OPTN

Mini-Brief

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

OPTN Executive Committee

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

Affected Policy: *Policy 1.4.F: Updates to Candidate Data During COVID-19 Emergency*
Sponsoring Committee: *Executive*

Executive Summary

The COVID-19 crisis has stressed the nation's health care system and providers since it was declared a U.S. public health emergency on March 13, 2020.[1] In the past two years since the declaration, the Organ Procurement and Transplant Network (OPTN) has faced several disruptions to normal operations, and has consequently had to operate in non-routine conditions. One area impacted has been the ability to obtain required clinical testing within specific time frames that candidates must have in order to maintain waitlist priority.[2]

To address this issue, at the beginning of the pandemic, *Policy 1.4.F: Updates to Candidate Data During the 2020 COVID-19 Emergency* was adopted on March 17, 2020 as an emergency policy.[3] This policy, the first of several emergency actions, allowed transplant programs to refresh candidate clinical data required to maintain waiting list status with previously obtained clinical testing data when obtaining updated data was not feasible or advisable due to patient safety or staffing concerns. This was performed at the discretion of a transplant program's medical judgement regarding the COVID-19 crisis. Use steadily declined beginning in 2021 and, therefore, finding the policy no longer necessary, the OPTN Executive Committee (Executive Committee) approved repeal of the policy, effective July 27, 2021.

In response to multiple concerns expressed to the OPTN by the transplant community surrounding the Omicron variant surge, the Executive Committee was asked to reinstate *Policy 1.4.F: Updates to Candidate Data During the COVID-19 Emergency,* effective immediately. The Executive Committee will continue to monitor the policy to ensure it is adequately addressing the challenges posed by the COVID-19 Omicron variant and ensuring the safety of transplant patients. The policy is proposed to expire in 90 days unless the Executive Committee deems it necessary to continue following the current COVID-19 situation and monitoring of policy use.

[1] The Office of the President, "Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak", *The Federal Register*, March 13, 2020, https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak.
[2] *OPTN Policy 9.2: Status and Laboratory Values Update Schedule.*
[3] OPTN Policy Notice 3/17/2020, https://optn.transplant.hrsa.gov/media/3722/candidatedata2020covid19emergency.pdf.

Purpose

The COVID-19 crisis is impacting both patients' ability to obtain required testing and transplant programs' abilities and capacity to bring in candidates for required testing. In the absence of test results submitted to the OPTN, a candidate will automatically have their allocation priority reduced, which consequently lowers their placement on a match run and reduces their chance of receiving an organ offer. By reinstating *Policy 1.4.F*, this proposal would ensure candidates are not adversely affected due to the extenuating circumstances of the pandemic.

Reinstating *Policy 1.4.F* will again authorize programs to "carry forward" the most recent clinical data when obtaining updated data is not feasible or advisable due to safety or resource concerns stemming from the COVID-19 crisis. It will only apply to candidates for whom transplant programs have previously submitted data required for listing.

Background

Policy 1.4.F: Updates to Candidate Data During the 2020 COVID-19 Emergency, received strong support from the community from inception and throughout its retrospective public comment in summer 2020.[4] The OPTN Board of Directors adopted this policy along with several other COVID-19 related policies at their December 7, 2020 meeting, noting that the policies would continue to be monitored and then repealed as necessary when the COVID-19 emergency no longer required their use.[5] The policy was repealed on July 27, 2021 due to declining usage, the nationwide distribution of a COVID-19 vaccination, and the development of safe candidate management practices from transplant hospitals operating within the COVID-19 pandemic.[6]

On January 3, 2022, the U.S. surpassed 1,000,000 single day new cases of COVID-19 recorded, following the outbreak of the Omicron variant.[7] The widespread infections have once again put significant stress on the healthcare system, limiting available staffing and resources in the transplant network. Additionally, the candidate management practices developed earlier in the pandemic cannot be used as effectively to protect patients when performing clinical testing.

With the Omicron surge, providers and patients who received vaccination are now at a higher risk of contracting COVID-19 due to the infectiousness of the variant. Hospital practices, such as mandatory mask wearing are also consequently impacted because of this infectiousness.[8] Finally, because of the staffing shortages that healthcare facilities are already facing, the mandatory isolation upon testing positive further contributes to the critical understaffing of some facilities.[9,10]

[4] "COVID-19 Emergency Policies and Data Collection", OPTN, December 7, 2020, https://optn.transplant.hrsa.gov/media/4200/covid-19-emergency-policies-and-data-collection.pdf.
[5] Ibid.
[6] OPTN Policy Notice 4/26/2021, https://optn.transplant.hrsa.gov/media/4575/policy-notice-repeal-policy-14f-04_26_2021_rb-st.pdf.
[7] New York Times Staff, "Coronavirus in the U.S.: Latest Map and Case Count", *The New York Times*, January 7, 2022, https://www.nytimes.com/interactive/2021/us/covid-cases.html.
[8] ACGIH Staff, "COVID-19 Fact Sheet: Workers Need Respirators", *American Conference for Governmental Industrial Hygienists*, November 2021, https://www.acgih.org/covid-19-fact-sheet-worker-resp/.
[9] Ernest Grant, Letter on Behalf of the American Nurses Association, September 1, 2021, https://www.nursingworld.org/~4a49e2/globalassets/rss-assets/analettertohhs_staffingconcerns_final-2021-09-01.pdf.
[10] Centers for Disease Control Staff, "Quarantine and Isolation", *Centers for Disease Control and Prevention*, January 4, 2022, https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.

Several transplant members have requested that the policy be reinstated due to difficulties in obtaining required tests during this massive Omicron surge. OPTN Heart, Liver, Lung and Pediatric Committee leadership have also been consulted regarding the requests. Liver and Pediatric Committee leadership urge a quick reinstatement as soon as feasible.

Proposal

This proposal would reinstate a policy which was initially implemented on March 17, 2020 in reaction to the Alpha variant of the COVID-19 crisis and repealed later after circumstances improved. The COVID-19 Omicron variant once again poses a challenge to transplant hospitals attempting to operate in compliance with OPTN policies. The Centers for Disease Control and Prevention (CDC) have cited the Omicron variant as exponentially more infectious than the Alpha variant,[11] and the U.S. is currently experiencing a 7-day average case count (481,147) that is significantly higher than the top 7-day average case count (259,616) when the policy was in previously in effect. The current daily average as of January 6, 2022 is 610,989.[12]

In addition, most predictive models anticipate the highest peak of the Omicron variant to arrive in February 2022.[13,14] Any present stress from the Omicron variant is likely to continue or be exacerbated through this peak. One projection calls for between 3 and 8 million new cases per week when the Omicron wave peaks[15]. Nearly all (98%) of U.S. communities are in the "high" transmission category as defined by CDC[16]. Transplant candidates are a vulnerable population due to their current illness necessitating the need for transplant. Furthermore, a large portion of healthcare facilities are experiencing staffing shortages, as, since the inception of the COVID-19 pandemic, staff turnover has increased from 18 to 30 percent in some hospital departments.[17]

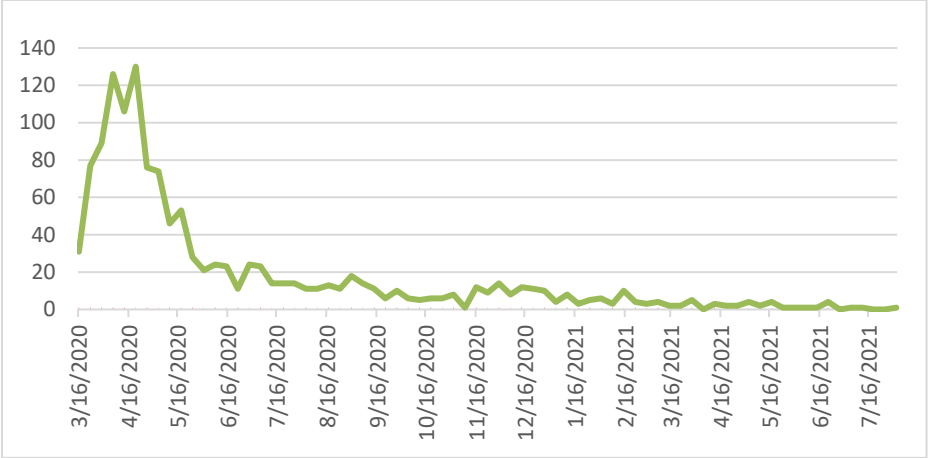
During the 72 total weeks that *Policy 1.4.F* was active between March 17, 2020 and July 27, 2021, the policy was likely used 1550 times. Among those instances monitored on a weekly basis, there were 1304 adult liver candidates, 34 pediatric liver candidates, 207 adult lung candidates, and 5 adult heart candidates.[18] Both the feedback from the retrospective public comment cycle, as well as the policy's usage rate, indicates it was positively received by the transplant community.

The policy was also consistently used across the 72 weeks. While usage significantly declined within the second half of its lifespan, there were only four weeks within the densest category, adult liver

[11] Centers for Disease Control Staff, "Potential Rapid Increase of Omicron Variant Infections in the United States", *Centers for Disease Control and Prevention*, December 20, 2021, https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html.
[12] New York Times Staff, "Coronavirus in the U.S.: Latest Map and Case Count", *The New York Times*, January 7, 2022, https://www.nytimes.com/interactive/2021/us/covid-cases.html.
[13] Centers for Disease Control and Prevention Staff, "Potential Rapid Increase of Omicron Variant Infections in the United States", *Centers for Disease Control and Prevention*, December 20, 2021, https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html.
[14] "Cumulative Deaths", COVID-19 Projections, accessed January 7, 2022, https://covid19.healthdata.org/united-states-of-america?view=cumulative-deaths&tab=trend.
[15] Jeffrey Shaman, "*Here's When We Expect Omicron to Peak*", *The New York Times*, January 6, 2022, https://www.nytimes.com/2022/01/06/opinion/omicron-covid-us.html.
[16] Centers for Disease Control and Prevention Staff, "Covid-19 Integrated County View (Data for week December 30, 2021-January 5, 2022", Centers for Disease Control and Prevention, accessed January 7, 2022, https://covid.cdc.gov/covid-data-tracker/#county-view?list_select_state=all_states&list_select_county=all_counties&data-type=Risk.
[17] Kelly Gooch, "7 Stats That Show Healthcare Workforce Staffing Challenges", *Beckers Hospital Review*, November 2, 2021, https://www.beckershospitalreview.com/workforce/7-stats-that-show-healthcare-workforce-staffing-challenges.html.
[18] OPTN Summary of COVID-19 Emergency Policy and IT Changes, https://optn.transplant.hrsa.gov/media/3985/data_report_executivecmte_covid_20200701_rpt3.pdf.

candidates, that no liver candidate used the policy. At its peak, during the week of April 6, 2020, 126 candidates used the policy as shown in ***Figure 1*** below.

Figure 1: Adult Liver Candidates Using Policy 1.4.F between 3/16/2020 and 7/27/2021



This proposal would reinstate the previous emergency policy for a 90 day period. The policy would expire after 90 days, unless the Executive Committee takes action to extend the policy based on circumstances at that time.

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".[19] The CDC has published guidelines on non-COVID related care,[20,21] 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.

This 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

Additionally, the proposed policy does 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

[19] 42 CFR §121.4(a)(2).
[20] https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html.
[21] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html.

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 policy change was previously analyzed and these changes:

- **Are based on sound medical judgment**[22] because they are evidenced-based changes relying on the following:
    - 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.[23,24,25]
- **Seek to achieve the best use of donated organs**[26] **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 transplantation**[27] **by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal will:
    - 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
    - Have potential to reduce waiting list mortality by decreasing the number of candidates exposed to COVID-19.

The policy change is not expected to impact the following aspects of the Final Rule:

- **Are designed to avoid wasting organs**[28] by decreasing the number of organs recovered but not transplanted
- **Are designed to avoid futile transplants**[29]**:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement**[30] by taking into account factors including the costs and logistics of procuring and transplanting organs

[22] 42 CFR §121.8(a)(1).
[23] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html.
[24] 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.
[25] 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.
[26] 42 CFR §121.8(a)(2).
[27] 42 CFR §121.8(a)(5).
[28] 42 CFR §121.8(a)(5).
[29] 42 CFR §121.8(a)(5).
[30] 42 CFR §121.8(a)(5).

- **Are not based on the candidate's place of residence or place of listing, except to the extent required**.[31]

The proposed action preserves the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[32] and is specific to each organ type.[33]

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 previously identify any populations that may be treated "less favorably than they would have been treated under the previous policies"[34,35] during their initial or subsequent assessments of these policies. Therefore, the Committee does not recommend adoption of transition patient procedures.

Implementation

This policy will go into effect immediately. There is no anticipated IT impact for implementation or upkeep.

Transplant programs will need to educate staff to this policy allowance. In instances when data cannot be collected or updated in compliance with OPTN policy due to issues stemming from the COVID-19 crisis, transplant programs may enter prior values from the most recently provided clinical data. This data may be used in place of data that is unable to be collected to ensure that candidates will not be disadvantaged due to the COVID-19 crisis.

The date on which the most recent previously provided clinical data are resubmitted pursuant to this 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 UNet^{SM} 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 policy, transplant hospitals must document these actions in the candidate's medical record. The documentation must include the circumstances that support using the 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 "1/20/2022 – updated candidate record in Waitlist. Due to COVID-19 emergency actions, candidate's previously reported clinical data was reported with today's date." [36]

Members can find more detailed instructions in UNet^{SM}.

As required by OPTN *Bylaw 11.7: Emergency Actions*, this policy will be retrospectively submitted for public comment during the winter 2022 public comment cycle. The OPTN plans to notify the community through a policy notice, a system notice in UNet^{SM}, and other appropriate communication channels. This action will not require programming in UNet^{SM}.

[31] 42 CFR §121.8(a)(8).
[32] 42 CFR §121.8(a)(3).
[33] 42 CFR §121.8(a)(4).
[34] https://optn.transplant.hrsa.gov/media/3755/20200317_executive-committee_meeting-summary.pdf.
[35] https://optn.transplant.hrsa.gov/media/3878/optn-executive-committee-meeting-4-03-20.pdf.
[36] Notice of OPTN Policy Change 3/17/2020, https://optn.transplant.hrsa.gov/media/3722/candidatedata2020covid19emergency.pdf.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal 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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Appendix A: Public Comment Feedback from 2020 Proposal

The following are public comments received for the proposal "*COVID-19 Emergency Policies and Data Collection*". The proposal was sent out retrospectively from August 4, 2020 – October 1, 2020 following the Executive Committee adopting several actions in March and April 2020 due to COVID-19 circumstances impacting the transplant community. These comments reflect sentiment about *Policy 1.4.F: Updates to Candidate Data During (2020) COVID-19 Emergency,* the first of several actions taken, as well as other COVID-19 related actions taken including COVID-19 testing data collection, modification of wait time for kidney candidates, and delay of certain data collection requirements. Overall, the transplant community was strongly supportive of the actions related to COVID-19[37] .

Sam Dey | 10/01/2020

It's absolutely necessary to adjust the rules based on impact from COVID-19. Thank you.

UT Health/Memorial Hermann Hospital | 10/01/2020

We strongly support this proposal in concept and support collecting data on COVID-19 diagnoses as they relate to transplant candidates. This will help us understand overall benefit of lung transplantation in this specific group of patients. Here are our recommendations.

1) COVID ARDS and COVID 19 Fibrosis option in listing diagnosis will help us identify this specific group of recipients in future analysis. We recommend using COVID 19 ARDS as secondary diagnosis in patients with primary end stage lung disease (Ex IPF, COPD). We recommend that anyone with worsening in respiratory status of chronic lung disease due to COVID 19 infection should be considered in same category. We recommend those specific patients should be added to Group D.

2) We recommend obtaining COVID 19 PCR data and Antibody status on all donors. We are increasingly recognizing the impact of COVID 19 on various organs including Heart and Kidney. This will provide data on whether these organs are safe to transplant. The pandemic is anticipated to continue for at least a couple of years. We will increasingly face this issue in future.

OPTN Data Advisory Committee (DAC) | 10/01/2020

The Data Advisory Committee (DAC) thanks the OPTN Executive Committee for their efforts in developing this public comment proposal, COVID-19 Emergency Policies and Data Collection. DAC supports this proposal with several comments. The actions the Executive Committee took were appropriate and effective in providing administrative relief during the pandemic. DAC expressed some support for retrospective data reporting after amnesty expires, emphasizing the need for accuracy and validity of these data, to maintain the integrity of OPTN data, future modeling, and evaluation. DAC emphasized the need for completeness of the data where possible. DAC recommended ending amnesty at the end of 2020. If retrospective reporting becomes required, DAC recommended implementing a data entry due date 90 days after the end of the amnesty period.

[37] COVID-19 Emergency Policies and Data Collection, OPTN Public Comment Web Page. Accessed January 10, 2022 at https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/covid-19-emergency-policies-and-data-collection/.

Region 11 | 10/01/2020

Region 11 vote: 5 strongly support, 13 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose.

Comments: Several attendees commented that there needs to be more guidance/data on recovering organs from previously COVID 19 positive donors as well as testing and transplanting candidates who had previously been COVID 19 positive. One attendee also recommended adding links on the UNOS website for resources developed by other organizations.

Region 9 | 10/01/2020

Region 9 vote: 10 strongly support, 8 support, 0 abstain/neutral, 1 oppose, 0 strongly oppose.

Comments: A member commended the Executive Committee for being proactive with these policies and that they deserve high praise, but said they do not believe collecting retrospective data on amnestied forms is the right method.

Carolina Donor Services | 10/01/2020

Carolina Donor Services found the initiation of the UNOS Emergency Policy process to be an effective response to the COVID-19 pandemic. We support the UNOS Executive Committee continuing to monitor the changing environment of the pandemic and repealing the emergency policy when appropriate. Due to the infection risks that will continue into the foreseeable future, Carolina Donor Services supports mandatory COVID-19 testing of donors and mandatory reporting of results. It is crucial that mandatory reporting of results in DonorNet not impact work flow of OPOs and the ability to generate timely match runs prior to test result.

Transplant Coordinators Committee | 10/01/2020

The Transplant Coordinators Committee thanks the Executive Committee for the opportunity to comment on the public comment proposal. The committee noted that as time goes on, more donors will have a history of COVID-19 infection. It is important that OPOs have a way to report that data so that the community can measure what effect a prior COVID-19 infection has on graft function. It was mentioned that the OPTN should analyze the type of COVID-19 testing that is being used across the country and issue recommendations for the community. The committee acknowledged that the OPTN response to the pandemic was timely and as COVID-19 testing becomes more readily available, the infectious disease testing field in DonorNet should become mandatory. In addition, the OPTN should add fields to the Transplant Recipient Follow-up form in order to track if a recipient has had a COVID-19 infection since the last follow up. In regards to amnesty status for data collection, the OPTN should hold off on setting an end date until the entire country is on an equal setting for COVID-19 containment. With such wide fluctuations across the country, one end date for the amnesty status will not fit all areas of the country. The committee noted that it will also be difficult to obtain the missing data from the amnesty period, given that many recipients and living donors are reluctant to come in for testing. In addition, larger transplant hospitals will have an even harder time getting missing data from their large patient population. The committee suggested that all data collection forms be made optional so that partial data could still be entered. In response to what could have the OPTN done to respond to the pandemic, the committee stated that standard registry for national COVID data would have been beneficial. Lastly, the committee asked that the SRTR evaluate their data collection metrics since there will be a lot of missing data from this period.

The committee indicated the following sentiments for the proposal: 2 Strongly Support, 12 Support, 0 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Association of Organ Procurement Organizations | 10/01/2020

The Association of Organ Procurement Organizations (AOPO) strongly supports the OPTN's effort to implement COVID-19 Emergency policies regarding data collection. OPOs were impacted as transplant programs accepting donor organs need to know if COVID-19 testing was performed. COVID-19 donor testing status and results were added to DonorNet to help OPOs and transplant programs communicate this important information in a standard way. We believe that the test results should remain in DonorNet and become a mandatory field to capture the data. The field should be managed like infectious disease testing results so it will not limit organ offers. In addition, proposed policies are put forward to lower the risk of spreading COVID-19, as most hospitals cut back on non-emergency visits. Transplant programs are required to do regular lab testing and clinical procedures for living donors, transplant candidates and recipients which involves routine visits to healthcare facilities. Requirements were relaxed, modified or suspended by the OPTN Executive Committee to protect patient safety by lessening the potential for COVID-19 exposures. AOPO appreciates the decision to improve patient safety during the COVID-19 Pandemic, and AOPO supports keeping these emergency policy measures in place. We support future actions by the OPTN, if necessary, in an emerging health crisis and believe the emergency policy process to be the most appropriate vehicle to ensure a prompt response for the donation and transplant community.

Region 3 | 10/01/2020

Region 3 vote: 6 Strongly Support; 18 Support; 2 Neutral/Abstain; 0 Oppose; 0 Strongly Oppose.
Comments: Several members voiced support for the actions the Executive Committee took and the process. Specific feedback included support from multiple members for requiring forms retrospectively as it allows us to understand the impact of the pandemic on transplantation and agreed that it should be for information gathering only and not public reporting. Another member stated that retrospective data entry could be burdensome for centers, and also the data availability may be inconsistent and also agrees it should be informational only. Multiple members voiced support for making the COVID testing field mandatory and requiring COVID testing before allocation can proceed with anticipation that OPOs will need to continue testing for one to two more years. Several members commented that the policies should remain in place due to the changing environment. One member stated the expiration date should be fluid, another suggested at least another year and someone else stated until the national emergency ends. One member commented that the change to kidney allocation should be postponed until the COVID crisis is over.

NATCO | 09/30/2020

NATCO strongly supports the OPTN's efforts to partner with transplant centers and OPOs during this pandemic to promote patient, and healthcare provider safety. We strongly support and applaud the OPTN Executive committee in coming up with the Policies for the COVID-19 Emergency Policies so quickly.

Were the Executive Committee's actions appropriate in the emergency? Yes. We strongly support the initiatives taken by the Executive Committee with the goal of reducing risk of exposure to COVID-19 for transplant patients, reducing the risk of spreading COVID-19, and to barriers that were met in accessing timely transplant care during this pandemic.

Should COVID-19 infectious disease testing remain in DonorNet? Should it be a mandatory field? Yes. This information should remain in DonorNet and should be a required field.

Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies. Yes. However, we believe that a longer extension may contribute to an increasing administrative burden if further data backlogs mount.
Is the emergency policy process used by the OPTN the most appropriate way to respond to an emergency health crisis? Yes. The use of Executive Committee action to address an emergency crisis is most appropriate. NATCO continues to support continuous monitoring by the OPTN of the circumstances related to COVID-19 as the pandemic evolves.

Donna Campbell | 09/30/2020

Recommend that centers not be required to back enter amnesty data- would be a burden

American Nephrology Nurses Association (ANNA) | 09/29/2020

ANNA supports this proposal.

Organ Procurement Organization (OPO) Committee | 09/29/2020

The OPO Committee supports making the COVID-19 testing fields in UNet mandatory. The only concern was whether OPOs could still send organ offers prior to receiving the test results. The Committee recommends that the policy language clearly address this issue.

American Society of Transplant Surgeons | 09/29/2020

The American Society of Transplant Surgeons (ASTS) supports the OPTN policy proposal as written; however, we recommend the following:

1) ASTS believes the OPTN's Executive Committee's actions are appropriate in the current pandemic emergency.

2) We believe that there should be no defined expiration date for these actions. With a spike in cases at different times/parts of the country, data capturing issues will persist until the incidence rate drops to a particular level. Perhaps the expiration should be deferred until we are notified at a Federal level that the entire country has returned to a Phase III or Phase IV reopening.

3) COVID-19 testing should remain in DonorNet and should be mandatory. OPTN should standardize how these are reported, so that every OPO checks off the same box and there is no confusion as to where this is reported. The OPTN should also clarify which COVID-19 testing is being done.

4) The OPTN should not require retrospective data entry on follow-up forms that are given amnesty status under the emergency policies. That will be too onerous a process, especially when we are requesting no defined expiration date.
5) We suggest that OPTN make a separate checkbox for COVID-19 antibody testing. There have been discussions amongst the transplant community about use of organs/recipients that are COVID-19 PCR negative but antibody positive. So if this could be voluntarily reported, the OPTN would strengthen itself by examining data regarding transplanting these subsets of organs and recipients.

Region 10 | 09/29/2020

Region 10 vote: 10 Strongly Support; 12 Support; 1 Neutral/Abstain; 0 Oppose; 0 Strongly Oppose.

Comments:

• An attendee voiced support of the emergency actions taken by the Executive Committee. They suggested that there needs to be a way to capture history of COVID infection for living donors both at time of living donor registration and for follow up care.

• Another attendee noted that at the beginning of the pandemic they decided to inactivate their whole program. Luckily, there was another program nearby that they could refer their patients to during that time. In the event of another emergency situation, the OPTN should look into ways of ensuring patients still have access to active programs.
• Three additional attendees made comments in support of the actions taken by the Executive committee. The swift action, ongoing timely communications, and support were very helpful. The Executive Committee should have the ability to extend the emergency policies or make the changes permanent.

Region 6 | 09/29/2020

Region 6 vote: 12 strongly support; 28 support; 3 neutral/abstain; 0 oppose; 0 strongly oppose.

Comments: A member commented that COVID-19 testing should remain in place, but that the data will be difficult to interpret due to the variety and quality of the tests that are out there.

Region 2 | 09/25/2020

Region 2 vote: 10 Strongly Support, 22 Support, 1 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Comments:

• One attendee expressed support in continued COVID testing on all deceased donors and that the OPTN should continue to review the impact of the pandemic on the transplant community.
• Another attendee commented that the missing data from the amnesty status is important, but larger centers will have a tough time trying to collect all of the missing data since they have large numbers of patients. The OPTN Committees should evaluate which data fields are the most important for centers to go back and submit once conditions improve.

Region 1 | 09/24/2020

Region 1 vote: 7 Strongly Support, 5 Support, X Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.
Comments: Region 1 supports this policy. A member asked if there is data comparing the number of transplants between the 2019 and 2020 for living donors, the speaker stated there was some data presented showing the number of living donor transplants between Jan-Aug 2020, but did not have the 2019 data available. Several members stated the Executive Committee took swift actions that were timely and well thought out. One member does not support requiring retrospective data entry on follow up forms given amnesty status under the emergency policies.

American Society of Transplantation | 09/24/2020

The American Society of Transplantation acknowledges and appreciates the timely actions taken by UNOS to address evolving issues and needs related to the COVID 19 pandemic in the setting of an unprecedented emergency to protect patients, providers, & resources and preserve outcomes, and minimize missed opportunity for transplantation. In response to the specific questions posed within the proposal:

• Were the Executive Committee's actions appropriate in the emergency? Yes.

• Should the Board of Directors select a date for the expiration of the emergency actions, or should they delegate the repeal to the Executive Committee based on review of the changing environment? Delegate the repeal to the Executive Committee

• Should COVID-19 infectious disease testing remain in DonorNet. Yes

• Should the COVID-19 infectious disease data fields become mandatory in DonorNet. Yes

• Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies? Yes

• Are there other things OPTN should have done, or can still do, to respond to the COVID-19 crisis? No

• Is the emergency policy process utilized by the OPTN the most appropriate way to respond to an emerging health crisis? Yes. There was not universal agreement from our membership in considering these issues. The AST shares its thoughts below regarding the four emergency actions taken:

Updating Candidate Data During 2020 COVID-19 Emergency: We agree with this policy in as far as programs are making the effort to collect and report interval data as they would under normal situations unless it is felt that an unreasonable risk or harm exists for a given patient. However, there should be clear explanation as to why there may be harm as there is strong potential to "game" the system and bypass crucial qualifying data hiding behind this policy. It should, however, be required that transplant centers submit updated clinical data for all wait-listed candidates to the OPTN, soon after they resume routine institutional practices and procedures. At any time, centers must inform the OPTN of acute changes in the candidates' clinical status that affect their status on the list. Modification of wait time initiation for non-dialysis renal transplant candidates is the correct action for the duration of time that transplant centers are unable to complete the required, standard testing for candidate registration. Since the trajectory of the COVID-19 pandemic is variable between different parts of the United States of America, it is ideal to define the time point for return to complete testing for candidate registration, based on the local circumstances in the state/region. If a state/region-specific policy cannot be created, OPTN can define a time point for return to routine candidate testing but allow transplant centers to submit requests for extension of that time based on their local COVID-19 related circumstances.

Relax Data Submission Requirements for Follow-up Forms: We also acknowledge the need for and the importance of retrospective data entry but would like to note that this could pose a financial and administrative burden on programs. These amnesty policies make sense during severe overwhelming outbreaks such as that seen earlier in the pandemic in NYC. As we do not know if future overwhelming outbreaks may occur, it makes sense to incorporate this policy for some future period of time. That being said, it does not make sense to have a huge backlog of data that either is never retroactively entered or places an even further burden on a center to enter retroactively down the road. As this data is critical to our knowledgebase going forward we favor (at least in part) ending this period of amnesty in the relative near future. For instance, it might make sense to end this at the set expiration date of 12/31/20. Short of an overwhelming surge, like that seen in the NYC area whereby it was an "all hands on deck" situation provider-wise, most programs will be at worst moving at a typical busy pace and at best possibly moving at a slower than typical pace (from a transplant volume perspective). Consequently, most programs should have the manpower to handle this paperwork in real time. We do recognize that there is geographic variability in the pandemic activity and accordingly transplant centers will have uneven disruption of their programs. As noted above, risk to patients from a COVID-19 transmission standpoint should be continuously monitored and amnesty used only judiciously in cases where risk is assessed as unacceptably high. It therefore may make sense to end amnesty for paperwork that does not require a physical recipient or LR donor visit in the near future but extend amnesty for reporting that does require a physical visit. This information is key to continued study of the epidemiology of post-transplant complications. The AST recommends that the amnesty on post-transplant and living donor monitoring data submission, be granted for a defined time period only. While some members of AST were concerned about the administrative burden and financial cost, most members supported mandating retrospective submission of TRF, PTM and LDF forms to the OPTN. Since this is an uneven and evolving pandemic, reassessment of the COVID-19 related amnesty time period should be permitted, and an appeal process should be instituted so that individual centers can contact the OPTN for extension of amnesty as needed based on their local/regional COVID-19 related circumstances. In addition, it should be emphasized that while retrospective data reporting is requested, centers will not be evaluated on comparative outcome benchmarking during the pandemic period. Incorporate COVID-19 Infectious Disease Testing into DonorNet®: The OPTN data provided demonstrates that between April 21, 2020 and June 30, 2020 100% of deceased donors were tested for COVID-19 (although only 72% were reported in the provided DonorNet fields with the rest being reported via attachments or free text). Incorporation of donor COVID-19 results into DonorNet is the correct action, but these fields should not be optional. This information is essential to patient safety during the transplant procedure, appropriate infection prevention for patients/healthcare teams, targeted post-transplant monitoring and timely management of complications. Data on COVID-19 testing should therefore be made available to all transplant teams across the United States and should at this time be maintained in the upcoming years given the evolving nature of this pandemic.

Heart Transplantation Committee | 09/24/2020

The OPTN Heart Committee thanks the OPTN Executive Committee for its responsive actions in developing and implementing the COVID-19 Emergency Policies and Data Collection actions this past spring. The Committee

expresses its concerns around potential effects form submission amnesty will have on SRTR outcome modeling and other data heart programs depend on. The Committee suggests expiring Action 1 in December rather than March.

Region 8 | 09/22/2020

Region 8 vote: 7 strongly support, 11 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose.
Comments: The committee was asked to consider how the changes to data collection allowing forms to be in amnesty will affect outcome letters for donor families. One member commented that the time frame to remain active should be fluid with the Executive Committee driving that decision. Several comments supported the action taken by the OPTN as timely and appropriate. One member stated that amnesty should continue; and that centers should be encouraged to enter data retrospectively if it is available. One member commented that COVID test results should be mandatory in UNET.

Lewis Teperman, MD & Colleen O'Donnell Flores | 09/21/2020

The following are in response to the questions:

1) Are the Executive Committee's actions appropriate in the emergency? Yes, we believe they can do more to proactively assist transplant patients, programs and OPOs.

2) Should the Board of Directors select an expiration date for these actions? Or, should the Board delegate the repeal to the OPTN Executive Committee to address the ongoing emergency? We believe that no, there should not be a specific date of expiration. If they wish to expire the actions, then a scientifically acceptable threshold of disease should be agreed upon. COVID will impact geographic areas differently.

3) Should COVID-19 testing remain in DonorNet? Absolutely, it will remain a confounding variable.

4) Should COVID-19 data fields become mandatory in DonorNet? Absolutely, they should be mandatory for the OPOs.

5) Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies? No, transplant programs are just digging out of the pandemic. It would be too onerous to complete this data as a look back and it would be accurate.

6) Are there other actions the OPTN can take to respond to the crisis?

*Mandate PPE for deceased donor procurements.

*Standardize required PCR testing and reporting.

*Add a field for COVID antibody testing.

*Discontinue standard program reviews (audits) during the pandemic.

*With new technology, we should be able to have better virtual/visualization of donor organs.

*Consider a review of impact on COVID 19 on the transplant recipient and donor pool with the minority communities.

*Consider recommending living donor guidelines.

*Continue to sponsor webinars with key partners, ASTS, AST, NATCO, etc.

*Clarification on donor vessel status/storage as it relates to COVID.

*Consider more frequent regional meetings.

7) Is the OPTN taking the most appropriate action to respond to the emerging health crisis? Yes, but we believe they can do more.

8) Any recommendations to add? See above.

OPTN Operations and Safety Committee | 09/18/2020

COVID-19 Emergency Policies and Data Collection The Operations and Safety Committee thanks the OPTN Executive Committee for their efforts in developing this special public comment proposal for the COVID-19 Emergency Policies and Data Collection. The Committee agreed that the Executive Committee took appropriate action and that tracking this data is important. The Committee agreed that COVID-19 infectious disease testing should remain in DonorNet®, but that it should not be a mandatory field, as it could stifle the allocation process. The Committee indicated the following sentiments for the proposal: 42% Strongly Support, 58% Support, 0% Neutral/Abstain, 0% Oppose, 0% Strongly Oppose

OPTN Membership and Professional Standards Committee | 09/16/2020

The MPSC thanks the Executive Committee for presenting its proposal "COVID-19 Emergency Policies and Data Collection." MPSC members were supportive of the regulatory relief provided to date, but they had mixed opinions on continuing to extend the policies. The committee offered the following feedback:

• The Board of Directors or Executive Committee should use evidence-based criteria such as disease prevalence or hospital admissions to determine when the emergency policy actions should end.

• The OPTN should clearly communicate that the emergency policy actions are only a short-term pause to long-term requirements. Hospital administrations continue to evaluate and adjust budgets and workforce staffing levels, and transplant programs may have challenges retaining staff while the emergency actions continue.

• The OPTN should consider the amount of data that may ultimately be lost when considering when to end the emergency actions.
The results of the MPSC's sentiment vote are 7 Strongly Agree, 19 Agree, 4 Neutral/Abstain, 1 Oppose, and 0 Strongly Oppose.

Region 7 | 09/10/2020

Region 7 vote: 9 Strongly Support, 7 Support, 0 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Region 7 supported the proposal and had the following comments:

• Attendee commented that this was an excellent, timely and balanced response to an unpredictable event.

• Another attendee added that the impact of COVID-19 is unknown. The OPTN and its members should remain vigilant, as long- term impacts on patients are unknown.

• An attendee commented that COVID-19 infectious disease testing should be mandatory. The responses of the executive committee was adequate.

• An attendee commented that this should be helpful in allowing a more granular look at the impact of COVID. May want to mirror this to other organs as well as indicated.
• An attendee agreed with all comments to add this to kidney and heart, have the kidney and heart committees consider. Also support adding this data collection element for other organs as well.

OPTN Ad Hoc Disease Transmission Advisory Committee | 09/04/2020

The DTAC requests that the COVID-19 infectious disease testing field in DonorNet® become a required field. The Committee recommends COVID-19 donor history and date of diagnosis be added to this proposal.

Region 5 | 08/28/2020

Region 5 vote: 8 Strongly Support, 21 Support, 2 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Region 5 supported the proposal and had the following comments:

• Good decisions were made by the Executive Committee. The Executive Committee should consider triggers as to which parameters they would like to see met before we can return to business as usual, with a grace period to follow.

• COVID testing data should remain in DonorNet.

• Retrospective data entry should be allowed in order to assess the effect on the pandemic on patient outcomes.

• This is what the Executive Committee is needed for. I would encourage UNOS to examine those changes that were implemented with a goal of adopting practices that were useful and more cost-effective as potentially permanent changes. For example, the use of local recovery teams to limit travel and contact is something that might have demonstrated no negative impact on transplant outcome as well as reduced risks and costs.

• Support continued monitoring for COVID for several more years.

• COVID testing should continue to be mandatory and reported in the required field in Donor Net. OPTN should follow up on any donors testing positive for COVID and report any outcomes of organs used (if any) or report how many donors offered and declined (if any). Agree with the Emergency policy and OPTN execution. Thank you for your efforts.

• The executive committee actions were appropriate in the emergency and I do not see any other actions the OPTN could have taken. COVID-19 testing should remain in DonorNet as long as pandemic continues without effective prevention or treatment. Should remain mandatory as long as there is not a treatment or immunization. It would be nice to have the retrospective data, but a significant requirement and challenge for transplant programs to retrieve data when many COVID-19 results may have been done in sites outside the transplant center.

• Absolutely, the emergency actions were appropriate. Timely and supportive actions of the transplant community by OPTN. Kudos!

• COVID19 infectious disease testing needs to remain in DonorNet and should be a mandatory field for now until a few years have passed and we have learned more with experience. If it turns out that there is no long term untoward consequence then this field can be removed.

Region 4 | 08/26/2020

Region 4 vote: 5 Strongly Support, 17 Support, 1 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Region 4 supported the proposal. During the discussion, one attendee commented that the performance of UNOS during the COVID pandemic has been exemplary. They went on to note that the OPTN has been out in front of the issue as much as is organizationally and humanly possible and have been responsive to member needs and open to expert opinion from stakeholders. They added that the OPTN has communicated clearly and honestly throughout the pandemic. The same attendee continued to say that in parallel, they have of course managed to keep their employees safe and productive, which has allowed the transplant community to continue to care for patients. Really, really impressive in real time as we moved through this, and really, really impressive in hindsight as well. Another attendee commented that the emergency polices are essential, sensitive to our current reality, and is the only course that makes sense. Finally one attendee recommended that UNOS put clear deadlines on input of retrospective data to insure programs start working in getting caught up and that all "forgiveness" for missing data/procedures should expire Dec 31.

UC San Diego Center for Transplantation, CASD | 08/20/2020

CASD applauds the OPTN's efforts to partner with transplant centers and OPOs across the country during these unprecedented times. In direct response to the requested feedback relating to the emergency actions takes, CASD offers the following:

• We strongly support each of the initiatives taken by the Executive Committee aimed at reducing unnecessary risk posed by the potential spread of COVID19 and barriers in accessing timely transplant related care.

• Initially these actions were set to expire within a 12 month timeframe. In light of the constantly changing environment and daily updates to national recommendations in best practices, CASD support the Board of Directors delegating the responsibility of continuing to monitor the situation and proposal of additional policy modifications and repeal of these emergency actions to the Executive Committee.

• It is imperative that COVID-19 infectious disease testing remain in DonorNet, and we would recommend that until the community has more reliable information available on the potential impact of the virus on our patient population these fields should require a response.

• We do not support the OPTN requiring retrospective data entry on the follow-up forms given amnesty status. This would create a significant and costly administrative burden on institutions that are already struggling due to the impact COVID19 has had on operations and finances.

• We would agree that the emergency policy process utilized by the OPTN was an appropriate way to respond in this event and would support a similar process for future incidents.

• The initial communications to members regarding these emergency actions were very confusing. While UNOS and the OPTN typically do not provide recommendations on how centers should translate policy to practice, it would have been very helpful to have had clearer guidance in these instances. MPSC and the survey teams should most certainly be involved in the development of such guidelines.

• Although CASD was not subject to a virtual audit, it seems contradictory that UNOS would continue routine surveys when federal agencies suspended theirs.