

Notice of Emergency OPTN Policy Change

Reinstatement of Updates to Candidate Data During the COVID-19 Emergency

Sponsoring Committee:	Executive Committee
Policy Affected:	<i>Policy 1.4.F: Updates to Candidate Data During the COVID-19 Emergency</i>
Executive Committee Approved:	January 11, 2022
Effective Date:	January 11, 2022
Expiration Date:	April 11, 2022
Retrospective Public Comment:	First quarter, 2022

Purpose of Policy Change

The policy change allows transplant programs to reuse a candidate's most recent clinical lab values when obtaining new values may not be advisable due to potential COVID-19 exposure or other resource constraints. This policy was put into usage at the beginning of the COVID-19 pandemic and was well utilized by OPTN members. The most current COVID-19 wave due to Omicron has put increasingly significant stress on Organ Procurement and Transplant Network (OPTN) members and their patients. OPTN organ allocation policies often require clinical testing to be performed on candidates within specific timeframes and reported to the OPTN in order to maintain transplant waiting list priority. If required testing is not performed within the timeframe, a candidate's status will automatically be "downgraded". This policy solution is being reinstated to preserve transplant candidate waitlist status as necessary to prioritize the safety of transplant candidates and their health care providers .

Proposal History

Policy 1.4.F: Updates to Candidate Data During the COVID-19 Emergency was first implemented on March 17, 2020 as a response to the national emergency declared on March 13, 2020 surrounding the COVID-19 pandemic.¹ The proposal was designed to promote the safety of transplant candidates and clinicians who may be at risk of COVID-19 infection when performing required laboratory testing while not jeopardizing a transplant candidate's opportunity for a life-saving transplant. The policy was broadly supported during a retrospective public comment period in summer 2020 and was widely used at implementation and throughout the year. Data on the policy's usage was collected by the OPTN for regular monitoring and to inform the Executive Committee on the continued necessity of the policy. On July 27, 2021, as programs adapted to COVID-19 and policy usage declined, the policy was repealed. However, under a similar and growing set of stresses due to the COVID-19 Omicron variant surge, the OPTN received multiple requests to reinstate the policy from the transplant community. The Executive

¹ "COVID-19 Emergency Policies and Data Collection", OPTN, March 17, 2020, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/covid-19-emergency-policies-and-data-collection/>.

Committee considered the action pursuant to *Bylaw 11.7: Emergency Actions* and has reapproved the policy as of January 11, 2022.

Summary of Changes

This policy is the same policy that was previously put into place on March 17, 2020. It allows transplant programs to reuse the most recently obtained clinical data for policy required updates. This will preserve a candidate's current waitlist priority when obtaining new clinical data is not feasible or advisable in the transplant program's medical judgement due to the current COVID-19 crisis.

Implementation

This policy will go into effect immediately on January 11, 2022. Transplant programs will need to educate staff on its availability and use. In instances when clinical data cannot be obtained or is not feasible to obtain within the required OPTN timeframes due to COVID-19 concerns, transplant programs may reuse the values from the most recent clinical testing.

Implementation does not require any changes to UNetSM systems. When resubmitting previous clinical data, the current date must be used for the test date field. Using the date that the data are being reported to the OPTN for the required fields will prevent a candidate from being automatically downgraded. This will effectively preserve their waiting time, status, or score.

Any usage of this policy must be documented within a candidate's medical record. The documentation must include the circumstances that support the use of this policy. Members have discretion as to how they document this policy, provided their documentation supports the usage of the policy. An example of acceptable documentation would be a note in the candidate's medical record such as "2/12/2022 – updated candidate record in Waitlist. Due to COVID-19 restrictions (*include brief description*), candidate's previously reported clinical data was reused with today's date."

This emergency policy will go into effect immediately on January 11, 2022. It will be submitted retrospectively as early as possible during the winter 2022 public comment period with a minimum of 30 days for comments. This policy will be in effect for 90 days. The Executive Committee will monitor and evaluate its use. Unless the OPTN Executive Committee determines through monitoring and continuing COVID-19 circumstances that the policy be extended, it will expire on April 11, 2022.

Affected Policy Language

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

Policy 1.4.F: Updates to Candidate Data During COVID-19 Emergency

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

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 judgement 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 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 policy.

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