

Notice of OPTN Policy and Data Collection Changes

COVID-19 Emergency Policy Package

Sponsoring Committee:

Policies Affected:

Executive

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

2.11: Required Deceased Donor Information

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

18.1: Data Submission Requirements

18.2: Timely Collection of Data

18.5.A: Reporting Requirements after Living Kidney Donation

18.5.B: Reporting Requirements after Living Liver Donation

August 4 - October 1, 2020

Public Comment:

Board of Directors Approved:

December 7, 2020

Effective Date:

Various

Purpose

The COVID-19 crisis has created challenges to conducting routine outpatient activities, including clinical testing, which are needed to obtain information required for transplant candidates, recipients, and living donors. The goal of these policies is to suspend or modify certain existing policy requirements due to unforeseen circumstances that prevent patients from reaching the transplant program or other health care facility for needed testing or evaluation. In addition, these policies were created with the intent for increasing patient safety. This is due to concerns about potential exposure to COVID-19 at health care facilities, especially since transplant recipients are at increased risk for infection due to immunosuppression.

Proposal History

This proposal was developed with input from multiple OPTN Committees. There were four actions collectively passed on March 17 and April 3, 2020, using OPTN *Bylaw 11.7: Emergency Actions* due to the COVID-19 public health crisis.¹ The Executive Committee has continued to review these actions at all of their 2020 meetings: on April 20, June 7, July 30, September 18, November 2, and December 6. At the July 30, 2020 meeting, the Executive Committee voted to extend the expiration date of emergency actions 2, 3,

¹Previously implemented language and data collection related to the emergency policy package can be found at <https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf> and https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf

and 4. The expiration dates were extended from September 30, 2020 to December 31, 2020 due to the continued impacts from the COVID-19 pandemic and to allow for full OPTN Board of Directors review. The expiration date for emergency action 1 was set as March 17, 2021, when passed, so didn't need extension at that time. The Executive Committee voted to send this proposal out retrospectively for public comment, August 4 – October 1, 2020, as required by OPTN *Bylaw 11.7*. Subsequently, after reviewing public comment feedback, the Executive Committee referred the proposal, with recommendations on all four actions, to the OPTN Board of Directors. At their December 7, 2020 meeting, the OPTN Board of Directors approved these actions as permanent, until such a time as the COVID-19 emergency no longer requires them. The OPTN Executive Committee has committed to review of these policies and their usage at every meeting, and will repeal these policies when they are no longer required by the conditions created by the COVID-19 pandemic. The exception is the donor COVID-19 testing data collection (action 4). The OPTN Board of Directors made it permanent and did not direct a future repeal.

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

Purpose

COVID-19 related circumstances may prevent a transplant program from obtaining clinical data updates required by OPTN policy for a candidate maintain their current allocation priority, such as liver candidate that must have updated lab values for their MELD or PELD score. 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 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.

Summary of Changes

This policy was approved as an emergency policy action by the OPTN Executive Committee and implemented on March 17, 2020, with the effective date of March 13, 2020. Originally set to expire on March 17, 2021, this policy is extended until no longer required by the conditions created by the COVID-19 pandemic. The OPTN Executive Committee has committed to review of these policies and their use at every meeting, and will repeal these policies when they are no longer required.

This policy is intended to address COVID-19 related circumstances, not other operational issues. Transplant programs are expected to make reasonable efforts to collect and report clinical data, however if use of this policy is needed, the transplant programs must document its use in the candidates' medical records.

Action 2: Relax data submission requirements

Purpose

Current OPTN policy requires that transplant programs submit post-transplant data for transplant recipients and living donors. This emergency policy change relaxes requirements for follow-up form submission. The intent of the policy is to prevent unnecessary exposure risk to transplant recipients and living donors, and also to alleviate data burden for hospitals in the midst of COVID-19 crisis.

Summary of Changes

This policy was approved as an emergency policy action by the OPTN Executive Committee and implemented on April 3, 2020, with the effective date of March 13, 2020. Previously set to expire on December 31, 2020, this policy is extended until no longer required by the conditions created by the COVID-19 pandemic. The OPTN Executive Committee has committed to review of these policies and their use at every meeting, and will repeal these policies when they are no longer required.

This emergency policy allows non-submission for the *living donor follow-up (LDF)*, *organ specific transplant recipient follow-up (TRF)*, and *recipient malignancy (PTM)* forms.

This does not suspend the requirement to report recipient death or graft failure, but will extend the timeframe for reporting that information from 14 to 30 days for transplant recipients.

Action 3: Modifications to wait time initiation for non-dialysis kidney candidates

Purpose

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

Summary of Changes

This policy was approved as an emergency policy action by the OPTN Executive Committee and implemented on April 3, 2020, with the effective date of March 13, 2020. Previously set to expire on December 31, 2020, this policy is extended until no longer required by the conditions created by the COVID-19 pandemic. The OPTN Executive Committee has committed to review of these policies and their use at every meeting, and will repeal these policies when they are no longer required.

OPTN *Policy 3.7.D: Applications for Modifications of Kidney Waiting Time during 2020 COVID-19 Emergency* was approved. With a completed application, including required documentation, a qualifying candidate will be able to have waiting time “backdated” to the date the program had documented intent to register. The OPTN implemented a waiting time modification form specific to this action in April 2020.

Action 4: Incorporate COVID-19 infectious disease testing into DonorNet®

Purpose

This data collection requires OPOs to report COVID-19 testing status of all potential deceased donors to the OPTN. DonorNet® captures information regarding potential infectious diseases identified as a result of testing performed on deceased donors but did not include COVID-19. The Executive Committee’s April emergency action added COVID-19 testing to DonorNet® so accepting centers can see whether donors were tested, and if so what the results were. The OPTN Board of Directors continued the established data collection and required its use for deceased donors.

Summary of Changes

This action requires that OPOs report the COVID-19 testing status of the donor. OPOs must report COVID testing results when testing has been conducted. Existing fields in DonorNet® exist for OPOs to enter information on COVID-19 testing specimen type(s), test type(s), and results. Upon implementation, the data field on whether the donor has been tested will become required to complete prior to sending out electronic organ offers.

Implementation

Programming is necessary to require these new data elements to DonorNet®. UNOS IT estimates approximately one week of work, and will issue applicable system notices when the fields become required.

Affected Policy Language²

New language is underlined (example) and language that is deleted is struck through (~~example~~).

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

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 Previously implemented language and data collection related to the emergency policy package can be found at <https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf>
https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf

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

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®

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.

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