OPTN | UNOS

Briefing Paper

Addressing HLA Typing Errors

OPTN/UNOS Histocompatibility Committee

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Contents

Addressing HLA Typing Errors

Affected Policies: *Policy 2.2 OPO Responsibilities, 4.3 Requirements for Performing and Reporting HLA Typing, 4.4 Resolving Discrepant Donor and Recipient HLA Typing Results, and Bylaw Appendix C.2.D OPO Affiliation.*
Sponsoring Committee: *Histocompatibility Committee*
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Executive Summary

The OPTN/UNOS does not have a system for timely reporting and reviewing human leukocyte antigen (HLA) typing errors. Because HLA typing discrepancies are flagged on the donor and recipient histocompatibility forms completed after transplant, there is no timely mechanism for detecting errors in the HLA information used for generating match runs used in organ allocation.

HLA data entry errors, specifically prior to match run generation, can have serious patient safety implications. These HLA typing errors can also create system inefficiencies.

Along with transcriptional errors caused by manual entry of HLA data, another cause of these data entry errors is the setup of HLA data in DonorNet®. A user can unknowingly change a donor's HLA information prior to the match run, which can result in match runs being executed with the incorrect HLA type.

The Committee is proposing changes to reduce the number of manual HLA data entry errors in UNet[SM]:

1. When HLA data is entered manually into UNet, it must be entered twice (by the same person) for verification of accurate data entry
2. When HLA data are uploaded directly into UNet, the member must have a process for verifying that the data are accurate
3. Raw HLA typing must be attached in the system for verification of lab results

The Committee believes these changes will increase patient safety by putting more verification processes in place to ensure accurate HLA data is entered into UNet.

What problem will this proposal address?

The OPTN/UNOS does not have a system for timely reporting and reviewing HLA typing errors. Because HLA typing discrepancies are flagged on the donor and recipient histocompatibility forms completed after transplant, there is no timely mechanism for detecting errors in the HLA information used for generating match runs used in organ allocation.

HLA typing errors, specifically prior to generating a match run, can have serious patient safety implications, such as unanticipated graft loss or accelerated rejection.[1, 2, 3] When HLA typing errors are discovered during the match run process, this can lead to system inefficiencies such as increased cold ischemia time while laboratory results are confirmed or rerun, discards from organs shipped far distances with incorrect HLA typing, and possible missed transplant opportunities for other candidates who may have been screened off of a match run because of incorrect HLA typing.

One cause of these data entry errors is the setup of HLA data in DonorNet®. Currently, HLA data are "live" and editable across different screens in DonorNet. This means a user accessing a donor record in DonorNet can unknowingly change a donor's HLA information prior to the match run by simply scrolling over an HLA data field while in the record for other purposes. Such errors have resulted in match runs being executed with the incorrect HLA type.

In a review of patient safety cases from 2016-2017 by the Operations and Safety Committee, 13 case subjects were laboratories (Figure 1). The subject of the reviews related to:

- WaitList HLA data entry error (1)
- DonorNet HLA data entry error (5)
- Incorrect typing (5)
- Issue reported in error (1)
- "Other" issues (1)

Figure 1: Patient Safety Cases by Subject from 1/1/17 – 12/31/17

Case Subject Member Type	Number of Cases	Percent of Total Cases
Lab	13	4.9

DonorNet HLA data entry errors made up over a quarter of all the reviewed cases categorized as data entry related (Figure 2).

Figure 2: Patient Safety Subcategories: Data Entry from 2016-2017

Data Entry	2016	2017	Total
DonorNet- ABO	1	0	1
DonorNet- ABO Subtyping	1	0	1
DonorNet- Demographics	0	3	3
DonorNet- HLA	11	7	18

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[1] Bray, R, et al., "Impact of Combined HLA-DRB1/DQB1 Matching on Deceased Donor Kidney Graft Survival: Review of OPTN Data", presentation World Transplant Congress 2014, San Francisco, CA, July 28, 2014.

[2] Schnitzler, MA, et al., "The economic implications of HLA matching in cadaveric renal transplantation", *New England Journal of Medicine* 19 (1999), DOI: 10.1056/NEJM199911043411906. Accessed July 6, 2018.

[3] Takemoto, S, Port, RK, Claas, F, and Duquesnoy, RJ, "HLA matching for kidney transplantation", *Human Immunology* 12 (2005), p 1497, doi:10.1016/j.humimm.2004.06.008. Accessed July 6, 2018.

Data Entry	2016	2017	Total
DonorNet- Increased risk (or high risk) status of donor	0	1	1
DonorNet- Infectious disease test result(s)	2	2	4
DonorNet- Labs	1	1	2
DonorNet- Other	2	1	3
Other (Not Related to DonorNet or Waitlist)	7	0	7
Waitlist- ABO	3	0	3
Waitlist- HLA	0	1	1
Waitlist- Inaccurate patient priority status	2	1	3
Waitlist- Labs	1	0	1
Waitlist- Other	7	11	18
Total	38	28	66

Additional information for these 18 DonorNet data entry reports is as follows:
- 4 instances of the host OPO incorrectly entering correct HLA data provided by the lab
- 5 transcription errors (the lab typed the information correctly but wrote it incorrectly on the worksheet used to then enter the data in DonorNet)
- 9 data entry errors (the lab typed the donor correctly but reported the information incorrectly in DonorNet)

Why should you support this proposal?

This proposal provides improvements to UNet that will help reduce the number of HLA data entry errors. Because organs are distributed nationally for highly sensitized kidney candidates, it is critical that the HLA information provided for the donor organ is accurate. Accurate HLA data entry promotes safety, reduces the risk or organ wastage (or discards), and directly contributes to improving transplant outcomes.

The Committee is proposing two changes to reduce the number of manual HLA data entry errors in UNet:

1. When HLA data is entered manually into UNet, it must be entered twice for verification of accurate data entry
2. When HLA data are uploaded directly into UNet, the member must have a process for verifying that the data are accurate
3. Raw HLA typing must be attached in the system for verification of lab results

How was this proposal developed?

The OPTN/UNOS Board of Directors approved policy changes in June 2014 that require laboratories to resolve any discrepant HLA results between the donor and recipient within 30 days of notification of the discrepant results.[4]. "Discrepant HLA typing" occurs if the HLA typing provided by the OPO does not match the HLA typing provided by the receiving transplant hospital's histocompatibility laboratory. While developing this policy, the Committee created the Discrepant HLA Typing Subcommittee (the Subcommittee) to take a closer look at historical and ongoing trends in discrepant HLA typing by analyzing discrepant typing reports and recommending future policy proposals to the Committee.

Background

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[4] OPTN Policy Notice, p 23, https://optn.transplant.hrsa.gov/media/1280/policynotice_20140724.pdf Accessed July 6, 2018.

The Subcommittee and Committee debated methods that would be most effective at reducing HLA data typing errors over several years. The Subcommittee's charge was to make recommendations regarding:

1) How to define "significant" typing errors for purposes of possible action
2) Whether or not to forward certain significant discrepancies to the Membership and Professional Standards Committee (MPSC)
3) Future policy proposals that may be needed to address inaccuracies of HLA typing

The Subcommittee requested detailed data on all HLA discrepancies in the Discrepant HLA Typing Reports in UNet from 2009 to 2012 (Figure 3).[5]

Figure 3: Discrepant Donor HLA Typing Report for Donors Recovered between June 1, 2009 – May 31, 2012

	06/01/2009-05/31/2010	06/01/2010-05/31/2011*	06/01/2011-05/31/2012
Total number of deceased donors HLA typed by a donor laboratory and retyped by kidney, kidney-pancreas and/or pancreas recipient laboratory	4,297	4,406	4,490
Total number/percent of discrepancies	156 (3.6%)	131 (3.0%)	113 (2.5%)
Resolved discrepancies	117 (75.0%)	84 (64.1%)	57 (50.4%)
Partially resolved discrepancies	34 (21.8%)	41 (31.3%)	47 (41.6%)
Number of laboratories with:			
at least one deceased donor HLA typed by donor laboratory and retyped by kidney, kidney-pancreas and/or pancreas recipient laboratory	133	135	133
at least one discrepancy	99	84	80
at least one unresolved discrepancy	50	46	64
at least one discrepancy unresolved by this laboratory	17	17	33

* Most recent changes to equivalency tables used for HLA Typing reports were implemented on March 16, 2011.

In each 12 month period, the percentage of donors with discrepancies was similar compared to the previous 12 months (3.6%, 3.0%, and 2.5%). The percentage of resolved discrepancies decreased from 75% during first era to 50% during the last era. In all three eras, most of the discrepancies were resolved or partially resolved. More than half of all laboratories had at least one discrepancy.

Figure 4 shows the reasons given in UNet for the donor HLA discrepancies. "Correct typing" was the most common reason reported by donor laboratories, while correct typing and transcription error were commonly reported by recipient laboratories.

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[5] Kucheryavaya, A. "Discrepant Donor and Recipient HLA Typing Results in UNet[SM]". OPTN Data Analysis. November 12, 2012.

Figure 4: Reasons for Donor HLA Discrepancies

Reported discrepancy reason	Era											
	06/01/2009-05/31/2010 Form				06/01/2010-05/31/2011 Form				06/01/2011-05/31/2012 Form			
	DHF		RHF		DHF		RHF		DHF		RHF	
	N	%	N	%	N	%	N	%	N	%	N	%
Correct Typing	99	70.7	80	36.0	77	74.0	78	41.9	63	84.0	65	43.3
Crossreactive Antigen	1	0.7	0	0	0	0	0	0	0	0	0	0
Incorrect Assignment	4	2.9	4	1.8	5	4.8	3	1.6	4	5.3	1	0.7
Incorrect Specimen	0	0	0	0	0	0	0	0	0	0	1	0.7
Incorrect Split	1	0.7	0	0	1	1.0	1	0.5	2	2.7	1	0.7
Low Antigen Expression	1	0.7	1	0.5	0	0	0	0	0	0	0	0
PBL vs. LN/Spleen	0	0	1	0.5	0	0	0	0	0	0	0	0
Parent vs. Split(s)	18	12.9	43	19.4	4	3.8	25	13.4	2	2.7	4	2.7
Serology vs. Molecular Typing	10	7.1	16	7.2	6	5.8	11	5.9	1	1.3	4	2.7
Transcription Error	4	2.9	76	34.2	9	8.7	63	33.9	2	2.7	71	47.3
Unable to Type/Identify Antigens	0	0	0	0	0	0	0	0	1	1.3	0	0
Other	2	1.4	1	0.5	2	1.9	5	2.7	0	0	3	2.0
All	140	100.0	222	100.0	104	100.0	186	100.0	75	100.0	150	100.0

* Based on resolved and partially resolved discrepancies

The Committee continued to examine trends over the years to get a more robust picture of the problem. Ultimately, they Committee decided to focus policy solutions on decreasing the rate of transcription errors since that reported reason for discrepancy was consistently high across the years.

In 2015, the rate of transcription errors continued to be an issue in the discrepant typing reports. Figure 5 and 6 below summarize the discrepancies according to error type and the number of cases where the match run was affected.

Figure 5: Error Type and Frequency for Q1 2015

Error Type	Frequency
Bw4/6	16
DRw51/52/53	26
DRw53 Null	8
Transcription	39
Transposed	0*
Incorrect Typing	65
Serology/DNA	16
Allele Level vs. Antigen	109

Error Type	Frequency
Incorrect Split	2
Split vs. Parent	53

* included with transcription

Figure 6: Impact on Match Run Q1 2015

Match Run Affected	Yes	Maybe	No
Frequency	43	14	257

The Subcommittee questioned whether alleles should be listed as discrepancies and requested defining discrepancy as a significant error (i.e. misallocation and not allele level typing error) for future reports. This topic was debated over time, and eventually the Subcommittee agreed that discrepancies should be interpreted as something significant that could impact patient safety or misallocation of an organ (not an allele level typing which is insignificant). This new definition took out items that were not considered critically discrepant, such as one center reporting A10 and another reporting A10:01. Under the old definition, this would be flagged as discrepant. Though it is technically discrepant, A10:01 adds an allele and is not the type of discrepancy that would rise to the level of patient safety risk that would significantly concern the Committee.

Figure 7 shows the number of discrepancies by quarter for 2015-2017. Of note, the definition of what was considered a critical discrepancy by the Subcommittee for these reports was changed as of Q2 2017 to not include allele level typing discrepancies.

Figure 7: 2015-2017 Quarterly Discrepant Typing Numbers

Year	Quarter	N of Donors Typed by Lab with HLA in DonorNet and on DHF	N of Discrepancies	% of Discrepancies
2015	Q1	2,102	59	2.80%
2015	Q2	2,236	56	2.50%
2015	Q3	2,294	38	1.70%
2015	Q4	2,210	42	1.90%
2015	**All**	**8,842**	**195**	**2.20%**
2016	Q1	2,350	119	5.10%
2016	Q2	2,455	115	4.70%
2016	Q3	2,453	86	3.50%
2016	Q4	2,543	79	3.10%
2016	**All**	**9,801**	**399**	**4.10%**
2017	Q1	2,509	56	2.20%
2017	Q2	2,539	34*	1.3%*
2017	Q3	2,570	45*	1.8%*
2017	Q4	2,509	54*	2.2%*
2017	**All**	**10,127**	**189****	**1.9%****

* New "critical discrepancy" definition
** Totals contain 3 quarters using new "critical discrepancy" definition and 1 quarter using old discrepancy definition, resulting in overall lower number than previous quarters.

After reviewing this data, the Subcommittee considered various solutions, and ultimately recommends the following changes to policy to decrease the number of transcription errors:

1. When HLA data is entered manually into UNet, it must be entered twice for verification of accurate data entry
2. When HLA data are uploaded directly into UNet, the member must have a process for verifying that the data are accurate
3. Raw HLA typing must be attached in the system for verification of lab results

The rationale for each of these proposed solutions is described in detail below.

1. Double Entry of Manual Data

The Committee explored the option to lock down the Crossmatch and HLA tab in DonorNet to prevent accidental changes by users accessing the page for other reasons. The Committee generally agreed this would be one easier way to lower the risk of HLA data being inadvertently changed by a user accessing the donor's file. Locking down of the match run page will be pursued as a system enhancement and is not part of the policy proposed in this project, but it will contribute to the goal of this project to reduce the number of HLA data errors.

The Committee reviewed programming options from UNOS IT for preventing manual HLA typing errors, and ultimately decided that double entry of HLA data by the same person (or different people if a center so chooses) would be a reasonable solution.

In contrast to requiring a second user verification step similar to ABO, double entry of the data can be performed by the same individual, which will allow for this option to be done during off-peak hours or when there may only be one person entering the data. As such, it will accommodate smaller staffed laboratories and OPOs.

For this proposed solution, the person entering the HLA data would enter the data a first time. Depending on the data and which system it is entered into (Waitlist^{SM}, DonorNet, TIEDI$^®$, or KPD^{SM}), the number of fields that will need to be entered will vary. The person would then be prompted to re-enter the same data. If any data differed between the first and second entries, a message would pop up identifying the discrepancy. Resolution of the discrepancy would be required in order for the user to proceed, and the user would only be required to re-enter the discrepant fields and not the entire HLA information.

2. Verification of Uploaded HLA Data by Programs

The Committee is in favor of uploading HLA data when possible into UNet directly from third party applications laboratories already use such as mTilda and HistoTrac. If a laboratory or OPO chooses to upload this information directly, the user will not be required to manually double enter the HLA data. The Committee still wanted to ensure that the data coming through these uploads had been verified. The Committee clarified the bylaw language to include that laboratories must have a process for verifying the HLA data as defined in the written agreement with each OPO they serve, similar to the verification process outlined in the written agreement between laboratories and transplant programs.

3. Raw HLA Typing Attachments

The third proposed solution to reduce the number of HLA data typing errors is to require raw HLA testing data that comes from the testing machines to be uploaded into UNet as an attachment. The Committee felt strongly that this data was important for verifying what was entered in UNet, and also to see if there was any detection for certain antigens that are critical for the recipient but may have been at a low enough level that the OPO's laboratory may not have reported them. Anecdotally, the Committee felt that a majority of laboratories are already attaching this data, and that this requirement would not be particularly burdensome to members. Because this documentation is similar to other source documentation that members are required to provide to the OPTN, the Committee added the requirement with the other source documentation in policy.

Alternate Solutions Considered

The Committee considered, but ultimately did not propose, multiple alternate solutions to prevent HLA typing errors from occurring prior to allocation or to detect them prior to transplant. The alternates are detailed below:

Require second person confirmation for reporting HLA

One solution would have required a second person at the lab to enter HLA information entered into DonorNet after a first person at the lab did so. The Committee was generally in favor of this solution and suggested clarifying that one of the reviewers must be from the histocompatibility laboratory. This was intended to address reporting errors that may be occurring because the person entering the data (OPO or transplant hospital staff) is not an HLA expert. One Committee member also pointed out that the American Society for Histocompatibility and Immunogenetics (ASHI) currently requires a second party verification on analysis of DNA based typing, but recognized that not all OPTN member laboratories are accredited by ASHI. Ultimately, the Committee recognized this option may pose an undue burden on smaller laboratories who may not have a second person available during off hours, and did not pursue this solution.

Require recipient laboratories to re-type deceased donors

Another solution would require the labs associated with the recipient transplant hospital to re-type the deceased donors. The Committee was somewhat divided on this idea. Several members of the Committee were in favor of this new requirement, arguing that donor retyping is essential in order to confirm that the organ received is the one accepted for the intended recipient.

However, the Committee was concerned that such a requirement could be financially burdensome for laboratories and OPOs. Several members also commented that the majority of typing errors were clerical or due to interpretation issues, and requiring recipient laboratories to retype will not necessarily solve this problem. The Committee instead focused on finding solutions that prevent HLA typing errors prior to allocation.

Require third party 'tie breaker' laboratory to resolve the error

In this solution, a third lab would be enlisted to type the donor in the event of a discrepancy between the OPO's lab and the recipient hospital's lab. Several Committee members had concerns about this solution, particularly with which party would ultimately be responsible for covering the cost of the retyping. One member suggested that the laboratory determined to be in error should pay for the cost. Others suggested that the OPTN pay for the third party typing, predicting that this would be a small number of cases. Another member suggested that, in certain circumstances, the laboratories involved in the discrepancy could submit their typing results to the third party laboratory in order to resolve discrepancies resulting from differences in interpretation of the results (not a typing error). Ultimately, the Committee did not pursue this solution due to its impracticality and potential high cost.

How well does this proposal address the problem statement?

This proposal aims to decrease the number of HLA typing discrepancies and reduce patient safety risk related to these discrepancies. Having users enter the data twice will ensure the HLA data are entered accurately and reduce discrepancies related to human error.

Was this proposal changed in response to public comment?

This proposal was discussed at each regional meeting. Each region overwhelmingly supported the proposal, with 94% of the regional votes supporting or strongly supporting the proposal (Figure 8).

Figure 8: Regional Meeting Votes on Proposal

Region	Strongly Support	Support	Neutral	Oppose	Strongly Oppose
Region 1	8	3	3	0	0
Region 2	19	9	1	0	0
Region 3	15	10	2	0	0
Region 4	19	5	0	0	0
Region 5	8	15	2	0	0
Region 6	19	15	0	5	0
Region 7	22	1	0	1	0
Region 8	16	5	0	0	0
Region 9	9	10	0	1	0
Region 10	11	10	0	0	0
Region 11	10	9	0	0	0

Many major societies voiced support for this proposal during the public comment period. The American Society of Histocompatibility and Immunogenetics (ASHI), the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the Association of Organ Procurement Organizations (AOPO), the American Nephrology Association (ANNA), and the National Kidney Foundation (NKF) all provided positive feedback.

The OPTN/UNOS Living Donor Committee, OPO Committee, and Patient Affairs Constituent Council also heard presentations on this proposal and were in favor of the outlined policy changes; specifically, the groups were in favor of the measures to improve patient safety. The OPO Committee expressed support of the proposal's measures to ensure accuracy in data entry.

Figure 9: Sentiment by State (n=286)
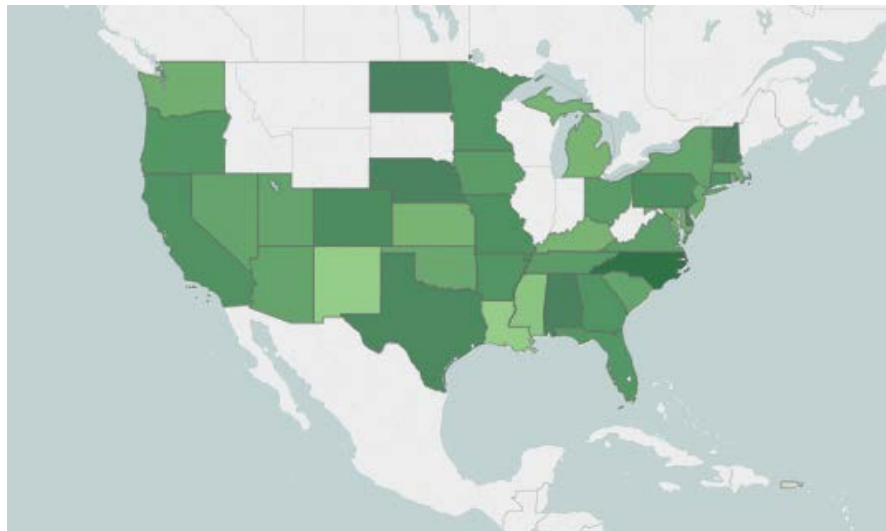
Note: The darker the shade of green, the more support. States with no votes are shown in white.

Figure 10: Sentiment by Member Type (n=286)
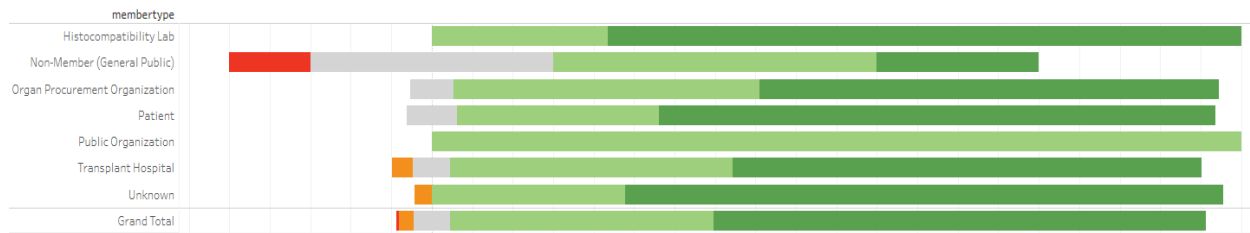
Overall, comments received focused on several areas: patient safety, data quality, and moving the data entry process to direct data transmission into UNet.

Patient Safety

Multiple comments addressed the proposal's intention to improve patient safety by putting verification steps into the HLA data entry process. Commenters were in favor of having extra verification steps in the process as a patient safety benefit. The Patient Affairs Constituent Council was especially supportive of this goal.

Data Quality

Many comments referenced the importance of data quality and accuracy. Commenters were largely in favor of the double entry component of the proposal. A few commenters expressed concern over a possible increase in data burden on the members, but overall supported the proposal. Others mentioned that the double verification should be by two users similar to ABO typing. The Committee considered the impact of data burden from double entry throughout the proposal's development and ultimately are keeping the proposal's double entry language as it is to allow for the same person to enter the HLA typings twice. It is important to note that the second time the user enters the HLA data, their first entries will not display for the user to see; users will not be able to reference their first entries, which will prevent them from entering the incorrect information two times as some commenters were concerned would happen.

Commenters were also in favor of the OPOs or labs attaching raw data outputs in UNet. AOPO confirmed the Committee's belief that most centers are already doing this so it should not create much new burden for centers. Several commenters did cite concern that it would be difficult to monitor whether or not the labs that are not manually entering information have a data verification step in place. The proposed policy and bylaw language ensures that labs and OPOs have their data verification process outlined in their written agreements. As mentioned in the implementation section, verifying that the raw data uploads are accurate will be part of the site surveys for OPOs.

Data Entry by Direct Data Transmission vs. Manual Entry

Many comments suggested moving towards direct data transmission methods as a way to reduce typing errors due to human error. The Committee is enthusiastic about this idea and supports pursuing this in the future. The Committee has spoken with members of the OPTN/UNOS Operations and Safety Committee about future policy work around this idea. At this time, the Committee recognizes that this change could be a large financial burden on smaller labs. It could require members to need to purchase data systems they may not already have at a potentially large expense. The Committee recognizes that the use of direct data transmission is a goal to work towards, and will continue to explore this idea.

Overall, the Committee was satisfied with the public comments received but did not feel that any warranted changes to the existing proposal so no language was changed as a result of public comment.

Which populations are impacted by this proposal?

While the solutions proposed are largely operational changes, this proposal has the potential to impact any donor or candidate who has HLA data reported in UNet. Any time HLA data are entered manually into UNet, there is the potential for human error. With double entry of the HLA data, the number of data entry errors should decrease which will benefit candidates receiving organs.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* By taking more steps to ensure accuracy of HLA data, this proposal has the potential to reduce the number of organ discards that are due to HLA data typing errors.

2. *Improve equity in access to transplants:* There is no impact to this goal.

3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* By taking more steps to ensure accuracy of HLA data, this proposal has the potential to improve graft survival if certain antigens are properly reported that would have been entered incorrectly, preventing transplantation of organs in recipients that are incompatible with the donors due to HLA type.

4. *Promote living donor and transplant recipient safety:* This proposal aims to improve recipient safety by preventing graft loss, accelerated rejection, or possibly death. Additionally, this project will reduce cold ischemia time, discards, and possible missed transplant opportunities for other candidates. This is the primary goal of this proposal.

5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

How will the OPTN implement this proposal?

Fiscal impact of this proposal across all departments is large. IT will program a double entry component for all HLA data entered in UNet that will alert users when there is a discrepancy in any field between the first and second entry of HLA data. Users will then be able to fix the discrepant data. Users will not be required to re-enter all the data if there is a discrepancy between the first and second entry; rather, they will only need to fix the fields that were discrepant.

UNOS will provide education to members on double entry and communicate these changes to the community.

How will members implement this proposal?

This proposal affects laboratories, OPOs, and transplant hospitals in varying capacities. The level of effort for implementation will depend on who enters the HLA data and the written agreement between the laboratory and the OPO or transplant center. This proposal should have minimal effect on transplant hospitals, as HLA data are largely entered by laboratories and OPOs.
Implementation costs may come in the way of updating written agreements between labs, OPOs, or transplant programs. This will require a few hours of administrative time to amend, review, and finalize the new agreements. Depending on the institution, there may be added layers of review.

Staff training would be required, either for OPO, lab, or transplant program staff who enter the data. The estimate for this process is very low, potentially six to eight hours (a few hundred dollars) and can be implemented in one to two weeks.

Ongoing expenses will be driven by donor and transplant candidate case volume. This would be a very low impact on staff to perform, perhaps a few minutes of time per occurrence. These costs are covered by

Medicare so there may be a slight increase in expenses claimed in the cost report. However, if the lab is freestanding and not a part of a transplant hospital, this expense may not be included in the cost report.

Will this proposal require members to submit additional data?

This proposal does not require members to submit any new data, but does require members to enter new or changed HLA data twice. This could mean that members entering this data may need to enter upwards of 21 HLA data fields twice.

How will members be evaluated for compliance with this proposal?

At OPOs, site surveyors will review a sample of deceased donors in UNet to verify that HLA typing source documentation was uploaded to UNet.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

This policy will be formally evaluated approximately one and two years post-implementation. The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- Has the number of HLA critical discrepancies decreased?
- Has the rate of HLA critical discrepancies decreased?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance pre- and post-implementation of this policy:

- The number (and percent) of HLA critical discrepancies

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

RESOLVED, that changes to Policy 2.2 (OPO Responsibilities) and to Bylaws C.2.D (OPO Affiliation) are hereby approved, effective March 1, 2019.

FURTHER RESOLVED, that changes to Policies 4.3 (Requirements for Performing and Reporting HLA Typing) and 4.4 (Resolving Discrepant Donor and Recipient HLA Typing Results) are hereby approved, effective pending implementation and notice to OPTN members.

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

39 4.3 Requirements for Performing and Reporting HLA Typing

40 Laboratories must ensure that all HLA typing is accurately determined and report HLA typing results to
41 the OPO or Transplant Program according to the ~~turnaround time~~ <u>deadlines</u> specified in the written
42 agreement between the laboratory and ~~any affiliated~~ the OPO or transplant program. <u>Laboratories must</u>
43 <u>report HLA typing results to the OPTN Contractor. HLA typing results that are entered manually must be</u>
44 <u>verified by reporting each result twice.</u>
45

46 4.4 Resolving Discrepant Donor and Recipient HLA Typing Results

47 Laboratories must submit donor and recipient histocompatibility forms to the OPTN Contractor after
48 transplant according to *Policy 18.0: Data Submission Requirements.* After laboratories submit donor and
49 recipient HLA typing results to the OPTN Contractor, the OPTN Contractor will provide a report to the
50 laboratories including any discrepant HLA typing results.

51 ~~The report includes *all* of the following donor information:~~

52 ~~1. Donor id~~
53 ~~2. HLA typing results~~
54 ~~3. Date of tests~~
55 ~~4. Test methods~~
56 ~~5. Laboratory Identifiers~~
57 ~~6. OPO Identifier (if applicable)~~
58
59 ~~The report includes *all* of the following recipient information:~~

60 ~~1. SSN~~
61 ~~2. HLA typing results~~
62 ~~3. Date of tests~~
63 ~~4. Test methods~~
64 ~~5. Laboratory identifier~~
65
66 Laboratories must resolve discrepancies within 30 days of notification of discrepant HLA typing results.
67 The Laboratory Director or designated staff must contact the other Laboratory Director or designated
68 staff to resolve the discrepancies. Each laboratory involved in the HLA typing discrepancy must identify
69 and report the reason for the discrepancy to the OPTN Contractor.

70 The OPTN Contractor will remove all discrepant flags from HLA typing results that have been resolved.
71 Discrepancies that have not been resolved will remain flagged. The Histocompatibility Committee will
72 review, at least every three months, any outstanding discrepant typing recorded since the last review.
73 The committee will use the results of these reviews to determine whether policy modifications are
74 required.
75

76 Bylaw Language:

77

78 C.2.D. OPO Affiliation

79   Histocompatibility laboratories must have written agreements with every OPO member the
80   laboratory serves, unless clinical urgency prevents such an agreement. Written agreements
81   between histocompatibility laboratories and OPOs must include *all* of the following:
82

83   1. The sample requirements for typing and crossmatching.
84   2. The loci and level of resolution typed.
85   3. A process for requesting extended HLA typing.
86   4. A process for <u>verifying and </u>reporting HLA typing results to the OPTN Contractor.
87   5. A process for resolving HLA typing discrepancies and errors.
88   6. The maximum turnaround time from receipt of donor sample to reporting of results to the
89   OPO.
90   7. A process for prioritizing donors for histocompatibility testing.
91   8. The length of time for which donor specimens are required to be stored for repeat or future
92   testing.
93   9. If the OPO performs crossmatching, then all methods used for crossmatching and the
94   interpretation and reporting of the results.

#