

Notice of OPTN Policy Change**Updates to Candidate Data during 2020
COVID-19 Emergency**

Sponsoring Committee:	Executive Committee
Policy Affected:	<i>Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency</i>
Executive Committee Approved:	March 17, 2020
Effective Date:	March 17, 2020

Purpose of Policy Change

The current COVID-19 crisis has created unprecedented challenges for the nation’s health care system. The transplant network is facing several actual and projected disruptions to normal operations. One of the many effects of the national emergency is the inability to conduct routine clinical testing that is needed to obtain data required for transplant candidates. Several OPTN organ allocation policies require periodic refreshing of clinical data to establish and maintain waitlist priority. If deadlines for refreshing these data are not met, candidates’ urgency, eligibility, or status can be automatically “downgraded.” The scope and scale of the COVID-19 crisis necessitates providing an emergency policy solution so that candidates waiting for lifesaving organ transplants are not adversely affected solely because they are unable to undergo testing.

Proposal History

COVID-19 was declared a national emergency on March 13, 2020 by the President of the United States. In response to multiple concerns expressed to the OPTN by the transplant community, this proposal was developed to assist with helping candidates not lose current allocation priority due to COVID-19 outbreak impacts. The proposal was discussed emergently with leadership from the Data Advisory, Liver, Membership and Professional Standards, Policy Oversight, Transplant Administrators, Transplant Coordinators, and Thoracic OPTN Committees. The Executive Committee considered the action pursuant to OPTN Bylaw *11.7: Emergency Actions* which allows the OPTN to create policy required due to an emergent public health issue. The Executive Committee, on behalf of the OPTN Board of Directors, met and approved the policy action on March 17, 2020.

Summary of Changes

This emergency policy will allow transplant programs to refresh candidate clinical data with data obtained through previous testing in order to maintain current waitlist priority when obtaining updated clinical data is not feasible or advisable in the transplant program’s medical judgment due to the current COVID-19 crisis.

Implementation

Transplant programs will need to educate staff to this policy allowance. When data cannot be collected and updated in accordance with regular OPTN policy due to issues related to the COVID-19 outbreak, then transplant programs may enter the same values from the most recent previously provided clinical data. Data used for the most recent prior qualification or extension can be used for the required update in order to ensure that candidates will not be disadvantaged due to the national public health emergency.

The date on which the most recent previously provided clinical data are resubmitted pursuant to this emergency policy must be used for the test date field. Using the date that the data is being reported to the OPTN for the date required in UNetSM will prevent an automatic downgrade or unintended change to the candidate's status and effectively extend or preserve waiting time, status, or score.

When using this emergency policy, transplant hospitals must document these actions in the candidate's medical record. The documentation must include the circumstances that support using this emergency policy. Members have discretion in the way they document their use of this policy, provided their documentation addresses the policy requirements. An example of acceptable documentation would be a note in the candidate's medical record such as "3/20/2020 – updated candidate record in Waitlist. Due to COVID-19 emergency actions, candidate's previously reported clinical data was reported with today's date."

Members can find more detailed instructions in UNetSM.

This emergency policy will go into effect immediately on March 17, 2020. This emergency policy will be reviewed by the OPTN Executive Committee at least every three months for the duration of the 2020 COVID-19 emergency. The emergency policy will expire on March 17, 2021 if the Executive Committee or Board of Directors has not acted before that date.

As required by OPTN Bylaw 11.7: *Emergency Actions*, this policy will be distributed for public comment before September 17, 2020 for at least a 30 day period. The OPTN is notifying the community through this policy notice, a system notice in UNetSM, and other appropriate communication channels. This action will not require programming in UNetSM.

Affected Policy Language

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

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

6
7 During the 2020 COVID-19 emergency:

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

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Mini-Brief

Updates to Candidate Data during 2020 COVID-19 Emergency

OPTN Executive Committee

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Updates to Candidate Data during 2020 COVID-19 Emergency

Affected Policies: Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency
Sponsoring Committee: Executive Committee
Date: March 17, 2020

Executive Summary

The current COVID-19 crisis has created unprecedented challenges for the nation's health care system. The transplant network is facing several actual and projected disruptions to normal operations. One of the many effects of the national emergency is the inability to conduct routine clinical testing that is needed to obtain data required for transplant candidates. Several OPTN organ allocation policies require periodic refreshing of clinical data to establish waitlist priority. If deadlines for refreshing these data are not met, candidates' urgency, eligibility, or status can be automatically "downgraded." The scope and scale of the COVID-19 crisis necessitate urgent and definitive action so candidates waiting for lifesaving organ transplants are not adversely affected solely because they are unable to undergo testing.

This Mini Brief presents a policy proposal that, if adopted, will allow transplant programs to refresh candidate clinical data with data obtained through previous testing. The OPTN Executive Committee is using the emergency pathway provided in the OPTN Bylaws for this action.

Purpose

COVID-19 presents significant and immediate challenges for transplant hospitals in managing transplant candidates on the waiting list. Current OPTN policy requires that transplant programs submit numerous lab results, clinical procedures, and other data in order to prioritize candidates waiting for transplant. Across organ types, OPTN policy requires these data to be submitted at specific intervals, with values representing the most updated clinical data. When submission timetables are not met, transplant candidates may be “downgraded” according to policy, and their prioritization could be negatively impacted.

Current OPTN policy has been developed under a model of normal transplant program circumstances, meaning programs can schedule outpatient appointments for routine patient testing and evaluation. The COVID-19 national emergency has introduced an unprecedented situation that is limiting transplant programs’ ability to maintain normal waitlist management procedures and, in some cases, meet the OPTN policy requirements for obtaining updated clinical data.

The goal of this proposed emergency policy is to prevent candidates from losing their allocation eligibility or priority due to unforeseen circumstances that prevent them from reaching the transplant program or other health care facility for needed testing.

The policy will authorize programs to “carry forward” past clinical data when obtaining updated data is not possible or advisable. It will apply only to candidates for whom transplant programs have previously submitted data required for listing.

Authority

The Executive Committee is authorized to approve emergency policies according to OPTN Bylaw 11.7. Under this Bylaw, an emergency policy is permissible if it is required due to an emergent public health issue or patient safety threats. On March 13, 2020, the President of the United States declared a national emergency concerning the Novel Coronavirus Disease (COVID-19) outbreak.¹ Bylaw 11.7 requires that emergency policy changes designate a future date upon which the policy will expire - which can be no more than 12 months beyond the policy’s effective date. Furthermore, the emergency policy must be distributed for public comment no more than 6 months after approval. (See **Implementation** section for more details.)

Proposal

This proposed policy will allow 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 candidate is unable to obtain updated lab results, this Policy will allow the transplant program to substitute the candidate’s most recent lab results as the candidate’s current lab values. Thus, candidates who have been appropriately prioritized within a status or score previously will maintain that prioritization until new clinical data can be obtained.

¹ <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

Under the proposed policy, transplant programs will 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 will have the effect of “telling” the system that new results were obtained, and therefore prevent auto-downgrading.

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

Alternate Approaches Considered

Alternate ideas for addressing this situation were considered. Primarily, several systematic programming approaches were evaluated. For example, the UNetSM system could be programmed to automatically extend expiration dates or create approved exceptions that would extend scores (such as the Lung Allocation Score (LAS)) for certain time periods. The complexity of executing such options without causing unintended consequences were a concern. Solutions would be needed for several specific organ types, including heart, liver and lung. Most significantly, executing an IT solution that would meet the varying needs of all organs and situations would take longer to implement.

Therefore, this proposal does not require any programming, and can be implemented as needed by different transplant programs facing different circumstances.

NOTA and OPTN Final Rule Analysis

This emergency policy change is consistent with the OPTN's policy development requirements in NOTA and the OPTN Final Rule. 42 U.S.C. Sec. 274(b)(2)(I) requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants." As such, the OPTN must issue policies concerning the collection of these data. Neither NOTA nor the OPTN Final Rule contain specific instructions regarding emergency policies but they do provide requirements for policy development.

Implementation

OPTN Actions

This emergency policy will go into effect immediately on March 17, 2020. This emergency policy will expire upon a superseding action of the OPTN Board of Directors or on March 17, 2021, whichever comes first.

As required by OPTN Bylaws: *11.7 Emergency Actions*, this policy will be distributed for public comment before September 17, 2020 for at least a 30 day period.

The OPTN will communicate this emergency policy action to all OPTN members through posting of a policy notice and other appropriate communications on the OPTN website. In addition, OPTN members will be emailed about the policy change.

This action will not require programming in UNetSM.

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.

Member Actions

Transplant programs will need to educate staff to this policy allowance. When data cannot be collected and updated in accordance with regular OPTN policy due to issues related to the COVID-19 outbreak, then transplant programs may enter the same values from the most recent previously provided clinical data. Data used for the most recent prior qualification or extension can be used for the required update in order to ensure that candidates will not be disadvantaged due to the national public health emergency.

The date on which the most recent previously provided clinical data are resubmitted pursuant to this emergency policy must be used for the test date field. Using the date that the data is being reported to the OPTN for the date required in UNetSM will prevent an automatic downgrade or unintended change to the candidate's status and effectively extend or preserve waiting time, status, or score.

When using this emergency policy, transplant hospitals must document these actions in the candidate's medical record. The documentation must include the circumstances that support using this emergency policy.

Policy Language

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

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

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

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

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11 During the 2020 COVID-19 emergency:

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

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