

Briefing to the OPTN Board of Directors on

COVID-19 Emergency Policies and Data Collection

OPTN Executive Committee

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COVID-19 Emergency Policies and Data Collection

<i>Affected Policies:</i>	<i>1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency</i> <i>2.11: Required Deceased Donor Information</i> <i>3.7.D: Applications for Modification of Kidney Waiting Time during 2020 COVID-19 Emergency</i> <i>18.1: Data Submission Requirements</i> <i>18.2: Timely Collection of Data</i> <i>18.5.A: Reporting Requirements after Living Kidney Donation</i> <i>18.5.B: Reporting Requirements after Living Liver Donation</i>
<i>Sponsoring Committee:</i>	<i>Executive</i>
<i>Public Comment Period:</i>	<i>August 4, 2020 – October 1, 2020</i>
<i>Board of Directors Date:</i>	<i>December 7, 2020</i>

Executive Summary

The current COVID-19 crisis has created unprecedented challenges for the nation's health care system and has caused several disruptions to normal transplant operations. Many OPTN policies require patient visits as well as test results to register on the waiting list, maintain waiting list status, and complete required follow ups. One of the many effects of the national emergency is the reduced ability to conduct routine outpatient procedures, including clinical testing. There is also the concern of projected or potential healthcare disruptions due to the ongoing crisis. Concerns include potential exposure to COVID-19 at health care facilities, especially since transplant recipients are at increased risk for infection due to immunosuppression. In addition, strain on healthcare resources may impact the ability to complete current OPTN requirements, especially in regards to candidate, recipient, and living donor data submission.

The public comment proposal presented a series of actions already approved by the OPTN Executive Committee using the emergency policy authority given by the OPTN bylaws. These actions assist the transplant community and promote patient safety during the COVID-19 pandemic:

- Updating Candidate Data During 2020 COVID-19 Emergency
- Relax Data Submission Requirements for Follow-up Forms
- Modify Wait Time Initiation for Non-Dialysis Kidney Candidates
- Incorporate COVID-19 Infectious Disease Testing into DonorNet®

These actions were intended to alleviate issues stemming from the COVID-19 crisis. The first action, Updating Candidate Data During 2020 COVID-19 Emergency, is scheduled to expire on March 17, 2021. The remaining three actions are scheduled to expire on December 31, 2020. Due to the evolving nature of the COVID-19 pandemic, and the range in operational effects of the emergency actions, the OPTN Executive Committee recommends a varied approach. As COVID-19 will likely remain an important factor for some time, the Executive Committee recommends the COVID-19 infectious disease deceased donor testing fields remain in DonorNet® for the time being, and requiring these data to be reported to better facilitate communication between OPOs and transplant programs. The Committee believes that

due to the ongoing COVID-19 pandemic, repeal of these policies could lead to candidates being unfairly disadvantaged when they are unable to reach medical facilities for additional testing, and could lead to increased exposure of candidates, living donors, and transplant recipients to COVID-19. Due to this, the Executive Committee recommends continuing the actions for relaxing data submission requirements for follow-up forms, updating candidate data during the 2020 COVID-19 emergency, and for modifying wait time initiation for non-dialysis kidney candidates. The Committee recommends the Board of Directors establish these policies as permanent, until a time that it is appropriate for the Executive Committee or the Board to eliminate them. The Executive Committee will continue to monitor the effects of the pandemic and usage of these policies at every meeting.

Background

COVID-19 presents significant and immediate challenges for transplant hospitals in managing transplant candidates, recipients, and living donors. OPTN policy requires that transplant programs submit numerous lab results, clinical procedures, and other data for transplant candidates, recipients, and living donors. These data are used for registering candidates, allocating organs, and monitoring member performance, as well as policy development. Current OPTN policy has been developed under a model of normal transplant program circumstances, meaning programs can schedule outpatient appointments for patient testing, evaluation, and post-transplant monitoring. The COVID-19 national emergency has introduced an unprecedented situation that is limiting transplant programs' ability to maintain normal procedures and, in some cases, meet the OPTN policy requirements for obtaining updated clinical data. Additionally, rapid spread of COVID-19 is causing disruptions to operations across the health care system. Patient safety is paramount, and is causing all stakeholders in the transplant system to modify operations due to infection control concerns. In light of the impact the pandemic had on transplant hospitals and operations, the OPTN continues to recognize the need to accommodate member circumstances. The OPTN identified policy and data reporting actions that would alleviate some of the data reporting strain and inequity reported as resulting from the ongoing crisis.

The OPTN developed four emergency actions in response to community requests from individual members and committees, with collaboration from the following OPTN committees and their leadership: Ad Hoc Disease Transmission Advisory Committee (DTAC), Data Advisory Committee (DAC), Heart Transplantation Committee, Kidney Transplantation Committee, Liver and Intestinal Transplantation Committee, Living Donor Committee, Lung Transplantation Committee, Membership and Professional Standards Committee (MPSC), Operations and Safety Committee (OSC), Organ Procurement Organization Committee (OPO), Pancreas Transplantation Committee, Policy Oversight Committee (POC), Transplant Administrators Committee (TAC), and Transplant Coordinators Committee (TCC).

The OPTN Executive Committee approved these four emergency actions in two stages. The Executive Committee utilized the OPTN *Bylaws 11.7: Emergency Actions* due to the emergent public health issue caused by COVID-19. *Updates to Candidate Data during 2020 COVID-19 Emergency* was approved on March 17, 2020¹, and is set to expire on March 17, 2021. This policy allowed extension of current lab results required to maintain waiting list status for liver, liver/kidney, heart, and lung candidates. *Relax Data Submission Requirements for Follow-up Forms and Modify Wait Time Initiation for Non-Dialysis Kidney Candidates* were approved on April 3, 2020², and are set to expire on December 31, 2020. The first policy provided amnesty for recipient and living donor follow up form submission. The second provided a pathway to modify wait time initiation for non-dialysis kidney candidates after a qualifying creatinine clearance or glomerular filtration rate (GFR) was reached. The data fields for COVID-19 infectious disease testing for deceased donors were also approved on April 3, 2020, with an end date of December 31, 2020. This added optional data fields in DonorNet® to communicate testing for SARS-CoV-2 (COVID-19).

¹ <https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf>

² https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf

Purpose

When emergency proposals are passed pursuant to OPTN *Bylaws 11.7: Emergency Actions*, they must be distributed for public comment within six months after approval. This provides the transplant community an opportunity to comment on these emergency policies, as well as comment on the timeframes for which they should remain in effect.

The goals of these policies were to suspend or modify certain existing policy requirements due to circumstances that prevent patients from reaching the transplant program or other health care facility for needed testing required for data reporting. Additionally, this proposal added additional data elements to more clearly and efficiently inform receiving hospitals about COVID-19 testing performed on donor organs. While the COVID-19 crisis has been impacting locations differently or at different times, the transplant community and the OPTN share a desire to protect transplant recipient and living donor safety by minimizing potential COVID-19 exposures.

Sentiment from Public Comment

The proposal was released for Public Comment from August 4, 2020 to October 1, 2020. During that time, it received 362 responses, 29 of which also had a written comment. Following are a summary of the overall sentiment for the proposal, as well as a summary of feedback on certain themes of the proposal. The major themes that the OPTN received feedback on were:

- The appropriateness of the actions taken by the Executive Committee
- When the emergency actions should expire
- How COVID-19 testing should remain operationalized in DonorNet®
- Whether or not retrospective data entry should be required for follow-up forms given amnesty status during the period these proposals are active
- Additional suggestions for actions the OPTN can take to alleviate the effects of COVID-19 on the transplantation community

The proposal was strongly supported across all member types, with an average sentiment score of 4.2/5 on the Likert sentiment scale. *Figure 1* shows the sentiment by member type, with all member types showing fairly uniform support.

Figure 1: Sentiment by Member Type³

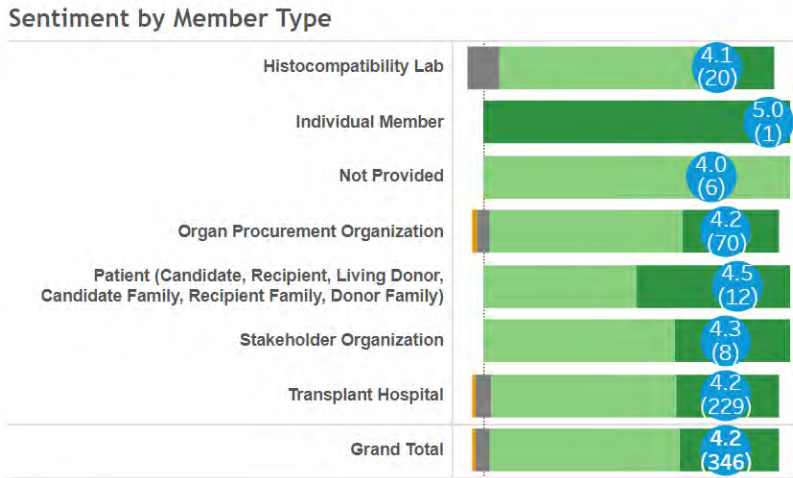
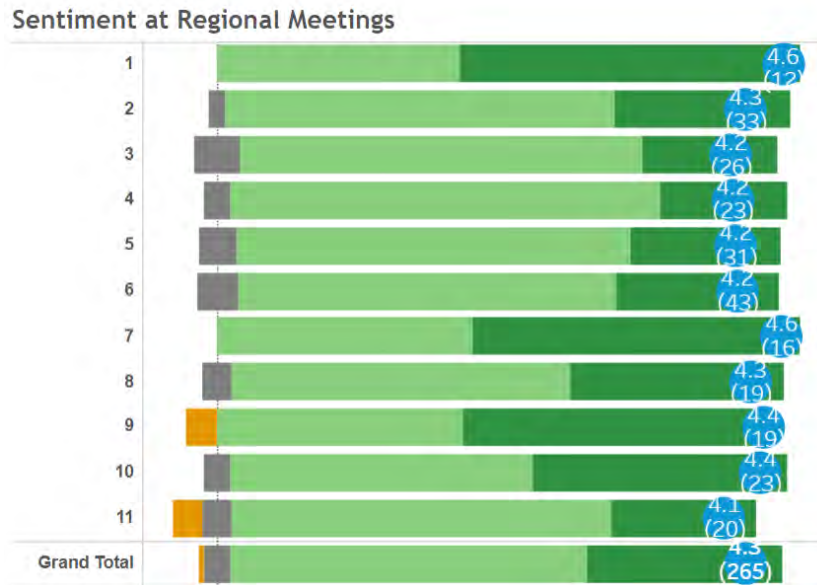


Figure 2 shows the sentiment by Region. The next graphic shows sentiment received at regional meetings. Again, overall sentiment was very supportive. Region 9 expressed that they do not believe requiring retrospective data entry on forms in amnesty status is the right path forward. Region 11 commented on a wish for more guidance and data on recovering organs from previously COVID-19 positive donors.

Figure 2: Sentiment by Region⁴

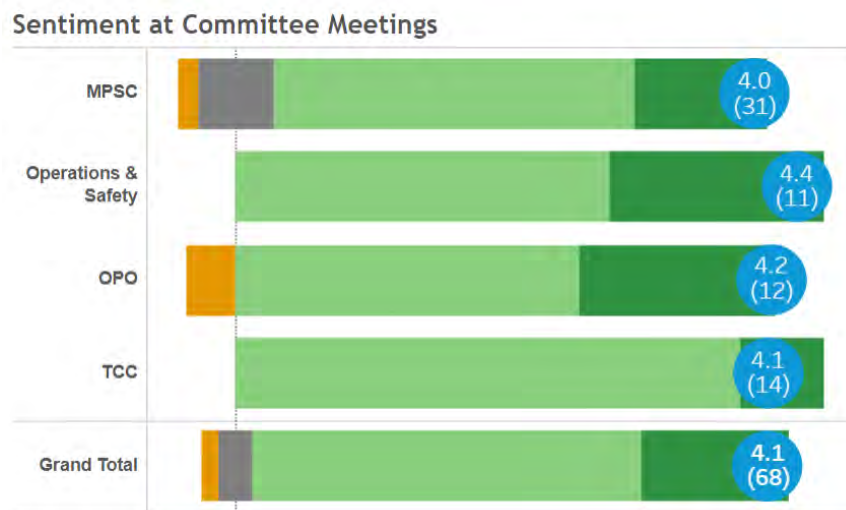


³ Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

⁴ Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 3 shows sentiment at OPTN committee meetings. This proposal was presented to a number of committees that chose to provide a comment without voting on the proposal. The OPTN Membership and Professional Standards Committee (MPSC) was supportive of the relief to date, but divided on whether or not to extend the emergency actions. They expressed a concern over the potential for data loss, and that this loss be taken into consideration when deciding an end date for the emergency actions. The OPTN Organ Procurement Organization (OPO) Committee commented that their only concern with the proposal was whether OPOs would be able to send organ offers prior to receiving results for COVID-19 testing. As currently written, the proposal would allow organ offers to be sent if results are pending, so long as question “Was COVID-19 testing completed?” is answered. That answer can be yes, no, or unknown. If the field is answered yes, the system triggers child fields and the OPO has the option to indicate that the test results are pending.

Figure 3: OPTN Committee Sentiment⁵



Appropriateness of Actions

The OPTN received 23 written comments on the appropriateness of the actions taken by the Executive Committee. Every comment was in support of the proposal and expressed a belief that the emergency actions taken were appropriate.

Expiration of Actions

The OPTN received 12 written comments on when the emergency actions should expire. There was universal support for keeping the COVID-19 infectious disease data fields in DonorNet®, but some division on the other actions. Nine comments proposed that the emergency actions not have a set expiration date, but that the Executive Committee should repeal the actions when needed based on the changing environment. The comments that proposed the actions be continued with no set expiration date include those by the American Society of Transplantation (AST), American Society of Transplant

⁵ Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committee meetings only includes attendees at that committee meeting. Not every committee who heard the proposal presented chose to vote on sentiment. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Surgeons (ASTS), North American Transplant Coordinators Organization (NATCO), Association of Organ Procurement Organizations (AOPO), and the OPTN Transplant Coordinators Committee (TCC).

Additional Suggestions

The OPTN received 10 comments suggesting other actions that could help alleviate the effects of COVID-19 pandemic for the transplant community. At this time, these recommendations are beyond the scope of this proposal. The suggestions below may be considered for future projects:

- Capture history of COVID-19 infection for living donors at time of registration and follow-up
- Capture COVID-19 donor history and date of diagnosis
- Publish guidance and/or data on utilizing previously COVID-19 positive donors
- Publish guidance and/or data on transplanting previously COVID-19 positive candidates
- Analyze COVID-19 testing occurring across the country and publish recommendations for the community
- Specify PPE required for deceased donor organ procurements
- Publish a review on the impacts of COVID-19 on the transplant recipients and donors in minority communities
- Publish guidance for living donors in regards to COVID-19
- Continue to sponsor webinars with key transplant community partners
- Clarify donor extra vessel storage policies in regards to COVID-19
- Prepare a system for mass waiting list referrals to ensure patient access in the event of another emergency situation, as some transplant programs had to discontinue operations temporarily
- Add fields to the transplant recipient follow-up (TRF) form to track recipient COVID-19 infections

Proposal for Board Consideration

The proposal consists of four actions that the Executive Committee recommends the Board of Directors allows to continue due to the ongoing COVID-19 pandemic.

Summary of Recommendations

The proposal submitted for Board consideration has one policy change from the proposals approved by the Executive Committee using the Emergency Action pathway. The Committee recommends these actions move from emergency actions to Board-approved policies, as outlined in *Table 1*.

Table 1: Executive Committee Recommendations

Action	Expiration Date
Action 1: Updating Candidate Data During 2020 COVID-19 Emergency	Establish as permanent, end on Executive Committee or Board repeal based on regular review of changing conditions
Action 2: Relax Data Submission Requirements for Follow-up Forms	Establish as permanent, end on Executive Committee or Board repeal based on regular review of changing conditions

Action	Expiration Date
Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates	Establish as permanent, end on Executive Committee or Board repeal based on regular review of changing conditions
Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®	Make permanent and required

Action 1: Updates to Candidate Data during 2020 COVID-19 Emergency

Overview

This policy allows transplant programs to use the most recently submitted clinical data for a candidate to maintain their current allocation priority. The policy addresses circumstances that may prevent a transplant program from obtaining updated clinical information on a candidate. For example, OPTN policy requires a liver candidate to have updated lab values in order to maintain his or her status, MELD, or PELD score.

In the event that a transplant program is unable to obtain updated lab results for a candidate, this policy allows the transplant program to carry forward the candidate’s most recently reported lab results as the candidate’s current lab values. Transplant programs use the same candidate data they previously entered for the data submission update, using the day of the updated submission as the “new” test result date. This prevents the system from lowering a candidate’s allocation priority due to inability to obtain updated testing. Thus, candidates who have been appropriately prioritized within a status or score previously will maintain that prioritization until new clinical data can be obtained.

This policy is intended to address COVID-19 related circumstances, not other operational issues. Despite this policy being in effect, transplant programs are expected to make reasonable efforts to collect and report clinical data as required by OPTN policy. When using this emergency policy, transplant programs must document its use in the candidates’ medical records.

Table 2 denotes the OPTN policies requiring regular candidate data updates that are affected by this policy.

Table 2: Policies requiring frequent candidate data updates

Organ	Policies describing extensions, downgrades, or certification requirements
Lung	10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old; 10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; 10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher; 10.2.B.i LRB Review Process; 10.2.B.v LAS Approved by the LRB
Liver, Liver/ Kidney	9.2 Status and Laboratory Values Update Schedule; 9.4.A MELD or PELD Score Exception Requests; 9.4.B NLRB and Committee Review of MELD or PELD Exceptions; 9.5 Specific Standardized MELD or PELD Score Exceptions; 9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older
Heart	6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO); 6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device; 6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia; 6.1.B Adult Heart Status 2 Requirements (subsections) ; 6.1.B.i Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD); 6.1.B.ii Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or Ventricular Assist Device (VAD) for Single Ventricle Patients; 6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction; 6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device; 6.1.B.v Intra-Aortic Balloon Pump (IABP); 6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF); 6.1.C Adult Heart Status 3 Requirements (subsections); 6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days; 6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring; 6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis; 6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis; 6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure; 6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection; 6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding; 6.1.C.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI); 6.1.C.ix VA ECMO after 7 Days; 6.1.C.x Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD) after 14 Days; 6.1.C.xi Percutaneous Endovascular Mechanical Circulatory Support Device after 14 Days; 6.1.C.xii Intra-Aortic Balloon Pump (IABP) after 14 Days; 6.1.D Adult Heart Status 4 Requirements (subsections); 6.1.E Adult Heart Status 5 Requirements; 6.1.F Adult Heart Status 6 Requirements; 6.2.A Pediatric Heart Status 1A Requirements; 6.3 Status Updates; 6.4 Adult and Pediatric Status Exceptions; 6.4.A.i. RRB Appeals; 6.4.A.ii Committee Appeals

Public Comment Sentiment

There was strong support for this policy in public comment. Out of all of the comments, only the OPTN Heart Committee recommended ending this policy on a fixed date. The Heart Committee expressed concerns about the submission of follow-up data and SRTR modeling, and recommended that candidate data be required to be updated starting in December 2020. Concern was expressed that some programs may unfairly take advantage of this policy.⁶ Of note, as of the close of public comment, only two heart candidates had potentially used this emergency policy.⁷

Usage

The peak utilization was highest for pediatric liver with 14% of candidates using previous lab values to maintain waitlist status. At this point in time of the COVID-19 pandemic, usage of Policy 1.4.F remains low. It is unknown if future trends in the pandemic may resurrect a greater need to use this policy. In addition, there is still a small subset of patients using this policy who would otherwise be disadvantaged. *Table 3* includes data on peak utilization of this emergency action as well as utilization during the most recent week included in the monthly monitoring report. This data is presented as a percentage of candidates utilizing the policy out of the total candidates with required data updates as per OPTN policies in a given week.

Table 3: Updates to Candidate Data Emergency Policy Usage⁸

	Adult Liver	Pediatric Liver	Adult Lung	Adult Heart
Peak utilization	6%	14%	12%	0%
Utilization week of September 30 th	1%	0%	3%	0%

Recommendation:

The Executive Committee recommends that the Board of Directors establish this policy as permanent, until a time that it is appropriate for the Executive Committee to eliminate it. In spite of its low usage, it has the potential to prevent candidate exposure to COVID-19. The Committee would like to continue to allow transplant program discretion as to whether or not to bring a candidate in if it is only for OPTN-required labs. As it could allow medically urgent patients to keep their appropriate allocation priority if they are unable to have repeat testing done in the scheduled prescribed by OPTN policy due to the effects of the pandemic, the OPTN Executive Committee feels that this policy should be continued for all organ types at this time. It may impact very few patients, but has the potential to greatly impact those it does. The Committee will continue to review the usage of the policy, as well as data on the effects of COVID-19 on transplantation, and can repeal when no longer necessary.

⁶ https://optn.transplant.hrsa.gov/media/4073/20200908_heart_meeting-summary.pdf

⁷ Cartwright, Laura, Amber Wilk, Sarah Taranto, Rick Franklin, John Beck, Brian Plucinski, Sarah Booker, and Alesha Henderson. "Summary of COVID-19 Emergency Policy and IT Changes." *OPTN Executive Committee Descriptive Data Request*, October 5, 2020, 1–53.

⁸ *Ibid.*

Action 2: Relax Data Submission Requirements for Follow-up Forms

Overview

Current OPTN policies require that transplant programs submit post-transplant data for transplant recipients and living donors in the *living donor follow-up* (LDF), *organ-specific transplant recipient follow-up* (TRF), and *recipient malignancy* (PTM) forms. These policy changes relaxed requirements for follow-up form submission so that recipients and living donors do not need to go in to health care facilities to get labs taken for the purpose of submitting post-transplant data to the OPTN. The intent of these changes is to prevent COVID-19 exposure risk to transplant recipients and living donors, and also to alleviate data entry demands of transplant programs in the midst of COVID-19 crisis.

These policy changes suspended the requirements for data collection and submission for the *living donor follow-up* (LDF), *organ specific transplant recipient follow-up* (TRF), and *recipient malignancy* (PTM) forms. The suspension of these requirements is backdated to March 13, 2020, the date the President of the United States declared a national emergency due to COVID-19.⁹ These OPTN policy changes did not suspend the requirement to report recipient death or graft failure, but did extend the timeframe for reporting that information from 14 days to 30 days from knowledge of the event. This policy change did not modify the reporting of living donor events such as organ failure or death, as outlined in OPTN Policy 18.6: *Reporting of Living Donor Events*. Follow-up forms will populate in a transplant program's queue as normal, but will automatically be marked in amnesty status if not submitted by the expected date. TRFs, LDFs, and PTMs in amnesty status are not considered incomplete for the purpose of OPTN data submission requirements, but members are encouraged to access these forms and submit data retrospectively. "Amnesty" status in this context is limited to only the TRF, LDF, and PTM forms.

Public Comment Sentiment

The OPTN received 16 comments on whether or not retrospective data entry should be required on forms granted amnesty status during the COVID-19 pandemic. Five commenters expressed concern that data would be lost and therefore not be available for SRTR modeling or other purposes. However, 12 commenters expressed concern about the burden of retrospectively entering data on all of the forms in amnesty status.

The OPTN Membership and Professional Standards Committee (MPSC) recommended that the Board of Directors or Executive Committee use evidence-based criteria to determine when these emergency actions should end. They expressed concern about the amount of data that may be lost while data submission policies are relaxed, and wanted to make sure that the OPTN clearly communicates that the long-term requirements will still be maintained.

The OPTN Data Advisory Committee (DAC) also expressed concern about data loss during the pandemic and how it would affect future modeling and evaluation. They proposed that the second action, to relax data submission requirements for follow-up forms, should expire in 2020 so that no further data loss would occur. In addition, they indicated that should retrospective data entry be required, they recommended a 90-day period for programs to submit data after the policy is repealed.

⁹ <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

Usage

As of September 30, 2020, 51,600 TRF forms, 2,879 LDF forms, and 494 PTM forms were in amnesty status.¹⁰ Overall, the proportion of TRF forms in amnesty status continues to hover around 25-30% per week while the proportion of LDF forms is about 30%. The number of PTM forms could increase if TRF forms currently in amnesty status are submitted, as they are automatically generated from the TRF form when a post-transplant malignancy is reported.

Recommendation

The Executive Committee recommends that the Board of Directors establish this policy as permanent, until a time that it is appropriate for the Executive Committee to eliminate it. While this is being used by a large number of programs, the Committee proposes that the MPSC and staff work together with programs who may be suffering variable effects from the pandemic to collect all data feasible. The Committee proposes to maintain transplant program discretion on whether or not it is safe to bring in transplant recipients or living donors, and recognizes that this could lead to a certain amount of data loss. The Committee feels that the OPTN should not penalize centers who are not able to collect patient data safely, and that instead the OPTN should support them in collecting the most data possible. The Committee will continue to review the usage of the policy, as well as data on the effects of COVID-19 on transplantation, and can repeal when no longer necessary. Prior to repeal, the Executive Committee will evaluate patterns of usage of the amnesty policy. The Committee will also review whether retrospective data collection should be required, what data on the forms are most needed retrospectively, and an appropriate timeframe for programs to retrospectively submit all possible data. The Committee is working with staff and SRTR to determine the most essential data points to collect during this time, while understanding that if a patient is not brought into the clinic a certain amount of this data may be unavailable.

Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

Overview

This policy is intended to prevent potential non-dialysis candidates who meet creatinine clearance or glomerular filtration rate (GFR) criteria required for waiting list registration from being disadvantaged due to inability of a transplant program to obtain additional required testing. The COVID-19 public health emergency has created a scenario where a patient with a qualifying GFR or creatinine clearance level, at a program that has decided to register the candidate, may be unable to obtain additional testing required for registration. As a result, a candidate would be eligible for registration but unable to begin accruing waiting time per OPTN *Policy 8.4: Waiting Time*. This emergency policy allows transplant programs to submit a waiting time modification application to retroactively apply waiting time once the candidate has completed all required testing for waiting list registration.

Public Comment Sentiment

No feedback specific to this action was given during the public comment period. The OPTN Kidney Committee leadership has since voiced support of continuing this emergency action until the pandemic has minimal national impact with no restrictions on travel.

¹⁰ Ibid.

Usage

80% of waiting time modification forms submitted to the OPTN Organ Center in September were COVID-19 related. This policy has been used for 156 candidates as of September 30, 2020.¹¹

Recommendation

The Executive Committee recommends that the Board of Directors establish this policy as permanent, until a time that it is appropriate for the Executive Committee to eliminate it. The OPTN received no public comments on waiting time modification for non-dialysis kidney candidates, but as there is still potential for delayed medical visits and testing, it seems appropriate to maintain the emergency policy at this time. This policy does not change the listing requirements for these candidates, but simply grants them retrospective waiting time once they are able to complete all of the required testing for listing if the testing or visits were delayed due to the COVID-19 pandemic. The Committee will continue to review the usage of the policy, as well as data on the effects of COVID-19 on transplantation, and can repeal when no longer necessary.

Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®

Overview

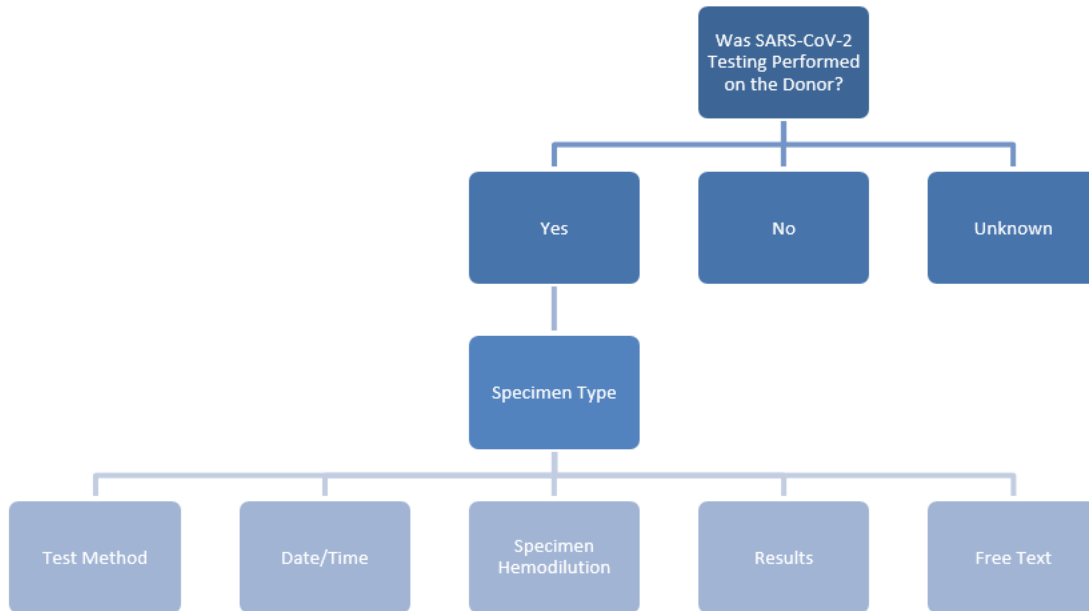
DonorNet® currently captures information regarding potential infectious diseases identified as a result of testing performed on deceased donors but did not include COVID-19. This action added COVID-19 testing data fields to DonorNet so accepting transplant programs can see whether donors were tested, and if so, the type of test and specimen used as well as the results. This action authorized addition of COVID-19 related data fields to DonorNet for OPOs to enter information on testing performed on deceased donors. The fields are included among the other infectious disease testing fields. Currently, the new data fields are optional.

These fields were initiated as optional to prevent any unintended consequences such as the interruption of OPO workflow and speed of organ offers. This data collection aligns with the OPTN Data Collection Principle of “ensuring patient safety when no alternative sources of data exist”¹² by capturing infectious disease testing information on donors and thus enabling the OPTN to monitor whether the disease impacts recipients. These data are important when assessing donors to protect patient safety and promote timely organ evaluation. These additional data elements were programmed in a format to allow for flexibility in recording test and specimen types, as more becomes known about COVID-19. *Figure 5* shows the parent question for SARS-CoV-2 testing as well as the subsequent available fields.

¹¹ Ibid.

¹² “Principles of Data Collection,” OPTN, accessed June 4, 2020, <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

Figure 5: COVID-19 Data Field Map



Public Comment Sentiment

The OPTN received 13 comments on whether or not COVID-19 infectious disease testing data fields should remain in DonorNet[®]. There was unanimous support for these fields to remain active beyond the other actions, with 12 responses in support of this being required data. There was one comment that this field should not be required, with concern that this could stifle the allocation process. Three other commenters mentioned that they support these data fields be required, but that they want the OPTN to be sure that it is operationalized in a way that does not delay organ offers. This can be programmed to allow match run generation, but so that electronic organ offers cannot be sent unless the field is completed. The data field can be answered yes, no, or unknown. If the field is answered yes, the system triggers child fields and the OPO has the option to indicate that the test results are pending.

There were four comments that also noted that making this field required would provide the OPTN with crucial data on the safety of transplants with COVID-19, and that the dissemination of this data would be extremely important.

The OPTN Organ Procurement Organization (OPO) Committee commented that their only concern with the proposal was whether OPOs would be able to send organ offers prior to receiving results for COVID-19 testing.

Usage

Approximately 80% of donors had COVID-19 test results indicated in the discrete infectious disease testing fields within DonorNet[®] between April 21 and September 30, 2020, although 100% of deceased donors have been tested since the implementation of the field on April 21, 2020.¹³

¹³ Ibid.

Recommendation

The Executive Committee recommends that the Board of Directors make this data collection permanent. In addition, the Committee recommends that the data fields within DonorNet® be required in order to allow for more efficient communication between OPOs and transplant programs as well as better data collection by the OPTN to assess the effects of COVID-19 on the transplant community.

Public comments received strongly supported OPTN data collection in regards to deceased donor COVID-19 testing. In addition, the OPTN received many comments that this data should be required. The only concerns expressed were about the how this would be operationalized if required, so that there would not be delays in allocation. As such, this proposal incorporated a policy change post-public comment to require data entry on whether or not COVID-19 testing was performed on a donor. This will not require COVID-19 testing to be performed, but will require data submission in the currently optional field.

OPOs will be able to execute a match run, regardless of whether the COVID-19 testing fields have been completed. The data entry will be required to send out electronic an organ offer. This simply means that there will need to be some entry to the question “Has COVID-19 testing been performed”. That entry can be yes, no, or unknown. If the field is answered yes, the system triggers child fields and the OPO has the option to indicate that the test results are pending.

Timing for Expiration of Actions 1, 2, and 3

As the effects of the COVID-19 pandemic are ongoing and variable across the country, the Executive Committee feels it is appropriate to continue these emergency actions at this time. The OPTN received nine comments on when to repeal these emergency actions, and all recommended that there should be no set date for the expiration of these actions. All of the commenters recommended that the OPTN Board of Directors or Executive Committee repeal these actions based on the changing environment, using evidence to determine when the COVID-19 pandemic is no longer impacting the transplant community. The Board of Directors is able to establish these policies as permanent, until a time that it is appropriate for the Executive Committee to eliminate them. The Executive Committee will continue to monitor the effects of the pandemic and usage of these policies at every meeting.

Retrospective Data Entry

The Executive Committee discussed the issue of retrospective data entry in regards to Action 2, *Relax Data Submission Requirements for Follow-Up Forms*, in depth at their October 20 and November 2, 2020 meetings. While they are concerned about patient safety and program resource limitations due to COVID-19, they would like to require retrospective submission of forms where expected patient data is available. They would like to leave clinical discretion to a program as to whether or not it is safe to bring a patient to a clinic for testing in a given area, at a given time, and do not wish to penalize a program if no clinical data is available. However, they also want to make sure that patient and graft outcomes are monitored and available for modeling to the extent possible while preserving patient safety. They are working together with staff and the SRTR to determine the most essential data points to collect when possible, but feel that they cannot currently determine a timeframe or the potential scope of retrospective submission requirements, as the effects of the pandemic are still ongoing.

NOTA and Final Rule Analysis

These actions are authorized pursuant to the OPTN Final Rule, which requires the OPTN to develop “Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases”.¹⁴ The CDC has published guidelines on non-COVID related care,^{15,16} and the OPTN recognizes that there are different levels of risk in different areas of the country. As such, the policies allow provider discretion on risk versus benefit when caring for candidates, living donors, and recipients regarding obtaining some OPTN policy-required testing requirements and follow up. Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®, is also consistent with this provision of the OPTN Final Rule, because it allows the OPTN to ensure it can develop policies for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious disease, and also to determine whether additional lab tests or clinical examinations of potential donors should or must continue to be performed “to determine any contraindications for donor acceptance.”¹⁷

The data collection is also consistent with the OPTN’s authority under the OPTN Final Rule, which requires the OPTN to “maintain records of all transplant candidates, all organ donors and all transplant recipients”¹⁸ and shall “...receive...such records and information electronically...”¹⁹ This proposal will allow the OPTN to better determine whether OPOs have performed such lab tests on potential organ donors, and will allow the OPTN to collect more complete data on donors and maintain such data in the OPTN dataset.

Additionally, Action 1: Updates to Candidate Data during 2020 COVID-19 Emergency and Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates, do not change the organ allocation policy, but may impact candidates’ priority on the match run. The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which requires that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.” The Action 1 and Action 3 policy changes:

- **Are based on sound medical judgment**²⁰ because they are evidenced-based changes relying on the following:
 - Feedback from 64 transplant hospitals and 27 OPOs

¹⁴ 42 CFR §121.4(a)(2).

¹⁵ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html>

¹⁶ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html>

¹⁷ 42 C.F.R. §121.6(a).

¹⁸ 42 CFR §121.11(a)(1)(ii).

¹⁹ 42 CFR §121.11(a)(1)(iii).

²⁰ 42 CFR §121.8(a)(1).

- Medical judgment that transplant candidates and recipients are likely to be at increased risk for COVID-19 infection due to their immunocompromised state and therefore permitting transplant programs to enter their most recent lab values rather than requiring the candidates to come in to obtain new lab values is a decision made with sound medical judgment.^{21,22,23}
- **Seek to achieve the best use of donated organs²⁴ by** ensuring organs are allocated and transplanted according to medical urgency. These proposals:
 - Maintain medical urgency statuses for candidates even if they are unable to update labs due to infectious risk or strained hospital resources.
- **Are designed to...promote patient access to transplantation²⁵ by** giving similarly situated candidates equitable opportunities to receive an organ offer. These proposals:
 - Prevent the system from lowering a candidate's allocation priority due to inability to obtain updated testing. Thus, candidates who have been appropriately prioritized within a status or score previously will maintain that prioritization until new clinical data can be obtained
 - Allow non-dialysis kidney candidates to retroactively obtain waiting time after a qualifying glomerular filtration rate (GFR) or creatinine clearance (CrCl), even if they are unable to complete all labs required for waiting list registration due to COVID-19 exposure risk or strained hospital resources.
 - Have potential to reduce waiting list mortality by decreasing the number of candidates exposed to COVID-19.

The Action 1 and Action 3 policy changes are not expected to impact the following aspects of the Final Rule:

- **Are designed to avoid wasting organs²⁶** by decreasing the number of organs recovered but not transplanted
- **Are designed to avoid futile transplants²⁷:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement²⁸** by taking into account factors including the costs and logistics of procuring and transplanting organs
- **Are not based on the candidate's place of residence or place of listing, except to the extent required.²⁹**

²¹ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html>

²² Fung, Monica, and Jennifer M Babik. "COVID-19 in Immunocompromised Hosts: What We Know So Far." *Infectious Diseases Society of America*, June 27, 2020. <https://doi.org/10.1093/cid/ciaa863>.

²³ Pereira, Marcus, Sumit Mohan, David Cohen, Syed Husain, Geoffrey Dube, Lloyd Ratner, Selim Arcasoy, et al. "COVID-19 in Solid Organ Transplant Recipients: Initial Report from the US Epicenter." *American Journal of Transplantation*, May 10, 2020. <https://doi.org/10.1111/ajt.15941>.

²⁴ 42 CFR §121.8(a)(2).

²⁵ 42 CFR §121.8(a)(5).

²⁶ 42 CFR §121.8(a)(5).

²⁷ 42 CFR §121.8(a)(5).

²⁸ 42 CFR §121.8(a)(5).

²⁹ 42 CFR §121.8(a)(8).

The Action 1 and Action 3 policy changes also preserve the ability of a transplant program to decline and offer or not use the organ for a potential recipient,³⁰ and are specific to each organ type.³¹

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.¹ The Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies”^{32,33} during their initial or subsequent assessments of these policies. Therefore, the Committee does not recommend adoption of transition patient procedures.

Alignment with OPTN Strategic Plan³⁴

Promote living donor and transplant recipient safety:

These proposals were intended to promote living donor and transplant recipient safety by allowing transplant programs to delay clinical visits to collect information for the purposes of OPTN data submission based on their clinical discretion and the impact of COVID-19 in their area.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

Requiring the COVID-19 testing information in DonorNet® will require new data collection from OPOs. This will not affect match run execution, but will require an OPO to answer as to whether or not COVID-19 testing was performed prior to sending electronic organ offers. This also does not mean that COVID-19 testing is required, as the data field options include yes, no, and unknown. If the OPO answers yes, they are able to specify that a result is pending under the results section. OPOs will need to educate staff on the new requirement.

Operations affecting Transplant Hospitals

These emergency actions are intended as a temporary relief measure during the COVID-19 pandemic. Transplant programs are allowed discretion on their use.

Operations affecting the OPTN

These emergency policies require continuous monitoring by the OPTN for their use. In addition, the application to modify wait time initiation for non-dialysis kidney candidates requires the Organ Center to process a much larger number of waiting time modification forms than normal. 80% of the waiting time modifications submitted in September were due to this policy.

³⁰ 42 CFR §121.8(a)(3).

³¹ 42 CFR §121.8(a)(4).

³² https://optn.transplant.hrsa.gov/media/3755/20200317_executive-committee_meeting-summary.pdf

³³ <https://optn.transplant.hrsa.gov/media/3878/optn-executive-committee-meeting-4-03-20.pdf>

³⁴ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on Histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on Organ Procurement Organizations.

Projected Impact on Transplant Hospitals

This proposal is not anticipated to have any fiscal impact on Transplant Hospitals.

Projected Impact on the OPTN

The only portion of the proposal that has not yet been implemented is requiring COVID-19 testing data fields within DonorNet. This would add 160 hours of IT implementation time.

In total, this proposal has required 1,100 hours of development time and 1,035 hours of implementation time. This proposal has required extensive involvement in a short period of time from IT, Research, Member Quality, Policy and Community Relations, Legal/Executive, Communications, and the Organ Center. In addition, there has been an even larger number of hours put into solely operational COVID-19 initiatives.

These policies require ongoing efforts from all of the above departments. Their repeal will require additional staff time, and Member Quality and Research will still continue to monitor the effects of these policies after.

Post-implementation Monitoring

Member Compliance

Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”³⁵ For retrospective site survey reviews of candidate data that are used to maintain a candidate's prioritization or eligibility reported during the 2020 COVID-19 emergency:

- Site surveyors will continue to verify that candidate data entered in UNetSM is consistent with documentation in the candidate's medical record.
- If a surveyor is unable to locate documentation in the medical record that corroborates the collection date entered in UNet, the surveyor will look for documentation that the transplant

³⁵ 42 CFR §121.8(a)(7).

program exercised authority under Policy 1.4.F to re-report the candidate’s most recently reported data on that date as the “collection date.”

Action 2: Relax Data Submission Requirements for Follow-up Forms

Follow-up forms due between March 13, 2020 and December 31, 2020 will be excluded from routine compliance monitoring of *Policy 18.1 Data Submission Requirements*, *Policy 18.2 Timely Collection of Data*, and *Policy 18.5 Living Donor Data Submission Requirements*. The end date of this monitoring change will be adjusted as needed to align with future Executive Committee or Board of Directors actions to extend or repeal this emergency action.

Action 3: Modifications to Kidney Wait Time Initiation for Non-Dialysis Candidates

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program.”³⁶ The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNetSM may be reviewed by the OPTN, and members are required to provide documentation as requested.

Action 4: COVID-19 Infectious Disease Testing in DonorNet[®]

This action will not change the current routine monitoring of members. Any data entered in UNetSM may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”³⁷ These policies are being and will continue to be reviewed on a monthly basis by UNOS Research for utilization. The level of utilization of these policies is not necessarily an indicator of whether or not they are effective, as the impacts of COVID-19 are variable across the country and over time.

Updates to Candidate Data during 2020 COVID-19 Emergency

The OPTN will analyze the following monthly:

The number and percentage of registrations, by week, that appear to be utilizing this policy based on the following process flow:

- a. The change date for urgency scores is after the policy was effective, and
- b. The change date for the urgency scores is different than a prior entry and the same as the modification date, and
- c. The dates for all required labs (or groups of labs expected to be completed simultaneously) for the urgency scores have changed and are identical, and
- d. None of the values for the required labs have not changed.

Potential policy usage will be reported for adult liver (MELD), pediatric liver (PELD), adult and pediatric lung (LAS), and adult and pediatric heart (status).

³⁶ 42 CFR §121.8(a)(7).

³⁷ 42 CFR §121.8(a)(6).

Modifications to wait time initiation for non-dialysis kidney candidates

The OPTN will analyze the following monthly as appropriate:

1. The number and percentage of adult kidney registrations added to waiting list that indicate no dialysis but have a calculated/lab CrCl/GFR of ≤ 20 , by week, since January 1, 2020, to determine if there is a decrease in listings for this subpopulation during COVID. This analysis will rely on dialysis data reported to the OPTN.
2. The number and percentage of wait time modification form requests submitted citing COVID, by week, since April 3, 2020.

Relax data submission requirements

The OPTN will analyze the following as appropriate, by month:

1. The number and percentage of TRF and LDF forms in each status (validated vs. amnesty), by week form expected and further stratified by organ and region.
2. The number of total PTM forms generated by week and by status (validated vs. amnesty), and further stratified by organ and region.
3. The number of recipient graft failure and death follow-ups reported by week and further stratified by organ and region. Include median days from event to report to monitor for delays in reporting of events.

COVID-19 data fields in DonorNet®

The OPTN will analyze the following on a monthly basis as appropriate:

1. The number and percentage of OPOs utilizing optional COVID testing fields.
2. The number and percentage of deceased donors indicating COVID testing was performed.
3. The national distribution of results if donor was indicated with a 'yes' to COVID testing:
 - a. Specimen type
 - b. Hemodiluted specimen?
 - c. Test method
 - d. Test result (positive, negative, unknown, cannot disclose, not done, indeterminate)
 - e. A thematic summary of free text entered.

Conclusion

The OPTN Executive Committee implemented four emergency actions in March and April 2020 to address the effects of the COVID-19 pandemic on the transplant community. Those actions were well-received by the community, and there was universal support on extending the data fields for COVID-19 testing within UNetSM. The vast majority of public comments also supported making this a required field to facilitate communication between OPOs and transplant programs, as well as provide the transplant community with additional data. The Committee is proposing that this become required data, as well as that these data fields remain in UNet until the transplant community feels they are no longer applicable. The Executive Committee recommends that the Board of Directors establish the remainder of the policies as permanent, until a time that it is appropriate for the Executive Committee to eliminate them. This will allow the transplant community a more flexible response, as the pandemic has variable effects across the country and over time. The Committee will review the usage of these policies and the impact

of COVID-19 on the transplant community at every meeting, and will repeal these policies when appropriate.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1.4.F Updates to Candidate Data during 2020 COVID-19 Emergency

This ~~emergency~~ policy is in effect due to the public health emergency declared by the President of the United States on March 13, 2020. This ~~emergency~~ policy only applies to transplant programs that have candidates who require clinical data updates per OPTN policy in order to maintain prioritization or eligibility.

~~During the 2020 COVID-19 emergency:~~

1. Transplant programs should continue to make all reasonable efforts to collect and report clinical data as required by OPTN Policy.
2. Any transplant program that is required by OPTN Policy to report clinical data in order to maintain a candidate's prioritization or eligibility, and: a) is prevented from collecting such data due to the COVID-19 emergency, or: b) in their medical judgment chooses not to collect such data due to the COVID-19 emergency, may use the candidate's clinical data values that were most recently reported to the OPTN. When reporting previous clinical data pursuant to this ~~emergency~~ policy, the transplant program must report the date the program is entering the data as the collection date.
3. While using this policy, transplant programs must document in the candidate's medical record the circumstances that support use of this ~~emergency~~ policy.

2.11 Required Deceased Donor Information

The host OPO must report to the OPTN upon receipt all of the following information for each potential deceased donor:

1. Age
2. Diagnosis (or cause of brain death)
3. Donor behavioral and social history
4. Donor management information
5. Donor medical history
6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
7. Ethnicity
8. Height
9. Organ anatomy and recovery information
10. Sex
11. All vital signs, including blood pressure, heart rate, and temperature
12. Weight
13. SARS-CoV-2 (COVID-19) testing status. If COVID-19 testing was performed, the host OPO must report to the OPTN the date and time, type of specimen, testing method, and results.

40 The potential transplant program team must have the opportunity to speak directly with
41 responsible onsite OPO donor personnel to obtain current information about the deceased
42 donor's physiology.
43

44 **3.7.D Applications for Modifications of Kidney Waiting Time during 2020 COVID-19** 45 **Emergency**

46
47 This emergency policy only applies to candidates whose ability to demonstrate eligibility for
48 kidney waiting time has been compromised by the COVID-19 public health emergency declared
49 by the President of the United States on March 13, 2020.
50

51 This emergency policy allows transplant programs to submit a waiting time modification for
52 candidates who were not on regularly administered dialysis and, due to the emergency, were
53 unable to begin accruing waiting time according to *Policy 8.4.A Waiting Time for Candidates*
54 *Registered at Age 18 Years or Older* or *Policy 8.4.B Waiting Time for Candidates Registered prior*
55 *to Age 18*.
56

57 To apply for a waiting time modification, the candidate's transplant program must submit an
58 application to the OPTN with *all* of the following information:
59

- 60 1. The requested waiting time start date for the candidate. The requested start date must be
61 the date when the transplant program made the decision to register the candidate.
- 62 2. Documentation explaining why the circumstances of the COVID-19 public health emergency
63 prevented the candidate from beginning to accrue waiting time according to *Policy 8.4.A*
64 *Waiting Time for Candidates Registered at Age 18 Years or Older* or *Policy 8.4.B Waiting*
65 *Time for Candidates Registered prior to Age 18*. For candidates registered at age 18 years or
66 older, documentation must include a date prior to the requested start date that the
67 candidate's measured or calculated creatinine clearance or GFR was less than or equal to 20
68 mL/min.
- 69 3. The name and signature of the candidate's physician or surgeon.

70 Upon receipt of a complete application the OPTN will implement the waiting time modification
71 for candidates who were impacted by the COVID-19 emergency.
72

73 This subsection supersedes any conflicting requirements in other sections of OPTN Policy for
74 candidates that apply for a waiting time modification pursuant to this subsection.
75

#

Appendix A: Current Policy and Enactment Language

Action 1: Updates to Candidate Data during 2020 COVID-19 Emergency

RESOLVED, that pursuant to OPTN Bylaw 11.7, the creation of Policy 1.4.F, as set forth below, shall be in effect on March 17, 2020, and will expire on March 17, 2021.

1.4.F Updates to Candidate Data during 2020 COVID-19 Emergency

This emergency policy is in effect due to the public health emergency declared by the President of the United States on March 13, 2020. This emergency policy only applies to transplant programs that have candidates who require clinical data updates per OPTN policy in order to maintain prioritization or eligibility.

During the 2020 COVID-19 emergency:

1. Transplant programs should continue to make all reasonable efforts to collect and report clinical data as required by OPTN Policy.
2. Any transplant program that is required by OPTN Policy to report clinical data in order to maintain a candidate's prioritization or eligibility, and: a) is prevented from collecting such data due to the COVID-19 emergency, or: b) in their medical judgment chooses not to collect such data due to the COVID-19 emergency, may use the candidate's clinical data values that were most recently reported to the OPTN. When reporting previous clinical data pursuant to this emergency policy, the transplant program must report the date the program is entering the data as the collection date.
3. While using this policy, transplant programs must document in the candidate's medical record the circumstances that support use of this emergency policy.

Action 2: Relax Data Submission Requirements for Follow-up Forms

RESOLVED, that the following actions are authorized by OPTN Bylaw 11.7: Emergency Actions. The actions below will be reviewed by the OPTN Executive Committee at all of the Executive Committee's regularly scheduled meetings, or at least every three months, whichever is sooner, until the actions expire on September 30, 2020.

FURTHER RESOLVED, that changes to Policies 18.1: Data Submission Requirements, 18.2: Timely Collection of Data, and 18.5: Living Donor Data Submission Requirements, as set forth below, are hereby approved, effective March 13, 2020, and will expire on September 30, 2020.

Implemented April 13, 2020, extended to December 31, 2020 via Executive Committee action on July 30, 2020.

18.1 Data Submission Requirements

Members must report accurate data to the OPTN using standardized forms according to *Table 18-1* below. Members are responsible for providing documentation upon request to verify the accuracy of all data that is submitted to the OPTN through the use of standardized forms.




Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	<i>Donor histocompatibility (DHS)</i>	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	<i>Recipient histocompatibility (RHS)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the <i>recipient feedback</i> 	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	<i>Death notification records (DNR)</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	<i>Monthly Donation Data Report: Reported Deaths</i>	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	<i>Potential transplant recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	<i>VCA Candidate List</i>	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	<i>Donor organ disposition (feedback)</i>	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Host OPO	<i>Deceased donor registration (DDR)</i>	30 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living donor feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	<i>Living donor feedback</i> Members must amend the form or contact the OPTN Contractor to amend this form according to <i>Policy 18.6: Reporting of Living Donor Adverse Events</i>	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	<i>Living donor registration (LDR)</i>	60 days after the recovery hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	<i>Living donor follow-up (LDF)</i>	Either: <ul style="list-style-type: none"> • 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency. 	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs. Non-submission of the full LDF is acceptable during the COVID-19 emergency.
Transplant hospitals	<i>Organ specific transplant recipient follow-up (TRF)</i>	Either of the following: <ul style="list-style-type: none"> • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency. • 30 days from notification of the recipient's death or graft failure 	Each recipient followed by the hospital Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.
Transplant hospitals	<i>Organ specific transplant recipient registration (TRR)</i>	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital submits the <i>recipient feedback</i> form	Each liver recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	<i>Recipient feedback</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	<i>Candidate Removal Worksheet</i>	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient malignancy (PTM)</i>	Either: <ul style="list-style-type: none"> • 30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form or • As determined possible by the transplant hospital during the COVID-19 emergency. 	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital. Non-submission is acceptable during the COVID-19 emergency.
Transplant hospitals	<i>Transplant candidate registration (TCR)</i>	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	<i>Organ specific transplant recipient registration (TRR)</i>	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	<i>Living donor registration (LDR)</i>	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first. This does not apply to VCA transplants.
Recovery hospital	<i>Living donor follow-up (LDF)</i>	Either: <ul style="list-style-type: none"> • 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency. This does not apply to VCA transplants. Non-submission is acceptable during the COVID-19 emergency.

18.5 Living Donor Data Submission Requirements

The follow up period for living donors will be a minimum of two years.

The OPTN Contractor will calculate follow-up rates separately, and at least annually, for the submission of the six-month, one-year, and two-year LDF forms.

Living donor follow-up reporting requirements do not apply to any transplant recipient whose replaced or explanted organ is donated to another candidate.

18.5.A Reporting Requirements after Living Kidney Donation

During the COVID-19 emergency, these policy requirements are suspended.

The recovery hospital must report accurate, complete, and timely follow up data for donor status and clinical information using the LDF form for at least:

- 60% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 70% of their living kidney donors who donate between January 1, 2014 and December 31,

2014

- 80% of their living kidney donors who donate after December 31, 2014

The recovery hospital must report accurate, complete, and timely follow up kidney laboratory data using the LDF form for at least:

- 50% of their living kidney donors who donate between February 1, 2013 and December 31, 2013
- 60% of their living kidney donors who donate between January 1, 2014 and December 31, 2014
- 70% of their living kidney donors who donate after December 31, 2014

Required kidney donor status and clinical information includes *all* of the following:

1. Patient status
2. Working for income, and if not working, reason for not working
3. Loss of medical (health, life) insurance due to donation
4. Has the donor been readmitted since last LDR or LDF form was submitted?
5. Kidney complications
6. Regularly administered dialysis as an ESRD patient
7. Donor developed hypertension requiring medication
8. Diabetes
9. Cause of death, if applicable and known

Required kidney laboratory data includes *all* of the following:

1. Serum creatinine
2. Urine protein

18.5.B Reporting Requirements after Living Liver Donation

During the COVID-19 emergency, these policy requirements are suspended.

The recovery hospital must report accurate, complete, and timely follow-up data using the LDF form for living liver donors who donate after September 1, 2014, as follows:

1. Donor status and clinical information for 80% of their living liver donors.
2. Liver laboratory data for at least:
 - 75% of their living liver donors on the 6 month LDF
 - 70% of their living liver donors on the one year LDF

Required liver donor status and clinical information includes *all* of the following:

1. Patient status
2. Cause of death, if applicable and known
3. Working for income, and if not working, reason for not working
4. Loss of medical (health, life) insurance due to donation
5. Hospital readmission since last LDR or LDF was submitted

6. Liver complications, including the specific complications
 - Abscess
 - Bile leak
 - Hepatic resection
 - Incisional hernias due to donation surgery
 - Liver failure
 - Registered on the liver candidate waiting list

Required liver laboratory data includes *all* of the following:

1. Alanine aminotransferase
2. Alkaline phosphatase
3. Platelet count
4. Total bilirubin

Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

RESOLVED, that the following actions are authorized by OPTN Bylaw 11.7: Emergency Actions. The actions below will be reviewed by the OPTN Executive Committee at all of the Executive Committee's regularly scheduled meetings, or at least every three months, whichever is sooner, until the actions expire on September 30, 2020.

FURTHER RESOLVED, that the creation of Policy 3.7.D: Applications for Modifications of Kidney Waiting Time during the 2020 COVID-19 Emergency, as set forth below, is hereby approved, effective April 3, 2020 and will expire on September 30, 2020.

Implemented April 10, 2020, extended to December 31, 2020 via Executive Committee action on July 30, 2020.

3.7.D Applications for Modifications of Kidney Waiting Time during 2020 COVID-19 Emergency

This emergency policy only applies to candidates whose ability to demonstrate eligibility for kidney waiting time has been compromised by the COVID-19 public health emergency declared by the President of the United States on March 13, 2020.

This emergency policy allows transplant programs to submit a waiting time modification for candidates who were not on regularly administered dialysis and, due to the emergency, were unable to begin accruing waiting time according *Policy 8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older* or *Policy 8.4.B Waiting Time for Candidates Registered prior to Age 18*.

To apply for a waiting time modification, the candidate's transplant program must submit an application to the OPTN with *all* of the following information:

1. The requested waiting time start date for the candidate. The requested start date must be the date when the transplant program made the decision to register the candidate.

2. Documentation explaining why the circumstances of the COVID-19 public health emergency prevented the candidate from beginning to accrue waiting time according to *Policy 8.4.A Waiting Time for Candidates Registered at Age 18 Years or Older* or *Policy 8.4.B Waiting Time for Candidates Registered prior to Age 18*. For candidates registered at age 18 years or older, documentation must include a date prior to the requested start date that the candidate's measured or calculated creatinine clearance or GFR was less than or equal to 20 mL/min.
3. The name and signature of the candidate's physician or surgeon.

Upon receipt of a complete application the OPTN will implement the waiting time modification for candidates who were impacted by the COVID-19 emergency.

This subsection supersedes any conflicting requirements in other sections of OPTN Policy for candidates that apply for a waiting time modification pursuant to this subsection.

Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®

RESOLVED, that the following actions are authorized by OPTN Bylaw 11.7: Emergency Actions. The actions below will be reviewed by the OPTN Executive Committee at all of the Executive Committee's regularly scheduled meetings, or at least every three months, whichever is sooner, until the actions expire on September 30, 2020.

FURTHER RESOLVED, that the following data fields shall be added to UNetSM effective upon implementation and notice to OPTN members. Implemented April 20, 2020, extended to December 31, 2020 via Executive Committee action on July 30, 2020.

Parent question field: "Was COVID-19 (SARS-CoV-2) testing performed on the donor?"

- a. Yes/No/Unknown field to allow OPOs to clearly indicate testing status related to COVID-19 (SARS-CoV-2)
 - i. If yes:
 1. ADD specimen date field
 2. ADD time field
 3. ADD specimen type field
 4. ADD hemodiluted specimen field
 5. ADD test method field
 6. ADD results field
 7. ADD "comments" field - free text box for entry for information relevant to COVID-19 testing (e.g. "results pending")
 - ii. If no: no child data fields will display