

OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
Meeting Minutes
March 29, 2018
In-Person Meeting

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Introduction

The Ad Hoc Disease Transmission Advisory Committee met in-person in Richmond, Virginia on 3/29/2018 to discuss the following agenda items:

1. Policy Oversight Committee (POC) Update
2. Informed Consent Policy Proposal
3. UNOS/OPTN Update
4. Hepatitis C (HCV) and Organ Donation
5. New Project and Case Review Ideas
6. Classification Rules and Efficiencies in Case Review
7. Abstract and Case Study Review
8. Data Requests
9. Confidential Case Review
10. New Business

The following is a summary of the Committee's discussions.

1. Policy Oversight Committee (POC) Update

Summary of discussion:

The Committee received an update on the Policy Oversight Committee (POC) from the DTAC vice chair who serves on this group. All vice chairs serve on the POC. Their job is to review all projects submitted by Committees. They do the following:

1. Assign the project to the correct primary strategic goal (1-5)
2. Continue to work towards alignment of the project portfolio with the OPTN Strategic Plan
3. Prioritize resources
4. Ensure collaboration with key stakeholders and provide feedback to sponsoring committees
5. Make a recommendation to the Executive Committee

The OPTN Strategic Plan designates the amount of resources that are targeted per goal (e.g. 40% of efforts for goal 1 which is to increase the number of transplants). It can be difficult to prioritize. The DTAC recently heard the proposal for next OPTN Strategic Plan (2018-2021). The POC has reviewed and recommended seven new projects since October 2017. These were shown to the DTAC. The POC also has reviewed and prioritized Goal 2 projects (equity in access) and in particular multi-organ allocation projects. In May, the POC will review entire committee project portfolio (all ongoing projects). The current project alignment, displayed in a Tableau dashboard, was shown. Currently, public comment just finished for 12 proposals, including the DTAC informed consent. DTAC leadership discusses projects or public comment of relevance to the Committee.

2. Informed Consent Policy Proposal

Summary of discussion:

The DTAC proposal to clarify informed consent on transmittable diseases was out for public comment from January 22- March 23, 2018. DTAC will complete their review of public comments on the proposal today. The goal is to vote on policy language that can be sent to OPTN/UNOS Board of Directors (BOD) for their consideration at their June 2018 meeting. It was shared that the Committee vote to send the proposal forward is required to be a majority vote and that a quorum must be in meeting attendance (via in person or teleconference). It was clarified that if a vote is sought by email that there must be 100% member participation and that the vote must be unanimous, according to Virginia statute. Therefore, the discussion and vote is best conducted at a face-to face meeting. The chair explained that he hoped the Committee could come to consensus and that all opinions will be discussed.

A brief history of the proposal was reviewed. A project was launched following a memo from the Membership and Professional Standards Committee (MPSC) sent to DTAC requesting that the Committee clarify a policy clause. Current OPTN Policy 15.3 states that “specific informed consent” must be obtained when “the donor has a known medical condition that may, in the transplant hospital’s medical judgment, be transmissible to the recipient, including HIV.” The MPSC explained that the language could have varying interpretations and could include common agents such as Epstein-Barr virus (EBV) and cytomegalovirus (CMV). The project was approved by the POC and Executive Committees in July 2017.

A workgroup was formed with representatives from the American Society of Transplantation (AST) and American Society for Transplant Surgeons (ASTS) to discuss the issue and formulate potential solutions. The work group met multiple times between July and November. The proposal that was developed for public comment contained the following changes:

- Rearrange policy order using chronology with general consent required of all candidates first
- Added a clause to general consent to reflect that testing results can result post-transplant treatment and management (for example, CMV and EBV)
- Dropped the requirement with the clause “known medical condition...in the transplant hospital’s medical judgment” for required informed consent after organ offer and before transplant
- Substituted a requirement that would require informed consent at that time for all instances when the donor tests positive for conditions listed in OPTN Policies for candidate screening and re-executing the match run

A summary of all public comments was shared along with regional votes for Committee review and discussion of potential post-public comment changes. Nine of eleven regions approved the proposal. All four professional organizations (AST, ASTS, NATCO, and ASHI) who commented support the proposal. Multiple committees (Pediatrics, Kidney, Thoracic, Liver and Intestines, Vascularized Composite Allograft (VCA), Operations and Safety, Patient Affairs, and MPSC) also reviewed and provides comments in general support. DTAC will present to Ethics next week. Specific recommendations were reviewed as well as responses to feedback questions.

One member voiced strong opposition to requiring consent for antibody (Ab) results. It was stated that CMV would be more dangerous and have more lifelong results.

Some of the regional variations were discussed. In Region 8 there were two opinions. The first was to please tell us exactly what to do so that there will not be interpretation issues at site survey. The other sentiment was that the proposal did not capture enough potential

transmissions, particularly emerging ones. Therefore no consensus was reached and a third of eligible programs abstained from voting.

It was noted that DTAC does maintain a list of special pathogens outside of policy which is reviewed every year. The idea was discussed about using this type of system however at this point is not the preferred solution.

Region 3 was the other region that did not approve the proposal. Their main concern was whether UNOS/OPTN should have any policy that names conditions for informed consent. Vocal members stated that it should be left up to the transplant programs to decide and deal with any legal ramifications. They also commented that to specify HBV and HCV without mention of other considerations was not to their preference.

The Committee discussed that per the Final Rule and the US PHS Increased Risk Recommendation 14 that the proposed policy must include HBV and HCV as conditions requiring consent. Members though had a lengthy discussion with concerns that including antibody was not appropriate because it does not indicate active viremia ((Infection). It was noted that the number one OPTN Strategic Plan Goal is to increase transplants and that including antibody results could lead to more organ turn downs and potentially fewer transplants.

One member shared how the community, including surgeons, are not fully knowledgeable about what the results mean. The member shared how they have worked over a year to get their program to use HCV Ab+/NAT- organs. The fear is by including these in informed consent policy that would mean they are high risk, which medically they are not considered to be likely to transmit infection. Another education issue is that surgeons and others assume that an organ positive for HCV or HBV is automatically considered increased risk. The misperceptions and lack of understanding could be compounded by keeping antibody results in the list and could have unintended consequences.

The group also discussed that often the individual making the call at organ offer will struggle with how to explain this nuance. The concern is that this will lead to additional calls in the middle of the night for unnecessary reasons with the risk of adding CIT or turn downs without fully understanding and taking into account that another organ offer might not be forthcoming.

It was noted that the MPSC must have a minimum because the current ambiguity in policy has caused issues. It does make sense to include HBV and HCV since these are obligations under being consistent with CDC recommendations per the Final Rule. The group though challenged what the definition of HBV and HCV infected should be. When the guidelines were written in 2013 to include antibody results and/or in their definition of infected, NAT testing was not as widespread and not required by OPTN policy. Since then policy and practices have changed. All deceased donors (except 2 or 3 out of 10,000 plus) had NAT testing last year. Members expressed that medically it makes sense to define infected consistent with the HCV Consensus Conference statement and current medical science.

The group also discussed issues around CMV. DTAC acknowledges that it can have serious consequences but that because of the greater than 50% probability of receiving a CMV positive donor that the conversation should take place up front during evaluation, listing, and management on the list but not at organ offer. The point of dying on the waitlist was also mentioned again as a balancing consideration.

DTAC discussed and strongly supported the need for extensive education on the topic. One member explained how they were at three different transplant programs and each handled consent differently. Some had expressed concerns that two consents would be required. It was explained that current policy already requires a general consent for all candidates before

transplant. This will not change. Additional consent is required for increased risk (included donors whose testing was done on hemodiluted samples) as well as those with a “known medical condition”. In current policy, as well as the proposed future policy, informed consent would be needed for specific conditions (e.g. increased risk) after organ offer as it relates to a donor, not any donor with the potential condition. This was mentioned as a point of continued confusion. It was discussed that many will get two consents-a general one and one at organ offer for use of an increased risk or HBV/HCV positive organ if the proposal passes. It is possible in emergent situations that both consents would be done at the same time and this could still be within the policy requirement since the general consent can be done at any time before transplant.

The DTAC reviewed comments on the specific feedback questions asked. The vast majority of respondents did not feel a signature was required but that medical documentation of an informed consent conversation would suffice. Exceptions to that sentiment were expressed by the Patient Affairs Committee and the ASTS. It was noted the official ASTS opinion differed from that of the work group representative.

On the second feedback question, most of the feedback was on the need not to include CMV although there was some individual comments contrary to that opinion. It again was noted that DTAC feels that the discussing CMV is important but belongs as part of the general informed consent. They also realize that there is no way to name everything individually as to what should be covered in a general consent. A few commenters, the Thoracic Committee and region 1, did mention that antibody results should not be included in the policy.

Other general themes that emerged from public comment were reviewed. These included:

- Support to simplify policy
- Clarify timing
- Importance of pre-transplant education
- Risk proportion needs balance
- Patient centric materials
- Frustration with PHS Increased Risk

To address these sentiments, DTAC has made language modifications to help with the timing issue. One members concerns with misperceptions of timing were discussed and the DTAC plans to work with staff to develop and provide a significant education effort to assist members with informed consent.

It was also noted that following public comment and subsequent discussions it was decided to decouple the proposal from policies addressing candidate screening and re-executing the match. HBV surface antigen (HBsAg) results were added to the list. It was noted that it would be OK to have different rationales for screening versus re-execute the match versus informed consent. Informed consent will be the smallest subset as indicating the highest risk of transmission. It was noted that candidate screening is appropriate to leave as is due to the need for individual program practices and to maintain efficiencies for those who would never consider certain positive results.

One member expressed concern that having inconsistent policies will potentially cause great confusion in the community. While medically a reduced informed consent policy makes sense, it might have unintended consequences of creating questions and confusion in practice. Another member spoke that we do not want to create increased complexity in policy and that the simpler the better.

It was also noted by the Chief Medical Officer, that informed consent lies with the transplant program. It is ultimately their responsibility and the policy does not reduce that responsibility or provide protections. It was mentioned that CMV has been part of clinical practice for a long time. It was noted that the HCV conference paper had stated that there was no risk for Ab+/NAT- but there have been some transmissions.

Members spoke again about the difficulty of having such difficult explanations at organ offer especially since the real concern is the risk associated with having donors who are at increased risk for infection or reinfection due to IVDU history/death due to IVDU. These are the donors who might be reinfected and in an eclipse period. Several members noted that if antibody is included in the policy that this will be perpetuated misperceptions and false science. Some stated that they should be having the same conversation whether the antibody is positive or negative. They again noted the desire not to increase complexity or the risk of organ turndown due to misunderstandings or difficulty in explaining.

The group then moved towards more consensus on having only NAT and HBV surface antigen. It was noted that HBV core antibody is low risk. Some reservoirs of virus can remain in the liver. There is treatment, prophylaxis, and vaccination available. For non-livers the risk is extremely low according to several members. It was noted that no matter what policy is settled upon that it will not be perfect and not everyone will agree.

Due to the HOPE Act, any positive HIV test (including antibody) will continue to require informed consent through that pathway and would not be modified by this policy.

DTAC members were surveyed by a straw poll for their preference. The majority did indicate a preference for only HCV NAT, HBV NAT, and HBsAg. The other choices were for HIV only or the public comment proposal conditions minus CMV. It was noted that the policy list is the minimum and that transplant programs must still do what is appropriate for their patients.

The Committee received an update on UNOS activities and reviewed the HCV data before returning to the discussion on the informed consent policy. The inclusion of HBsAg was discussed. It was noted that if it was a liver recipient the transplant hospital could consent but that the other organ recipients would not need to consent and so not including this will be the same concept as HCV. One member did comment again on the inconsistencies among the policies and the potential confusion or complexity this could cause. Another member indicated that it is acceptable to have different standards and reasoning for different concepts. A poll was launched through Poll Everywhere on the options. The straw poll results were shared and 81% favored the current approach.

Although the Committee had reached a majority consensus on the concept for post public comment changes, there was a concern regarding a cross reference to informed consent policy that would need to be amended. This cross reference was explained as it applies to a candidate who has accepted an organ then positive results were received that by policy requirement require a re-execution of the match run. The person who has accepted the organ, however, does have the right to continue with the acceptance and transplant but must provide informed consent to do so. As proposed, the two policies would refer to the same conditions and this might cause confusion.

It was decided to further work on the proposed language and plan for a vote at the regularly scheduled April 10, 2018 teleconference.

3. UNOS/OPTN Update

Summary of discussion:

The OPTN/UNOS Chief Executive Officer provided an update on geography, improving the efficiency of the allocation system, and potential committee restructuring.

An Ad Hoc Geography Committee has been formed with representatives from multiple Committees. The purpose is to develop principles that are consistent to become the basis of distance considerations for all organ allocations systems. Currently, there are some differences among organ allocation policies. One of their first tasks was to document current unwritten principles that are do have impacts (e.g. allowable cold ischemic time (CIT) which differs between hearts and kidneys for example). The Committee will be providing a report at the June OPTN/UNOS Board of Directors (BOD) meeting in June 2018.

Another effort out for public comment as a concept paper is looking at how the allocation system can become more efficient so that long match lists do not time out before organ placement. It was noted that the system does not require that every program get every organ offer every time. Conversely the system is not so narrow that a program is informed of which organ they will get for a specific candidate. The goal is to get somewhere closer to the middle. Modeling has been performed that can replicate the behavior and acceptance patterns down the exact donor and recipient for 95% of matches and transplants performed. The idea is to use this modeling to make the system more efficient. For example, if a program has never taken a DCD donor then perhaps they are not included on these matches. Although the system would have to find a trigger to re-include programs to account for potential or new acceptance patterns.

The other update item was on the potential restructuring concept that was also out for public comment. Due to public comment, an immediate change is not forthcoming but the structure has never been evaluated. For the DTAC, one question involves the need for real-time case review. Is this providing data and results needed to improve the transplant system or would retrospective review suffice? There is no desire to interfere with public health implications of real time review but to make sure that the current system is producing the results needed for the community.

4. Hepatitis C (HCV) and Organ Donation

Summary of discussion:

Staff presented data on increases in the recovery of HCV-positive donors across the country. In 2013, there was one donation service area (DSA) with a rate 15-20 HCV positive donors per 100 deceased donors recovered. During 2017, there were two DSAs with a rate of 20-25 and three DSAs with a rate of 15-20 HCV positive donors per 100 deceased donors recovered.

DTAC has been examining transmissions of HCV among antibody positive yet NAT negative (Ab+/NAT-) donors. A retrospective analysis was conducted to look at patterns of HCV Ab+/NAT- donor use and potential HCV seroconversions from recipient TIEDI® data. The OPTN started collecting NAT data in August 2015. The risk of HCV transmission from seropositive (Ab+) but non-viremic (NAT-) donors to HCV-negative recipients is thought to be low risk (HCV Consensus Conference 2017) because active viremia is not present. There is some risk due to the possibility of false negative or yet undetectable NAT results due to very recent reinfection. A recent publication by Bari et al. (2017) in *Hepatology* observed post-tx viremia in 4 out of 25 recipients after 11 months (median follow-up). All of these donors had died of drug overdose.

The data reviewed included 156 HCV Ab+/NAT- donors that had at least one organ transplanted from August 2015 through May 2017. There were 117 recipients from 90 donors with six-month HCV status follow up reported as required when receiving an organ from an increased risk donor. Among this cohort, there were 20 recipients with possible donor transmission (7 NAT conversions, 6 Seroconversions with unknown NAT, and 7 NAT seroconversions). Of the 7 NAT seroconversions, three were known to DTAC but four are not

identified as possibly reported. There was not more than one potential infected recipient per donor. The Committee asks that PDDTE staff conduct outreach requests to these transplant programs to request retrospective reporting. It was noted that DTAC only recently clarified that HCV transmissions from HCV Ab+/NAT- would be considered unexpected transmissions and need to be reported. Expected transmissions are not expected reporting.

Members discussed that data presented do not include donors not used at all due to HCV status. Tissue from donors that have any positive HCV results or any increased risk factor are automatically ruled out from donation. OPOs have some data on donors evaluated but without any organs recovered. One member has some of this OPO data and is currently analyzing the data. It was also noted that the OPTN does collect the increased risk status of deceased donors but does not collect individual reasons why a donor is categorized as increased risk. OPTN data does reflect whether a specimen is hemodiluted (one increased risk factor) as well as whether the donor had any history of IVDU.

Members discussed that if these data from potential reports can be captured then the Committee might need to revisit published rates for HCV conversion among donors with known IVDU. The guidance published earlier cites 1% yet there might be newer trends and/or changing epidemiology among populations that could impact the rate. One member asked about the value of still performing antibody testing and this was a comment among at least one public commenter. This is subject that might be revisited at a later date.

CDC also commented on their analysis of these donors. These donors were increased risk. One potential conclusion about HCV Ab+ results is that they might be correlated with certain environmental or behavioral patterns (e.g. more likely to have needle sharing in history). The CDC also had a more sensitive, research use NAT test available that did pick up some positives that OPO results did not. It was noted that in some cases the viral load was too low to detect at admission but upon retrospective testing of later specimens (closer to recovery) by CDC using their NAT test that the HCV was detectable. The DTAC oral presentation at ATC will review some of these findings.

Next steps:

- Request retrospective reporting of possible cases
- Amend analysis if additional reports received
- Complete oral presentation for ATC and submit for HRSA approval

5. New Project and Case Review Ideas

Summary of discussion:

Tuberculosis study:

A CDC representative led a discussion about a recent tuberculosis (TB) case investigation and a request to DTAC to look at historical data and possibly develop recommendations for donors who might be at high risk for TB infection.

The CDC would reviewed the case details and previously published recommendations. In 2012, recommendations published in the *American Journal of Transplantation* (AJT) by Morris et al. called for all deceased lung donors to have an acid-fast bacillus (AFB) smear and culture. These recommendations also called for testing to be done on living kidney donors if they were born or lived for more than three months in a country with a high rate of TB defined as ≥ 25 per 10,000 persons as well as those with a history of IVDU or working in a high-risk institutional setting (e.g. jail). CDC primary care recommendations call for testing immigrants from TB endemic areas (not defined). The California Department of Health recommends screening for

foreign-born persons except for those from Canada, Australia, New Zealand, or western/northern Europe.

The CDC would like DTAC to review the magnitude of proven and probable TB cases during the past five years. The review would include data abstraction to ascertain how these cases might fit within a high-risk definition. Depending on results, recommendations for testing high-risk donors might be considered. The method of publishing would be up for discussion as to not create unnecessary burden but to provide some methodology and definition regarding donors who might be at high-risk for TB donors.

A current DTAC project reviewing reported cases with granulomas has identified TB cases. It was decided to include all data although it was noted that testing capabilities differed ten years ago than what is available today. Members discussed questions and concerns related to TB identification such as will the goal be to identify active versus latent infection and to minimize testing that would lead to results that could raise more questions versus provide useful direction.

It was noted that polymerase chain reaction (PCR) testing could be helpful in identifying active TB but that latent testing has the possibility of leading to false positives and a negative impact on organ utilization. It was noted that lung donors in certain areas frequently have *Mycobacterium avium* complex (MAC) on AFB smears that is not clinically impactful on recipients. The concern for results leading to recipients taking significant drug regimens that might not be warranted needs to be considered as well.

Autopsy study:

Due to potential concerns about the impact of late autopsy finding reports, a study of 42 donors in 2017 that had autopsies has been started. While not yet complete, preliminary findings show that while most autopsies do not have major findings there are some identified cases where significant findings (e.g. lung cancer) have been found with delayed reporting (2-4 months in several cases). The goal of the study is to finish compiling data and use the findings to educate pathologists and others about the need to communicate significant findings as soon as possible to help mitigate risk and inform timely follow up for recipients.

Next steps:

- Form work group with CDC representation to review approximately 90 TB cases identified through the granuloma study
- Share findings with the full Committee to help determine what recommendations might be considered
- Form a work group to review cases with autopsy findings
- Expand autopsy study years will expand to include more immediate years where autopsy identification can be done with relative efficiency
- Share findings with full Committee to determine communication needs

6. Classification Rules and Efficiencies in Case Review

Summary of discussion:

DTAC members were given an overview of the adjudication status of all 2017 cases. Out of 272 cases, 141 have been completed. In order to make the best use of volunteer time and maximize efficiency, the DTAC will have a consent versus discussion case review agenda. Consent cases will be those that do not need full discussion by the Committee. Cases will qualify for consent if both reviewers agree on the adjudication and the adjudication would be intervention without disease transmission (IWDT), unlikely, or excluded. Cases will remain on the discussion agenda for the following circumstances:

- CDC led investigation
- Primary and secondary reviewers have differing opinions
- Reviewers would like a full Committee recommendation
- Proven, probable, and possible adjudications
- IWDT as needed for determination of treatment reason or efficacy
- Educational value to discuss case

DTAC members asked that a form be provided to summarize cases that are recommended for consent so that the full Committee can review these ahead of the meeting without looking at the full case. Notes from email discussions as well as future notes will be helpful when doing condition reviews to help understand historical thoughts and case nuances. It was also suggested that a REDCap be developed to capture case recommendations and notes. The EMPiR database under development by UNOS will provide this functionality.

The additional severity index classification that has been added to the adjudication for donor-derived likelihood was reviewed. The severity index provides additional information regarding the impact the case. The severity index includes: death, severe, non-severe, non-evaluable (rule out), and potential for late morbidity. The index was modified from a schema used by CDC in assessing transfusion associated infections.

Next steps:

- Provide members with definitions and guidelines for case determinations for donor-derived infection, severity index, and determination of consent versus discussion agenda
- Develop and provide form for case notes for review prior to meeting

7. Abstract and Case Study Review

The following works by DTAC have been accepted for upcoming transplant professional meetings:

International Society for Heart & Lung Transplantation (ISHLT) (April 2018)

Poster:

- Don't Pass the Peanuts: Donor-Derived Nut Allergy in Lung Transplant

American Transplant Congress (ATC): (June 2018)

Oral presentations:

- Donor Derived Transmissions in 2016-2017: Analysis of the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC)
- HCV Ab+/NAT- Organ Donors, and the Challenges of 'Eclipse Windows': Analysis of the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee (DTAC)
- Donor Derived Renal Cell Carcinoma (RCC) Transmission Events 2008-2016: A Report of the OPTN Disease Transmission Advisory Committee (DTAC)

Posters:

- Donor Transmitted Nut Allergy Following Solid Organ Transplantation: Analysis of the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC)
- Donor-Derived Hepatitis B Virus (HBV) Infection: Analysis of the OPTN/UNOS Ad Hoc Disease (DTAC)a

Data from the proposed ISHLT poster was reviewed. This poster provides an opportunity for DTAC to reach an audience not typically targeted. The peanut allergy study showed high donor-

derived penetrance in lung recipients with four out of four bilateral lung recipients having anaphylactic reactions including one death. Donors were all adolescents (11-20 years of age) and all had known nut allergies. Some of the deaths involved respiratory events. The level of communication and follow up implications of this finding is unknown as it is typically a script or medical history upload finding (versus discrete data field) in DonorNet®. The study highlights the importance of communicating nut allergy history and recommending post-transplant recipient nut avoidance and allergy testing. Members spoke about how this type of transmission is likely to increase as rates of nut allergy are increasing with younger generations.

Data from the RCC and HBV items were also reviewed. These are both under development. For the RCC study, the preliminary findings show that transmission of RCC is rare. For example, none of the non-renal organ recipients developed RCC from donors who had a suspected RCC at recovery. The HBV preliminary data show that 10 out of 13 proven/probable had serologic findings (positive core antibody; surface antigen). The relatively late diagnosis time in the DTAC cases supports US PHS increased risk guidelines for post-transplant HBV testing at 12 months. The findings also highlighted the need to educate the community regarding post-transplant prophylaxis/treatment and measuring titers to determine immunity levels from vaccination.

Next steps:

- Finish development of posters and oral presentations
- Submit for HRSA approval
- Share ATC presentation schedule with Committee members

8. Data Requests

Summary of discussion:

Staff provided an update on the policy evaluation for improving post-transplant communication of results passed by the OPTN/UNOS Board of Directors in June 2016. The goal of the policy was to reduce unnecessary PDDTE reporting. The data do show that reports received but not needed to have review were reduced to 375 in 2017, the lowest level since 2012. Data also showed reductions in variations at both the regional and donation service area (DSA) levels. This trend was not visible in transplant hospitals. This finding supports the policy goal of emphasis on sick recipient reports.

Findings from an additional analysis to evaluate whether toxoplasmosis testing has impacted kidney discards were shared and discussed. DTAC had received anecdotal reports that positive toxoplasmosis results have led to organ turn downs versus organ acceptance and prophylaxis. The raw numbers do show that donors positive for toxoplasmosis have higher incidence of kidney discard. To determine if the positive test result versus other factors were significant a logistic regression was conducted. Eleven variables were originally considered and nine fit within the model. The final analysis showed positive toxoplasmosis results did not significantly increase the odds of kidney discard (OR 1.01; p = .88). Other factors, such as HCV serostatus, had more impact.

These findings would support that the policy has not had unintended consequences. It was noted that the study does not provide data on potential increased cold ischemia time (CIT) or increased difficulty in placement. Anecdotally, the DTAC believes that during early implementation there might have been a learning curve in the effective way to handle toxoplasmosis mismatches (donor positive/recipient negative) through prophylaxis. The data do not support concerns that the transplant community is unnecessarily discarding donor kidneys with positive results.

Next steps:

- No additional policy evaluation is needed at this time
- No other data requests were made by the Committee

9. Confidential Case Review

Summary of discussion:

Members conducted confidential medical peer review of reported PDDTE cases.

10. New Business

Summary of discussion:

No new items were brought forward for discussion.

Upcoming Meetings

- April 10, 2018 (Monthly teleconference and case review)
- May 8, 2018 (Monthly teleconference and case review)

Attendance

- **DTAC Members**
 - Cameron Wolfe (Chair)
 - Marian Michaels (Vice Chair)
 - Remzi Bag
 - Gerald Berry
 - Jamie Bucio
 - Lara Danziger-Isakov
 - David Goldberg
 - Chak-Sum (Sam) Ho
 - Ricardo La Hoz
 - Kathleen Lilly
 - Maricar Malinis
 - Aneesh Mehta
 - Michael Nalesnik
 - Robert Sawyer
 - Nicole Theodoropoulos
 - Patrick Wood
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **CDC Representatives**
 - Pallavi Annambhotla (via GoToTraining)
 - Sridhar Basavaraju
 - Jefferson Jones (via GoToTraining)
- **OPTN/UNOS Staff**
 - Susan Tlusty
 - Cassandra Meekins
 - Gabe Vece
 - Darlene Arrowood
 - Ann-Marie Leary
 - Jason Livingston
 - David Klassen
 - Michelle Wilson
 - Tory Boffo
 - Kate Breitbeil
 - Leigh Kades
 - Leah Slife (via GoToTraining)
 - Kimberly Taylor
 - Emily Womble
 - Anne Paschke