

**OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
November 8-9, 2010
St. Louis, Missouri**

Summary

Action Items for Board Consideration

- The Board is asked to approve changes to the OMB forms. (Item 1, Page 3)

Other Significant Items

- The Committee is working with the Executive Committee to define its role in evaluating policy proposals at the early stages and prior to being distributed for public comment. (Item 2, Page 4).
- The Committee is developing some principles to address multi-organ allocation policies. (Item 5, Page 7).
- The Committee reviewed 6 proposals that were distributed for public comment on Oct. 1, 2010. (Items 7-12, Pages 8-12)

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Stuart C. Sweet, MD, PhD, Chair

This report represents the deliberations and recommendations of the Policy Oversight Committee during its meeting on October 7, 2010, in Chicago, Illinois.

1. Office of Management and Budget (OMB) Forms Review. All OPTN forms must be reviewed and approved by the OMB every three years. The OPTN initiated a review of the data elements in early 2009 in order to identify any necessary changes. Following a comprehensive review of all the data elements by OPTN Committees, the Ad Hoc Data Management Group (AHDMSG), an Expert Panel on Cardiovascular Risk Factors in Renal Candidates/Recipients (Expert Panel), and the POC, the Committee submitted a proposal for public comment in March 2010. The purpose of the proposed changes was to add important variables that are not currently collected, clarify or modify questions on the forms, and eliminate variables that are redundant or no longer needed.

Due to the significant opposition to this proposal, OPTN/UNOS leadership decided in April 2010 that the current proposal *would not* be submitted to the Board of Directors in June 2010. A conference call with the leadership of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) was held on May 24, 2010 in order to discuss their concerns with the proposal. It was agreed that a revised proposal would be submitted to the ASTS and AST for their review prior to the POC meeting. This revised proposal was sent to the leadership of the ASTS and AST on August 20, 2010, and a formal response from them was received on September 16, 2010.

A detailed description of the original proposal, copies of all comments received, the revised proposal, and a copy of the correspondence letters with the ASTS and AST, is included in the briefing paper *which is available in electronic format upon request.*

It was noted that since most of the opposition to the proposal was to the data elements proposed to improve the program specific reports (PSRs); these were removed from the proposal. These data elements were originally proposed because there was concern about the data currently being collected and whether it was enough to do adequate risk adjustments on the PSRs. Another significant issue that was raised during public comment was the cost of submitting these additional data elements. Based on the feedback from public comment as well as the ASTS/AST, the revised proposal was presented to the POC during its October 7, 2010 meeting.

Highlights of the revised proposal include:

- Deceased Donor Registration Form – one clarification and one minor modification based on public comment.
- Recipient and Donor Histocompatibility Forms – a few minor modifications from the original proposal.
- HCC Pathology Form – this will only be required for recipients with an HCC exception at the time of transplant.

- Limited number of additions and modifications to the living donor registration (LDR), living donor follow-up (LDF), transplant candidate registration form (TCR), transplant recipient registration form TRR), and transplant recipient follow-up TRF) forms.

The Committee submits the following for consideration by the Board of Directors:

**** RESOLVED, that the OMB forms shall be modified following approval by HRSA, submission to the OMB, and pending programming in UNet. *(The final list of proposed changes can be found on pages 15-28 of this report)***

Committee vote: 10 in favor, 0 opposed, and 0 abstentions.

Following the vote, the committee briefly discussed some ways to improve the process of revising data collection in the future. For this round of OMB forms, UNOS staff solicited recommended changes from every committee as well as the SRTR and the management of this large amount of information required a lot of staff and volunteer time. Some possible solutions could be:

- Alternative means of data collection.
- Consideration of funding to do “pilot studies” on samples of data.
- When a group or committee requests the addition of data elements, what sort of evidence does there need to be?

This issue will be discussed further over the next year or so in preparation for the next round of forms review.

2. POC Role in Early Evaluation of Committee Activities. The committee discussed a potential new role in the policy development process, although it might actually be just a clarification of the original intended role of the POC in the process. Over the past few years, the leadership of the OPTN has recognized that the policy development process has encountered a few barriers. These include:

- Financial constraints, for the OPTN and the membership.
- Proposals being distributed for public comment before full stakeholder involvement.
- The development of policies has created a backlog in programming and some policy changes are no longer relevant by the time they get programmed.

In response to this, the Executive Committee has been charged with a more active role in monitoring policy development to:

- Ensure cost-effective use of committee time and policy development resources.
- Ensure that proposals achieve cost-effective improvement in allocation policy consistent with the Final Rule.
- Ensure key stakeholders are engaged early and often.
- Ensure proposals are not out of date when implemented.

There are certain realities that need to be addressed. First, the computer systems are currently undergoing a major redesign that will hopefully make them more flexible and allow for more efficient and effective programming of future policy changes. Second, even with a new computer system in

place it is not going to be possible to implement every project or idea that gets proposed by the various committees. What is being proposed is a rational process for looking at projects early on and trying to decide what projects have the highest value and the most impact on patients and on transplant centers. This is especially important in order to prevent a committee from spending time and resources on a project that might not be a high priority or does not fit into the strategic goals of the OPTN. The POC could serve a valuable role in advising the Executive Committee because of its broad representation from the committees and its expertise. Some of the ideas for what the POC could do include:

- Provide objective assessment of the proposal's potential to further the OPTN mission
- Provide objective assessment of the anticipated impact on other OPTN policies
- Help identify key stakeholders (within and outside the OPTN)
- Help establish anticipated development, implementation, and maintenance costs.
- Help establish an estimated timeline for the proposal so, if approved, resources are in place to begin programming soon after Board approval.

Although the overall structure and process has not been finalized yet, there is a plan for the Executive Committee to start prioritizing policy development and implementation. The basic idea is that the Executive Committee will establish a set of key goals for the organization. This will include things like patient safety, increasing the number of transplants, equal access, etc. The Executive Committee would then look at the committee projects and try to decide which projects would have the highest impact while staying within the estimated resources available to develop and complete the projects.

Some of the comments received from the committee members include:

- A lot of policy proposals are multi-year projects so that needs to be accounted for, especially with constant changes in the leadership within the organization as well as the other professional organizations.
- For some of the larger projects (e.g. kidney allocation) it would be nice to get input and direction from executive leadership and the government early on.
- Communication is going to be extremely important. This includes communication between the committees, the various levels of leadership, and key stakeholders including many of the professional societies/organizations.

Following the discussion, the Committee made the following motion:

MOTION: That the Executive Committee clarify the role of the POC in the process of policy development so that the POC can provide objective review of policies and make recommendations to the Executive Committee at various stages in the policy development process. The POC requests that it be a requirement for committees to get input and feedback from the POC at the initial idea stage and prior to be distributed for public comment. The POC will not approve or disapprove of policy proposals, instead the POC will provide an objective recommendation to the Executive Committee about the strengths of the proposal and provide specific feedback to the committee about how the proposal can be improved as necessary. The POC also recommends that a work group be formed with the Executive Committee to work on the details of this proposal and develop a process for this review.

Another issue that the POC will need to address is the membership of the committee. It was suggested that additional committee vice-chairs need to be added to the POC, including the vice-chairs of the Transplant Administrators Committee, DTAC, and several other important constituent committees. It was also noted that it would be advantageous for the POC to have a vice-chair in order to allow for a smooth transition of committee leadership. It was noted that the representation of the committee is listed in the both the OPTN contract and the bylaws but can be modified by sending a recommendation to the OPTN Project Officer. UNOS staff and committee leadership will work on these recommendations.

3. Structure of Deceased Donor and Living Donor Policies. During the ongoing policy rewrite project, it was noted that a vast majority of OPTN policies were written with deceased donation in mind. However, since the OPTN has taken on a greater role in the oversight of living donation there has been some confusion about what policies apply specifically to living donors. Several years ago, a new section of policies were created to deal with living donation issues; however there is still some confusion about other policies that could be interpreted in such a way that they could be applied to either living or deceased donation. Some are specific about this, other are not. So as the policy rewrite project has been working to make the policies more clear and easy to understand, several questions have come to mind:
 - Does a certain policy apply to living donation only?
 - Does a certain policy apply to deceased donation only?
 - Does a certain policy apply to both?

An example of this was when the Living Donor Committee decided to work on organ transportation policy. They wanted to address this because more living donor organs were going to be transported due to the increase in paired donation pilot programs. They initiated work on this by using the current policies for transporting deceased donor organs, but it soon became clear that there were many other issues to be considered. Who pays for the transportation? Who is liable? Is it under an OPO or transplant center's contract? So it is not as simple as taking deceased donor policies and replacing the word "deceased" with the word "living." There is an incorrect assumption that living donation policies can mirror deceased donation policies; however, areas are constantly being identified that prove this is simply not the case. It was noted that there are actually more differences than similarities between living and deceased donation.

UNOS staff provided a proposed framework for addressing this issue (**Exhibit B**); however the committee felt that the most important issue that needs to be addressed is making the policies more user-friendly so people can find what they are looking for within the policies. From a practical standpoint, we live in an electronic world and it is important to put things in an easily accessible place depending on the user's needs.

4. Rewrite Project Update. UNOS staff provided a brief update on the policy rewrite project. This project is a comprehensive look at all the policies and is trying to make sure people can understand them and find what they need. Some of the changes are as simple as adding glossaries and indexes. The project has tried to limit the amount of policies being moved because this impacts the cost, both the administrative costs to the community as well as the OPTN. This does not mean that things are not being moved, because there are a lot of things that are out of place. For example, there are numerous places where requirements are hidden in definitions.

The question was raised about whether there was any discussion at the beginning of this process to reorganize the framework so it is easy to find whatever the user needs? As noted in the previous discussion, we at least need to change the ability to access information. There are simple things that you can do on a website such as linking the policy numbers to the other relevant places on the website. Also, think about how end users are going to navigate the policies and provide that framework as an entry point to find information. It was noted by UNOS staff that a usability test is being set up with some members of the transplant community so once we have a product that is ready to be reviewed, we will be able to test it to see if has accomplished the goal or not. The reality is that it is less important where you put information, it is more important that you create a mechanism for people to easier access the information.

It was noted that once the internal review of the non organ-specific allocation policies are completed, the POC will need to review them to make sure the structure makes sense and it is easier to read and understand before it gets presented to the broader public. The POC should see something in the next 6 months or so. The question was raised about the status of the external advisory board that was recruited and it was noted that they have not yet seen any finished product. There was a suggestion that the POC could actually serve the role as the external group.

5. Multi-Organ Allocation Policies. The POC has recently been charged with addressing multi-organ allocation policies. It was noted that the goal of the discussion during the meeting was not to solve the problem, but instead to create a path forward. The POC could work on establishing some principles that can be endorsed by the Board and then be used by the organ-specific committees. The individual committees can look at the policies within the framework of the principles and decide what needs to be changed.

Dr. Stuart Sweet used heart/lung allocation as an example of how multi-organ allocation policies are confusing and ambiguous. The Thoracic Organ Transplantation Committee has been discussing ways to improve heart/lung allocation. Current policy is set up to avoid using combined heart/lungs in one patient when there is a sicker patient who could benefit from one of those two organs. For example, the policies state that you cannot allocate a heart to a heart/lung candidate if there is a Status 1A candidate available, yet it does not specify if that is locally, by zone, or nationally. This leads back to the balance of utility and equity. If you go strictly on benefit, you run the risk of creating a situation where a multi-organ candidate will never get access to an organ, therefore compromising equity. The reality is that heart/lung candidates are waiting several years because their waiting list mortality is not the same as a Status 1A candidate.

Numerous questions and concerns were raised by the committee members:

- How are we going to rank candidates in terms of what their priority should be? For example, should isolated heart candidates get priority over heart/lung candidates because the pre-transplant survival is worse and the post-transplant survival is better? This is definitely an issue in kidney/pancreas.
- Why would we use what could potentially save three lives by allocating two isolated lungs and a heart instead of a single heart/lung bloc?
- How do we clearly define equity? We are nowhere close to defining it when talking about geography, race, socioeconomic status, etc.

- How do we define lifesaving organ? It is wrong to assume that a kidney is not a lifesaving organ because there are plenty of people waiting for a kidney alone that are going to die on the wait list.
- Balancing equity and utility is challenging because what our policies try to do is balance that within the same organ based on urgency so candidates get the best chance at an organ before they die on the waiting list.
- Is there an equity bailout? If a certain population is disadvantaged by the system how do they get access?
- Do you have to go nationally before you can move down the list or do you do it within a certain allocation zone, depending on what organs you are allocating?

The committee agreed to form a work group to begin working on a set of principles to guide further discussions. It was noted that the Ethics Committee should be involved in the discussions. UNOS staff will set up a conference call in the next couple of months and this approach will be part of the POC presentation to the Board in November to make sure they approve of this path forward.

6. Committee Updates. The vice-chairs represented on the POC provided updates on their individual committee projects. Since the POC is proposing to provide feedback on committee projects during the early stages, this was a way to get an idea of things coming down the pike. Some highlights of the presentations included:

- Living Donor Committee - ongoing work to improve donor follow-up.
- Kidney Transplantation Committee – currently working on reviewing all the variances.
- OPO Committee – currently working on a proposal for OPO performance metrics. The question was raised about whether the metrics included post-transplant outcomes. The reason being that recipient outcomes can be influenced by how the donor was managed prior to transplant. It was noted that this is not currently in the proposal but it was something that will be taken back to the committee for their review.

The issue of geography was brought up and lead to a considerable amount of discussion. It was noted that the geographic barrier issue needs to be addressed and it needs to be based on science and data, not political or administrative boundaries. It was noted that the POC could make a big impact by addressing this complicated issue because if it is left up to the individual committees it will never get done. The Pediatric Committee has made some good progress in the area of geography. For example, livers get allocated through national Status 1 candidates before being allocated regionally and there is good data to show that it works.

It was acknowledged that geography is a real political issue. That was clearly evident last year with the liver proposal for regional sharing of MELD/PELD. It was noted that once the POC establishes some principles to address multi-organ allocation, they could possibly do the same for the geographic issue.

Review of Proposals Circulated for Public Comment, October 1, 2010 (Scores Provided in Table 1)

7. Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs (Thoracic Organ Transplantation Committee)

Policy 3.7.12.1 does not require the collection of HLA Class I and II data on deceased donor thoracic organs. Also, Policies 3.7.12.1.1 (Essential Information for Lung Offers), 3.7.12.2 (Desirable Information for Heart Offers), and 3.7.12.3 (Desirable Information for Lung Offers) do not recommend collection of HLA data from deceased donor thoracic organs. Clinical practice and a brief review of the literature inform that knowledge of thoracic donor HLA allows for the most suitable candidate to receive a thoracic organ offer.

Coupled with recently developed techniques to determine HLA antibody specificity and perform virtual crossmatching, having donor HLA data available at the time of a thoracic organ offer will allow centers to consider offers for sensitized recipients in circumstances where prospective crossmatch is not practical. Enabling virtual crossmatching for thoracic organs also has the potential to reduce post-transplant morbidity and mortality by preventing unanticipated positive crossmatches. Therefore, the proposed policy change requires provision of HLA typing at the time a transplant program receives a thoracic organ offer.

There was some concern about the lack of an exception for expedited consent. In some situations, there is an ability to move forward quickly following consent and there might be a disadvantage to some OPOs that are unable to respond to a prescriptive requirement. Alternately, some centers that have hospital-based OPOs may be at an advantage because they can mobilize a recovery team and have them ready in the operating room with the knowledge that no HLA is going to be available and could affect other transplant centers ability to accept the thoracic organ offers. It was noted that offers could go out without HLA being available, but if there was a request for HLA typing from a transplant center getting a primary offer, the OPO would have to do their best to provide it.

Another issue that was raised was that the documentation requirement could potentially be burdensome. Everything outlined in the proposal seems to be based on paper documentation which could be burdensome to the OPTN, transplant centers, and OPOs when it comes time for DEQ audits. It was noted that the committee did discuss mechanisms to document the process but decided to move it forward this way so that no programming would be required. There could certainly be a recommendation that as soon as UNetsm can be programmed to handle the documentation it should be done. It was noted that OPOs could actually document in the DonorNet[®] record that they received the request for HLA. That is probably the better way of handling that than a paper-based system where you have to match up two different records to figure out what really happened. UNOS staff noted that when they consulted with DEQ site auditors to come up with the appropriate monitoring plan, the auditors stated that they look at patient records and that DonorNet[®] is not considered an official patient record. There was some question about whether this communication really needed to be part of the patient record if the information is accessible.

It was suggested that what needs to be considered is if an OPO is unable to comply with the request for HLA typing, they must document the reason in DonorNet[®]. This will help with the collection of information about what the barriers are so it can be reviewed over time. The committee requested a data search for the missing HLA match runs.

The Committee voted to support the proposal with the understanding that there is an opportunity for documenting not having HLA typing in a DonorNet[®] record. Committee vote: 8 in favor, 0 opposed, and 0 abstentions.

8. Proposal to Clarify Adult Heart Status 1A Exception Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetsm (Thoracic Organ Transplantation Committee)

This proposal clarifies language about Status 1A-exception (“general Status 1A-exception”) and Status 1A-exception by criterion b. Both sections are in Policy 3.7.3. Status 1A exception language does not state explicitly that clinicians requesting Status 1A-exception may only do so for candidates who are admitted to their listing hospital. Language in Status 1A-criterion “b” does not state that clinicians may enter a mechanical circulatory support device complication not listed in policy as examples. Language in Status 1A-criterion b does not state that when a clinician reports an “other” complication, UNOS staff processes this entry as a request for Status 1A-exception by criterion b. Finally, a request for Status 1A exception by criterion b does not require that the candidate be an inpatient, but policy does not explicitly state this flexible hospitalization status for this exception scenario.

The Committee supported the proposal by a vote of 8 in favor, 0 opposed, and 0 abstentions.

9. Proposal to Shift Responsibility for Elements of the Living Donation Process to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy (Living Donor Committee and Membership and Professional Standards Committee)

The purpose of this proposal is to clarify and, in some cases, change which transplant program is responsible for specific elements of the living donation process. Under this proposal, the transplant program that operates on the living donor will be responsible for that process, which includes the consent, medical and psychosocial evaluations, peri-operative care, and required follow-up reporting on the donor. The intended goals for this policy include improving living donor follow up by shifting the responsibility for living donor follow-up to the hospital that has an established relationship with the living donor. Additionally, the revisions may lead to improved living donor safety by requiring that transplant hospitals can only accept living donor organs from transplant programs that have the appropriate protocols and staff in place to recover that type of living donor organ.

The Committee supported the proposal by a vote of 8 in favor, 0 opposed, and 0 abstentions.

10. Proposal to include Qualifications for Director of Liver Transplant Anesthesia in the Bylaws (Membership and Professional Standards Committee)

This proposal would require liver transplant programs to designate a Director of Liver Transplant Anesthesia who has expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team; and who has the appropriate board certification. It will also delineate certain administrative and clinical responsibilities that should be handled by the Director, as well as minimal qualifications that should meet.

There was some question about why this was done only for liver transplant anesthesiologists. It was noted that there was not a lot of support for it being done across all organs and it was the liver group that had been working on this proposal for quite a few years. There are already specialized cardiac anesthesiologists for heart and lung and it was acknowledged that the anesthesiologists are not going to agree that they need specialized training for kidney transplantation. It was also noted that there should be some sort of clinical data to show that special training for anesthesiologist makes a difference before even trying to address this issue for kidney transplantation.

The Committee approved the proposal by a vote of 8 in favor, 0 opposed, and 1 abstention.

The POC recommends that the MPSC look at existing practice for specialized anesthesia and consider documenting what currently exists. This could include documenting the director, listing the board certifications, and coming up with suggestions for qualifications that are specific to the various organs.

11. Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries. (Membership and Professional Standards Committee)

The proposal recognizes that surgeons who are designated and qualified to perform laparoscopic living donor nephrectomies, are also designated and qualified to perform open donor nephrectomies. The goal of the proposal is to provide an additional means for meeting the open donor nephrectomy qualifications. The revisions also eliminate the requirement for approving kidney transplant programs to be specifically designated to perform open donor nephrectomies since the majority of donor surgeries are performed laparoscopically. These proposed revisions more closely align the bylaws with current practice.

It was noted that this is good proposal that recognizes changing surgical practice, however the MPSC should look at increasing the number of procedures required in order to properly protect donors. A laparoscopic donor nephrectomy is a potentially high-risk operation but is safe with the proper training.

The committee supported this proposal with the caveat that the MPSC have a discussion with the professional societies about potentially increasing the total number procedures required in order to protect living donors.

Committee vote: 8 in favor, 0 opposed, and 0 abstentions.

12. Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels. (Operations and Safety Committee)

The Operations and Safety Committee has proposed policy language for OPTN policy 5.10.2 (Vessel Storage) to prohibit the storage of Hepatitis C antibody positive and Hepatitis B surface antigen positive extra vessels. The proposed addition of policy is meant to improve patient safety and recipient outcomes related to the storage and transplant of extra vessels. This change is expected to reduce the risk of disease transmission from transplant of extra vessels into secondary recipient(s) when the vessels are not transplanted into the recipient for whom the donor's organ was originally procured.

One committee member felt that this proposal was an unnecessary change made following one documented incident of disease transmission. A better approach would have been to improve the communication and establish some safety measures by requiring a time out to check the documentation and serologies prior to implanting an extra vessel. There are plenty of centers that do a lot of hepatitis C transplants and these extra vessels are important and need to be saved in case they are needed during the peri-operative period.

The question was raised about whether there was any consideration given to modifying the labels so that it restricts the use of the vessel to only the original recipient? It was noted that the labeling did not seem to be the issue with this particular case; it was more of an issue that the transplant center did not verify the information that was on the vessel label prior to implant. It was noted by the OPO representative that a new labeling system has recently gone into effect and there is a specific vessel label that lists every serology so you no longer have just a blank label where you fill in every reactive serology. Every serology is listed and you simply check off whether it is reactive or non-reactive.

It was suggested that instead of restricting the use of these potentially important vessels, the committee should consider:

- Implementing the timeout process described in this proposal
- Limiting the use of these vessels to only the original recipient
- Having some very clear differences in the labels for these vessels to make sure it specifies that they are only to be used for a single recipient.

The Committee did not support this proposal by a vote of 0 in favor, 6 opposed, and 0 abstentions.

13. POC Scorecard. Following the review of public comment proposals, the committee discussed some ways to potentially improve the POC scorecard which has been in place for 4 years. Some of the suggestions include:

- Evidence of collaborative effort – score how well a committee brought the key stakeholders into the process early on.
- Special populations such as pediatric, minorities and special diagnosis groups. It is important as we look at policies to be sure there is an objective measure on something that addresses a special population. Proposals may not always benefit a large number of patients but may be designed to address a specific needs population.
- Maximum capacity – This question may not be relevant for all proposals. For example, it might send a wrong message to maximize the number of living donor transplants.
- Patient safety is a broad category – it was suggested that we look at creating a couple of subsections under patient safety.
- Cost considerations – a common issue raised during public comment is the unfunded mandate that a policy change will have on the membership. It was noted that part of the process for the earlier evaluation projects will be the cost aspect. These include the development costs, programming, and potential costs to the membership. It was noted that this is a perfect example of why the POC needs to have representation from the transplant administrators.

The scorecard should be viewed in two parts. The first 5 questions address how the proposal falls within the strategic priorities of the organization. It was noted that these priorities might change based on future discussions by the Executive Committee. The last 5 questions address how well the policy was developed. The real challenge in modifying the scorecard is making it simple while encompassing all the key components. It was noted that we simply want to raise questions that the experts did not consider and provide feedback on the delivery of the information.

UNOS staff and committee leadership will work on some proposed changes and circulate it by e-mail for review.

Table 1	Thoracic HLA	Heart Status 1A	Shift Responsibilities for Elements of Living Donor Process
Patient Safety and Transplantation Oversight	1.9	2.0	2.8
Best Use of Donated Organs	1.9	1.7	1.0
Geographic Equity	0.8	0.6	0.5
Maximum Capacity	0.8	0.7	0.9
Operational Effectiveness	1.8	1.7	1.4
Statement of the problem	2.0	2.1	2.4
Evidence	2.1	2.3	2.1
Assessment	1.6	1.7	2.0
Patient Impact	1.9	1.7	2.4
Degree of Criticality	1.4	1.3	2.0

Table 1 (continued)	Liver Anesthesiologists	Living Donor Recoveries Hospital Requirements	Hepatitis C Extra Vessels
Patient Safety and Transplantation Oversight	2.3	1.4	2.8
Best Use of Donated Organs	0.9	0.4	1.8
Geographic Equity	0.4	0.5	0.4
Maximum Capacity	0.5	0.9	0.3
Operational Effectiveness	1.4	1.3	1.3
Statement of the problem	2.3	2.1	2.6
Evidence	2.4	2.4	2.4
Assessment	2.0	1.9	2.1
Patient Impact	2.1	1.6	1.9
Degree of Criticality	2.0	1.1	2.1

Attendance at the October 7, 2010 meeting of the OPTN/UNOS Policy Oversight Committee

<u>Member</u>	<u>Position</u>	<u>Attended</u>
Stuart C. Sweet, MD, PhD	Chair	X
John Freidewald, MD	At-Large	X
David Axelrod, MD	At-large	X
Richard E. Pietroski, MS, CPTC	At-large	X
Heung Bae Kim, MD	At-large	X
Laura Ellsworth, MBA	At-large	X (phone)
Silas Norman, MD	At-large	X
Mary Kelleher, MS, CIP	At-large	X
Kim Olthoff, MD	At-large	X (phone)
Steven Webber, MBChB	At-large	
Amy Waterman, PhD	At-large	X
Robert Walsh	Ex-Officio	X
Christopher McLaughlin	Ex-Officio	X
UNOS Staff in Attendance		
Erick Edwards, PhD	Assistant Director, Research	X
Robert Hunter	Policy Analyst/Liaison	X
Brian Shepard	Director of Policy	X
Vipra Ghimire	Liaison, Thoracic Organ Transplantation Committee	X
Sally Aungier	Liaison, MPSC	X
Lee Bolton	Liaison, Living Donor Committee	X
Kimberly H. Taylor	Liaison, Operations and Safety Committee	X
Ann Harper	Liaison, Liver and Intestinal Organ Transplantation Committee	X
SRTR Staff in Attendance		
Ajay Israni, MD, MS	MMRF-CDRG	X
Jon Snyder, PhD, MS	MMRF-CDRG	X

Living Donor Registration Form

Eliminate Unknown

- Biliary Complications (Liver)
- Vascular Complications Requiring Intervention (Liver/Kidney)
- Other Complications Requiring Intervention (Liver/Kidney)

Non-PSR Additions

- Country of Permanent Residence (only collected for those indicated to be non-resident aliens)
 - o *Principle of Data Collection: Compliance, Safety*
 - o *Rationale: This request came from the Ad Hoc International Relations Committee and is requested in order to better monitor issues and increase transparency regarding living donors coming from other countries. The intent is to enable the identification of patterns of living donations from a single country across multiple centers.*

Non-PSR Modifications (Related Deletions/Additions)

- *Modify CMV to CMV Total, Delete CMV Culture, CMV Clinical Disease*
- *Replace EBV DNA, EBV Clinical Disease with EBV Total*
- *Modify HBV DNA to HBV DNA (NAT/PCR), Delete HBV Clinical Disease, HBV Liver Histology*
- *Modify HCV DNA to HCV DNA (NAT/PCR), Delete HCV Clinical Disease, HCV Liver Histology*
- *Replace HIV Confirmation, HIV Screening, HIV Clinical Disease with HIV Status*
 - o *Principle of Data Collection: Safety*
 - o *Rationale: When LDR originally created, serology section was taken directly from the recipient forms. It does not make sense to collect information about clinical disease and liver histology on living donor forms. These modifications will be more relevant to living donors and will allow for standardized assessment of risk of viral transmission from donor to recipient.*

Deletions

- Post-op height
- Did organ recovery and transplant happen at same center?
- Kidney biopsy
- Glomerulosclerosis
- HDV (Delta Virus)

Living Donor Follow-Up Form

Non-PSR Modifications (Related Deletions/Additions)

- *Replace* CAT Scan, MRI, Ultrasound (3 questions) with ER or urgent care visit related to donation since last follow-up (1 question)

Non-PSR Additions

- Dates for individual post-donation tests and measurements (weight, serum creatinine, blood pressure, bilirubin, SGOT/AST, SGPT/ALT, alkaline phosphatase, serum albumin, INR)
[Supported by AST/ASTS]
 - o *Principle of Data Collection: Safety*
 - o *Rationale: allows more precise assessment of donor outcomes and center performance*

Transplant Candidate Registration Form

Eliminate Unknown

All Organs

- Any previous malignancy (y/n)

Non-PSR Additions

All Organs

- Country of Permanent Residence (only collected for those indicated to be non-resident aliens)
 - o *Principle of Data Collection: Compliance, Safety*
 - o *Rationale: This request came from the Ad Hoc International Relations Committee and is requested in order to better monitor issues and increase transparency regarding travel for transplantation. The intent is to enable the identification of patterns of listings from a single country across multiple centers.*

Pancreas, Kidney-Pancreas

- C-peptide value [Supported by AST/ASTS]
 - o *Principles of Data Collection: Allocation Policy Development and Compliance*
 - o *Rationale: C-peptide is one of the qualifying criteria for the proposed pancreas allocation system that is under development. These data will be collected on the waiting list, but are also needed on the TCR to capture candidates who do not meet qualifying criteria and are not accruing waiting time.*

Liver

- Has the candidate ever had a diagnosis of HCC?
 - o *Principle of Data Collection: Allocation Policy Development*
 - o *Rationale: The current system does not identify all candidates with HCC. Adding this field will enable the Liver Committee to develop better policy regarding HCC by including the outcomes of all candidates with HCC, not just those who meet exception criteria. The question should be required for all patients as previously endorsed by the Liver Committee. A recipient may have an incidental HCC and have been transplanted w/o exception at a higher (or lower) MELD.*

Intestine

- Total Bilirubin (for adults) [Supported by AST/ASTS]
 - o *Principle of Data Collection: Allocation Policy Development*
 - o *Rationale: Total bilirubin was collected for pediatrics but not adults. The Committee agreed that this may be an important factor to consider in the development of future*

intestine organ allocation policy as it has been shown to have predictive value in the pediatric population.

Non-PSR Modifications (Related Deletions/Additions)

None.

Deletions

All Organs – Adult Forms (Note: These are collected only for candidates <19 years)

- Academic Activity Level
- Academic Progress

All Organs – Pediatric Forms

- Previous Pancreas Islet Infusion

Kidney, Kidney-Pancreas

- Drug Treated COPD

Heart, Heart-Lung, Lung

- Previous Pancreas Islet Infusion

Transplant Recipient Registration Form

Modification/Eliminate Unknown

Kidney, Kidney-Pancreas

- Malignancies between listing and transplant (eliminate unknown)
- Change number of previous pregnancies to any previous pregnancy (yes/no)

Non-PSR Additions

All Organs

- HBV Surface Antibody Total, only for recipients of HBV positive donor organs.
 - o *Principle of Data Collection: Safety and Donation Policy Development*
 - o *Rationale: Currently, the collection of recipient data for hepatitis B is limited to HBV Core Antibody and HBV Surface Antigen. Some centers additionally test for HBV Surface Antibody and presently there is no way for the center to provide that information. In a recipient that was vaccinated for HBV, they would be HBV Surface Antibody positive, but HBV Surface Antigen and HBV Core Antibody negative. Collecting this additional information would allow for further investigation into the usage of HBV positive donor organs (i.e. are they only going into recipients already positive and/or those that are HBV- but previously vaccinated). If those results suggest that HBV positive donor organs can be safely transplanted into recipients with evidence of protection, it could allow for greater utilization of those organs. We could also look at utilization of HBV infected donors by whether the recipients had evidence of protection from prior exposure or vaccination and further estimate the risk of disease transmission through organ transplantation.*

Kidney, Kidney-Pancreas

Liver

- Has the candidate ever had a diagnosis of HCC?
 - o *Principle of Data Collection: Allocation Policy Development*
 - o *Rationale: The current system does not identify all candidates with HCC. Adding this field will enable the committee to develop better policy regarding HCC by including the outcomes of all candidates with HCC, not just those who meet exception criteria. Collecting this information on both the TCR and TRR will allow for identification of patients who develop HCC while waiting. If the recipient was indicated to have HCC at the time of listing or an HCC exception at time of removal from the waiting list, the field would pre-populate with a positive response.*

Lung, Heart-Lung

- Components of ISHLT primary graft dysfunction (PGD) grade
 - o Intubated at 72 hours
 - o PaO₂ at 72 hours
 - o FiO₂ at 72 hours
 - o ECMO at 72 hours
 - o Inhaled NO at 72 hours
 - o *Principle of data Collection: Allocation Policy Development*
 - o *Rationale: The LAS is currently based only on patient survival (pre- and post-transplant). But if PGD grade is available, the Thoracic Committee could explore incorporating a measure of graft function in the allocation system to divert organs away from patients in whom PGD is likely.*

Non-PSR Modifications (Related Deletions/Additions)

- Replace CMV IgG and CMV IgM with a single CMV status field. Documentation will specify that positive CMV IgG or positive CMV Total result should be reported as positive.
 - o *Principle of Data Collection: Safety*
 - o *Rationale: In reviewing the data provided from 2008, only 1% of transplants report only an IgM result without an IgG result. It is believed that it is much more common for transplant centers to perform the CMV Total or CMV IgG test than the currently collected CMV IgM. After further discussion, the DTAC believes a single CMV field will provide the necessary information currently collected in two fields.*

Deletions

All Organs – Adult Forms [NOTE: These are collected only for recipients <19 years]

- Academic Activity Level
- Academic Progress

Liver, Intestine, Heart, Lung, Heart-Lung

- Malignancies between listing and transplant

Kidney, Kidney-Pancreas

- Pretransplant transfusions

Kidney, Kidney-Pancreas, Pancreas

- Medical Condition at Transplant

Transplant Recipient Follow-up Form

Eliminate Unknown

None.

Non-PSR Additions

All Organs

- HIV serology, HIV NAT results at six months and one year post-transplant
- HbsAg, HBV DNA, HBV Core antibody results at six months and one year post-transplant
- HCV serology, HCV NAT results at six months and one year post-transplant
 - o *Note that these questions will be required for transplants where donor was indicated to be “CDC High Risk” on Deceased Donor Registration form. Centers will have the ability to mark “not done” as an option.*
 - o *Principle of Data Collection: Safety*
 - o *Rationale: One of the main goals of the DTAC is to evaluate the risk of donor transmitted infections in recipients of deceased donor organs. Currently, no post-transplant viral detection information is collected other than CMV for kidney recipients. This type of information for the other viruses was dropped from the forms during the Data Reduction effort of 2007. However, since that time there has been renewed discussion and interest in the appropriate use of organs from deceased donors meeting the CDC “high risk” criteria. Several conferences have been held discussing these issues and the use of NAT testing for screening deceased donors. The recommendation coming from those groups is that post-transplant testing for HIV/HCV/HBV in recipients of these organs should be the standard of care. The collection of this information would be useful in two ways. First, it is necessary to have information on any newly positive results in order to identify any donor transmissions that may not have been recognized as such by the recipient transplant center. Secondly, it will allow the OPTN to determine how often these recipients are being tested post-transplant.*
- Malignancy Site/Type Donor Related Tumors
 - o *Principle of Data Collection: Safety*
 - o *Rationale: Currently no data are collected regarding the type or site of donor related and recurrent tumors. Without knowing anything about type or site of the tumor it is not possible to compare the malignancies reported by different recipients from the same donor in order to identify potential cases of donor transmitted tumors that may not be recognized as such by the recipient center. This proposal is to collect the same type/site information for donor related tumors as it currently collected for de novo tumors. Identifying the risk of donor transmission is one of the goals of the DTAC.*

Non-PSR Modifications (Related Deletions/Additions)

None.

Deletions

All Organs – Adult Forms [NOTE: These are collected only for recipients <19 years]

- Academic Activity Level
- Academic Progress

Deceased Donor Registration (DDR) Form

Data elements proposed for all organ donor DDR forms:

- *Add to existing forms:*
 - TB History
 - Chagas History
 - Type of Skin Cancer at Time of Procurement
 - Clinical Infection Confirmed
 - Confirmed Clinical Infection Source
 - Type of Intracranial Cancer at Time of Procurement
 - Type of Extracranial Cancer at Time of Procurement
 - Type of Left/Right Kidney Pump
 - Liver Machine Perfusion
 - Machine Type
 - Heart Machine Perfusion
 - Left/Right Lung Machine Perfusion
 - NAT Results (HIV, HTLV, HBV, HCV, Chagas, West Nile)
 - Serology Results (Chagas, West Nile)
 - Was Patient Declared Legally Brain Dead?
 - FiO2
 - PEEP
 - Ventilator Mode
 - *For DCD: Any Extracorporeal Support Given and How Long
 - *Left and Right Kidney Biopsy Type
 - *Left and Right Kidney Biopsy, Number Glomeruli Visualized
 - *Left and Right Kidney Biopsy, Interstitial Fibrosis (Grade)
 - *Left and Right Kidney Biopsy, Vascular Changes (Grade)
 - *Liver Biopsy Type
 - *Liver Biopsy, Fibrosis (Grade)
 - *Liver Biopsy, Portal Infiltrates (Grade)
 - *For DCD: If yes to Any Extracorporeal Support Given, Flow Rate

- *Modify existing forms:*
 - Collect every 5 minutes between withdrawal of support and start of agonal phase (currently collected every 15 minutes)

- Date, Time, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Blood Pressure, O2 Saturation
 - Collect every 1 minute between start of agonal phase and cardiac death (currently collected every 5 minutes)
 - Date, Time, Systolic Blood Pressure, Diastolic Blood Pressure, Mean Arterial Blood Pressure, O2 Saturation
- *Race to follow CMS 2728 form (White, Black or African American, American Indian/Alaska Native, Asian, Native Hawaiian or Other Pacific Islander)
- *Ethnicity (Not Hispanic or Latino, Hispanic or Latino)
- *Delete from existing forms:*
 - Clinical Infection
 - Source
 - Confirmed by Culture
 - Estimated Warm Ischemic Time
 - Inotropic Dosage
 - Inotropic Dosage Units
 - Inotropic Dosage Duration
 - Three or More Inotropes at Time of Incision
 - Was pO2 Done?
 - *Liver Biopsy, Other Histology
 - *Anticonvulsants

Data elements proposed for all Pancreas and Liver donor DDR forms:

- *Add to existing forms:*
 - Volume of Initial Flush Solution
 - Volume of Back Table Flush Solution

Data elements proposed for all Pancreas donor DDR forms:

- HbA1c

New Explant Pathology Form For Liver Recipients

**The first two questions on the form must be answered for all liver recipients who had an HCC
Exception at the time of transplant:**

- Was evidence of HCC (viable or non-viable tumor) found in the explant?
- Pre-transplant treatment for HCC?

If “No” is answered to both questions, the form is complete. Otherwise, additional information is requested:

- Number of tumors
 - Satellite lesions?
 - Tumor size, location, necrosis for each tumor
 - Worst tumor differentiation
 - Vascular invasion
 - Lymph node involvement
 - Other extrahepatic spread
-
-

Histocompatibility (HF) Form

Data elements proposed on Donor HF:

- *Add:*
 - 2 DQA fields (0101, 0102, 0103, 0201, 0301, 0302, 0303, 0401, 0501, 0503, 0505, 0601, No 2nd antigen detected, Not tested)
 - 2 DPA fields (0103, 0104, 0105, 0201, 0202, 0401, No 2nd antigen detected, Not tested)
 - *Delete:*
 - Haplotype Match for Living Donor Recipients
-
-

Data elements proposed on Recipient HF:

- *Add:*
 - Recipient HLA typing:
 - 2 DQA fields (0101, 0102, 0103, 0201, 0301, 0302, 0303, 0401, 0501, 0503, 0505, 0601, No 2nd antigen detected, Not tested)
 - 2 DPA fields (0103, 0104, 0105, 0201, 0202, 0401, No 2nd antigen detected, Not tested)
 - Anti-HLA antibodies:
 - Were any HLA antibodies detected by Cytotoxicity? (Yes, No, Not Done)
 - Were any HLA antibodies detected by Solid Phase? (Yes, No, Not Done)
 - Was there current donor specific HLA antibody? (Yes, No, Unknown)
 - Was there historical donor specific HLA antibody? (Yes, No, Unknown)
 - CPRA (%) – Most Recent (only for recipients of thoracic organs) – laboratories will use the calculator to determine the CPRA value based on detected HLA antibodies
 - CPRA (%) – Peak (only for recipients of thoracic organs) – laboratories will use the calculator to determine the CPRA value based on detected HLA antibodies
 - Crossmatch:
 - Cell source
 - Which T-cell crossmatch tests were performed? (Cytotoxicity No AHG; Cytotoxicity AHG; Flow Cytometry; Solid Phase, Not Tested)

- Which B-cell crossmatch tests were performed? (Cytotoxicity No AHG; Cytotoxicity AHG; Flow Cytometry; Solid Phase, Not Tested)
- Which historical crossmatch tests were performed? (Cytotoxicity No AHG; Cytotoxicity AHG; Flow Cytometry; Solid Phase, Not Tested)
- Crossmatch results for each of the reported historical crossmatch tests (Positive, Negative)
- Donor Retyping:
 - 2 DQA fields (0101, 0102, 0103, 0201, 0301, 0302, 0303, 0401, 0501, 0503, 0505, 0601, No 2nd antigen detected, Not tested)
 - 2 DPA fields (0103, 0104, 0105, 0201, 0202, 0401, No 2nd antigen detected, Not tested)
- *Delete:*
 - Anti-HLA antibodies
 - Most recent class I and II PRA/ HLA antibody screening:
 - serum date
 - target
 - technique
 - technique, specify
 - technique measures
 - anti-HLA interpretation
 - PRA (%) – Most Recent Class I
 - PRA (%) – Most Recent Class II
 - Peak class I and class II PRA/ HLA antibody screening:
 - serum date
 - target
 - technique
 - technique, specify
 - technique measures
 - anti-HLA interpretation
 - PRA (%) – Peak Serum Class I
 - PRA (%) – Peak Serum Class II
 - Was serum screened for anti-HLA class II antibody?
 - Were any sera tested pre-transplant that contain anti-HLA Class I antibody?
 - Were any sera tested pre-transplant that contain anti-HLA Class II antibody?
 - Crossmatch:
 - Most recent crossmatch (for up to 5 crossmatches):
 - cell type
 - target

- technique
 - technique, specify
 - measures
 - autocrossmatch result using this target and technique
 - Date of crossmatch serum - least recent
 - Positive crossmatch with sera other than the most recent by any method (Yes, No
 - Positive crossmatch with sera other than the most recent by any method (for 5 crossmatches):
 - serum date
 - cell type
 - target
 - technique
 - technique, specify
 - measures
 - negative crossmatch by any other technique with this serum
 - autocrossmatch result using this target and technique
 - Autocrossmatch results:
 - Has autocrossmatch ever been positive?
 - Autocrossmatch date – positive autocrossmatch
 - Donor retyping:
 - target cell source class I
 - target cell source class II
- *Modify:*
 - Crossmatch:
 - Crossmatch results – collect crossmatch results for all reported T-cell and B-cell crossmatch tests (up to 8 results) and delete Indeterminate and Weak Positive options