Determination of Human Leukocyte Antigen (HLA) Type for Thoracic Organ
Results of a Survey of Histocompatibility Laboratories

Dear Histocompatibility Laboratory Professionals,

The Thoracic Organ Transplantation Committee (Committee) is planning to add HLA type to Policy 3.7.12.1 (Essential Information [for Thoracic Offers]). Knowledge of deceased donor HLA antigens will allow transplant centers to accept, on behalf of sensitized thoracic candidates, organs from donors without a prospective crossmatch, if the donor does not contain antigens to which the candidate is known to be sensitized ("virtual crossmatch").

The number of candidates for heart and lung transplantation that are sensitized is steadily increasing. Hence, it is paramount for thoracic programs to know the HLA type of deceased donors to define if organs offered to them can be considered for use in candidates that are known to be sensitized.

The Committee's anecdotal and experiential knowledge is that many organ procurement organizations (OPO) already provide HLA type information to programs when offering deceased donor hearts and lungs. This provision of information, however, is not mandated in policy. To ensure that sensitized candidates have access to medically suitable donated hearts and lungs, the Committee is planning to add HLA type to Policy 3.7.12.1.

The following is the current language of Policy 3.7.12.1:

The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;
(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;
(v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
(vi) Accurate height, weight, age and sex;
(vii) ABO type;
(viii) Interpreted electrocardiogram and chest radiograph;
(ix) History of treatment in hospital including vasopressors and hydration;
(x) Arterial blood gas results and ventilator settings; and
(xi) Echocardiogram, if the donor hospital has the facilities.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

Appendix: Survey of Histocompatibility Laboratory Directors
(June 16, 2010-June 30, 2010)

The Committee continues to discuss two salient components of the proposed policy: 1) the specificity of HLA type provided; and, 2) the time when OPOs must provide HLA type information to transplant programs, i.e., at the time of the organ offer or before a match-run.

The Committee is working with the following OPTN/UNOS Committees to develop this proposal: Histocompatibility, Operations and Safety, and Organ Procurement Organization. To best understand the operational impact, the four Committees have developed this survey.

Completing the survey is voluntary and confidential. The Committee will analyze the results in aggregate. However, to best understand the national practice of obtaining HLA type on deceased thoracic organ donors, the Committee would tremendously value responses from all OPTN member Histocompatibility laboratories. Therefore, could one representative from each laboratory complete the following survey on or before June 30, 2010?

If you have questions, please contact Vipra Ghimire at ghimirev@unos.org or 804-782-4071. Thank you for your time and response.

Sincerely,

The Thoracic Organ Transplantation Committee

Appendix: Survey of Histocompatibility Laboratory Directors
(June 16, 2010-June 30, 2010)

Question 1: What is the deceased donor sample you HLA type at your laboratory most frequently? Please select one answer from the options provided below:

Number of organizations that answered question: **73** (number used to calculate percentage)
(Number of organizations that skipped the question: 3)

- Peripheral blood: 59 (80.8%)
- Lymph nodes: 14 (19.2%)
- Spleen: 0
- Buccal swab: 0

Question 2: What primary method do you use for deceased donor typing of Class I HLA? Please select one answer from the options provided below:

Number of organizations that answered question: **72** (number used to calculate percentage)
(Number of organizations that skipped the question: 4)

- Serology: 13 (18.1%)
- Sequence-specific primers (SSP): 47 (65.3%)
- Sequence-specific oligonucleotides (SSO): 12 (16.7%)

Question 3: What primary method do you use for deceased donor typing of Class II HLA? Please select one answer from the options provided below:

Number of organizations that answered question: **73** (number used to calculate percentage)
(Number of organizations that skipped the question: 3)

- Serology: 9 (12.3%)
- SSP: 51 (69.9%)
- SSO: 13 (17.8%)

Question 4: Do you require a different deceased donor sample than indicated above if the donor has received multiple blood transfusions?

Number of organizations that answered question: **72** (number used to calculate percentage)
(Number of organizations that skipped the question: 4)

- Yes: 25 (34.7%)
- No: 47 (65.3%)

Question 5: What is the average time from receipt of deceased donor blood or tissue to reporting the HLA type to the OPO? Please respond in hours to the nearest half hour.

Number of organizations that answered question: **70**
(Number of organizations that skipped the question: 6)

Responses:

- 4-5 hrs on average.
- 3-4 hrs
- 4 hours
- 5 hours
- need more information to respond
- 4-5hrs.
- 4 hours
- 6 hours
- 4 hrs
- 3.5 hours
- 6 to 8 hours
- 4hrs
- 5 hours
- 3.5 - 4 hrs
- 5.0 hours
- 6
- 2.5
- 6 Hours
- 5 hrs
- 3 hours
- 5
- 6 HRS.
- 4
- 3 hours
- 72 hrs
- 2.0
- Actually it is the OPO that performs the typing and reports to the HLA Laboratory. It usually takes approximately 4 hours.
- 3.5 h
- 5.5
- 4.5 hrs
- 4.5
- 4 to 5 hours
- 5
- 4.0
- 5 hours
- 5 hours or less
- 4.5 hours
- 3.5
- unknown
- 8 hours
- 6 hours
- 5 hours
- 4 hrs
- Our dd typing is confirmatory only. We report it along with the crossmatch results.
- 4
- 4 hours
- 5 hours
- 8
- Our lab is not an OPO lab but rather a transplant program lab. We do not report HLA types to the OPO. We could report HLA types within 5 hours.
- 3 hours
- 5 hours
- 5.0 hours
- 3.5 hrs
- reviewed last 12 months of deceased donors.
  Average time from sample to match run=4.5 hours alwways by serology. Range 2.5 to 6.25 hours.
- 3.5 - 4.0 hrs
- 4
- 5 hours
- 5 hours
- 4-5 hrs
- 4.5 hrs
- 2.5 to 3 hrs
- 5.5 hours
- 4 hours
- 3.5 hours
- about 5 hours. note above that we use both serology and SSP on local donors.
- 4-4.5 hpors
- 4 hours
- we are not opo lab, so I cannot answer this accurately
- 3.0
- 3 hrs

Question 6: Which HLA loci do you currently type for deceased thoracic donors? Please select all applicable answers from the options below.

Number of organizations that answered question: **73** (number used to calculate percentage)
(Number of organizations that skipped the question: 3)

- HLA-A: 73 (100.0%)
- HLA-B: 73 (100.0%)
- HLA-Bw4/6: 69 (94.5%)
- HLA-Cw: 63 (86.3%)
- HLA-DR: 73 (100.0%)
- HLA-DR51/52/53: 68 (93.2%)
- HLA-DQ: 70 (95.9%)
- HLA-DP: 10 (13.7%)

Question 7: What general comments do you have about the proposed addition of HLA type to Policy 3.7.12.1? Please write below.

Number of organizations that answered question: **65**
(Number of organizations that skipped the question: 11)

Responses:

- We do not perform deceased tissue typing in our lab

- -Another local lab does the deceased donor HLA typing for the OPO.
  -Our thoracic transplant team inquired if any extra allocation points or priority was given to highly sensitized candidates (e.g. similar to kidneys for 80%+). Would like to see graduated points/priority for thoracic (and kidney) candidates, e.g. 4 points for 80%+, 3 points for 60-79%, 2 points for 40-59%, 1 point for 20-39%.
  -Detailed donor HLA typing especially important for import offers/virtual crossmatches for these sensitized candidates.
  -Clinicians have also requested details for (more) standarization of HLA ab measurement (beyond the CPRA).
  2. Comment: class I done by both serology and SSP. Make sure DR53 null alleles are ruled out.
  4. comment: since most transfusion products are leuko-reduced, it's very rare for deceased donors (or any heavily transfused patient) to receive enough WBC (intact or fragments) to interfere with the HLA typing. There's no need to require lymph node or spleen (and therefore delay testing) for HLA typing. Refer to publications related to this topic. (Confirmatory HLA typing lymph node or spleen advised when any typing needs verification.)

- Currently we automatically use pronase cross matching for all sensitized thoracic donors, and we beleive that this should be adopted for all deceased donor labs(our bias). Also recently we have noted the occurance of DP antibodies in ~20% of the thoracic sensitized

recipients but we don't type for DP in the donors. Therefore, we can't use DP for virtual crossmatch.

- I support the proposed addition

- no comment

- Good idea for allocation to sensitized patients. Will increase access for the sensitized patient since the catchment area for donor availability can be expanded.

  NOTE: Labs must do complete HLA typing (A, B, C, DRB1, DRB3,4,5, DQB, DQA and DP) in order for this approach to be the most successful. Patients make antibodies against HLA- C, DQB, DQA and DP. Not providing typing for these loci so that a virtual crossmatch can be performed will clearly disadvantage some recipients. If the policy is designed to increases access and provide equity to all sensitized patients then these loci should be included. Molecular methods are readily available from several vendors to accomplish this task at a very modest increase in cost/typing.

- it will be important for us to have HLA type before a match run

- It's a must

- HLA typing is necessary to meet the needs of current clinical practice for thoracic organ transplant and should be required. Typing for all of the above loci, but HLA-DP, should be strongly encouraged, if not required. Laboratories should also be encouraged to have the ability to type for specific common HLA subtypes, as detected by microarray antibody testing, at the request of the importing laboratory/transplant center to assist with "virtual crossmatch" interpretation.

- This change is long overdue.
  HLA-DP typing should be at a minimum strongly recommended. Requirement should be considered.

- Good idea.

- Great idea! Pretransplant, to estimate risks of rejection, we need to know the HLA type of the donor, the immune status (HLA abs) of the patient, and crossmatch results. Post transplant, we need to know if any DSAs are developing, which again requires a HLA typed donor, and HLA antibody identification. Virtual XMs are most accurate when the patient has a no HLA abs, less so when there are significant levels of antibodies. We are not serving our patients well, when we transplant in the dark. We are disadvantaging patients with significant CPRA, if we are not typing donors.

- I think HLA typing should be required. There should also be a requirement to perform typing by DNA methods. Serology alone should not be used for HLA typing of deceased donors. Although the thoracic program we support does not currently required HLA-Cw

typing, we already perform it for the renal programs.

It is too soon to mandate HLA-DP typing. It is starting to become routinely available, but a mandate would be premature. We will be contacting our OPO in the near future to suggest we perform HLA-DP typing on all deceased donors. We are also going to suggest to the transplant programs we support that we perform HLA-DP typing on all potential recipients who have an HLA-DP antibody.

- The more loci that are typed (which can all be done within the same time period as currently), the better the virtual crossmatch and the more efficient the allocation. Patients have antibodies to DR51/52/53 and DP with a high frequency. They also have a high frequency of antibodies to DQalpha (the other half of the DQ molecule). There is no place in UNET to list DQalpha antibodies. But for thoracic organs, the class II antibodies (DR, DQ, DP and especially DQalpha) are the most problematic for AMR and the most resistant to anti-rejection therapy.

  Usually the testing for the additional loci is not performed for reasons of cost. However, when considering the benefits of timely allocation and increased transplants, the cost is virtually insignficant.

- Completely agree and support proposal.

- None

- no pun intended - it's about time

- With the increase of VAD pts to the transplant list there has been an increase to pts. with HLA antibodies. Requiring the HLA type for thoracic donors would be beneficial in doing a virtual crossmatch and accepting a heart from outside the OPO in these pts.

- great idea to consider, also, listing of unacceptable antigens

- good idea. we plan to soon do DP typing on donors.

- Response to question #1 has two answers: PBL are used for primary typing of OPO donors done by DNA methodology. LN is used for confirmatory typing of donors (also by DNA) brought for solid organ crossmatching rather than primary typing.

  It is my opinion that the HLA type of donors should be reported for all organ transplants.

  If acceptance of an organ is related to "virtual" crossmatch, then the HLA type is needed at the time of, or. before an offer.

  Actual crossmatches also will be done, won't they? Patient's antibody profiles are variable with time and circumstances.

- long overdue and would reduce errors in virtual crossmatches

- I think this is an excellent idea

- Our program obtains the donor's HLA type before the trasplant occurs. Our HLA laboratory performs high resolution level typing once donor tissue is available. The high res type is used for post-transplant monitoring of DSA.

- I think it is an excellent idea to have donor phenotype at the time of offer as many of our lung recipients are sensitized. I would suggest that both DP and DQA be included in the phenotype requirement when revising the policy.

- Agree that this information should be made available at time of organ offer because of the utility of virtual cross-match for recipients with anti-HLA antibody. Having this information at time of organ offer will improve organ distribution.

- We favor addition of HLA typing for heart donors, provided it does not delay placement or increase discards.

- I think it seems very appropriate and timely to implement "virtual crossmatching" for cardio-thoracic transplants offers.

- I think it is a good idea.

- In our program at TGH we have being using virtual crossmatch to accept offers from other OPO's in State and out of Stte. A concurrent FCXM is done while patient is in surgery.

- I think the addition of the HLA type to the policy indicated is vital for the proper selection of compatible donor by the virtual crossmatch. Accurate and complete molecular typing is necessary for proper interpretation.

- Overdue and highly necessary.

- All laboratories typing for an OPO must be required to type donors at 5 loci (A,B,C,DR,DQ) at a molecular low resolution level.
  2. All donor typings, with the exception of for a hemodiluted donor, must be done pre-harvest.
  3. DP typing is optional, but can be suggested and should be a goal for requirement within 3 years.

- We fully type all local deceased donors without regard to the specific organs to be recovered. However, matchruns may be completed for thoracic organ offers prior to the entry of the donor typing into DonorNet. Since we already fully type all donors, there is no increased cost. The main concern is that if a matchrun is completed prior to entry of the donor antigens, offers are made for recipients with known antibodies that are

predicted to result in positive crossmatches. It is essential that matchruns and offers not be made prior to entry of the donor antigens, for all organs with the possible exception of liver. I applaud the Thoracic Organ Transplantation Committee for considering this action.

- General, regarding above questions. First: We prefer lymph nodes for our studies, but this is impractical for heart-lung transplantation, so we use blood. Second: We type by SSO and serology, and if there is ambiguity, confirm with SSP. Third: Based on studies performed in our lab, there must be greater than 10% WBC from a separate source present in someones blood to interfere with HLA typing by SSO (and typically greater than 30% for serology), so that WBC from the potential donor are typically more that adequate, without confusion of separate WBCs that had come from blood product transfusions.

  Regarding the Proposal: An HLA type should be obtained as early as possible, prior to withdrawal of life support and harvest, in order to successfully perform a virtual crossmatch, and in order to allow correct organ placement. Since there is accumulating evidence that Cw and DQ antibodies may adversely affect transplant outcomes, these must be included in the typing, for consideration in the "virtual crossmatch".

- I'm all for it.

- Should not be a problem.

- We are not an OPO Lab, but we do type all of our Heart and Lung Deceased Donors retrospectively by SSO. Many of our patients are highly sensitized and we it would be very benefial to have donor typings prior to accepting organs for this group of patients.

- We are not an OPO lab so I didn't answer the questions, but do support a Thoracic transplant program. We strongly support having donor HLA typing provided.

- We have no issue adding HLA requirements to the policy the only issue is that we many need to being placement before the HLA is identifed. HLA should be a desired data element but not required to begin the heart allocation. You would potentially compromise organ function (lungs and even heart) to delay allocation and recovery. Especially in cases where the donor s unstable or when the family has established time limits on the donation process (religious or emotional reasons).

- HLA-DQA and DP typing of donor material should be performed to facilitate virtual crossmatching

- I support this change in policy.

- A very important addition. We have highly sensitized donors in our program. This is very important information to have at the earliest possible time.

- It represents an improvement. A better definition of donor (and recipient) HLA, based on DNA typing, would provide a stronger basis for antibody/virtual XM analysis (including allele-specific antibody, DQ alpha etc).

- It is overdue.
  Labs can now test for antibodies by sensitive solid phase methods. The OPOs must be able to provide molecular HLA types for donors reflecting the HLA antibody specificities fdetected by the transplant centers on their recipients especially for thoracic organs which may be transplanted prior to crossmatch.

  I would add testing for DQA and DP also as soon as possible.

- With the increased frequency of HLA sensitized heart transplant candidates, obtaining HLA types on potential donors can facilitate selecting patients for crossmatching as well as offering the possibility of providing "virtual" crossmatching for import donors. This will greatly facilitate transplanting these difficult patients.

- It should be required.

- Our center definitely uses HLA information if it is available as some of our sensitized recipients have clearly identified anti-HLA specificity. HLA typing by DNA can readily be done using blood samples, even in donors who have received some blood transfusions. Our laboratory routinely does this, and it is clear when contaminants are present, but surprisingly rare. In those cases, typing must defer until tissue is available. However, HLA typing can also be performed by SSO from buccal swabs; this mitigates the blood "dilution" variable, but can add a bit of time (~1 hr) to the typing process.

- This is a good idea and will speed allocation of hearts and lungs to predicted negative crossmatch candidates, rather than having time lost waiting for samples and crossmatching potential donors with candidates who would be predicted to be and turn out to hours later positive crossmatch. It can end delays waiting for heart teams to commit resources to a procurement. Can speed allocation and reduce time from declaration to procurement on multi organ donors, possibly improving quality od all donated organs.

  Heart lung offers should not be made by OPOs in the absense of HLA data on the donor. There is a concern that the proposed shift to mandated DNA based HLA typing of deceased donors will slow the process, delaying all matchruns. Still trying to determine overall benefit of molecular typing to determine serological antigens on all donors.

  At present we do not require different sample on multi transfused deceased donors since we use serological typing. Cross contamination of deceased donor samples with DNA in blood products needs to be considered(studied) and may be more or less dependent on which DNA method is in use. Alternative sample would be preprocurement nodes which arrive in insufficient quantity to complete DNA typing AND in-depth final crossmatching on multiple candidates.

- Virtual crossmatching should only be performed with molecular level typing of the donors HLA. Serological typing of the donor has potential for discrepancy and should not be used when "virtually" crossmatching against a patient's unacceptable antibodies.

- I agree with requiring HLA typing be reported to recipient center. Frankly, it is long overdue.

- Serologic typing is not adequate for HLA -C and DP and can be challenging for DR and DQ.

  Molecular typing should be mandatory.

- I think the change is needed and with the comparatively stable and reproducible results of solid state antibody identification "virtual crossmatching" is a very realistic goal. Virtual crossmatching may not be accurate 100% of the time but the upside is the increased donor selection area for heart and lung patients leading to more use of those organs and less waste. Concerning typing for DP mentioned above: I would suggest that we might consider adding that to routine typing of DD, since roughly 10% of our patients do have significant DP antibodies and I'm sure we are not alone. That would improve the efficiency of the virtual crossmatch and, ultimatelu, organ allocation.

- I propose to list the unacceptable antigens the laboratory have tested and know that will cause positive crossmatch. In our area, we already type donors before the offer has taken place and we require prospective crossmatch for highly sensitized cardiothorasic transplant patients. Virtual crossmatch is used for low or moderately sensitized patients who are stable in respect to their HLA antibodies.

  I am glad the committee is finally looking into this issue and would highly recommend to go beyond the typing only.

- It is an addition whose time has come. Knowing a donor's HLA type will allow virtual preliminary crossmatching, which drastically decreases the negative consequences of the recipient making anti-donor antibodies.as donor antigens can be compared with recipient antibodies: potentially reactive combinations can then be eliminated from consideration.

  Our Laboratory does not type for thoracic transplantation, hence I did not answer the last two questions. However for #6, we type for almost all HLA antigens listed for kidney and KP transplants.

- I believe this policy is long overdue because of the increase in sensitized heart and or heart lung transplant recipent wait list. HLA typing can be done in a timely fashion at the donor center prior to harvest. This does not increase cold storage time because the typing is done pre-harvest on deceased donor blood. HLA A, B, DR and DRw typing provides sufficient information for identification of virtual crossmatches with greater than 85% accuracy. However I must speak a word of warning. HLA antibodies identified in the sera

of recipient candidates can cause false positive virtual crossmatch because 20% of the time commercially available single antigen beads denatured (broken) HLA molecules to which sera would bind but cells would not. Consequently one may have bead-positive but cell-based negative crossmatches.

- We are in support of it - 99.9% of the time we have HLA typing data available prior to organ offers including hearts.

- Thank you for addressing this issue. This will really benefit our patients. We have used a virtual XM for thoracic patients since 2004. Modifying this policy to include HLA typing at the time of the match run or organ offers will allow our sensitized patients better access to (virtually) compatible organs. HLA typing at the time of the match run with automatic rule out of donors with unacceptable antigens (like the kidney allocation programs does) would be preferable if time allows; but even if the HLA typing is not available until organ offers are made, we would be happy to screen offers (perform the virtual XM) on behalf of our thoracic transplant program.

- I feel it is essential that complete typings be provided with offers, and that OPO HLA labs be required to type for all HLA loci that could be targeted by recipient alloantibodies.

- It is extremely useful. We have been doing virtual XMs for all of our thoracic patients for several years and usually they have the type when the offer is made. I would suggest giving extra "points" to patients with high PRA that have a negative virtual XM with donors since we occasionally find that there is a compatible virtual XM but the patient who is very hard to find donors for but that they are too far down the list to get that donor.

- at least we can have HLA typing information to avoid unacceptable antigens, especially, we have luminex information to help us better donor selection and increase the survival rate of transplant.

- I believe HLA typing data (minimum HLA- A, B, DR) should be available before match run to allow for virtual crossmatching in all thoracic transplants for those who wish to take that approach. That said, I think the transplant center itself should have the lattitude to define their own HLA clinical labortory criteria for acceptance/rejection within the context of the clinical status of the recipient.

- 1.
  Type for DP if we have a waitlisted candidate with anti-DP antibodies
  2.
  Do not require a different sample than pripheral blood from a multiply transfused donor if we obtain a clear typing.

- I believe it is long overdue. As we have increased used of VADs, sensitization and issues related to sensitization have become critical to the heart program. Since there is rarely a

heart donor without a kidney donated, HLA typing is always done and typically available before allocation.

- We are only involved in living donor HLA typing.

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

Survey of Organ Procurement Organizations (OPO) Concerning the Determination of Donor Human Leukocyte Antigen (HLA) Information for Thoracic Organ Offers

Dear OPO Executive Directors,

The Thoracic Organ Transplantation Committee (Committee) is planning to add HLA identification to Policy 3.7.12.1 (Essential Information [for Thoracic Offers]). Knowledge of deceased donor HLA antigens will allow transplant centers to accept, on behalf of sensitized thoracic candidates, organs from donors without a prospective crossmatch, if the donor does not contain antigens to which the candidate is known to be sensitized ("virtual crossmatch").

The number of candidates for heart and lung transplantation that are sensitized is steadily increasing. Hence, it is paramount for thoracic programs to know the HLA of deceased donors to define if organs offered to them can be considered for use in candidates that are known to be sensitized.

The Committee's anecdotal and experiential knowledge is that many OPOs already have HLA identified prior to making thoracic organ offers. This provision of information, however, is not mandated in policy.

The following is the current language of Policy 3.7.12.1:

> *The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:*
>
> *(i) The cause of brain death;*
> *(ii) The details of any documented cardiac arrest or hypotensive episodes;*
> *(iii) Vital signs including blood pressure, heart rate and temperature;*
> *(iv) Cardiopulmonary, social, and drug activity histories;*
> *(v) Pre- or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);*
> *(vi) Accurate height, weight, age and sex;*
> *(vii) ABO type;*
> *(viii) Interpreted electrocardiogram and chest radiograph;*
> *(ix) History of treatment in hospital including vasopressors and hydration;*
> *(x) Arterial blood gas results and ventilator settings; and*
> *(xi) Echocardiogram, if the donor hospital has the facilities.*
>
> *The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.*

The proposal in development would add HLA to the list of required elements for thoracic donor offers. The Committee continues to discuss two salient components of the proposed policy: 1) the time when OPOs must provide HLA information to transplant programs, i.e., at the time of the organ offer or before a match-run; and 2) the specificity of HLA provided. The Committee is

working with the following OPTN/UNOS Committees to develop this proposal: Histocompatibility, Operations and Safety, and Organ Procurement Organization. To best understand the operational impact, the four Committees have developed this survey.

Completing the survey is voluntary and confidential. The Committee will analyze the results in aggregate. However, to best understand the national practice of obtaining HLA on deceased thoracic organ donors, the Committee would tremendously value responses from all 58 OPOs. Therefore, could one representative from each OPO complete the following survey on or before June 30, 2010?

If you have questions, please contact Vipra Ghimire at ghimirev@unos.org or 804-782-4071.

Thank you for your time and response.

Sincerely,

The Thoracic Organ Transplantation Committee

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

Survey Title: Determination of Donor Human Leukocyte Antigen (HLA) Information for Thoracic Organ Offers (OPO)

1. Upon receipt of typing specimen, how much time, on average, does your affiliated HLA laboratory require to provide HLA of thoracic deceased donors? Please respond to the nearest half hour and elaborate on your response. Download

	Response Count
Show replies	33
answered question	33
skipped question	0

Responses for question 1 are below:

1.	4 hours	Wed, Jun 30, 2010 2:43 PM	Find...
2.	from the time of receipt our HLA labs provide results on average within 6 1/2 hours but due to our geographical challenges we have some very active donor hospitals where it takes an average of 4-6 hours for the specimen to travel to the designated HLA labs.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	4-6 hours	Wed, Jun 30, 2010 12:46 PM	Find...
4.	It takes approximately 5 to 5.5 hours.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	4hrs	Tue, Jun 29, 2010 4:29 PM	Find...
6.	5 hours	Tue, Jun 29, 2010 3:51 PM	Find...
7.	4 hours	Tue, Jun 29, 2010 2:58 PM	Find...
8.	6 hours.	Tue, Jun 29, 2010 10:52 AM	Find...
9.	6 hours - depends on whether the receiving center requires a CDC crossmatch in addition to the flow crossmatch.	Tue, Jun 29, 2010 10:46 AM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

10.	4-6 hours. Depends upon whether or not the tech is in house or has to be called in.	Mon, Jun 28, 2010 11:55 PM	Find...
11.	4 hours	Mon, Jun 28, 2010 6:01 PM	Find...
12.	After the HLA Lab receives the specimen, the average time is 5 hours until HLA is reported. This may take longer if nodes are required or if they run into technical issues	Mon, Jun 28, 2010 4:01 PM	Find...
13.	3 hours	Mon, Jun 28, 2010 9:28 AM	Find...
14.	four and a half to five hours	Sun, Jun 27, 2010 2:37 PM	Find...
15.	4-6 hours	Fri, Jun 25, 2010 10:11 PM	Find...
16.	6 hours	Fri, Jun 25, 2010 4:10 PM	Find...
17.	donor blood - 5 hours donor lymph node 4 hours Includes HLA typing and flow cross match	Fri, Jun 25, 2010 3:39 PM	Find...
18.	5-6 hours. At present results are required for deceased donors in general.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	6 hours	Fri, Jun 25, 2010 8:19 AM	Find...
20.	4 hours	Wed, Jun 23, 2010 2:34 PM	Find...
21.	We have 2 centers. 1 center averages 2 hours. The other center is almost always at least 5 hours.	Tue, Jun 22, 2010 10:02 AM	Find...
22.	The average time from receipt of specimens to determining HLA typing in our service area is 4 hours.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	5 hours	Mon, Jun 21, 2010	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

		3:41 PM	
24.	Our lab uses PBL testing and does not require pre-recovery nodes. 4-4.5 hrs for typing. Additional time required for pt cross-matching	Mon, Jun 21, 2010 2:24 PM	Find...
25.	4 1/2 hours. There are outliers of course dependent on quality of tissue received when typing on nodes vs. bloods.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	4 hours	Mon, Jun 21, 2010 10:46 AM	Find...
27.	Our affiliated HLA lab receives the blood tubes for typing typically within 2 hours after consent is given. After receipt, it typically takes approx. 5hr 30 min for the OPO coordinator on call to be contacted with the HLA results, (A,B, DR, DWw, DQ, CW)	Mon, Jun 21, 2010 10:18 AM	Find...
28.	4 hours	Mon, Jun 21, 2010 9:15 AM	Find...
29.	6 to 8 hours	Mon, Jun 21, 2010 6:54 AM	Find...
30.	6-8 hrs upon receipt. time to get specimen to lab can also vary by donor clinical scenario. (distance from donor center to lab (4-5 hrs) and ability to donor type from peripheral blood. Some donor conditions require donor type from lymph node that takes significant time to coordinate the recovery.(10-12hrs)	Fri, Jun 18, 2010 12:22 PM	Find...
31.	4 hours	Fri, Jun 18, 2010 11:57 AM	Find...
32.	5 hours	Thu, Jun 17, 2010 8:44 AM	Find...
33.	It depends on the quality of the cells. Usually less than 6 hours with local XM. Four for typing only	Wed, Jun 16, 2010 4:51 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

2. Does your OPO currently attempt to obtain HLA of thoracic deceased donors before making thoracic organ offers via DonorNet®? Download

	Response Count
Show replies	33
answered question	33
skipped question	0

1.	no	Wed, Jun 30, 2010 2:43 PM	Find...
2.	We do not currently send HLAs for donors who are ruled out for kidney donation. For thoracic and kidney donors, HLAs are always in transit prior to making thoracic offers in DonorNet.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	No, but HLA is often completed before thoracic offers go out.	Wed, Jun 30, 2010 12:46 PM	Find...
4.	No.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	Always	Tue, Jun 29, 2010 4:29 PM	Find...
6.	No	Tue, Jun 29, 2010 3:51 PM	Find...
7.	Yes.	Tue, Jun 29, 2010 2:58 PM	Find...
8.	Yes	Tue, Jun 29, 2010 10:52 AM	Find...
9.	yes	Tue, Jun 29, 2010 10:46 AM	Find...
10.	Yes, but it is sometimes coincidence, not a requirement of our OPO	Mon, Jun 28, 2010 11:55 PM	Find...
11.	No	Mon, Jun	Find

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

		6:01 PM	
12.	No, we will make thoracic organ offers prior to obtaining HLA. We accept a provisional yes from a transplant center pending HLA.	Mon, Jun 28, 2010 4:01 PM	Find...
13.	most if not all thoraciic donors are kidney donors as well. so i would say always.	Mon, Jun 28, 2010 9:28 AM	Find...
14.	yes	Sun, Jun 27, 2010 2:37 PM	Find...
15.	No	Fri, Jun 25, 2010 10:11 PM	Find...
16.	Yes	Fri, Jun 25, 2010 4:10 PM	Find...
17.	yes	Fri, Jun 25, 2010 3:39 PM	Find...
18.	No.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	No, if we have a good organs we do not wait for HLA but we could.	Fri, Jun 25, 2010 8:19 AM	Find...
20.	Yes on local recipients, no on non local.	Wed, Jun 23, 2010 2:34 PM	Find...
21.	Yes, we wait to run our lists until HLA is available on all of our cases.	Tue, Jun 22, 2010 10:02 AM	Find...
22.	Not necessarily, but in general, HLA is probably available since it takes time to do the thorough thoracic evaluation before making offers.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	no	Mon, Jun 21, 2010 3:41 PM	Find...
24.	Yes	Mon, Jun 21, 2010 2:24 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

25.	As a rule, yes. Exceptions may occur when faced with time constraints.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	yes, we always run kidney lists first so we always have HLA done.	Mon, Jun 21, 2010 10:46 AM	Find...
27.	No, not intentionally.	Mon, Jun 21, 2010 10:18 AM	Find...
28.	NO	Mon, Jun 21, 2010 9:15 AM	Find...
29.	no	Mon, Jun 21, 2010 6:54 AM	Find...
30.	No. Offers made contigent in HLA coming out. Delaying offer process until donor type is back would significantly delay allocation process and makes no sense at all. Teams can be out for other reasons and OPOs should be able to work down allocation list to expedite process. Patients without any antigenicity could be at top of list and wont even care about donors HLA type and the OPO and transplant center shouldnt have to wait for donor HLA type. If heart candidate has UA and the center finds the donor heart otherwise acceptable they can conditionally accept pending donor hla determination. This allows than the OPO to properly back up the heart as well.	Fri, Jun 18, 2010 12:22 PM	Find...
31.	yes	Fri, Jun 18, 2010 11:57 AM	Find...
32.	Yes	Thu, Jun 17, 2010 8:44 AM	Find...
33.	No. We use size and ABO	Wed, Jun 16, 2010 4:51 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

3. Does your OPO receive HLA of thoracic deceased donors before it begins the organ allocation process (i.e., before making organ offers)? Please elaborate on your response.	Download	Response Count
	Show replies	33
	answered question	33
	skipped question	0

Responses to question 3 are below:

1.	no - not too any ask for them	Wed, Jun 30, 2010 2:43 PM	Find...
2.	No. As stated above, it is not our process to wait for HLAs prior to making non-renal organ offers because HLAs (depending on donor hospital) may not be resulted for 12-15 hours after consent.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	No	Wed, Jun 30, 2010 12:46 PM	Find...
4.	We do typically recieve HLA well before initiating thoracic organ offers.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	Yes, we do our best to always have HLA before running any lists. We recently placed a heart for a pt with UAs and a virtual xmatch was performed and the heart was placed!	Tue, Jun 29, 2010 4:29 PM	Find...
6.	No	Tue, Jun 29, 2010 3:51 PM	Find...
7.	Most often, yes. We do not intentionally wait for HLA unless we see that the higher patients on the list require a crossmatch. Nearly always, though, the HLA is completed before we begin making thoracic offers.	Tue, Jun 29, 2010 2:58 PM	Find...
8.	We use the HLA on deceased donors if it is available. We have it available 80% of the time. The only time it wouldn't be available is if we have time constraints from the family, or if the patient is unstable.	Tue, Jun 29, 2010 10:52 AM	Find...
9.	no - we wait for the receiving center to request the test specifically.	Tue, Jun 29, 2010 10:46 AM	Find...
10.	Sometimes. It depends if our local centers have patients with avoid antigens or crossmatching required.	Mon, Jun 28, 2010 11:55 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

11.	No	Mon, Jun 28, 2010 6:01 PM	Find...
12.	No, we don't receive HLA before making thoracic organ offers	Mon, Jun 28, 2010 4:01 PM	Find...
13.	if HLA results are not available we make offers based on the information we have at the time. once the HLAs are available we discuss with provisional yes centers. to my knowledge there is no point system for thoracic HLA and therefore the list order does not change based on HLA results.	Mon, Jun 28, 2010 9:28 AM	Find...
14.	yes	Sun, Jun 27, 2010 2:37 PM	Find...
15.	Often we do. It is more dependent on when we the echo and/cat are available. Usually, HLA is back prior to this. However, making offers is not dependent on the HLA currently in our OPO.	Fri, Jun 25, 2010 10:11 PM	Find...
16.	Yes. By the time we are able to perform all the testing needed to allocate thoracic organs the HLA is complete.	Fri, Jun 25, 2010 4:10 PM	Find...
17.	yes we allocate after receipt of HLA	Fri, Jun 25, 2010 3:39 PM	Find...
18.	No. We run the lung list and make offers as soon as we confirm ABO and upload our required data elements for thoracic organ placement.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	No, but we could	Fri, Jun 25, 2010 8:19 AM	Find...
20.	Yes for kidney and pancreas offers only.	Wed, Jun 23, 2010 2:34 PM	Find...
21.	Yes, we do this in every case we work	Tue, Jun 22, 2010 10:02 AM	Find...
22.	In most cases, the answer is yes.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	no	Mon, Jun 21, 2010 3:41 PM	Find...
24.	Yes. Most of the time HLA is complete as the clinical team is optimizing the potential	Mon, Jun	Find...

	organ donor.	21, 2010 2:24 PM	
25.	Again, for the majority of cases we do. Family imposed time constraints and emergent situations are times when this may not happen.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	Yes	Mon, Jun 21, 2010 10:46 AM	Find...
27.	Electronic offers for kidneys/panc are not started until the HLA is entered into UNET as per policy. Thoracic organs are offered to local centers prior to receiving HLA if the donor is stable. If donor management requires multiple nterventions (T4 protocals, transfusions, etc) to stablize the donor for the cardiac/pulmonary evaluations, that may take 5-6 hours before the initial offers are made. In those scenario's HLA may well be back prior to the first thoracic organ offer is made.	Mon, Jun 21, 2010 10:18 AM	Find...
28.	NO	Mon, Jun 21, 2010 9:15 AM	Find...
29.	no	Mon, Jun 21, 2010 6:54 AM	Find...
30.	No as in above answer. Additionally donor conditions do exist where logistically you can not wait for donor hla determination to be back to schedule an OR	Fri, Jun 18, 2010 12:22 PM	Find...
31.	yes	Fri, Jun 18, 2010 11:57 AM	Find...
32.	Yes. Thoracic organ allocation is usually delayed until we are able to aggressively manage and improve hemodynamic stability. Echocardiogram, cardiac caths, etc. are delayed until donor stability is "optimized" and this also allows time for serological testing for communicable disease and HLA typing to be accomplished. Both sets of tests are turned around in 5 hours on average after arriving in the respective labs.	Thu, Jun 17, 2010 8:44 AM	Find...
33.	No. We usually start placement before typing is completed.	Wed, Jun 16, 2010 4:51 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

4. What percentage of the time is the HLA of thoracic deceased donors available before thoracic organ allocation? Download

		Response Count
	Show replies	33
	answered question	33
	skipped question	0

1.	10%	Wed, Jun 30, 2010 2:43 PM	Find...
2.	5-10%	Wed, Jun 30, 2010 1:01 PM	Find...
3.	80% or greater	Wed, Jun 30, 2010 12:46 PM	Find...
4.	Estimated 90%.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	95%	Tue, Jun 29, 2010 4:29 PM	Find...
6.	Zero	Tue, Jun 29, 2010 3:51 PM	Find...
7.	98%	Tue, Jun 29, 2010 2:58 PM	Find...
8.	80%	Tue, Jun 29, 2010 10:52 AM	Find...
9.	50-60%	Tue, Jun 29, 2010 10:46 AM	Find...
10.	60%	Mon, Jun 28, 2010 11:55 PM	Find...
11.	50%	Mon, Jun 28, 2010 6:01 PM	Find...
12.	<10%	Mon, Jun 28, 2010 4:01 PM	Find...
13.	50-70% of the time.	Mon, Jun 28, 2010 9:28 AM	Find...
14.	90%	Sun, Jun 27, 2010	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

		2:37 PM	
15.	50-75 %	Fri, Jun 25, 2010 10:11 PM	Find...
16.	80%	Fri, Jun 25, 2010 4:10 PM	Find...
17.	>95%	Fri, Jun 25, 2010 3:39 PM	Find...
18.	<50% of the time.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	50	Fri, Jun 25, 2010 8:19 AM	Find...
20.	>75%	Wed, Jun 23, 2010 2:34 PM	Find...
21.	100%	Tue, Jun 22, 2010 10:02 AM	Find...
22.	Probably 80-90% of the time.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	20%	Mon, Jun 21, 2010 3:41 PM	Find...
24.	>95%	Mon, Jun 21, 2010 2:24 PM	Find...
25.	At a minimum, 90%.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	100%	Mon, Jun 21, 2010 10:46 AM	Find...
27.	approximately 75% of the time. Not all are due to donor issues, some are delayed due to after hours availability for ECHO, Bronch, etc	Mon, Jun 21, 2010 10:18 AM	Find...
28.	50	Mon, Jun 21, 2010 9:15 AM	Find...
29.	10	Mon, Jun 21, 2010 6:54 AM	Find...
30.	0% before allocation 80% just prior to scheduled OR time	Fri, Jun 18, 2010 12:22 PM	Find...
31.	100%	Fri, Jun 18, 2010	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

		11:57 AM	
32.	100%	Thu, Jun 17, 2010 8:44 AM	Find...
33.	Maybe 20%	Wed, Jun 16, 2010 4:51 PM	Find...

5. How much time, on average, does your OPO need to gather blood or tissue samples for the purposes of HLA from thoracic deceased donors? Please respond to the nearest half hour and elaborate on your response. Download

	Response Count
Show replies	33
answered question	33
skipped question	0

1.	This question is not clear as to what is being asked.	Wed, Jun 30, 2010 2:43 PM	Find...
2.	This answer is dependent on whether or not blood or lymph nodes are needed for tissue typing. For HLAs to be run on blood samples the average time for collection is 1 1/2-hours post consent. If a donor is hemodiluted, lymph node excision takes on average 4-5 hours and many variable affect this timeframe. If we are evaluating DCD lungs from a serodiluted donor and lymph nodes are needed for HLA typing, it is our practice that nodes will be recovered at the conclusion of the case after cross clamp.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	1-2 hours there is additional transportation time depending on the location of the donor.	Wed, Jun 30, 2010 12:46 PM	Find...
4.	We do not require much time to gather the blood sample for HLA testing. We draw and send our infectious disease testing and HLA testing samples at the same time, so the majority of that time is needed for calculating hemodilution or finding a sample that qualifies. On an average it most likely takes only 1 hour.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	30 mins	Tue, Jun 29, 2010 4:29 PM	Find...
6.	2 hours	Tue, Jun 29, 2010 3:51 PM	Find...
7.	On average, it takes about 2-4 hours to obtain the specimens. Our geopraphy is large, so getting the specimens to the lab can then take anywhere from 4 hrs to 8 hrs, depending whether we need a courier or the specimens are being flown back to the LAB from our regional areas.	Tue, Jun 29, 2010 2:58 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

8.	1-2 hour. Then another hour for it to be delivered.	Tue, Jun 29, 2010 10:52 AM	Find...
9.	1 - 2.5 hours. - It depends on travel time from the donor hospital.	Tue, Jun 29, 2010 10:46 AM	Find...
10.	2-4 hours. It depends on what time we get on site to the donor.	Mon, Jun 28, 2010 11:55 PM	Find...
11.	3 hours	Mon, Jun 28, 2010 6:01 PM	Find...
12.	This is very dependent on the donor and the hospital but estimate 4 hours. We draw 10-12 yellow tubes for HLA typing. Before drawing this much blood we make sure we have a current H/H and that we have PRBC's available which requires an updated type and cross (when the patient is switched to donor status). Then we often have to get lines placed because many of our patients don't have a CVP or arterial line. Nodes take longer and we use blood for HLA whenever possible based on adequate lymphocyte count.	Mon, Jun 28, 2010 4:01 PM	Find...
13.	30 minutes	Mon, Jun 28, 2010 9:28 AM	Find...
14.	two hours	Sun, Jun 27, 2010 2:37 PM	Find...
15.	4 to 8 hours dependent on the location of the donor and transport time to the lab.	Fri, Jun 25, 2010 10:11 PM	Find...
16.	1/2 hour	Fri, Jun 25, 2010 4:10 PM	Find...
17.	2 hours, may need lines placed or staff assistance with blood draw	Fri, Jun 25, 2010 3:39 PM	Find...
18.	1-2 hours from consent, then depending on which donor hospital, there are courier pick-up and delivery times to the specific HLA lab for that region..	Fri, Jun 25, 2010 11:18 AM	Find...
19.	2 hours	Fri, Jun 25, 2010 8:19 AM	Find...
20.	2 hours	Wed, Jun 23, 2010 2:34 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

21.	3 hours	Tue, Jun 22, 2010 10:02 AM	Find...
22.	From the time of authorization for donation, specimens for HLA typing are probably obtained within two hours or so. Of course, there is additional time needed to transport those specimens from the donor hospital to the tissue typing/HLA laboratory. It's possible that once those specimens are obtained that it may take another 5 or more hours to transport the specimens.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	3 hr	Mon, Jun 21, 2010 3:41 PM	Find...
24.	Each case varies, but it should not be any different than our normal practice is currently. One hour is the normal for collection of blood samples and to determine hemodilution status. The transport time varies depending on location of potential donor.	Mon, Jun 21, 2010 2:24 PM	Find...
25.	Blood is readily obtained within 1 half hour of consent and declaration. Nodes, on average and when we are able is 3 hours.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	2 hours. But, it depends on where our donor hospital is located in comparison to our HLA lab. Some of our hospitals are 1-5 hours away.	Mon, Jun 21, 2010 10:46 AM	Find...
27.	2 hours for blood specimens this OPO waits for the OR to recovery nodes/spleen.	Mon, Jun 21, 2010 10:18 AM	Find...
28.	12 HOURS	Mon, Jun 21, 2010 9:15 AM	Find...
29.	2 hours	Mon, Jun 21, 2010 6:54 AM	Find...
30.	peripheral blood: 1-2 hrs lymph nodes 12-14, sometimes not able to get a lymph node prior to OR, Lymph nodes needed especially in young trauma patients who required large volume of blood transfusion.	Fri, Jun 18, 2010 12:22 PM	Find...
31.	30mins	Fri, Jun 18, 2010 11:57 AM	Find...
32.	2.5 hours AFTER consent/authorization and pronouncement of death. Generally, within 2 to 3 hours of being onsite, our coordinators are able to obtain blood and lymph nodes. If the donor is at a remote location (140 miles +) distant, travel delays delivery to central labs by 2 to 3 additional hours.	Thu, Jun 17, 2010 8:44 AM	Find...
33.	It depends on the case but we can usually get blood drawn in about an hour. It takes a	Wed, Jun	Find...

	couple of hours if we plan to recover lymph nodes for typing and XM	16, 2010 4:51 PM

6. If your OPO does not currently receive HLA prior to allocation of thoracic organs, what is the time lapse between your OPO's performance of a thoracic match-run and its receipt of the deceased donor's HLA? Download

	Response Count
Show replies	28
answered question	28
skipped question	5

1.	1 to 2 hours	Wed, Jun 30, 2010 2:43 PM	Find...
2.	the average time lapse from when a thoracic match run is generated and HLAs are resulted is 5-6 hours but again this is highly variable within our OPO due to our DSA geography and travel time of lab specimens from our remote area hospitals.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	4-6 hours on the cases HLA isn't completed prior to offer	Wed, Jun 30, 2010 12:46 PM	Find...
4.	N/A	Tue, Jun 29, 2010 4:29 PM	Find...
5.	2 hours	Tue, Jun 29, 2010 3:51 PM	Find...
6.	N/A	Tue, Jun 29, 2010 2:58 PM	Find...
7.	On the times where we do not have HLA when we run lists, it is usually another 6-10 hours, as those cases would probably have blood drawn and sent from the OR	Tue, Jun 29, 2010 10:52 AM	Find...
8.	n/a	Tue, Jun 29, 2010 10:46 AM	Find...
9.	4 hours	Mon, Jun 28, 2010 6:01 PM	Find...
10.	We estimate 3-4 hours time lapse between thoracic match run list and later receiving	Mon, Jun	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

	HLA report.	28, 2010 4:01 PM	
11.	sometimes 1-2 hours.	Mon, Jun 28, 2010 9:28 AM	Find...
12.	n/a	Sun, Jun 27, 2010 2:37 PM	Find...
13.	Could be 12 hours	Fri, Jun 25, 2010 10:11 PM	Find...
14.	n/a	Fri, Jun 25, 2010 4:10 PM	Find...
15.	NA	Fri, Jun 25, 2010 3:39 PM	Find...
16.	Depends on logistics, but anywhere from 1 to 6 hours	Fri, Jun 25, 2010 11:18 AM	Find...
17.	3-4 hours	Fri, Jun 25, 2010 8:19 AM	Find...
18.	N/A	Tue, Jun 22, 2010 10:02 AM	Find...
19.	In the cases when the thoracic match run is done prior to receipt of the HLA information, the HLA is probably entered within two to three hours of the performance of the thoracic match run.	Mon, Jun 21, 2010 4:01 PM	Find...
20.	5 hr	Mon, Jun 21, 2010 3:41 PM	Find...
21.	N/A.	Mon, Jun 21, 2010 1:22 PM	Find...
22.	approximately 2 hours in the 25% of cases where offers are not delayed due to the reasons described in #4.	Mon, Jun 21, 2010 10:18 AM	Find...
23.	4 HOURS	Mon, Jun 21, 2010 9:15 AM	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

24.	6 to 8 hours	Mon, Jun 21, 2010 6:54 AM	Find...
25.	12-15hrs However once donor HLA is received allocation of heart is already completed and OR can be scheduled. Candidates with UA are offered these hearts (ie not skipped or disadvantaged) and centers will place a provisional "yes" in donornet. This then allows OPO to have further discussions re: 1) recipients list of UA 2) potential need for both virtual and serologic crossmatch and delivery of specimens to accepting center 3) donor conditions that may effect centers acceptance. If we had to wait for HLA to begin allocating we would be at ground zero and would only add unnecessary delays for no benefit!! The patients swith UA still would get offerrs and are not disadvantaged. Under proposed policy patients with no listed UA are significantly delayed in getting offers.	Fri, Jun 18, 2010 12:22 PM	Find...
26.	n/a	Fri, Jun 18, 2010 11:57 AM	Find...
27.	N/A	Thu, Jun 17, 2010 8:44 AM	Find...
28.	2-3 hours	Wed, Jun 16, 2010 4:51 PM	Find...

7. What operational impact would your OPO experience if the Board of Directors approves the addition of HLA to 3.7.12.1? Please elaborate on your response. Download

	Response Count
Show replies	33
answered question	33
skipped question	0

1.	slow down organ placement increase fees to transplant programs	Wed, Jun 30, 2010 2:43 PM	Find...
2.	This could significantly impact our OPO's case length of potential thoracic donors, especially in hospitals furthest from our designated HLA laboratories, adding as much as 12-15 hours to the length of our donor cases where thoracic organs were being evaluated. Also our local thoracic transplant centers (primarily lung) desire preliminary offers made in order of the PTR very early in our thoracic donor cases (within 2-3 hours of consent) and this policy revision will significantly impact that process and their identification and travel of potential suitable recipients	Wed, Jun 30, 2010 1:01 PM	Find...
3.	None	Wed, Jun	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

		30, 2010 12:46 PM	
4.	We do not foresee any significant operational impact as we typically have HLA results well before making any thoracic organ offers. The logistics of coordinating thoracic evaluation usually takes more time than waiting for HLA results. We do however move forward with liver allocation prior to thoracic organ allocation. There is potential for delaying liver offers if we are waiting for HLA for thoracic placement. In our DSA it is becoming more common to have double organ allocation from the heart matchrun.	Tue, Jun 29, 2010 4:31 PM	Find...
5.	I think it would benefit all recipients to have HLA prior to organ allocation, we already practice this to the best of our ability.	Tue, Jun 29, 2010 4:29 PM	Find...
6.	Delay in organ allocation. Prolonged stay in ICU.	Tue, Jun 29, 2010 3:51 PM	Find...
7.	I think there would be minimal impact for our OPO.	Tue, Jun 29, 2010 2:58 PM	Find...
8.	It would force the issue to get blood early to send for HLA. This would be a good thing.	Tue, Jun 29, 2010 10:52 AM	Find...
9.	No impact - already performing HLA determinations for our local heart centers.	Tue, Jun 29, 2010 10:46 AM	Find...
10.	None really. It would delay some inital thoracic offers, but would not be insurmountable in the grand scheme of organ allocation	Mon, Jun 28, 2010 11:55 PM	Find...
11.	Delayed surgery, increased cost of the donor, increased staffing for longer cases. Daytome OR is not available, so case could be very prolonged.	Mon, Jun 28, 2010 6:01 PM	Find...
12.	We believe this could delay the organ allocation process by several hours.	Mon, Jun 28, 2010 4:01 PM	Find...
13.	none. it would delay heart offers as it does pancreas and kidney offers currently.	Mon, Jun 28, 2010 9:28 AM	Find...
14.	minimal	Sun, Jun 27, 2010 2:37 PM	Find...
15.	Not sure	Fri, Jun 25, 2010 10:11 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

16.	n/a	Fri, Jun 25, 2010 4:10 PM	Find...
17.	No impact on current practice	Fri, Jun 25, 2010 3:39 PM	Find...
18.	At times may extend completion times of donors. These times are getting longer as is with availability of operating rooms. Families are beginning to complain about how long the process takes from the time they consent to when they can get their loved one's body for funeral home.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	None, we could wait in most cases. I would like to have the opportunity to do allocation without HLA for those times when blood HLA cannot be identified.	Fri, Jun 25, 2010 8:19 AM	Find...
20.	Delay in case time and allocation	Wed, Jun 23, 2010 2:34 PM	Find...
21.	None, we do this already.	Tue, Jun 22, 2010 10:02 AM	Find...
22.	We would need to expedite the delivery of tissue typing specimens for each and every case. We would also need to retrain staff so that thoracic organ match runs are not performed prior to HLA typing.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	Delay in thoracic organ offers. Since many transplant coordinators take the thoracic and abdominal organ offers, these transplant center persons will be hit with offers for multiple organs at the same time, rather than thoracics earlier, followed by abdominal.	Mon, Jun 21, 2010 3:41 PM	Find...
24.	I believe the impact would be minimal. Would like some allowance for unstable donors that cannot be maintained for thoracic allocation. (rapid response)	Mon, Jun 21, 2010 2:24 PM	Find...
25.	I feel it would have minimal impact as we currently do this on the majority of cases. Those outliers are unavoidable and would be handled by writing a letter of explanation.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	none	Mon, Jun 21, 2010 10:46 AM	Find...
27.	minimal.	Mon, Jun 21, 2010 10:18 AM	Find...
28.	MINIMAL	Mon, Jun 21, 2010 9:15 AM	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

29.	offering hearts without HLA speeds up the allocation process; the timing may mean delay of the match run and offering organs for allocation	Mon, Jun 21, 2010 6:54 AM	Find...
30.	This policy should not be passed. This would significantly impair an OPOs ability to effectively allocate hearts in an expeditious way. Need for donor HLA prior to allocation will impair an OPO to effectively plan for an OR. Also in our experience many centers will also still want a final serologic crossmatch for candidates who are "virtually" compatabile. By not being able to begin the allocation process and have these type of conversations with tx ctr personnel, OPOs will not be able to effectiely plan and it will cause significant delays in the donor recovery.	Fri, Jun 18, 2010 12:22 PM	Find...
31.	Our organizational SOP's allow for us to have our typing back prior to allocation so there should be no operational changes to our OPO.	Fri, Jun 18, 2010 11:57 AM	Find...
32.	None. We encourage approval of this policy as we believe it will improve outcomes and patient safety.	Thu, Jun 17, 2010 8:44 AM	Find...
33.	Not a big problem it would dely placement only slightly and it probably wouldn't impact the scheduled surgery time unless the transplant team needs a final XM	Wed, Jun 16, 2010 4:51 PM	Find...

8. Should this proposed change become policy, what negative impact or situations might your OPO encounter? Download

	Response Count
Show replies	31
answered question	31
skipped question	2

1.	Hard to predict maybe longer case times.	Wed, Jun 30, 2010 2:43 PM	Find...
2.	-significant increase in length of cases / associated cost for potential thoracic donors in our hospitals in outer regions of our DSA due to the extended transportation time of blood/tissue sent for typing -would not be able to evaluate DCD lungs from hemodiluted donors where HLAs are processsed on lymph nodes because we will not perform lymph node recovery until after crossclamp -significantly impact the timeline of our offer process to our thoracic centers within our DSA	Wed, Jun 30, 2010 1:01 PM	Find...
3.	No negative impact	Wed, Jun 30, 2010 12:46 PM	Find...
4.	We will need to be mindful of the potential for double organ allocation. Our local centers	Tue, Jun	Find...

	do have recipients on the heart list that also require other organs, mostly liver or kidney. We will need to be mindful of the timing of generating matchruns and the timing of liver offers so that we are preparing for instances of double organ allocation on the heart matchrun. This may affect either the timing of generating matchruns or the timing of liver offers. We do not want to be in the position of placing a liver locally prior to HLA results, then running a heart matchrun and noting that the liver should be allocated with the heart locally.	29, 2010 4:31 PM	
5.	DCD lungs may be difficult to obtain HLA before placement when a family has time constraints. Same with brain dead donor if family has time constraints.	Tue, Jun 29, 2010 4:29 PM	Find...
6.	Same as # 7.	Tue, Jun 29, 2010 3:51 PM	Find...
7.	There could be a very small percentage of the time that waiting for the HLA would lead to a delay in beginning thoracic placement.	Tue, Jun 29, 2010 2:58 PM	Find...
8.	Potentially prohibit heart allocation on young unstable donors. But not many.	Tue, Jun 29, 2010 10:52 AM	Find...
9.	Cannot think of any	Tue, Jun 29, 2010 10:46 AM	Find...
10.	None that I can think of.	Mon, Jun 28, 2010 11:55 PM	Find...
11.	see above	Mon, Jun 28, 2010 6:01 PM	Find...
12.	From our perspective, the negative impacts of policy change could include longer donor time in the ICU and delayed communication of information to the transplant center for evaluation of donor suitability and surgeon availability. Currently, transplant centers will enter a provisional yes and make no contact with the OPO until notification they are primary center. Often only one person (either a coordinator or at times a call center) have reviewed the offer. Then we have a discussion with the transplant center about the donor and often they decline and we go down the list and repeat the process. This takes time and we feel the sooner we start the process the better.	Mon, Jun 28, 2010 4:01 PM	Find...
13.	none	Mon, Jun 28, 2010 9:28 AM	Find...
14.	there may be times when this would increase the overall time needed to complete the donation process	Sun, Jun 27, 2010 2:37 PM	Find...
15.	Not sure. Could delay the donor, and increase costs ultimately	Fri, Jun 25, 2010	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

		10:11 PM	
16.	n/a	Fri, Jun 25, 2010 4:10 PM	Find...
17.	None	Fri, Jun 25, 2010 3:39 PM	Find...
18.	Yes, if it improves recipient outcomes. Thoracic transplant centers need to be held to task to have viable serum to do prospective cross-matches in a timely manner. We have had families pull consent in the past for extended process timeframes. No one wants to lose a potential donor because of this issue. We have 4 separate HLA labs we use depending on where the donor is, We have 2 local thoracic lung center's that we allocate to. Serum is not shared between the HLA labs so it would require added blood quantity, courier charges and time to each prospective thoracic donor.	Fri, Jun 25, 2010 11:18 AM	Find...
19.	None	Fri, Jun 25, 2010 8:19 AM	Find...
20.	Possible delay in case times	Wed, Jun 23, 2010 2:34 PM	Find...
21.	None that can envision. we have already worked with our local centers to make this a standard way of operating. we and our local centers are used to it already.	Tue, Jun 22, 2010 10:02 AM	Find...
22.	As mentioned, there might be a bit of a delay in making thoracic organ offers since our service area involves several states and we have one central tissue typing laboratory so there are logistical and transportation issues involved in delivering specimens to the tissue typing laboratory.	Mon, Jun 21, 2010 4:01 PM	Find...
23.	No. Negative impact stated in item 7 above.	Mon, Jun 21, 2010 3:41 PM	Find...
24.	May not always be in compliance with policy if decision is made to allocate prior to HLA determination. We would send in a proactive response why outside of policy in those cases.	Mon, Jun 21, 2010 2:24 PM	Find...
25.	I don't see it as affecting us negatively.	Mon, Jun 21, 2010 1:22 PM	Find...
26.	Delay in offers when time limitations are in place.	Mon, Jun 21, 2010 10:18 AM	Find...
27.	NONE	Mon, Jun 21, 2010 9:15 AM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

28.	hearts not transplanted	Mon, Jun 21, 2010 6:54 AM	Find...
29.	Lost donors due to unneccasry delays (from hemodynamic status, from family rescinding consent due to delays) OPOs unable to allocate to top candidates on a match run who dont have UA listed OPOs unable to allocate and eliminate centers who are interested in donor for other nonHLA reasons until HLA back (donor seros, echo, high risk behavior) This policy has not operationally been thought through and donor HLA should not be mandatory prior to allocation. (maybe prior to OR if possible)	Fri, Jun 18, 2010 12:22 PM	Find...
30.	None.	Thu, Jun 17, 2010 8:44 AM	Find...
31.	See above. Shouldn't be a big problem	Wed, Jun 16, 2010 4:51 PM	Find...

9. If the impact is potentially unfavorable, how can the OPO community assist your organization in complying with the policy and your organizational needs? Download

	Response Count
Show replies	22
answered question	22
skipped question	11

1.	?	Wed, Jun 30, 2010 2:43 PM	Find...
2.	n/a	Wed, Jun 30, 2010 12:46 PM	Find...
3.	Advice and/or recommendations on standardizing the timing of generating matchruns or making organ offers on livers while waiting for HLA for thoracic organs would be insightful.	Tue, Jun 29, 2010 4:31 PM	Find...
4.	N/A	Tue, Jun 29, 2010 4:29 PM	Find...
5.	N/A	Tue, Jun 29, 2010 2:58 PM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

6.	n/a	Tue, Jun 29, 2010 10:46 AM	Find...
7.	no	Mon, Jun 28, 2010 6:01 PM	Find...
8.	If this policy change is approved the OPO community will comply. From our perspective, it would be a big help if transplant centers listed they patients properly and seriously reviewed offers before they became the primary. HLA is not the only reason a center may reject an offer. There are so many other factors that are included in an organ offer. Holding up the sharing of the information for HLA will slow the process of thoracic organ placement.	Mon, Jun 28, 2010 4:01 PM	Find...
9.	na	Mon, Jun 28, 2010 9:28 AM	Find...
10.	n/a	Sun, Jun 27, 2010 2:37 PM	Find...
11.	Not sure	Fri, Jun 25, 2010 10:11 PM	Find...
12.	n/a	Fri, Jun 25, 2010 4:10 PM	Find...
13.	NA	Fri, Jun 25, 2010 3:39 PM	Find...
14.	Make sure their thoracic transplant centers add the unacceptable antigens into UNET and have updated serum at the their respective HLA labs.	Fri, Jun 25, 2010 11:18 AM	Find...
15.	I can make it work	Fri, Jun 25, 2010 8:19 AM	Find...
16.	Is it possible for a trial period to be considered so that each OPO will have the opportunity to assess any issues with the proposed policy change?	Mon, Jun 21, 2010 4:01 PM	Find...
17.	Have the transplant centers hire more staff to handle the multiple, simultaneous, offers.	Mon, Jun 21, 2010 3:41 PM	Find...
18.	N/A	Mon, Jun 21, 2010 1:22 PM	Find...

Appendix: Survey of OPO Executive Directors (June 16, 2010-June 30, 2010)

19.	n/a	Mon, Jun 21, 2010 10:18 AM	Find...
20.	by not passing the policy. This is not about an OPOs ability this is about understanding how allocation works.	Fri, Jun 18, 2010 12:22 PM	Find...
21.	N/A	Thu, Jun 17, 2010 8:44 AM	Find...
22.	I don't forsee a big problem, maybe some billing issues	Wed, Jun 16, 2010 4:51 PM	Find...

10. What additional comments do you have about the proposed addition of HLA to Policy 3.7.1.12? Download

	Response Count
Show replies	24
answered question	24
skipped question	9

1.	At this time nothing.	Wed, Jun 30, 2010 2:43 PM	Find...
2.	Our suggestion would be modifying proposed policy to allow an OPO to generate PTRs and offer thoracic organs without HLAs resulted in DonorNet and the transplant centers requiring HLAs for their highly sensitized patients can provisionally accept organs pending HLA results.	Wed, Jun 30, 2010 1:01 PM	Find...
3.	I like the idea of this policy and hope it is implemented.	Wed, Jun 30, 2010 12:46 PM	Find...
4.	We send HLA via 3 yellow top tubes as close to consent as possible. We are fortunate that our most outlying hospital is only 1 hr from our HLA lab.	Tue, Jun 29, 2010 4:29 PM	Find...
5.	None. The proposed addition to the policy seems logical, and would be of benefit to the recipients. That's who we are here to serve.	Tue, Jun 29, 2010 2:58 PM	Find...
6.	This would be a positive change for our DSA.	Tue, Jun 29, 2010 10:52 AM	Find...

Appendix: Survey of OPO Executive Directors
(June 16, 2010-June 30, 2010)

7.	none	Tue, Jun 29, 2010 10:46 AM	Find...
8.	It may be benefiical to some programs and especially to programs with patients who have VAD devices and are sensitized. I don't see this as a huge issue for OPO's. We serve the largest geographic region in the country and we can obtain HLA prior to offers. Unless I'm missing something, this seems like a reasonable proposal.	Mon, Jun 28, 2010 11:55 PM	Find...
9.	Our suggestion is to have those centers who require HLA typing enter a provisional yes (pending HLA). Communicating this to the on-site coordinator would allow the on-site coordinator to obtain a backup in case the recipient is sensitized while allowing the case to go forward. Many families have time constraints and the delay of placing thoracic organs may result is less thoracic organs transplanted.	Mon, Jun 28, 2010 6:01 PM	Find...
10.	As it stands now, serology results are not required to make organ offers, then why should HLA be necessary to make the INITIAL offer? DonorNet is a screening tool and direct communication is vital in placement of donor organs with recipients. OPO’s are willing to take provisional YES responses based on the other information provided such as HLA and serology results.	Mon, Jun 28, 2010 4:01 PM	Find...
11.	none	Sun, Jun 27, 2010 2:37 PM	Find...
12.	No comments at this time.	Fri, Jun 25, 2010 10:11 PM	Find...
13.	N/A	Fri, Jun 25, 2010 4:10 PM	Find...
14.	No comments	Fri, Jun 25, 2010 3:39 PM	Find...
15.	I am in favor of this policy but would evenually like it to screen out unacceptable antigen patients so they do not even print on our list.	Fri, Jun 25, 2010 8:19 AM	Find...
16.	Make it happen.	Tue, Jun 22, 2010 10:02 AM	Find...
17.	In general, I think that OPO's will be able to facilitate this, but as mentioned above, I wonder if a trial period could be considered.	Mon, Jun 21, 2010 4:01 PM	Find...
18.	Would surgeons really trust the "virtual" system or would they require us to send blood anyway for pre-recovery cross-match. This would not always be optimal for our process.	Mon, Jun 21, 2010 2:24 PM	Find...
19.	If the heart transplant programs are mandated to list unacceptables, I feel it would be to	Mon, Jun	Find...

	our advantage and would facilitate the placement process.	21, 2010 1:22 PM	
20.	none	Mon, Jun 21, 2010 10:18 AM	Find...
21.	Don't do it	Mon, Jun 21, 2010 6:54 AM	Find...
22.	I would strongly urge this policy not to be passed as written. Tx centers can consider heart offers pending hla determination and OPOs can then effectively make back up contigencies should a donor have UA to the recipient.	Fri, Jun 18, 2010 12:22 PM	Find...
23.	This policy will increase opportunities for thoracic patients who require prior crossmatching. It will also allow these patients to be eliminated from consideration if they have identified unacceptable antigents entered.	Thu, Jun 17, 2010 8:44 AM	Find...
24.	If it will help get patients transplanted, we should do it.	Wed, Jun 16, 2010 4:51 PM	Find...

Response from an OPO Executive Director by E-Mail

1. Upon receipt of typing specimen, how much time, on average, does your affiliated HLA laboratory require to provide HLA of thoracic deceased donors? Please respond to the nearest half hour and elaborate on your response.

4-6 hours

2. Does your OPO currently obtain HLA of thoracic deceased donors before making thoracic organ offers via DonorNet®?

Yes, most of the time, but not always, unless it is needed for a sensitized patient at the top of the list).

3. Does your OPO receive HLA of thoracic deceased donors before it begins the organ allocation process (i.e., before making organ offers)? Please elaborate on your response.

80% of the time approximately. see above answer

4. What percentage of the time is the HLA of thoracic deceased donors available before thoracic organ allocation?

N/A

5. How much time, on average, does your OPO need to gather blood or tissue samples for the purposes of HLA from thoracic deceased donors? Please respond to the nearest half hour and elaborate on your response.

I think this question is not worded correctly. I think what you are trying to ask is ***"from the time the OPO is prepared to gather specimens for HLA typing during the donor process, how long does it take to gather, transport, and accession the specimen before the HLA typing process can begin?"***

The answer to that question varies widely depending on the location of the donor and location of the HLA Laboratory. For example, if our OPO is recovering a donor in [City, State]; we have to draw and label the specimens, arrange for a courier to take them to the airport, have to utilize (usually a charter aircraft) an aircraft to fly the specimens back to [City, State] (450 miles) have a courier pick up the specimens deliver them to the HLA Laboratory, before accessioning can begin. At best it can take 3-5 hours just in this time frame.

6. If your OPO does not currently receive HLA prior to allocation of thoracic organs, what is the time lapse between your OPO's performance of a thoracic match-run and its receipt of the deceased donor's HLA?

N/A

7. What operational impact would your OPO experience if the Board of Directors approves the addition of HLA to 3.7.12.1? Please elaborate on your response.

If nodes can be recovered quickly during the case, then only transport time is involved, however, it could add up to 7-11 additional hours.

8. Should this proposed change become policy, what negative impact or situations might your OPO encounter?

a) Increased donor expense (adding thousands of donor management dollars) associated with maintaining a donor an additional hours in the ICU.

b) Some of the donors could become unstable and potentially will be lost due to the time delay in trying to comply with the proposed policy.

c) Some hospital personnel, particularly physicians, currently are upset at the prolonged amount of time it can take to perform an organ donor, much of which is already directly associated with efforts to recruit thoracic organs. The additional delays could further exacerbate the problem of using hospital resources for up to an additional hours, in order to be compliant with such a policy. The support of donor physicians and hospital is critical to maximizing organ procurement, making the donor process more unpalatable could have deleterious efforts of future organ procurement in those hospitals.

d) Some donor families already hesitate to consent if we tell them the donor process will be prolonged, some may not want to prolong this time further, thereby limiting their consent to those organs that can be recovered expeditiously.

e) Substantial increased OPO staffing resource expenditures associated with having to prolong the donor management and total donor process for up to double digit hours.

In summary, thoracic organ and potentially all organ acquisition expenses will increase significantly (increased donor management and OPO staff expenses), some donors will become unstable and will be lost (lost organs), some families will not be willing to accept the prolonged time frame and with draw consent for some (thoracic) or all organs (lost organs).

9. If the impact is potentially unfavorable, how can the OPO community assist your organization in complying with the policy and your organizational needs?

The above impacts are logistic impacts, and the "OPO community" cannot assist in addressing these observations.

10. What additional comments do you have about the proposed addition of HLA to Policy 3.7.1.12?

I understand what the Thoracic Committee is trying to accomplish and why. More and more thoracic patients are becoming sensitized prior to transplant, and centers desires to have the immunologic consideration addressed before they can commit to transplanting a patient. If OPOs, are bypassing

patients in the allocation process because of the timing logistics, expense, donor hospital or family considerations, then these patients are at a disadvantage to the non-sensitized patients in the allocation process.

I would suggest that the key issue is; is this a problem and how big of a problem? Meaning have we studied and have a good handle on knowing if this problem exists, exactly how often does this occur, and what has been the impact on the number of patients who have been "skipped" in the allocation process? For example, if there is a perception that this is a wide spread problem and based on that perception we are going to implement a policy that may have potentially significant negative cost and donor, hospital, and OPO impacts, it would seem prudent to study and validate with data the true nature and extent of the problem. The benefit of such knowledge would be to have a good handle on how many people are being disadvantaged, so that could be balanced against the cost of the PROPOSED solution. If the number of people who are being disadvantaged is small, I would think the cost of this solution would far outweigh the advantage of helping those patients, and an alternate means of addressing the problem should be sought. The other benefit of such knowledge is that if there are a significant percentage of the heart patients being disadvantaged, it would make the policy easier for the OPO and transplant community as a whole to understand why the entire community should consider taking such a "negative hit" meaning that the benefit would be worth the added time to do a donor, and the associated cost and lost organ impact. (It could help sell the policy)

I believe that if UNOS were to consider applying this type of policy is would undeniably have negative effects; including increased expense, increased personnel resource expenditure for all organs, significantly prolong the donor process, delay recovery, and would result in the loss of some organs.

I am unclear as to whether the scope of the problem would warrant such a policy that would bring with it such a significant negative impact.

Finally, though you did not ask this question, I do have a potential "middle ground" for such a policy. That would be to build in some flexibility to the policy and grant the OPO the latitude on a case by case basis, to bypass the policy if the donor, hospital, or family logistics would be in conflict with the policy of making every effort to get the organ to a sensitized patient. You could add a bypass code for thoracic organ offers that the OPO could use to indicate when it had to bypass a sensitized patient for logistical considerations.