is evaluating a survey of OPO practices regarding uncontrolled DCD (u-DCD) and reviewing policies to identify potential needs for policy development. (Item 5, Page 8)
- **Use of an Alternate Label for Preservation Machines.** The Committee wishes to align deceased donor shipping policy with that of living donor shipping policy and eliminate the ability to use an alternate label for preservation machines. (Item 6, Page 9)
- **Consent vs. Authorization.** Relative to deceased donors/donation, the Committee wishes to change the term “consent” with “authorization” throughout OPTN policy. (Item 10, Page 11)
- **Alternative Methods to Track Organs during Shipping.** The Committee continues to evaluate effective ways to track organs during shipping in order to reduce/eliminate the potential for error. (Item 11, Page 12)

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OPTN/UNOS Organ Procurement Organization (OPO) Committee
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Lori Brigham MBA, Chair
Richard Pietroski MS, CPTC, Vice Chair

This report details the OPO Committee's deliberations during its meeting on March 10, 2011, and Committee conference call/Live Meeting on January 18, 2011. Additionally, the, joint OPO/OAC DCD Work Group, Labeling Subcommittee, and Imminent and Eligible Death Definition Subcommittee have met by conference calls/Live Meeting and in person on March 9, 2011.

1. Data Review. UNOS staff provided a summary of donation-related data for the past year. **(Exhibit A)** Data demonstrate an increase in deceased donors recovered. The number of Standard Criteria Donors (SCD) remained the same even though the number of SCD organs transplanted per donor (OTPD) increased. The number of Extended Criteria Donors (ECD) decreased by 5%, and the OTPD decreased by 4.2% for ECD donors. Donation after Cardiac Death (DCD) donors increased by 2.1%, and the number of OTPD from DCD donors increased by 1.6 %. Fifty-five DSAs recovered at least one DCD donor in 2010 and the range was 1 to 83 donors per DSA.

Members commented that allocating DCD organs can be challenging. Some physicians are refusing to use DCD livers as the performance of these organs is unpredictable once transplanted. The Operations and Safety Committee is currently coordinating an Effective Screening work group to develop tools that may assist transplant centers in eliminating offers for those donors from whom they would not wish to procure organs.

2. Imminent and Eligible (I & E) Death Data Collection. The Committee is identifying ways to make the imminent and eligible (I & E) death data collection more consistent by refining the I & E definitions. It has been determined that the data are inconsistent due to several factors: 1) the definitions are being interpreted differently throughout the country (i.e. multi system organ failure) and 2) some state laws or hospital protocols require two (sometimes more) brain death exams while others only require one. This is particularly important to the data collection because when two exams are required, and only one is completed, the patient is not reported as an imminent or an eligible death. This results in incomplete and inconsistent data.

Jeff Orłowski MS, Chair of the I & E Subcommittee, reported on the Subcommittee's activities. In order to make the data reporting more consistent, the Subcommittee recommended the following fundamental conceptual changes to the eligible definition. It was stressed that the definitions are "reporting" definitions and are not to be considered a guideline for practice.

At the January 18, 2011, meeting, the Committee suggested the following fundamental conceptual change:

Motion: That the Multi System Organ Failure exclusion be removed entirely from the definition as it is inconsistently applied. In its place, there should be a "rule out" criteria for each individual organ system. This would result in a person being reported as imminent or eligible if they have one organ that is transplantable, as long as the person does not have any of the other exclusionary factors. This concept is more simplistic and more easily applied. This would create an inclusionary type of system because if one organ passes through the list of rule out criteria, it can be transplanted.

The motion was passed by a vote of 16-0-0.

The Committee suggested the possibility of collecting donor and non-donor permanent home zip codes on the DDR. This information will provide valuable demographic information about a given DSA's donor pool. There is a field in DonorNet[®] to enter the donor's zip code; however, it is not currently required that it be completed. Although adding this requirement is not a large programming issue, data will be incomplete as frequently a zip code is not available. Members agreed that the hospital's zip code should not be entered in lieu of the lack of a zip code for the patient's residence. If the Committee proposes that the patient's zip code be required, education will be needed. UNOS Research staff will develop recommendations as to how to handle those patients that do not have zip codes listed.

At the March 10, 2011, meeting, the Committee considered the current definition for eligible death that requires that brain death has been declared, that the patient be between 0 and 70 years of age, and that there are none of the exclusionary conditions (i.e. active infections, malignancy) that are listed in policy.

These proposed criteria were based on data that determined where less than 1% of donors fall. **(Exhibit B)** These parameters include 99.6% of all recovered donors on weight and BMI and would fall within the "eligible death" criteria. Members stressed that these exclusionary criteria are for reporting purposes and do not necessarily exclude an OPO from pursuing an organ from these donors. After considering the data, the Committee proposed that the following changes be made to the definition:

- Add minimum weight to the definition that would
 - Exclude patients less than 5 kg or
 - Include patients that weighted 5 kg or greater
- Add Maximum Body Mass Index (BMI)
 - Exclude patients with a BMI greater than 50
 - Include patients with a BMI of 50 or less

Motion: That the proposed changes to the "eligible death" definition, which include a minimum weight and maximum BMI, be accepted.

The motion was passed by a vote of 15-0-0.

As this work is ongoing, further changes to the "eligible death" definition will be made prior to the final proposed changes being distributed for public comment. Additionally, the Committee recommended the removal of the criteria "Multi System Organ Failure" from the list of exclusionary criteria that are included in the I & E definition. MSOF is open to interpretation and applied differently in reporting the data. In lieu of MSOF as an exclusionary criteria, the patient would be deemed eligible if they have at least one transplantable organ from the four major organs (kidney, liver, heart or lung). The Subcommittee also established a list of organ specific exclusionary criteria that would eliminate the donor being considered as an eligible death. In other words, rather than ruling out a donor that has 3 or more failing organs, a donor would be "ruled in" if they have at least one transplantable organ.

The following proposed changes were considered:

A patient that has at least one transplantable organ will be considered an eligible death if they meet all the criteria.

The kidney would be deemed suitable for transplant unless the donor has one of the following:

- Polycystic kidney disease
- Glomerulosclerosis $\geq 30\%$
- Chronic Renal Failure
- No urine output ≥ 24 hours
- **No candidates on the list/exhausted the list

The Liver would be deemed suitable unless the donor has one of the following:

- Cirrhosis
- Direct Bilirubin/Total Bilirubin $\geq 15\text{mg/dl}$ over 24 hours with no trauma or transfusion
- Portal hypertension
- Macrosteatosis $\geq 60\%$ or bridging fibrosis \geq stage III
- Fulminant hepatic failure
- Terminal AST/ALT > 5000 U/L
- **No candidates on the list/exhausted the list

The heart would be deemed suitable for transplant unless the donor has one of the following:

- History of Coronary Artery Bypass Graft (CABG)
- History of coronary stent/intervention
- Current or past medical history of myocardial infarction (MI)
- Severe vessel diagnosis as supported by cardiac catheterization (i.e. $>50\%$ occlusion or 2+ vessel disease)
- Acute myocarditis and/or endocarditis
- Heart failure due to cardiomyopathy
- Internal defibrillator or pacemaker
- Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
- Serial echo results showing severe global hypokinesis
- Myxoma
- Congenital defects (whether surgically corrected or not)
- **No candidates on the list/exhausted the list

The lung would be deemed suitable for transplant unless the donor has one of the following:

- Diagnosed COPD (emphysema)
- Terminal P/F <250
- Asthma (with daily Rx) in which COD due to asthma
- Pulmonary Fibrosis
- Previous lobectomy
- Multiple blebs documented on Computed Axial Tomography (CAT) Scan
- Pneumonia as indicated on Computed Tomography (CT), Xray, bronchoscopy, or cultures
- Diagnosed tumor
- Bilateral severe pulmonary contusions as per CT
- **No candidates on the list/exhausted the list

Based on these screening criteria, if the donor has at least one organ that is transplantable, the death is classified as an imminent or eligible death. Each of the organ specific criteria and the single criteria for “No candidates on the list/exhausting the list” that is on each organ specific list were voted on separately.

Motion: That the Committee accept the proposed changes for the criteria defining a transplantable kidney:

The motion passed with a vote of 15-0-0.

Motion: That the Committee accept the proposed changes for the criteria defining a transplantable liver under the imminent and eligible definition.

The motion passed with a vote of 15-0-0.

Motion: That the Committee accept the proposed changes for the criteria defining a transplantable heart under the imminent and eligible definition.

The motion passed with a vote of 15-0-0.

Members voiced concerns about the terms “diagnosed tumor” as it does not define the tumor as being benign or malignant. As there is currently an exclusion for malignancy, members agreed that this criteria would apply to a tumor that does not yet have a diagnosis, but is a mass found on CT. If malignant, the donor would be ruled out. Some suggested terms be included “evidence of tumor,” “tumor identified on CT” (or other study that has not been biopsied), or tumor “suspicious.” Members agreed that a “tumor identified with CT scan but not yet confirmed as malignant” would be the most acceptable criterion. Members felt that this was covered under general checklist. Clinical judgment is necessary to determine if a biopsy need be performed. Members agreed that the criterion of “diagnosed tumor” should be removed.

Motion: That the Committee accept the proposed changes for the criteria defining a transplantable lung under the imminent and eligible definition with the removal of the criterion “diagnosed tumor.”

The motion to accept the lung criteria as amended passed with a vote of 15-0-0.

- Diagnosed COPD (emphysema)
- Terminal P/F <250
- Asthma (with daily Rx) in which COD due to asthma
- Pulmonary Fibrosis
- Previous lobectomy
- Multiple blebs documented on Computed Axial Tomography (CAT) Scan
- Pneumonia as indicated on Computed Tomography (CT), X-ray, bronchoscopy, or cultures
- Bilateral severe pulmonary contusions as per CT
- **No candidates on the list/exhausted the list

The Committee discussed the criterion, “No candidates on the list/exhausted the list,” that appears on each organ specific list. The Subcommittee, after considering multiple alternatives, agreed that a death should not be reported as an imminent or eligible death when the OPO “works up” the organ and no one will accept it. So in order to define “exhausting the list, the Subcommittee recommended the following:

A death is not considered eligible in the following situations:

- If a potential donor has no suitable organ or if the OPO has exhausted the list, if either a match run has been run and all centers and patients on the list have declined the organ preoperatively or

- If the donor goes to the operating room with the intent to recover organs for transplant but upon visualization of the organ, all surgical teams determine not to take an organ, and no organ is actually recovered based on visualization, then this death would not be considered an imminent or eligible death
- If an OPO pursues a donor but stops the pursuit, it is not considered exhausting the list
- If kidneys are recovered but biopsy results are bad and the intent was to transplant; this death would be considered an eligible death
- When a donor is “consented but not recovered” and if the biopsy does not discount the organ but no one wants it, this death is considered an eligible death

Motion: That the following definition of “exhausting the list” be accepted: A death is not considered an eligible death if:

- The donor has no suitable organ, or
- have exhausted the list, or
- either a match run has been run and all centers and patients on the list have declined the organ preoperatively, or
- the donor goes to the operating room with the intent to recover organs for transplant but upon visualization of the organ, all surgical teams present determine not to take an organ, and no organ is actually recovered based on visualization, then this death would not be considered an imminent or eligible death

The motion passed with a vote of 15-0-0. This work is ongoing and once a proposed change to the imminent and eligible death definition is finalized, it will be distributed for public comment.

The Subcommittee will consider various issues such as mechanical preservation pump issues or parameters. It was also suggested that the different definitions of conversion rates be made consistent. The Advisory Committee on Transplantation (ACOT) is currently formulating a plan to explore the possibility of aligning the various conversion rate definitions that exist. The Committee will review the ACOT recommendations. Additionally, if the biopsy or other issue does not eliminate a donor as being considered eligible, but no one wants the organ, the Committee questioned whether that death should it be considered as eligible. The Subcommittee will also work on the Imminent Death definition, as they want to narrow the imminent definition and align it with the eligible definition. Additionally, there are some “systemic” problems or metabolic issues (I.e. high ammonia level, toxic exposure) that should be considered as an absolute rule out and might be listed to the list.

3. OPO Metric Public Comment. The OPO Committee co-sponsored the original Work Group that developed the OPO Performance Metrics. Some members felt that the metric is exclusive of conversion and as such, focuses on yield. This may result in an unintended consequence that OPOs will no longer seek out the “one organ” donor as it would affect their results. Ms. Brigham provided an explanation that the metric defines the projected yield based on 58 characteristics of the individual donor. Therefore, a donor should be identified with an expected yield of one and the actual yield would meet that expectation.

Motion: That the OPO Committee has been involved in the development of the OPO Performance Metrics and fully support the model.

The motion was passed by a vote of 15-0-0.

4. Effective Screening Work Group. Mr. Orłowski provided an update of the work of the Effective Screening Work Group. This group evolved from the Tiered Acceptance Work Group that worked under the concept that transplant centers would define the listing characteristics based on a multi-variable table (i.e. ECD, age, Hepatitis C) as to what type of organ the center would accept for an

individual donor. Prior to completion of that work, UNOS implemented DonorNet[®] and the Work Group disbanded as they concluded that the electronic service would help to streamline allocation and eliminate the problem; however, this was not the case.

The Effective Screening Work Group is currently focused on kidney allocation. The mission is to improve the use of screening tools, to reduce unwanted offers, improve the efficiency of organ placement, and reduce organ wastage and deterioration due to increased cold ischemic time. The group has concentrated on identifying opportunities for better screening of non-local marginal organs.

The Work Group has conducted transplant center education, an e-newsletter on screening tools and how to better list patients, regional and NATCO presentations, a UNOS Update article, an ATC abstract that will be presented at the May meeting, and a webinar in September, 2010, as to how to better list patient. One hundred and fifty individuals attended the webinar, which was recorded and available for ongoing education.

The Work Group also sent a targeted letter to approximately 40 centers and provided them with their data regarding their patient listing practices and the actual acceptance practice. It was noted that some of these centers had never accepted an ECD kidney. The individual center's data may not be available to OPOs. Data showed that centers were not willing to accept an ECD kidney when imported, but did accept ECD kidneys when locally procured. Mr. Orłowski will discuss OPO involvement with the Work Group in order to determine if OPOs can discuss acceptance practices with transplant centers. It was suggested that this information be shared with DEQ and at regional meetings. It would be important for the Work Group to consider who is doing the screening to determine if it is a third party and what affect that might have on acceptance rates.

The Work Group will continue to screen centers regarding their acceptance practices and will provide additional education and e-newsletters. The Group will also consider how the system can promote change in acceptance practices. The MPSC is considering pre-transplant metrics for centers and a component is acceptance rates.

5. DCD Model Elements. Mr. Pietroski MS, u-DCD Subcommittee Chair, provided a summary of the activities of the OPO/OAC Joint Work Group. The Committee will distribute the proposed policy changes to the DCD Model Elements for public comment on March 11, 2011. Subsequent to public comment, the Committee will meet by conference call to discuss the comments that are posted.

The changes to the DCD definitions will be posted in the Help Documentation. The Committee agreed that it is important to provide education to the community (i.e. webinars) about the changes to the Help Documentation on the topic to ensure that members enter their data consistently through the use of these definitions. Julie Mirkin and Esther Marie Carmichael agreed to join the Subcommittee.

The Subcommittee met on March 9, 2011, and reviewed a 2008 survey of uncontrolled DCD (u-DCD) and developed a strategy to pursue u-DCD recommendations. The Subcommittee will work with the OAC Work Group to consider:

- How to approach the environment for u-DCD
- How to better document and establish protocols for pre-hospital interventions (i.e. ambulance)
- How to best manage those patients that go from a controlled to uncontrolled DCD (i.e. those patient that arrest in the ICU and change from DCD to u-DCD)
- How to best develop protocols
- How to put safeguards in place
 - Medical or procedural
 - Declaration of death and refining the requirements

- Precautions for reanimation
 - How to address the candidate for DCD has a first person consent and narrow the scope of practice and philosophy, and
 - Update the survey
6. **Packaging and Labeling of Living Donor Organs.** Mr. Van Slyck, Label Subcommittee Chair, provided a summary of the work conducted by the Label Subcommittee. The Subcommittee met March 9, 2011, and discussed the implementation, training and use of the new label system that was implemented January 10, 2011. They discussed the following:
- The need for a tissue typing and vessel label. The current label was modified for this purpose.
 - “Tissue typing and vessel” replaced the organ heading
 - “Originating OPO” was changed to “Originating OPO/Transplant Center” and “Originating OPO Phone number” was changed to “Telephone number.” This was done so both OPOs and transplant centers can use this label
 - The OPTN would provide both a standard size label and a smaller one (4 X 6 inches)

Motion: That the Tissue Typing and Vessel label changes be adopted to read “Originating OPO/Transplant Center” and “Telephone Number.” An appropriate color will be selected, and several sizes, as noted, will be available.

The motion was passed by a vote of 15-0-0. The Committee will request that UNOS change the labels accordingly.

The Living Donor Committee has asked the OPO Committee to consider appropriate changes to the label system that would allow the transplant centers to label living donor organs when transporting them outside the donor hospital.

Motion: That the same changes be made on all labels in the label system to allow OPOs and transplant centers to use the labels for living donors as well and that the date on the labels be updated when the changes are made.

The motion was passed by a vote of 15-0-0. The Committee will request that UNOS change the labels accordingly.

At the request of the Living Donor Committee, the Committee discussed Policy 5.1.3 language related to the ability of an OPO to use an alternate label when shipping or transporting organs that are on mechanical preservation machine perfusion or packaged in coolers. Policy 5.3 also states similar language. The Subcommittee recommends that this language be stricken from Policy 5.0 in order to make all labeling consistent.

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

5.1 EXTERNAL PACKAGING SPECIFICATIONS [No Change]

5.1.1 – 5.1.2 [No Change]

5.1.3 Mechanical preservation machine

- Mechanical preservation machines are permitted for transporting an organ.
- The cassette containing the organ must be labeled with the organ type (i.e. left kidney, right kidney), ABO, and UNOS ID.
- The external surface of a mechanical preservation machine must be labeled with:
 - ⊖ the standardized external label distributed by the OPTN contractor, ~~or~~
 - ⊖ ~~an alternate label that contains all information included on the OPTN contractor standardized label.~~

- Before re-using a mechanical preservation machine that was used to transport an organ, all labels from the previous donor organ must be removed.

5.2 INTERNAL PACKAGING SPECIFICATIONS [No Change]

5.3 EXTERNAL LABELING REQUIREMENTS

When a disposable shipping box or cooler is used to transport a deceased donor organ, the Host OPO must use the standardized external label distributed by the OPTN contractor. ~~When a mechanical preservation machine is used, the OPO or Transplant Center, as applicable, may use an alternative label if the label contains all of the required information.~~

5.4 INTERNAL LABELING REQUIREMENTS—5.11 TRANSPORTATION RESPONSIBILITY [No Change]

Motion: That all references to an alternate labels when shipping or transporting organs that are on mechanical preservation machine perfusion or packaged in coolers be removed from Policy 5.0 and that this proposed change be distributed for public comment.

The motion was passed by a vote of 15-0-0. These proposed changes will be distributed for public comment.

The Committee discussed several issues affecting the labeling of perfusion machines:

- 1) the size on the Waters pump vs. the large label, and
- 2) the inability to remove the label on the ORS pump (which leaves pieces of label on a very expensive machine)

It was suggested that a smaller sized label be developed for pumps with an alternate way to tie it on. One member suggested that a sleeve be attached to the machine handle and a label can be inserted in the sleeve. The Subcommittee will discuss the suggestions and make recommendations to the Committee.

7. Vessel Recovery Storage and Transplant Work Group. Mr. Orlowski reported that the Operations and Safety Committee will recommend to the Board that:

- vessels from any donor who is considered high risk not be stored, and
- all vessels that are stored should have the label provided by the OPTN contractor affixed to them as mandated by policy

The CDC also recommends no storage of high-risk vessels. Although there has been resistance to this change, the Committee supported the change.

8. Terms, “Minimum standards” in OPTN Policy – An OPTN member asked the Committee to consider whether the terms “minimum standards” are appropriate for use in policy language. The member suggested that the term “minimum” standard creates a potential dilemma for UNOS in civil litigation cases whereby a plaintiff’s attorney may argue that a minimum standard or requirement, although met, is only minimum and that more could have been done. The member also felt that the term has unintended consequences for OPOs through an increased risk for liability.

The Committee considered the term and agreed that a minimum standard does not restrict anyone from doing more than what is required. The removal of the term minimum does not change the intent of the term “standard” as it is a minimum requirement. As such, members agreed that they do not consider the term a problem or a liability. Alone, the term “standards” implies that they are the only standards or that they are the minimum standards. The Committee did not feel that policy should be changed as this is a state of the art term.

Motion: That the chair communicate with the member and say that the Committee does not feel that the term “minimum” poses a problem and that it should remain in policy. The member may wish to seek legal counsel on this issue.

The motion was passed by a vote of 15-0-0.

9. Donor & Recipient Information Sharing Task Force – Charles Alexander RN, MBA, UNOS President, formed a Task Force to address issues regarding sharing of information between recipients and donor families. One of the issues that OPOs must address is how to best provide donor families with feedback about their transplant recipient. OPOs frequently share donor information confidentially and protect the identity of the transplant recipient when providing it to the donor family. OPOs also provide information to a variety of people (i.e. medical examiners, ICU staff).

OPOs have reported that some transplant programs are resistant to sharing recipient information. This Task Force will identify how the type of information that is shared could be standardized to ensure that restrictions from the Health Insurance and Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, and any confidentiality issues have been addressed. The Task Force will meet on April 28, 2011, in Chicago. Member comments include:

- Transplant centers interpret HIPAA differently and some do not provide any information while others are willing to share specific unidentified information. Members recommended that an attorney participate on the Task Force
- There is no uniform practice. One member suggested their protocol was ideal when on pre-transplant, the recipient receives a form that they sign giving permission to share specific information. This form is sent to the OPO to indicate what information the recipient wants shared. Maintaining confidentiality is very challenging in today’s electronic environment
- The Task Force should consider a Living Donor and recipient component to the discussion
- There should be a technology component to the initiative so data can be shared electronically. It would be important to define what information should be included and entered into this data system
- Committee members were encouraged to share any policies and procedures with the Task Force
- The Task Force should consider whether the graft survival should be included as part of the information shared by the recipient

10. Consent vs. Authorization – The Committee suggested that the term “consent” be replaced by the term “authorization” in all OPTN policies when referring to consent for donation. The Committee felt that the term consent denotes “informed consent” which is not appropriate for what occurs during the donation process when securing authorization from donor families. Consent for donation is not at the level of the standard of informed consent. It was also suggested that donor registries use terms consent/authorization during the transitional period.

Members suggested that the Committee put forward a proposed policy change relative to deceased donors, when the donation is not occurring as a result of 1st person consent or donor designation, that the term “consent” throughout policy be replaced by “authorization.” It was determined during discussion that policy should not include the term “1st person consent” because it may confuse individuals. As such, the terms “donor designation” should be used. Authorization is a term of art for the procurement field and needs to be redefined in registries. Authorization in registries was intended to be an advanced directive and the term authorization more clearly defines the action.

Motion: That relative to deceased donors/donation, that the term “consent” be replaced throughout OPTN policy by the terms “donor designation/authorization.”

The motion was approved by a vote of 15-0-0. This proposed change in policy will be prepared for the next public comment cycle. It was noted that CMS does not have the term “authorization” in their regulations. Mr. Orłowski, MS, AOPO President, will support this change with a letter and will discuss it with CMS.

11. Tracking Methods for Shipping Organs. Tom Starr, member of the Patient Affairs Committee, provided an overview of various systems that could track organs in a safe and cost effective manner during shipping. Some of the examples included bar coding, Global Positioning Systems (GPS), and Wi-Fi Systems. Each system has specific benefits. Bar coding can be described as a license plate that requires scanners (usually at a close range). However, if damaged, the bar coding is unreadable. A portable data file is similar to a stacked bar code where all the information is coded inside the data file.

With today’s technology, donor information could be put into the high density bar code which is about the size of a postage stamp. Wi-Fi requires at least 3 receivers and tracks location within a large geographic area. It was suggested that the two systems that might be most workable for the industry would be a GPS system or bar coding. The current system relies on human accuracy (as labels must be filled in manually) and color recognition (there is a chance a person would be color blind). A GPS device would be inexpensive and a GPS chip could be placed on each container. These chips are virtually indestructible. A transponder would be needed to provide power at an estimated cost of under \$10 per container. It was determined that special equipment is needed in order to place the donor information on the chip, but the equipment is readily available.

Members agreed that a system should have the ability to track organs as well as contain information that can be shared (i.e. donor chart). Concerns were voiced regarding the need for transplant centers to use electronic tracking devices and the need for consistency in systems between OPOs and centers. It was suggested that the Transplant Administrators and Transplant Coordinators Committee work with the Subcommittee on this project. The Label Subcommittee will continue to explore possibilities for tracking organs and sharing information.

12. Policy 6.0 Transplantation of Non- resident Aliens. At the request of the Ad Hoc International Relations Committee, the OPO Committee considered “pre-proposal” policy language changes to Policy 6.0 regarding the transplantation of non-resident aliens. None of the Committee members has formal agreements with centers outside of the United States. Several members described their need to contact the Organ Center (i.e. email, phone call, fax form) in order to export organs to Canada. Members voiced their confusion regarding the correct way to handle foreign imports and exports and recommended more clarity in policy. Members agreed that there needs to be specific triggers and procedures in place for OPOs to ensure timely and accurate allocation.

Members suggested that information in policy regarding importing organs should be separated from the information on exporting organs to promote clarity. Additionally, information should be divided into two policies, one for transplant center requirements and one for OPO requirements.

In Policy 6.4.3 (Ad Hoc Organ Exchange), organs imported by OPOs must include documentation certifying that the donor has met brain death or donation after cardiac death (DCD) protocols and must be in compliance with recognized standards for domestic organ procurement. Policy also states that for organs imported by OPOs, the donor organization must include documentation certifying the informed consent of the donor (or his or her legal representative) and documentation verifying the donor’s ABO.

Currently, there is no consistency for determining brain death throughout the United States and members questioned how OPOs would determine if brain death had been declared appropriately. Documentation also varies in the U.S. from state to state and would need clarification as to specific minimum requirements. Policy regarding brain death declaration would also need to be very explicit in the instruction for certifying that the donor has met neurologic death standards. OPOs are not familiar with other countries' requirements for declaration of neurologic death and therefore should not have to certify that brain death had been declared appropriately. The OPO should only need to document that brain death has been declared, not how it was declared. Any imported organs should be reported to UNOS so they can be tracked and evaluated.

The process for importing and exporting organs must be clear and will require education for transplant centers and OPOs. OPOs understand that they must exhaust the waiting list in order to meet the requirements for exporting an organ. OPOs do not need a complex method or system that will slow down the process. These organs are usually offered late in the process as they have already been offered to anyone on the list. The Committee suggests that policy not make it so restrictive that a patient in another country receives a compromised organ due to extensive delay. There is a public trust issue in that some may see it as organs leaving the country as unfair while US citizens wait for organs. It must be clear that the OPO must exhaust the list prior to an organ being offered outside of the country.

Additionally, there are situations that may require some flexibility. For example, an OPO may have four procurement teams waiting and under time restraints with a Canadian patient that is one hour away compared to a US candidate that is 6 hours away. Members suggest that these policies not be so restrictive that a patient in another country will not get a transplant and/or an organ be wasted, recovery delayed or an organ not recovered.

The Committee agrees with the following recommendations:

- That the policy be divided into several sections regarding importing and exporting to a foreign country
- That procedures to allocate organs for the transplantation of resident aliens be clearly stated, and
- That a living donor policy be created that is separate from deceased donor

It was unclear as to why special arrangements are needed when UNOS runs the match, and members agreed that the current system was working and did not need to be changed. It is a very rare occasion that organs would be exported and it is most likely that these organs would not be transplanted in the US. Members agreed that when no one in the US wants to transplant a particular organ that the organ be offered outside the US in order to get it transplanted and not wasted. When revising the policy, it would be helpful to focus on importing organs and patient safety issues.

13. Liver Biopsy Form – The OPTN Organ Availability Committee (OAC) has asked for Committee input regarding a standardized Donor Liver Biopsy Form with some Web based training for labs, transplant surgeons and fellows. The Committee agreed that the form was a dramatic improvement; however, members agreed that pathologists may not wish to use it or have difficulty using it. Additionally, the Committee felt this form should be recommended and not required because of the number of small hospital pathologists that would not know how to complete it and may cause them to be cited for a violation of policy.

Members agreed that education was essential regarding how to get images posted on DonorNet[®] so transplant surgeons and transplant pathologists might read the actual images as opposed to looking at the form. It was determined that getting pictures of the slides would be difficult, particularly in

small hospitals that do not have all of the needed equipment. Many community hospitals do not look at liver biopsies frequently enough and do not have the technology (i.e. scopes to take pictures) to provide pictures. Based on this policy, if a member asked for a slide, the pathologist is obliged to provide it. It was suggested that the OAC work with the American Society of Clinical Pathology as they provide educational modules for their members.

Members agreed that the form is very comprehensive; however, some information may be daunting to the pathologist (i.e. inflammation with Hepatitis C+ donors, interface hepatitis vs. lobular inflammation and damage) and would create a challenge for many. If the form is required, information would need to be transcribed which also increases the risk of transcription error.

Members agreed that:

- Instead of a required form, guidelines for providing the required information would be very helpful
- This form is very involved for the type of information that community pathologists can provide. Members suggested that information be identified that could be provided by a community hospital pathologist
- Members commented that the information is presented in a much better way than in the past. This form represents a “gold standard,” but practically it is too complicated. In the Committee’s experience, small hospital pathologists will not know how to fill out all of the information while pathologists in a major center would have no difficulty in doing so
- One member opined that if someone was accepting a hepatitis C+ organ, that they should have their own pathologist review the biopsy results
- With inflammation, classifications that would be needed are “minimal, moderate or severe.” More sophisticated explanations are not necessary

Although the Committee agreed that the form is excellent, it may not be suitable for the pathologist who practices at a small community hospital. The Committee suggests that the OAC seek guidance from community pathologists regarding the level of information that is possible.

14. Public Comment. The Committee considered each of the proposals that have been distributed for public comment.

1. Proposal for Improved Imaging Criteria for HCC Exceptions.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

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

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

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

The Committee agreed that this system will create an incentive for a center to recover and split livers, as the center will be able to transplant both liver segments. However, the surgical team needs to communicate with the OPO so that the OPO is made aware that the liver will be split and to whom the segment is allocated. Therefore, there needs to be a process in place to notify the OPO at the time of allocation regarding who will receive the additional segment. This will provide the OPO with the opportunity to ensure that the

recipient is properly listed. The Committee also discussed the situation that might occur when a liver is recovered with the intent to split it, and then it is not split.

Motion: That the Committee support this proposal with the recommendation that a process be required to notify the OPO at the time of allocation regarding the split and who will receive it. This provision is made so that the OPO can verify that the organ is allocated according to the list.

The proposal with the recommendation was approved by a vote of 15-0-0.

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

The Committee discussed the requirement of a bronchoscopy for all lung offers and agreed that this requirement is not a burden to the OPO. Additionally, Committee members voiced confusion as to the need to “encourage” an OPO to provide a CT scan. Policy currently requires OPOs to provide additional testing “if requested.” Therefore, if a CT scan is requested, the OPO will provide it, if possible. This change is redundant and is setting up an expectation that may be unrealistic. One member who performs CT scans on all potential lung donors discussed the benefits and suggested that more lungs are being shared as a result. However, members agreed that it should not be required, but should remain a test that can be requested. Organ acquisition fees are impacted by this policy change and would help the OPO to explain why there is an increase in costs. Members also agreed that there should be some reason to do the CT scan; it should be “medically indicated.”

The interpretation of CT scans can vary and could result in a decline in the number of organs accepted. Some members suggested that these tests may encourage more declines. One member explained that when the OPO conducted more CT scans, there were more pathology reports that stated, “Cannot rule out (a given condition...)”, which resulted in wasting good, transplantable lungs.

Members also questioned why there are two different places listing what tests are necessary for lung donors. The Committee suggests that a reader be referred to Policy 2.0 and that the information does not need to be repeated in this policy. It is the OPO’s responsibility to ensure that the quest for every piece of information be balanced with the reality of organ procurement and the many factors that influence the ability to get certain test results.

The Committee suggests that Policy 2.0 be reviewed. If the thoracic Committee wishes to place the proposed changes in this policy, then the changes should mirror the information in Policy 2.0. The Committee agreed that this information should not be in two places and suggests that this information be removed from policy 3.0 and placed in policy 2.0.

There can be no absolutes in evaluating organ donors because each is unique and the resources at each donor hospital are unique. When there is a donor in the middle of the night with no one that might conduct the test, it will not be completed.

In summary, having the information in various places is confusing and inconsistent. A bronchoscopy is essential, but OPOs cannot always get one. As such, it should not be required, but should be encouraged.

Motion: That the Committee support the proposal.

The Committee did not support the proposal by a vote of 0-15-0 but agreed that:

- Information should not occur in two places in policy and any additional language should be placed in Policy 2.0.
- Policy 2.0 addresses the need for additional testing as it includes language regarding the OPOs responsibility to provide testing that is requested.

5. 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.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

6. Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

7. Proposal to Improve the Reporting of Living Donor Status.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

8. Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials.

The Living Donor Committee is aligning the packaging and labeling of living donor requirements with those of deceased donor requirements. The Donor Recovery Transplant Center has the responsibility to package and label living donor organs.

If repackaging of an organ is necessary, the transplant center should notify the recovery center. It is possible that someone could open and tamper with the organ and ship it elsewhere. If done, the Donor Recovery Transplant Center should be notified. The Committee is supportive of any policy that protects patient safety and minimizes the risk of an organ being wasted. Some of the language is difficult to follow and some members would like the language simplified. The Committee questioned whether there are living donor intestine transplants and if that needs to be in the policy.

Motion: That the Committee support the proposed changes to this policy.

The Committee supported the proposed modifications to this policy with a vote of 15-0-0.

9. Proposal to Require Confirmatory Subtyping of Non-A₁ and Non-A₁B Donors.

Members considered the proposed changes to Policy 3.1.1.3 regarding confirmatory ABO sub-typing of Blood Group Non A₁ and Non A₁B Donors. Members stated that there is potential difficulty in obtaining sub typing results. Generally they can get the test done at their designated or contracted laboratories, but may be unable to get this sub-typing done at their donor hospitals. If the donor hospital is a considerable distance from a contracted laboratory, this will present challenges and delays in organ recovery.

If sub-typing is completed within the donor hospital, there can be various interpretations and different results. As such, if there are doubts regarding the results, there should be an option of defaulting to using only A or AB list for allocation.

This policy also requires two pre-transfusion samples. Members voiced concern as this requirement is extremely difficult, if not impossible, to fulfill. Many donors are transfused, and it may not be possible to get adequate pre-transfusion sample size to run two tests.

Additionally, the term "confirmation" that, from a laboratory point of view, refers to a different type of test that would confirm the original test. Members agreed that the terms "verification" or "determination" should be used as opposed to the term "confirmation." Additionally, some clarification is needed regarding whether the test can be verified at the same laboratory or if there a requirement to use a different laboratory.

Motion: That the Committee support the policy change with the recommendations outlined above and that the terms "verification" or "determination" be used as opposed to the term "confirmation."

The Committee supported the policy with the proposed modifications to this policy with a vote of 14-0-0.

10. Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport. (OPO Committee Proposal)

11. Proposal to Update and Clarify Language in the DCD Model Elements. (OPO Committee Proposal)

12. Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

13. Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B.

The Committee did not comment on this proposal, as there were no issues identified that affect OPOs.

15. Future Meetings. The next Committee meeting will be held September 14, 2011, with conference calls that will be planned for June and July.

Attendance

OPO COMMITTEE		MONTH	Jan	March
		DAY	18	10
		FORMAT (select)	Live Meeting/ Teleconference	In Person
NAME	COMMITTEE POSITION			
Lori Brigham MBA	Chair		X	X
Richard Pietroski MS, CPTC	Vice Chair		X	X
George Lipkowitz MD	Regional Rep.			
Susan Stuart RN, MPM	Regional Rep.		X	
Lynn Williams	Regional Rep.		X	X
Patrick Giordano FACHE	Regional Rep.		X	X
Lisa Stocks FNP, RN	Regional Rep.		X	X
Katherine Kickertz BSN, CPTC	Regional Rep.		X	X
Meg Rogers	Regional Rep.		X	X
Rob Linderer RN, BSN	Regional Rep.			X
Julie Mirkin MA, RN	Regional Rep.			X
Gordon Bowen MS	Regional Rep.		X	X
Michael Marvin MD	Regional Rep.		X	X
Esther Carmichael	At Large		X	X
Meredith Harrison	At Large		X	
Jeffrey Orłowski MS, CPTC	At Large			X
Richard Padula RN	At Large		X	X
William Reitsma BSN	At Large		X	X
Sean Van Slyck BA,CPTC	At Large		X	X
Teresa Beigay DrPH	HRSA		X	By phone
Robert Walsh	HRSA		X	
Monica Lin	HRSA			
David Zaun	SRTR Liaison			X
Ajay Israni	SRTR Liaison			X
Stacey Burson	Business Analyst		X	X
John Rosendale	Support Staff		X	X
Franki Chabalewski RN, MS	Committee Liaison		X	X
Margaret Kearns	DEQ		X	By Phone
Tiffany Lord	DEQ		X	By phone
Sarah Herbert	DEQ			By Phone