

**OPTN/UNOS Organ Procurement Organization Committee  
Meeting Summary  
June 10, 2014  
Conference Call**

**Richard E. Pietroski, MS, CPTC, Chair  
Sean F. Van Slyck, MPA, HSA, CPTC, Vice Chair**

*Discussions of the full committee on June 10, 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.*

**Committee Projects**

Not discussed

**Committee Projects Pending Implementation**

Not discussed

**Implemented Committee Projects**

Not discussed

**Review of Public Comment Proposals**

- 1. Proposal to Align OPTN Policies with the PHS guideline for Reducing Transmission of Human Immunodeficiency virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation.**

The Committee met by conference call to respond to the following specific questions (in *italics*) contained in the Ad Hoc Disease Transmission Advisory Committee proposal.

*Which implementation timeframe (6 months, 1 year, longer?) is appropriate, reasonable and practical to allow for OPOs to make necessary changes in policies and procedures, contracts, logistical practices, etc. to comply with revised donor testing requirements?*

The OPO Committee recommended an implementation timeframe of one year.

*What, if any, is the impact of the revised policy on delay in organ procurement offers and procurement, and potential loss of organs (and donors) due to an initial positive HCV nucleic acid testing (NAT) result that may require completion of additional testing?*

The main focus of the Committee's discussion centered on logistical issues. Occasionally there are challenges in getting NAT results based on such factors as the location of the donor hospital, equipment issues, weather, etc. While it is ideal to wait for final NAT results, if the serology results are negative, the transplant centers should have the option of proceeding with allocation and transplant. There are also scenarios where the family might consider withdrawing consent if there are delays or if the donor is unstable, hence the reason to allow for the option to proceed to transplant if deemed clinically appropriate.

The Committee discussed why there would be a need to retest following an initial positive NAT result. One Committee member noted that labs will sometimes perform “batch testing” and if results are positive the labs will perform discriminatory testing. As previously discussed, there could be an option for the transplant center(s) to accept and transplant the organ(s) before receiving final discriminatory results. The Committee discussed the scenario where multiple organs are accepted by different transplant centers but not all of the centers agree to wait for final test results. This could be due to logistical issues or how sick the candidates are at a particular transplant center. This creates the need to negotiate and come up with a consensus among all involved transplant centers. Once again, the Committee agreed that it is ideal to wait for final test results, but also having an available option to proceed if requested as long as the reasons are documented.

The Committee discussed rerunning the match run when final serology or NAT results are received. One Committee member noted that it is the practice in her OPO to rerun the match run based on updated serology or NAT results. UNOS staff noted that a joint subcommittee is currently addressing this issue.

The Committees’ final recommendations: 1) If logistical reasons require the OPO to move forward to allocate organs without NAT results, the reasons should be documented. 2) OPOs are always encouraged to wait for final NAT results but there should be an ability to proceed if deemed clinically necessary. 3) If the transplant center accepts the organ prior to final results, the testing process should continue and results reported to the transplant center as soon as possible.

*What are the consequences for recipient informed consent and acceptance of organ when an unsuspected initial HCV NAT positive result is reported after procurement but prior to transplant procedure?*

The Committee agreed that every patient should be advised about the potential for disease transmission, even with a non-reactive serology or negative NAT. The Committee agreed that transplant centers need to be notified immediately so they can make the decision about whether to use that organ or not, and if not then the OPO will need to find an appropriate recipient. This might include rerunning the match run.

*What are potential legal and ethical impacts and consequences on OPOs and transplant centers for obtaining a delayed positive HCV NAT result after organ procurement and transplant of an organ? What about receiving an initial positive HCV NAT result after organ procurement and transplant?*

The Committee agreed that as long as available information is being reported in a timely manner, the transplant centers will have the information necessary to make a medical decision regarding the acceptance and transplant of organs from a particular donor. Results received after procurement or transplantation can lead to complications but are part of the medical decision making process and patients need to be informed.

*How are the above questions affected by labs that run a “triplex” (combined HCV, HIV, HBV) NAT test even when only the HCV NAT is ordered? This could lead to the potential for multiple false positives that need to be investigated and resolved?*

The Committee acknowledged that the testing technology is changing and there will always be false positive or false negatives, but the rate should remain low. Most OPOs are testing for HIV, HCV, and HBV so the use of a “triplex” test will better facilitate the testing. The Committee agreed that the test does not change the answers to the previous questions.

*What are the potential legal, logistical, and ethical impacts and consequences on lab, OPO, and transplant center of running the “triplex” (HCV, HIV, and HBV) NAT test to comply with the revised policy? Must a lab report the results of the HIV and HBV NAT even if the test was not specifically ordered?*

The Committee previously addressed the logistical, legal, and ethical issues. The Committee agreed that all results should be reported even if not specifically ordered. One Committee member noted that some labs bundle their services in order to avoid reporting issues.

*What sort of data are available that would assess the extent and variability of false positive rate (in deceased donors with no “increased risk” factors) of HCV NAT in the various high volume “batch” labs (e.g., regional blood donor testing labs) versus individual stand-alone and hospital based labs?*

The Committee discussed how some OPOs or labs send their samples out for a secondary confirmatory test. The Committee questioned the need for a secondary confirmatory test on NAT reactive donors because once an OPO receives a positive result they treat it as a positive. The Committee also cautioned against requiring this because states have different health department reporting requirements. Additionally, OPOs would need to further communicate with the legal next of kin about this additional testing. The Committee recommended that no additional testing be required to verify a true or false positive result.

*Might there be special subpopulations or subgroups of deceased and living donors where it may be reasonable to exempt “universal HCV NAT” testing to avoid a false positive scenario (e.g., pediatric deceased donors with no “increased risk” factors or living donors with well documented medical and social behavioral health history)?*

The Committee agreed that the requirement to perform HCV NAT should be universal.

*Including additional wait list screening criteria for HCV and HBV NAT will carry substantial programming costs. Is it necessary to have separate wait list screening criteria for serology and NAT results for these two viruses?*

DTAC staff noted that the proposal includes that addition of specific NAT fields in DonorNet®. In the interim, OPOs are including the information in the donor highlight field. The Committee supports this practice until programming can be completed in DonorNet®.

*The current medical-social criteria for determining increased risk include dialysis as a risk factor for HCV. Should short term dialysis or continuous veno-venous hemofiltration (CVVH) only at the time of the terminal hospitalization carry the same risk as chronic dialysis for potential transmission? Should this be clarified in policy or in a guidance document?*

The Committee discussed how OPOs vary in their interpretation of the PHS guideline. Some OPOs are classifying these donors as “increased risk” while other are not. One Committee member reached out to colleagues from the PHS guideline work group and the opinion was that short-term dialysis or CVVH during terminal hospitalization should not trigger classification as “increased risk.” Additionally, the journal article cited by the PHS guideline work group addressed only chronic dialysis and the risk factors associated with the treatment. However, the PHS guideline does not specifically state “chronic dialysis” but instead mentions those who “have been on hemodialysis in the previous 12 months.” The Committee agreed that individuals who have no previous history of renal disease or dialysis but undergo dialysis or CVVH due to acute renal failure should not be classified as “increased risk.” Additionally, some donor hospitals perform hemodialysis for donation purposes which should not count as “hemodialysis in the past 12 months.” Following the conference call, one Committee member noted that the leadership of the PHS guideline work group has reached out to HRSA for clarification on this issue.

The Committee recommended further clarification of the following PHS guideline:

“Donors who meet the following criterion should be identified as increased risk for recent HCV infection only: People who have been on hemodialysis in the preceding 12 months.”

### **Other Significant Items**

#### **2. Final review and approval of VCA (vascularized composite allograft) internal and external labels.**

The VCA Committee requested guidance from the OPO Committee in developing a new label for packaging and transporting VCA grafts. The VCA Committee, Operations and Safety Committee, and OPO Committee reviewed various drafts of the external label. The OPO Committee was asked to review the final version of the internal and external vessel labels. One Committee member noted one error on the label (duplicate upper limb right check boxes) which was subsequently fixed. The Committee approved the label by a vote of 13 in favor, 0 opposed, and 0 abstentions. The final new VCA internal and external labels are available on the UNOS Store at <http://store.unos.org/search.php?q=labels>.

### **Upcoming Meeting**

- September 23, 2014