OPTN

Public Comment Proposal

COVID-19 Emergency Policies and Data Collection

OPTN Executive Committee

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COVID-19 Emergency Policies and Data Collection

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Sponsoring Committee:	*Executive*
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Executive Summary

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

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

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

These actions were intended to alleviate issues stemming from the COVID-19 crisis. They are scheduled to expire within 12 months from their effective date unless further amended by the Executive Committee. The OPTN Board of Directors will consider the public comments and will determine whether revisions to the policies or changes to the effective dates are warranted. If they deem modifications are necessary, they will vote on them at a meeting following the public comment period.

Following the requirements of OPTN *Bylaw 11.7*, the OPTN is seeking the following feedback:

- Were the Executive Committee's actions appropriate in the emergency?

- 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?
- Should COVID-19 infectious disease testing remain in DonorNet?
- Should the COVID-19 infectious disease data fields become mandatory in DonorNet?
- Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies?
- Are there other things the OPTN should have done, or can still do, to respond to the COVID-19 crisis?
- Is the emergency policy process utilized by the OPTN the most appropriate way to respond to an emerging health crisis?
- Additional feedback and recommendations are appreciated.

Background

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

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

The OPTN Executive Committee approved these four emergency actions in two stages. The Executive Committee utilized the OPTN *Bylaws 11.7: Emergency Actions* due to the emergent public health issue caused by COVID-19. *Updates to Candidate Data during 2020 COVID-19 Emergency* was approved on March 17, 2020[1], and is set to expire on March 17, 2021. This policy allowed extension of current lab results required to maintain waiting list status for liver, liver/kidney, heart, and lung candidates. *Relax Data Submission Requirements for Follow-up Forms* and *Modify Wait Time Initiation for Non-Dialysis Kidney Candidates* were approved on April 3, 2020[2], and are set to expire on December 31, 2020. The first policy provided amnesty for recipient and living donor follow up form submission. The second provided a pathway to modify wait time for non-dialysis kidney candidates after a qualifying creatinine clearance or glomerular filtration rate (GFR) was reached. The data fields for COVID-19 infectious disease testing for deceased donors were also approved on April 3, 2020, with a current end date of December 31, 2020. This added optional data fields in DonorNet® to communicate testing for SARS-CoV-2 (COVID-19).

Purpose

When emergency proposals are passed pursuant to OPTN *Bylaws 11.7: Emergency Actions*, they must be distributed for public comment within six months after approval. This provides the transplant

[1] https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf
[2] https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf

community an opportunity to comment on these emergency policies, as well as comment on the timeframes for which they should remain in effect.

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

This proposal also provides an initial evaluation of the transplant community's experience with and response to the COVID-19 crisis. Appendix A shows the OPTN's monitoring of the emergency actions enacted by the Executive Committee. Appendix B shows donor testing for COVID-19 reported to the OPTN.

Overview of Proposal

The proposal consists of four actions in response to the COVID-19 crisis, the first of which was approved by the OPTN Executive Committee as an emergency action on March 17, 2020[3], and the remaining three that were approved by the OPTN Executive Committee as emergency actions on April 3, 2020.[4]

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

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

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

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

Table 1 denotes the OPTN policies requiring regular candidate data updates that are affected by this policy.

[3] https://optn.transplant.hrsa.gov/media/3687/covid-19-policy-notice-and-supporting-mini-brief.pdf
[4] https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf

Table 1: Policies requiring frequent candidate data updates

Organ	Policies describing extensions, downgrades, or certification requirements
Lung	10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old; 10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old; 10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher; 10.2.B.i LRB Review Process; 10.2.B.v LAS Approved by the LRB
Liver, Liver/ Kidney	9.2 Status and Laboratory Values Update Schedule; 9.4.A MELD or PELD Score Exception Requests; 9.4.B NLRB and Committee Review of MELD or PELD Exceptions; 9.6 Specific Standardized MELD or PELD Score Exceptions; 9.9.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older
Heart	6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO); 6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device; 6.1.A.iii Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia; 6.1.B Adult Heart Status 2 Requirements (subsections) ; 6.1.B.i Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD); 6.1.B.ii Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD), or Ventricular Assist Device (VAD) for Single Ventricle Patients; 6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction; 6.1.B.iv Percutaneous Endovascular Mechanical Circulatory Support Device; 6.1.B.v Intra-Aortic Balloon Pump (IABP); 6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF); 6.1.C Adult Heart Status 3 Requirements (subsections); 6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days; 6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring; 6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis; 6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis; 6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure; 6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection; 6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding; 6.1.C.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI); 6.1.C.ix VA ECMO after 7 Days; 6.1.C.x Non-Dischargeable, Surgically Implanted, Non-Endovascular Left Ventricular Assist Device (LVAD) after 14 Days; 6.1.C.xi Percutaneous Endovascular Mechanical Circulatory Support Device after 14 Days; 6.1.C.xii Intra-Aortic Balloon Pump (IABP) after 14 Days; 6.1.D Adult Heart Status 4 Requirements (subsections); 6.1.E Adult Heart Status 5 Requirements; 6.1.F Adult Heart Status 6 Requirements; 6.2.A Pediatric Heart Status 1A Requirements; 6.3 Status Updates; 6.4 Adult and Pediatric Status Exceptions; 6.4.A.i. RRB Appeals; 6.4.A.ii Committee Appeals

This policy is set to expire on March 17, 2021. The OPTN would like input on when is the most appropriate time for regular candidate testing to go back into effect.

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

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

These policy changes suspended the requirements for data collection and submission for the *living donor follow-up* (LDF), *organ specific transplant recipient follow-up* (TRF), and *recipient malignancy* (PTM) forms. The suspension of these requirements is backdated to March 13, 2020, the date the President of the United States declared a national emergency due to COVID-19.[5] These OPTN policy changes did not suspend the requirement to report recipient death or graft failure, but did extend the timeframe for reporting that information for transplant recipients from 14 days to 30 days. This also did not modify the reporting of living donor events such as organ failure or death, as outlined in OPTN *Policy 18.6: Reporting of Living Donor Events*. Follow-up forms will populate in a transplant program's queue as normal, but will automatically be marked in amnesty status if not submitted by the expected date. TRFs and LDFs in "amnesty" status require no further action and are not considered incomplete for the purpose of OPTN data submission requirements, but members are encouraged to access these forms and submit data retrospectively if feasible. "Amnesty" status in this context is limited to only the TRF and LDF forms.

These policy changes are set to expire on December 31, 2020. The OPTN would like to know when is the most appropriate time to no longer automatically grant amnesty status again.

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

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

[5] https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/

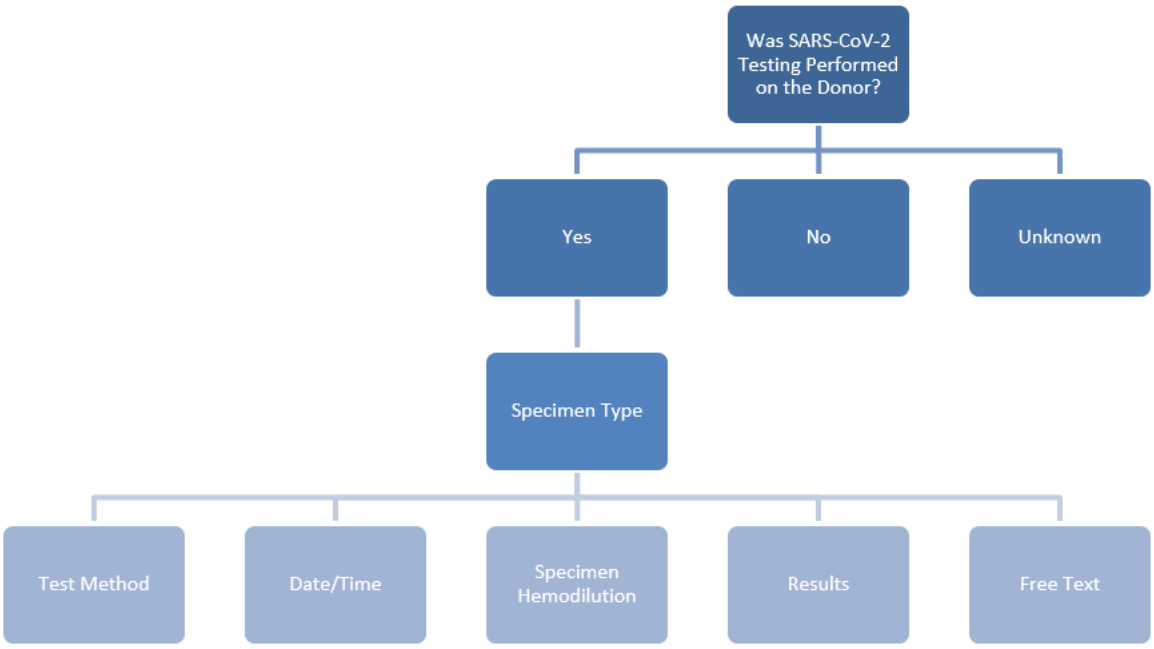
This policy is set to expire on December 31, 2020. The OPTN would like to know when is it most appropriate to require all candidate testing to be complete for registration again.

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

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

These fields were initiated as optional to prevent any unintended consequences such as the interruption of OPO workflow and speed of organ offers. This will allow data to be gathered on testing methods, frequency and results to better inform potential future requirements and needed policy changes, consistent with the OPTN Principles of Data Collection. These data are important when assessing donors to protect patient safety and promote timely organ evaluation. These additional data elements were programmed in a format to allow for flexibility in recording test and specimen types, as more becomes known about COVID-19. *Figure 1* shows the parent question for SARS-CoV-2 testing as well as the subsequent available fields.

Figure 1: COVID-19 Data Field Map



Appendix B shows the utilization of these data fields. It also shows that all deceased donors were tested for COVID-19 between April 21, 2020 and June 30, 2020.

These data fields are set to expire on December 31, 2020. The OPTN would like to know at what time, if any, these data fields should be removed from DonorNet. The OPTN would also like to know if it should become mandatory to enter COVID-19 testing status of the donor prior to OPOs sending out organ offers. Making this field mandatory would not make donor testing for COVID-19 mandatory.

NOTA and Final Rule Analysis

These actions are in accordance with §121.4(2) "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".[6] The CDC has published guidelines on non-COVID related care,[7,8] and the OPTN recognizes that there are different levels of risk in different areas of the country. As such, the emergency policies give providers discretion on risk versus benefit when caring for candidates, living donors, and recipients regarding obtaining some OPTN policy-required testing requirements and follow up. Collecting data on the COVID-19 infectious disease testing results in DonorNet allows the OPTN to ensure it can develop policies for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious disease, and also to determine whether additional lab tests or clinical examinations of potential donors should or must continue to be performed "to determine any contraindications for donor acceptance."[9]

[6] 22 CFR §121.4(2).
[7] https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html
[8] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/immunocompromised.html
[9] 42 C.F.R. §121.6(a).

Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®, is consistent with NOTA, which requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants".[10]

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

- **Are based on sound medical judgment[11]** because they are evidenced-based changes relying on the following:
    - Feedback from 64 transplant hospitals and 27 OPOs[12]
    - 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.
- **Seek to achieve the best use of donated organs[13] 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[14] by** giving similarly situated candidates equitable opportunities to receive an organ offer. These proposals:
    - Prevent the system from lowering a candidate's allocation priority due to inability to obtain updated testing. Thus, candidates who have been appropriately prioritized within a status or score previously will maintain that prioritization until new clinical data can be obtained
    - Allow non-dialysis kidney candidates to accrue waiting time after a qualifying glomerular filtration rate (GFR) or creatinine clearance (CrCl), even if they are unable to complete all labs required for waiting list registration due to COVID-19 exposure risk or strained hospital resources.

[10] 42 C.F.R. §274(b)(2)(I)
[11] 42 CFR §121.8(a)(1).
[12] Appendix A: Transplant Community Request for Feedback Results
[13] 42 CFR §121.8(a)(2).
[14] 42 CFR §121.8(a)(5).

- Have potential to reduce waiting list mortality by decreasing the number of candidates exposed to COVID-19.

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

- **Are designed to avoid wasting organs**[15] by decreasing the number of organs recovered but not transplanted
- **Are designed to avoid futile transplants**[16]**:** This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement**[17] by taking into account factors including the costs and logistics of procuring and transplanting organs
- **Are not based on the candidate's place of residence or place of listing, except to the extent required**.[18]

The Action 1 and Action 3 policy changes also preserve the ability of a transplant program to decline and offer or not use the organ for a potential recipient,[19] and are specific to each organ type.[20]

Implementation Considerations

The OPTN Executive Committee reviews these actions at every meeting, along with monitoring data on their usage by the community. The Executive Committee has so far reviewed these proposals on April 3,[21] April 20,[22] June 7,[23] and July 30, and agreed that the proposals need to remain in place at this time. At the July 30, 2020 meeting the Executive Committee voted to extend the expiration dates of the latter three actions to December 31, 2020 so that they do not expire before the full Board of Directors meeting.

The expiration dates for these policies will be assessed by the OPTN Executive Committee and Board of Directors at every meeting. Any future actions will be based on the state of the COVID-19 crisis and its impact on the transplant community, as evidenced by feedback from the community and regular data monitoring. Feedback received during public comment on whether these proposals should remain in effect, and when they should be removed, will be crucial in OPTN considerations of these actions. A policy notice will be sent to members informing of this change, as well as a systems notice if or when fields are removed from UNet[SM].

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[24] The Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" when discussing the adoption of these procedures on March 17 and April 3, 2020. These policies will not change organ

[15] 42 CFR §121.8(a)(5).
[16] 42 CFR §121.8(a)(5).
[17] 42 CFR §121.8(a)(5).
[18] 42 CFR §121.8(a)(8).
[19] 42 CFR §121.8(a)(3).
[20] 42 CFR §121.8(a)(4).
[21] https://optn.transplant.hrsa.gov/media/3878/optn-executive-committee-meeting-4-03-20.pdf
[22] https://optn.transplant.hrsa.gov/media/3880/20200420-optn-executive-committee-meeting-summary.pdf
[23] https://optn.transplant.hrsa.gov/media/3893/20200607-optn-executive-committee-meeting-summary.pdf
[24] 42 CFR § 121.8(d).

allocation priority, and this will only affect candidates who are potentially disadvantaged due to the public health crisis, so they are not expected to treat any populations less favorably.

Member and OPTN Operations

Operations affecting Transplant Hospitals

The primary intent of these proposals is to increase patient safety for transplant candidates, recipients, and living donors. These proposals are also intended to mitigate data entry demands in a time of increased healthcare need, as well as reduce healthcare requirements for follow up testing in areas of high medical need due to COVID-19. Hospitals should have already educated staff on the use of the COVID-19 testing field and retroactive wait time adjustment applications for non-dialysis kidney candidates. Follow up forms will automatically be marked in amnesty status, so there was no additional effort or education required from hospitals.

Operations affecting Organ Procurement Organizations

Action 4, COVID-19 testing in DonorNet®, added optional data elements. Due to concerns in the community surrounding COVID-19, these data were already being requested by accepting transplant programs. This field was intended to standardize communication for efficiency of organ offers, and to ensure that critical disease testing information about the donor was provided to transplant programs.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Operations affecting the OPTN

Changing data submission requirements and adding a COVID-19 testing field required significant programming effort in UNet℠. Overall, this was a large effort over a short time frame.

Action 3, Modification of Kidney Wait Time for Non-Dialysis Candidates, also requires significant Organ Center effort for wait time adjustments, depending on how widely it is utilized. From April 2019 to April 2020, the Organ Center averaged about 12 waiting time modifications per month across all organs. In May 2020 the Organ Center processed 25 COVID-19-related modifications, out of 43 total modifications.

All of the emergency actions require significant monthly monitoring effort from Research. These reviews will continue as long as the policies are active.

The UNOS Communications department has been distributing notices for system changes due to COVID-19 emergency actions, as well as periodic notices to keep the transplant community up to date on these actions as well as the general community response.

Potential Impact on Select Patient Populations

Relaxing data submission requirements could lead to fewer follow up visits and medical complications not being detected among transplant recipients and living donors. However, as a whole this is anticipated to alleviate exposure risk to COVID-19 for immunocompromised individuals.

Modifying kidney wait time for non-dialysis candidates is also intended to ensure that medically vulnerable patients and patients with limited healthcare access due to location or socioeconomic status can accrue wait time while unable to finish testing required for transplant candidate registration, as well as ensure that these candidates maintain waiting list status if they are unable to get updated labs for the same reasons as above. In addition, it is intended to reduce risk of exposure to COVID-19 for these individuals.

Post-implementation Monitoring

Member Compliance

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

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program." [25] For retrospective site survey reviews of candidate data that are used to maintain a candidate's prioritization or eligibility reported during the 2020 COVID-19 emergency:

- Site surveyors will continue to verify that candidate data entered in UNet℠ is consistent with documentation in the candidate's medical record.
- If a surveyor is unable to locate documentation in the medical record that corroborates the collection date entered in UNet, the surveyor will look for documentation that the transplant program exercised authority under Policy 1.4.F to re-report the candidate's most recently reported data on that date as the "collection date."

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

Follow-up forms due between March 13, 2020 and December 31, 2020 will be excluded from routine compliance monitoring of data accuracy and data submission according to *Policy 18.1 Data Submission Requirements*, *Policy 18.2 Timely Collection of Data*, and *Policy 18.5 Living Donor Data Submission Requirements*.

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

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program." [26] The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet℠ may be reviewed by the OPTN, and members are required to provide documentation as requested.

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

As this field is not required, it will not be routinely monitored. Any data entered in UNet℠ may be reviewed by the OPTN, and members are required to provide documentation as requested.

[25] 42 CFR §121.8(a)(7).
[26] 42 CFR §121.8(a)(7).

Policy Evaluation

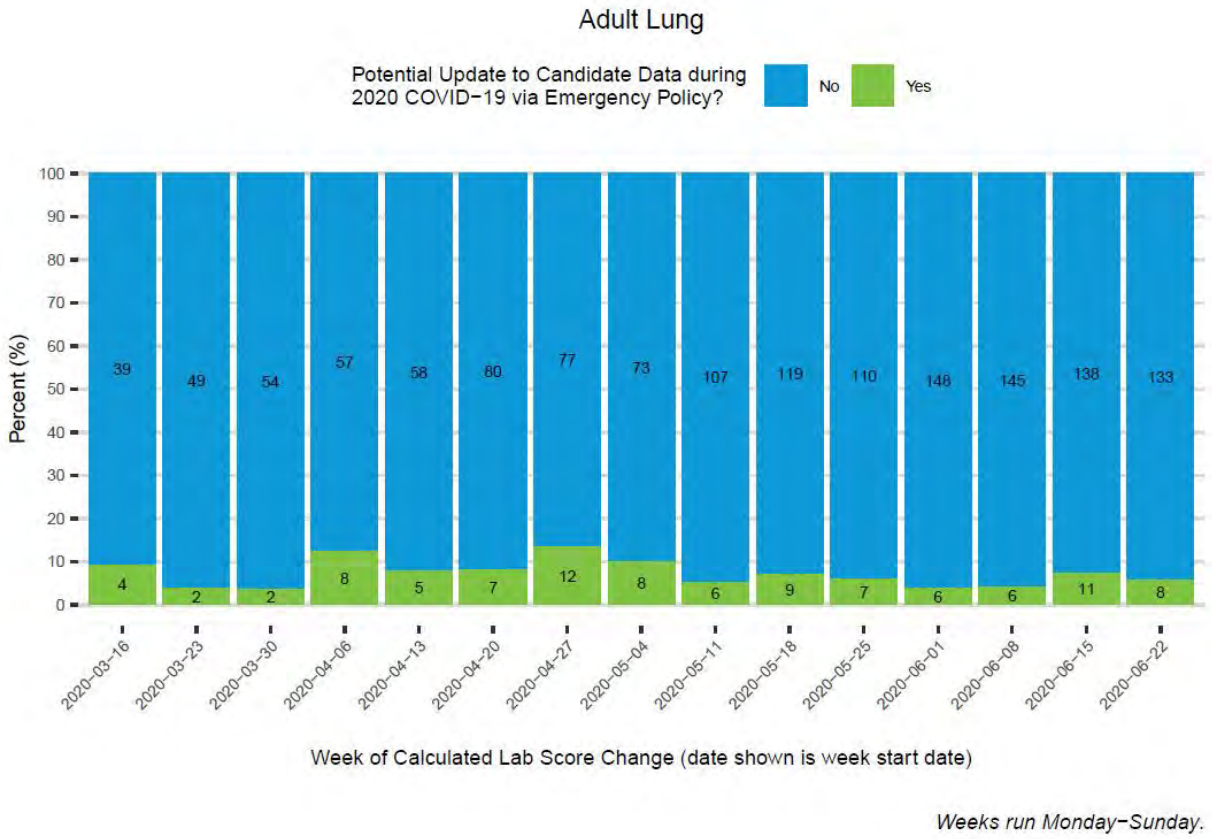
These policies are being and will continue to be reviewed on a monthly basis by UNOS Research for utilization. The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[27] Appendix A contains a monitoring report on updates to candidate data, data submission for follow-up forms, and modifications to wait time for non-dialysis kidney candidates. Appendix B contains a monitoring report on COVID-19 infectious disease monitoring in UNet[SM]. Both appendices contain the methods for monitoring the use of these emergency actions.

The level of utilization of these policies is not necessarily an indicator of whether or not they are effective, as the impacts of COVID-19 are variable across the country and over time.

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

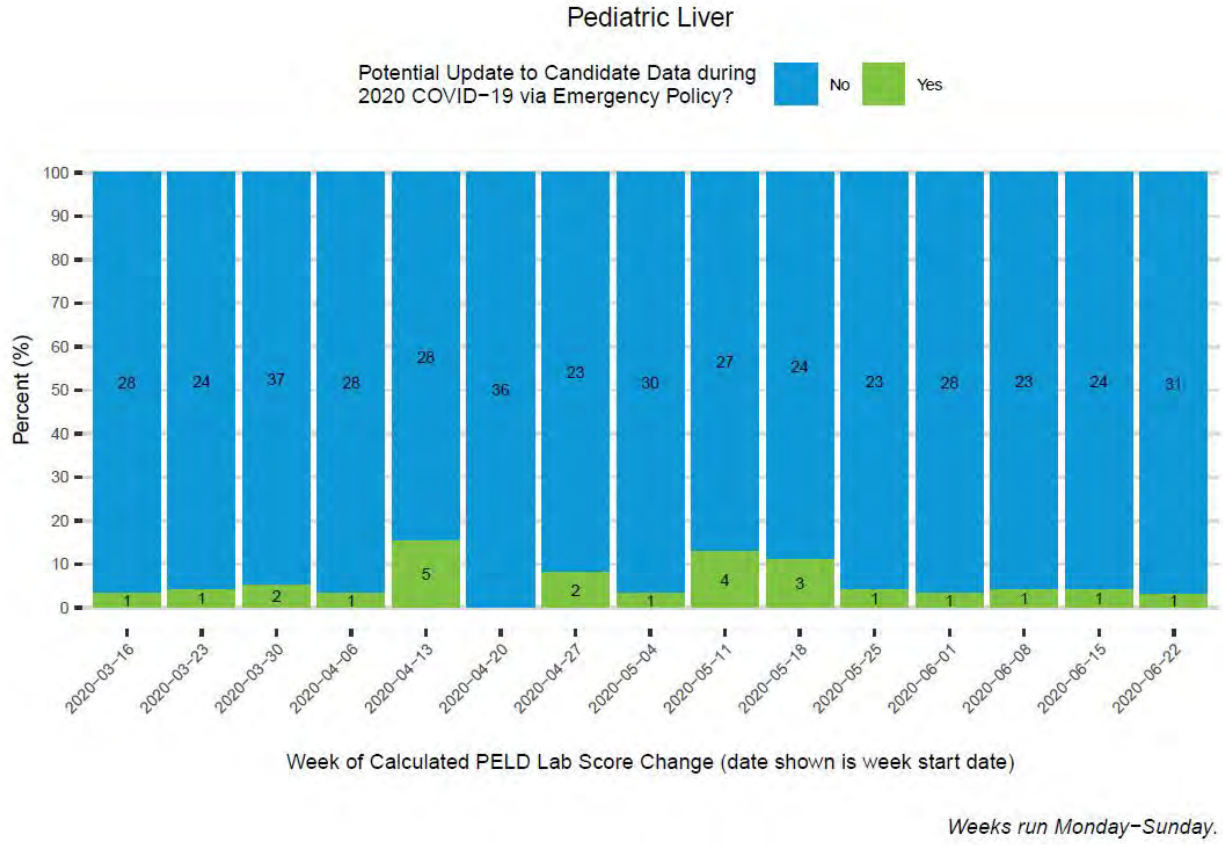
Action 1 was most utilized in adult lung and pediatric liver candidates. Figure 1 shows the utilization over time by adult lung candidates, and Figure 2 shows the utilization over time for pediatric liver candidates.

Figure 1: Emergency Action 1 Utilization in Adult Lung Candidates



[27] 42 CFR §121.8(a)(6).

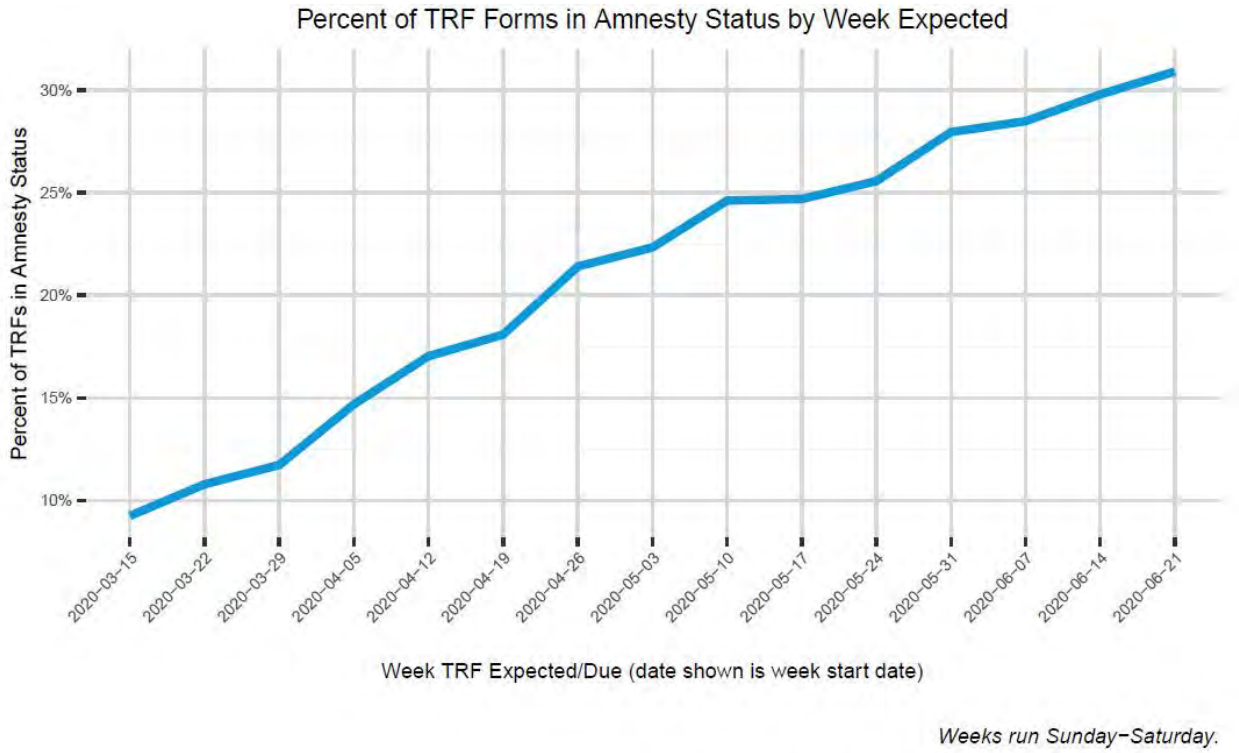
Figure 2: Emergency Action 1 Utilization in Pediatric Liver Candidates



There was only one adult heart candidate who potentially utilized this policy, and a more comprehensive data report on the utilization of this policy by various candidate populations can be found in Appendix A. This policy was only intended for use when hospitals cannot safely or logistically obtain updated labs on candidates, and with a relatively low utilization across organ types it seems likely that it is being used as intended.

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

The percentage of follow-up forms by week expected has steadily increased over time. Below is a graph of TRF forms in amnesty status by week expected. Over 30% of TRF forms were not validated and switched into amnesty status the week of June 21, 2020. A more complete breakdown, including TRF and LDF forms in amnesty status by region and by organ, is available in Appendix A.



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

Action 3 has been utilized by 48 candidates as of June 30th. The proportion of non-dialysis kidney alone candidates registered has remained fairly stable. A full breakdown of kidney alone registrations between The week of January 6, 2020 and June 22, 2020 can be found in Appendix A. There could be an increase in waiting time modifications once healthcare conditions normalize, but there appears to be a

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

All deceased donors between April 21, 2020 and June 30, 2020 were tested for COVID-19. In total, the data fields have been utilized in 71.9% of deceased donors. Other methods of communication via DonorNet® included indicating testing in free text fields or attached testing results. A more complete breakdown by week and method of reporting can be found in Appendix B.

Conclusion

This public comment consists of four proposals that were approved as emergency actions:

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

Each of these proposals is intended to address a specific concern of the transplant community pertaining to operational effects of the COVID-19 emergency. The OPTN is seeking the following feedback on these proposals, for relevance and to gauge current and future need of the transplant community.

- Were the Executive Committee's actions appropriate in the emergency?
- 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?
- Should COVID-19 infectious disease testing remain in DonorNet?
- Should the COVID-19 infectious disease data fields become mandatory in DonorNet?
- Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies?
- Are there other things the OPTN should have done, or can still do, to respond to the COVID-19 crisis?
- Is the emergency policy process utilized by the OPTN the most appropriate way to respond to an emerging health crisis?
- Additional feedback and recommendations are appreciated.

Appendix A: COVID-19 Emergency Actions Monitoring Methods

Data Source

OPTN data analyzed are as of July 1, 2020 and subject to change based on future data submission or correction.

Methods and Cohort:

Updates to Candidate Data during 2020 COVID-19 Emergency

Adult (age 12 and older) Liver:

The following database fields that have associated dates are required reporting for the re-certification and calculation of MELD labs for candidates age 12 and older: Serum Creatinine, had dialysis twice (24 hours of CVVHD within a week prior to the Serum Creatinine test), Serum Sodium, Bilirubin or Bilirubin (PBC/PSC/Other Cholestatic), and INR.

All instances of a modification to the labs or their corresponding dates, for waiting list registrations of liver candidates age 12 and older since implementation of the policy on March 17, 2020 at 7pm EST, were reviewed.

Waiting list registrations were flagged as potential users of this policy based on the following (with the exception of the dialysis field since the OPTN does not collect a date for this):

- The change date for the calculated MELD lab score is on or after March 17, 2020 at 7pm EST, and
- The change date for the calculated MELD lab score is different than the prior entry, and
- The dates for all required labs for the calculated MELD lab score have changed, and
- None of the values for the required labs have changed.

Pediatric (age 11 and younger) Liver:

The following database fields that have associated dates are required reporting for the re-certification and calculation of PELD labs for candidates age 11 and younger: Albumin, Bilirubin or Bilirubin (PBC/PSC/Other Cholestatic), and INR.

All instances of a modification to the labs or their corresponding dates, for waiting list registrations of liver candidates age 11 and younger since implementation of the policy on March 17, 2020 at 7pm EST, were reviewed.

Waiting list registrations were flagged as potential users of this policy based on the following (with the exception of the dialysis field since the OPTN does not collect a date for this):

- The change date for the calculated PELD lab score is on or after March 17, 2020 at 7pm EST, and
- The change date for the calculated PELD lab score is different than the prior entry, and
- The dates for all required labs for the calculated PELD lab score have changed, and
- The values for none of the required labs have changed.

Adult/Adolescent (age 12 and older) Lung:

The following groups of database fields that have associated dates are required reporting for the recertification and calculation of LAS labs for candidates age 12 and older: CVP (central venous pressure), Hgb/Hct Test, Pulmonary.

Function Testing Results (including FVC and FEV data), Bilirubin and Creatinine, Blood Gas information (including pH, pCO2, and PO2), and Heart Catheterization results (including Pulmonary Artery Systolic/Diastolic Pressures, Mean Pulmonary Artery Pressure, Cardiac Output, and Cardiac Index).

All instances of a modification to the labs in each section or their corresponding dates, for waiting list registrations of lung candidates age 12 and older since implementation of the policy on March 17, 2020 at 7pm EST, were reviewed. Waiting list registrations were flagged as potential users of this policy if the following occurred in any one of the groups of testing results:

- The date of modification to the LAS elements is on or after March 17, 2020 at 7pm EST, and
- The given lab date for one of the group of elements is different than the prior entry and the same as the date of the modification, and
- The values for all the elements in the corresponding group have not changed from the prior entry.

Pediatric (age 11 and younger) Lung:

The following groups of database fields that have associated dates are required reporting for the recertification and calculation of pediatric Priority 1 Status for candidates age 11 and younger: Blood Gas information (including pH, pCO2, and PO2) and Heart Catheterization results (including Pulmonary Artery Systolic/Diastolic Pressures, Mean Pulmonary Artery Pressure, Cardiac Output, and Cardiac Index).

All instances of a modification to the labs in each section or their corresponding dates, for waiting list registrations of lung candidates age 11 and younger in pediatric Priority Status 1 since implementation of the policy on March 17, 2020 at 7pm EST, were reviewed. Waiting list registrations were flagged as potential users of this policy if the following occurred in any one of the groups of testing results:

- The date of modification to the elements used in determination of Priority 1 status is on or after March 17, 2020 at 7pm EST, and
- The given lab date for one of the group of elements is different than the prior entry, and
- The values for all the elements in the corresponding group have not changed from the prior entry.

Adult (age 18 and older) Heart:

The following groups of database fields that have associated dates are required reporting for the recertification of heart statuses for candidates age 18 and older:

- Status 1: Criteria 1 (hemodynamics, without hemodynamics), or
- Status 2: Criteria 1 (MAP and CI and PCW and SvO2) or Criteria 4 (hemodynamics, without hemodynamics) or Criteria 5 (hemodynamics, without hemodynamics), or
- Status 3: Criteria 2 (CI and PCW and SBP) or Criteria 5 (Therapies A and/or B), or
- Status 4: Criteria 2 (CI and PCW), or

- Statuses 5 and 6 do not have labs that require accompanying dates entries: Criteria 1 (hemodynamics, without hemodynamics).

All instances of a modification to the required labs or their corresponding dates, for waiting list registrations of heart candidates age 18 and older since implementation of the policy on March 17, 2020 at 7pm EST, were reviewed. Waiting list registrations were flagged as potential users of this policy based on the following:

- The change date for the adult heart justification form is on or after March 17, 2020 at 7pm EST, and
- The adult heart justification form is to qualify the candidate for the same status as the previously submitted form (but can be for different criteria within the same status), and
- The change date for the adult heart justification form is different than the date for the previous justification form, and
- The values for all the labs within criteria that were required on the previous adult heart justification form have not changed.

Only candidates remaining in the same status were considered; justification forms to move from one status to another were not tabulated.

Modifications to wait time initiation for non-dialysis kidney candidates

Adult kidney/kidney-pancreas registrations added to waiting list that indicate no dialysis but have a CrCl/GFR of <= 20 when added to the waiting list (i.e. at listing) from January 6, 2020 to present. Dialysis indication was based on data reported to the OPTN only.

Waiting time modification forms submitted to the UNOS Organ Center were counted for each month based on submission date, and the percentage of COVID-19 specific requests out of all requests was computed.

Relax data submission requirements

All TRF (transplant recipient follow-up), LDF (living donor follow-up), and PTM (post-transplant malignancy) forms due/expected between January 5, 2020 and present were compiled. Data around the percent of forms in an amnesty status is limited to those forms with a due date/expected date on or after March 15, 2020, the week in which the policy change occurred. Reporting of graft failures and patient deaths on TRF forms were compiled based on the date the form was validated since it can be from the original standard follow-up form. Data were stratified by form validation type, organ type, OPTN Region of responsible transplant program, and week form due. Reports of recipient graft failure and death were also displayed by week form validated and the median days from event (graft failure or patient death) to form validation to assess the impact of lengthening the requirement for reporting of these events from 14 to 30 days.

Results

Updates to Candidate Data During 2020 COVID-19 Emergency

The following sets of graphics and tables shows the number and percent of candidates that appear to use the emergency policy, allowing them to carry labs forward to maintain their wait list status. In general, there appears to be low usage of this policy across all organs/age groups examined. The data presented are the maximum count we can identify, but it's possible that candidates may have had their labs redone and returned the same values, which the OPTN cannot identify.

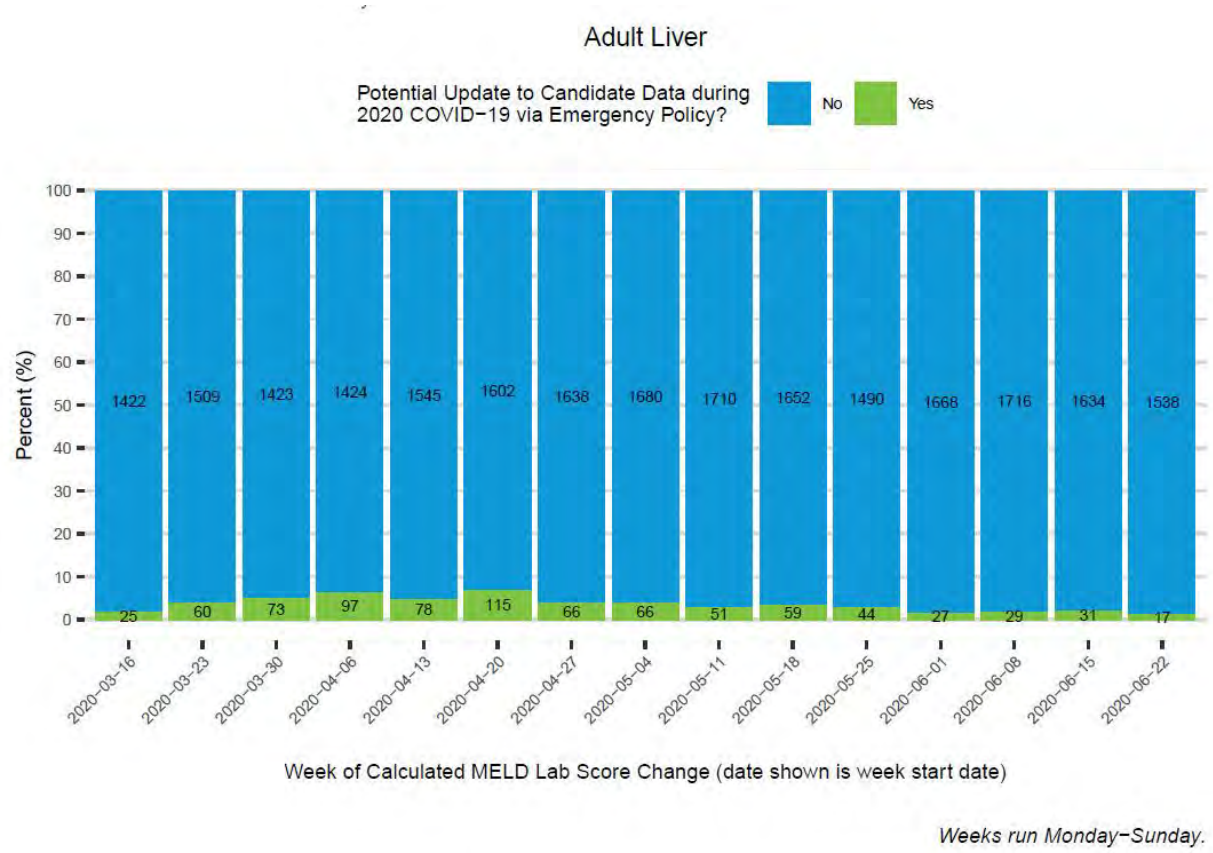
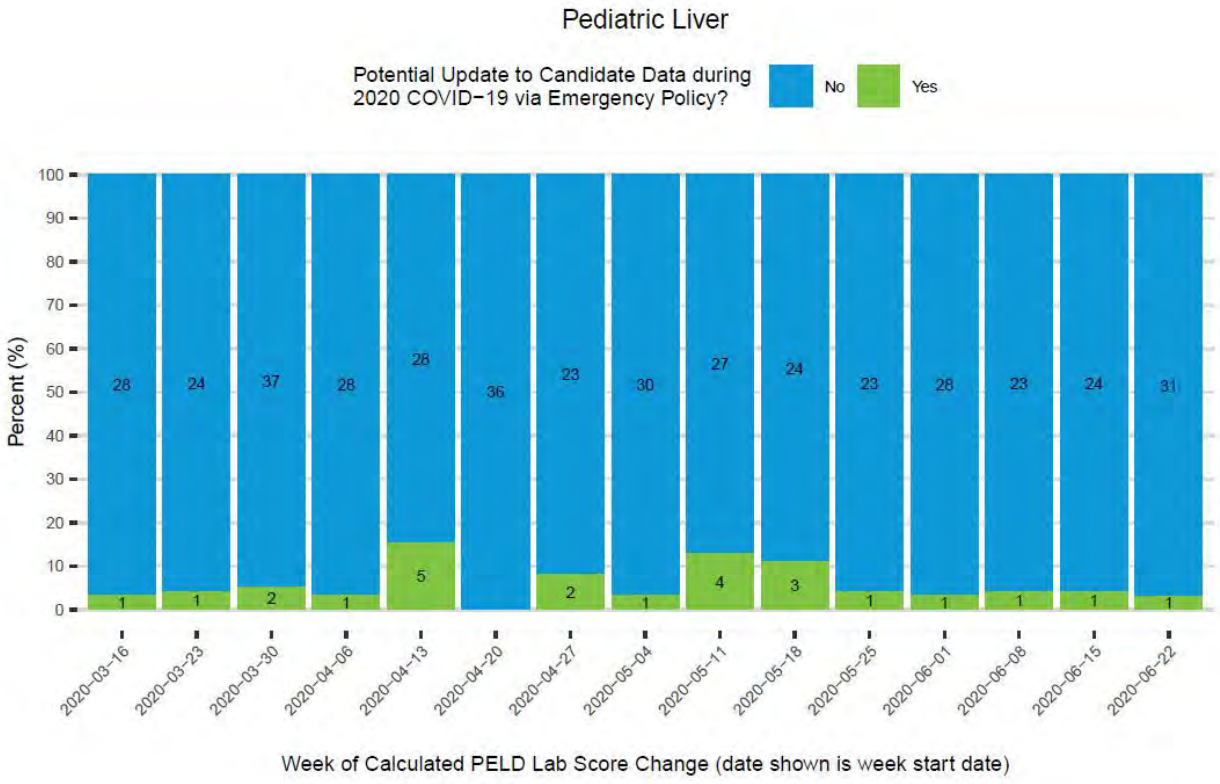


Table 1: Adult Liver Candidate Labs

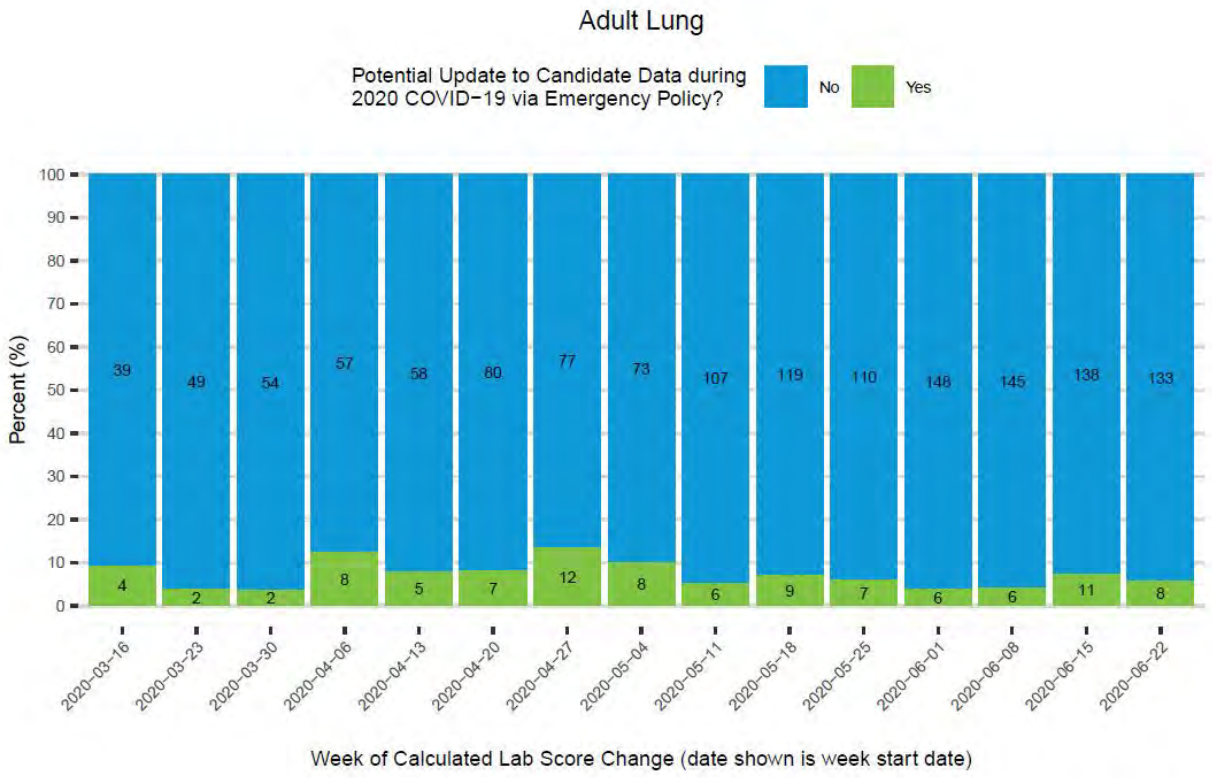
	Potential Emergency Policy for Calculated Lab MELD	
Week (start)	No	Yes
2020-03-16	1422 (98%)	25 (2%)
2020-03-23	1509 (96%)	60 (4%)
2020-03-30	1423 (95%)	73 (5%)
2020-04-06	1424 (94%)	97 (6%)
2020-04-13	1545 (95%)	78 (5%)
2020-04-20	1602 (93%)	115 (7%)
2020-04-27	1638 (96%)	66 (4%)
2020-05-04	1680 (96%)	66 (4%)
2020-05-11	1710 (97%)	51 (3%)
2020-05-18	1652 (97%)	59 (3%)
2020-05-25	1490 (97%)	44 (3%)
2020-06-01	1668 (98%)	27 (2%)
2020-06-08	1716 (98%)	29 (2%)
2020-06-15	1634 (98%)	31 (2%)
2020-06-22	1538 (99%)	17 (1%)



Weeks run Monday−Sunday.

Table 2: Pediatric Liver Candidate Labs

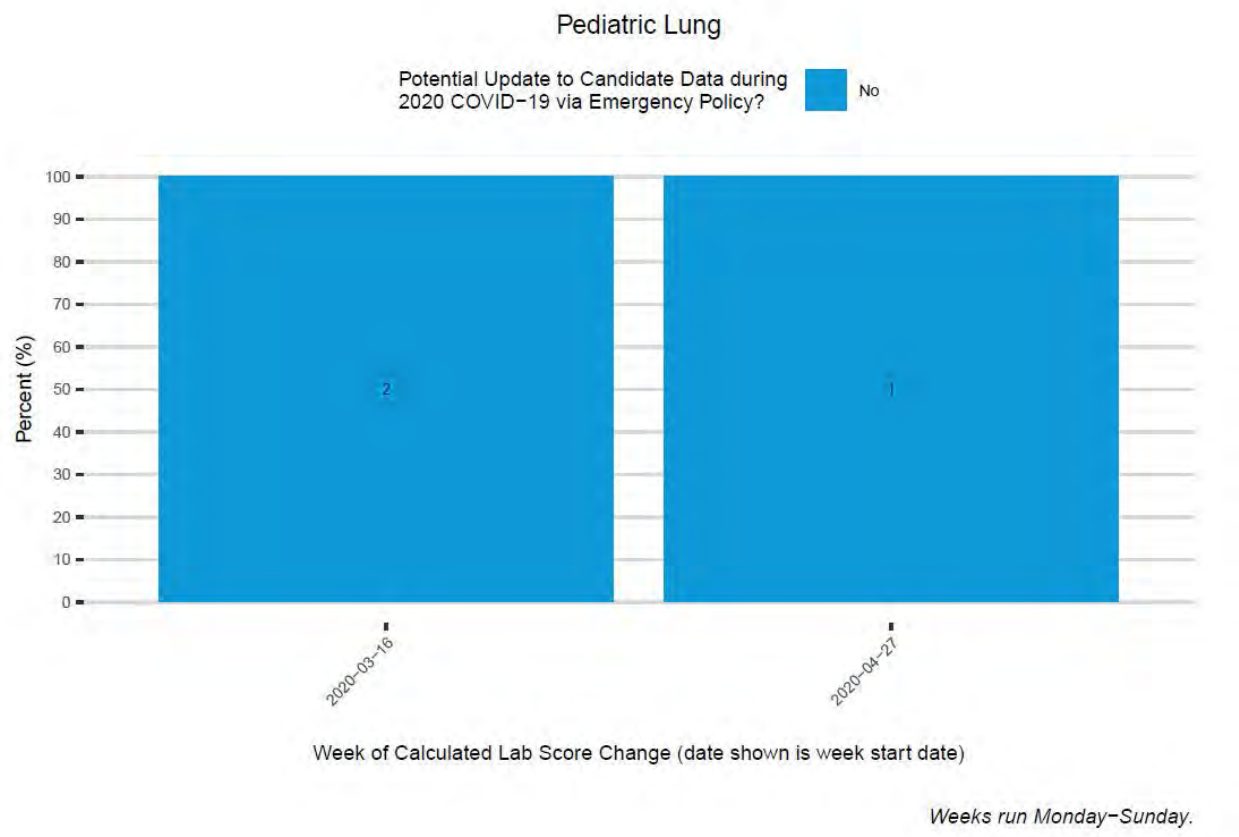
	Potential Emergency Policy for Calculated Lab PELD	
Week (start)	No	Yes
2020-03-16	28 (97%)	1 (3%)
2020-03-23	24 (96%)	1 (4%)
2020-03-30	37 (95%)	2 (5%)
2020-04-06	28 (97%)	1 (3%)
2020-04-13	28 (85%)	5 (15%)
2020-04-20	36 (100%)	0 (0%)
2020-04-27	23 (92%)	2 (8%)
2020-05-04	30 (97%)	1 (3%)
2020-05-11	27 (87%)	4 (13%)
2020-05-18	24 (89%)	3 (11%)
2020-05-25	23 (96%)	1 (4%)
2020-06-01	28 (97%)	1 (3%)
2020-06-08	23 (96%)	1 (4%)
2020-06-15	24 (96%)	1 (4%)
2020-06-22	31 (97%)	1 (3%)



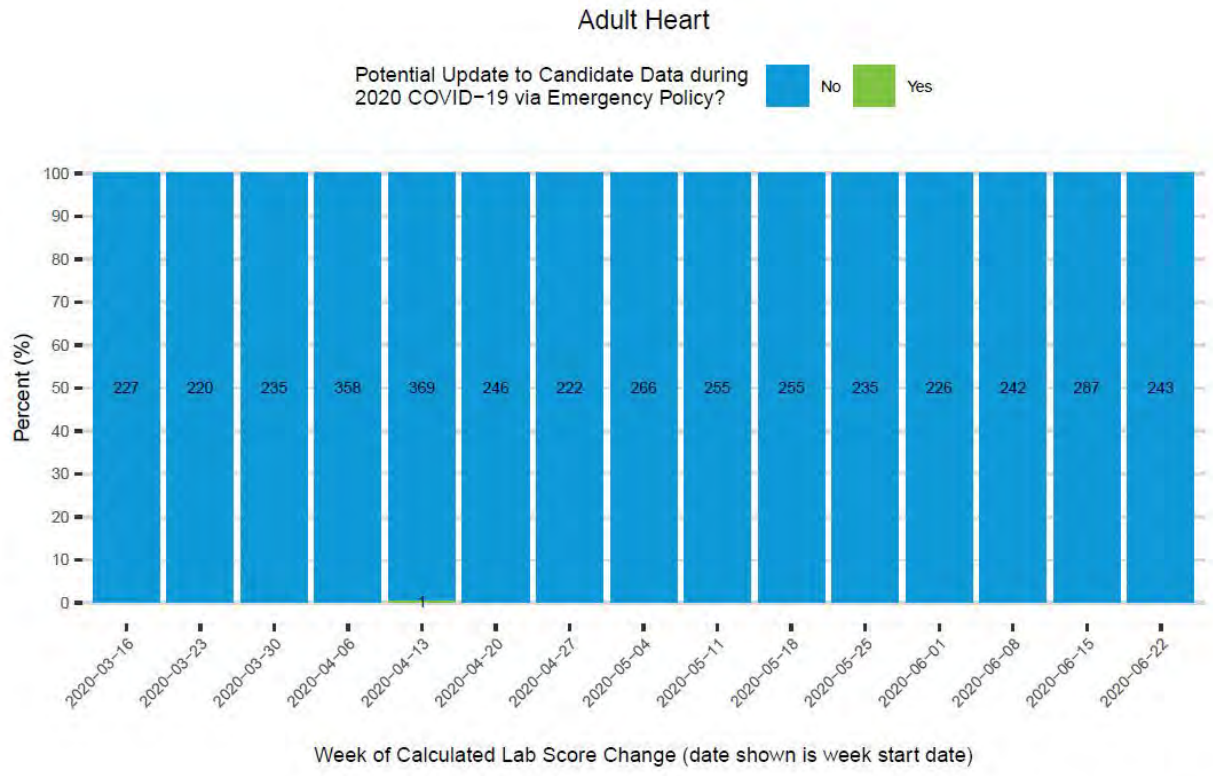
Weeks run Monday−Sunday.

Table 3: Adult Lung Candidate Labs

	Potential Emergency Policy for Calculated Labs	
Week (start)	No	Yes
2020-03-16	39 (91%)	4 (9%)
2020-03-23	49 (96%)	2 (4%)
2020-03-30	54 (96%)	2 (4%)
2020-04-06	57 (88%)	8 (12%)
2020-04-13	58 (92%)	5 (8%)
2020-04-20	80 (92%)	7 (8%)
2020-04-27	77 (87%)	12 (13%)
2020-05-04	73 (90%)	8 (10%)
2020-05-11	107 (95%)	6 (5%)
2020-05-18	119 (93%)	9 (7%)
2020-05-25	110 (94%)	7 (6%)
2020-06-01	148 (96%)	6 (4%)
2020-06-08	145 (96%)	6 (4%)
2020-06-15	138 (93%)	11 (7%)
2020-06-22	133 (94%)	8 (6%)



No table is provided for pediatric lung due to small sample size.



Weeks run Monday−Sunday.

Table 4: Adult Heart Candidate Labs

	Potential Emergency Policy for Calculated Labs	
Week (start)	No	Yes
2020-03-16	227 (100%)	0 (0%)
2020-03-23	220 (100%)	0 (0%)
2020-03-30	235 (100%)	0 (0%)
2020-04-06	358 (100%)	0 (0%)
2020-04-13	369 (100%)	1 (0%)
2020-04-20	246 (100%)	0 (0%)
2020-04-27	222 (100%)	0 (0%)
2020-05-04	266 (100%)	0 (0%)
2020-05-11	255 (100%)	0 (0%)
2020-05-18	255 (100%)	0 (0%)
2020-05-25	235 (100%)	0 (0%)
2020-06-01	226 (100%)	0 (0%)
2020-06-08	242 (100%)	0 (0%)
2020-06-15	287 (100%)	0 (0%)
2020-06-22	243 (100%)	0 (0%)

Modifications to Wait Time Initiation for Non-Dialysis Kidney Candidates

The next set of graphics and tables show the number of adult (18+) kidney alone registrations. The proportion of candidates that were non-dialysis (i.e. qualified for waiting time through eGFR or Creatinine Clearance thresholds) remained stable.

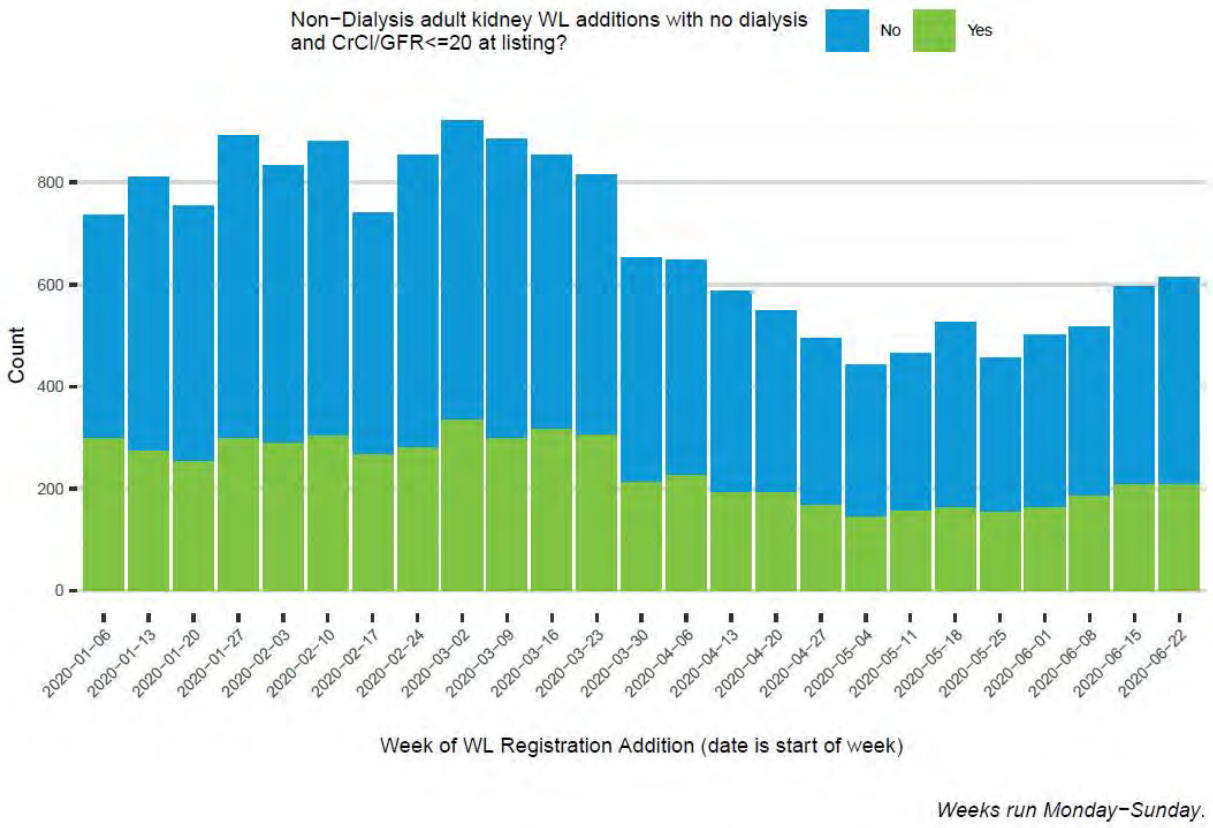
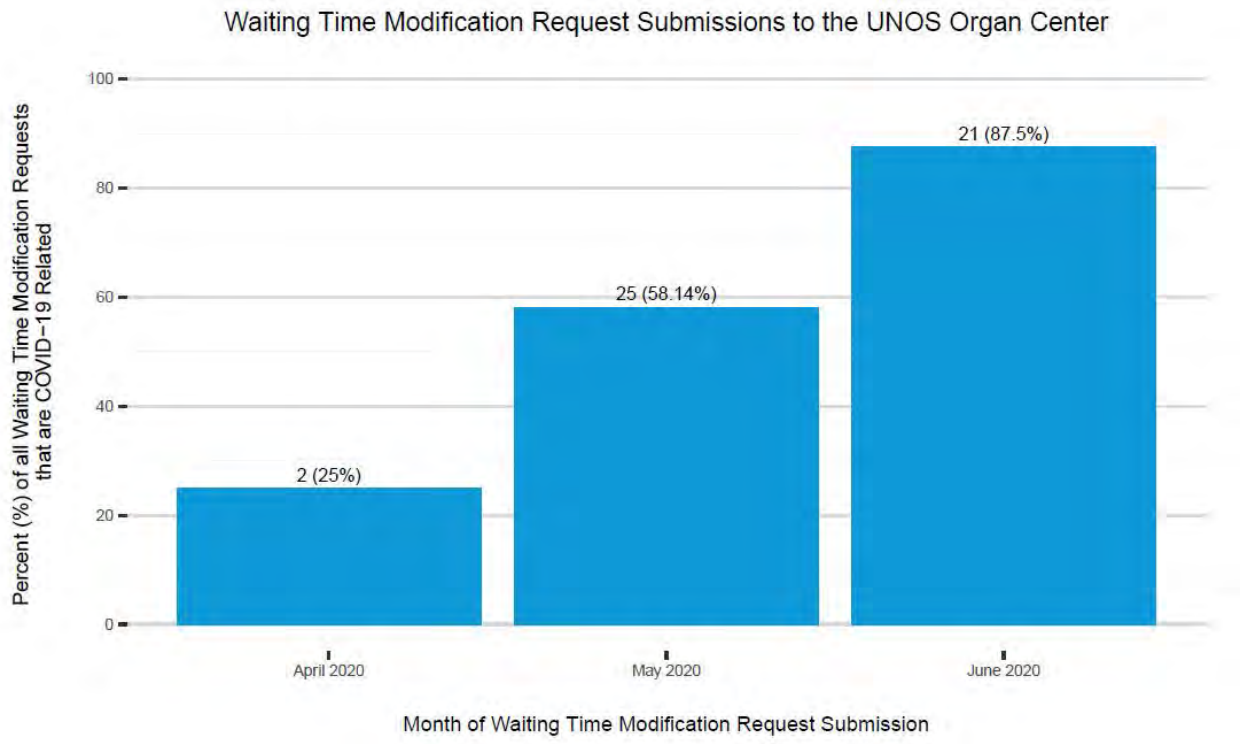


Table 5: Non-Dialysis Adult Kidney WL Additions

	Non-Dialysis adult kidney WL additions with no dialysis and CrCl/GFR<=20 at listing?	
Week (start)	No	Yes
2020-01-06	440 (59.7%)	297 (40.3%)
2020-01-13	537 (66.3%)	273 (33.7%)
2020-01-20	502 (66.6%)	252 (33.4%)
2020-01-27	596 (66.7%)	297 (33.3%)
2020-02-03	544 (65.2%)	290 (34.8%)
2020-02-10	579 (65.7%)	302 (34.3%)
2020-02-17	474 (64%)	267 (36%)
2020-02-24	575 (67.3%)	279 (32.7%)
2020-03-02	587 (63.7%)	335 (36.3%)
2020-03-09	587 (66.3%)	298 (33.7%)
2020-03-16	537 (62.9%)	317 (37.1%)
2020-03-23	511 (62.7%)	304 (37.3%)
2020-03-30	440 (67.4%)	213 (32.6%)
2020-04-06	423 (65.3%)	225 (34.7%)
2020-04-13	396 (67.3%)	192 (32.7%)
2020-04-20	357 (65%)	192 (35%)
2020-04-27	327 (66.2%)	167 (33.8%)
2020-05-04	298 (67.4%)	144 (32.6%)
2020-05-11	311 (66.7%)	155 (33.3%)
2020-05-18	364 (69.2%)	162 (30.8%)
2020-05-25	304 (66.5%)	153 (33.5%)
2020-06-01	339 (67.7%)	162 (32.3%)
2020-06-08	332 (64.2%)	185 (35.8%)
2020-06-15	388 (65.1%)	208 (34.9%)
2020-06-22	408 (66.3%)	207 (33.7%)

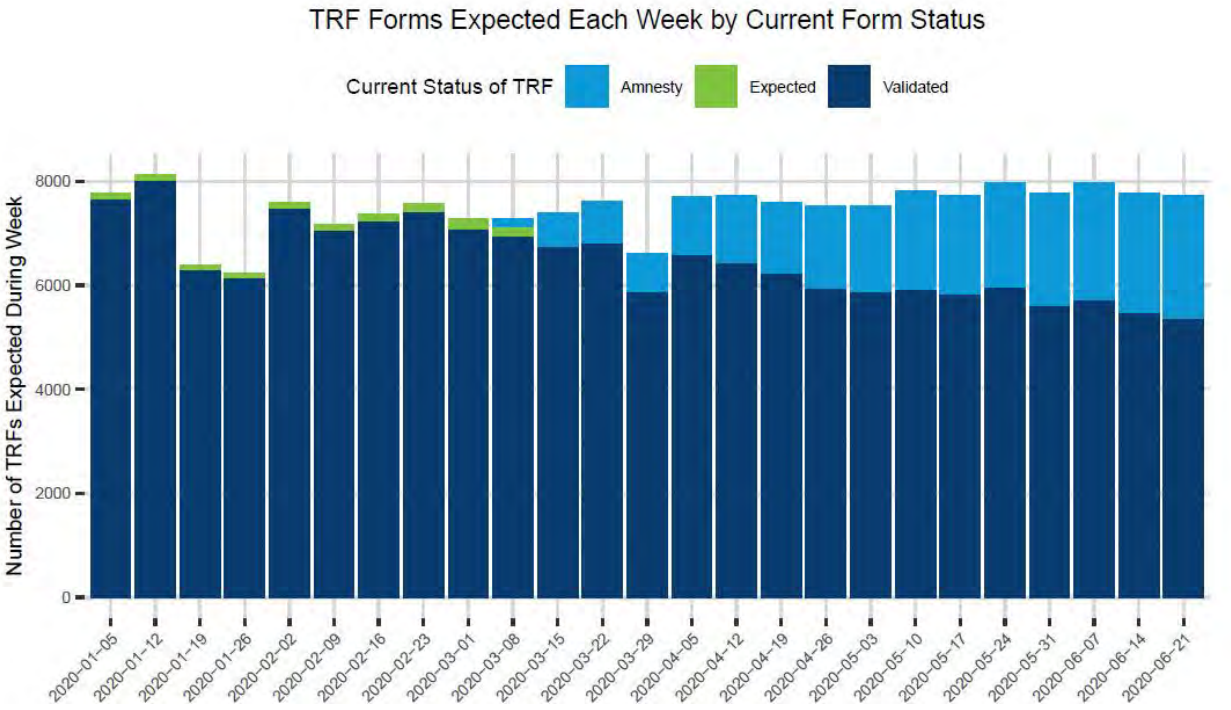
The next graphic shows the number and percent of waiting time modification request forms submitted by month to the UNOS Organ Center that were related to COVID-19, meaning the candidate could be ready for registration during COVID-19 but unable to begin accruing waiting time per OPTN *Policy 8.4: Waiting Time* if they weren't able to obtain other testing required for registration during this time.

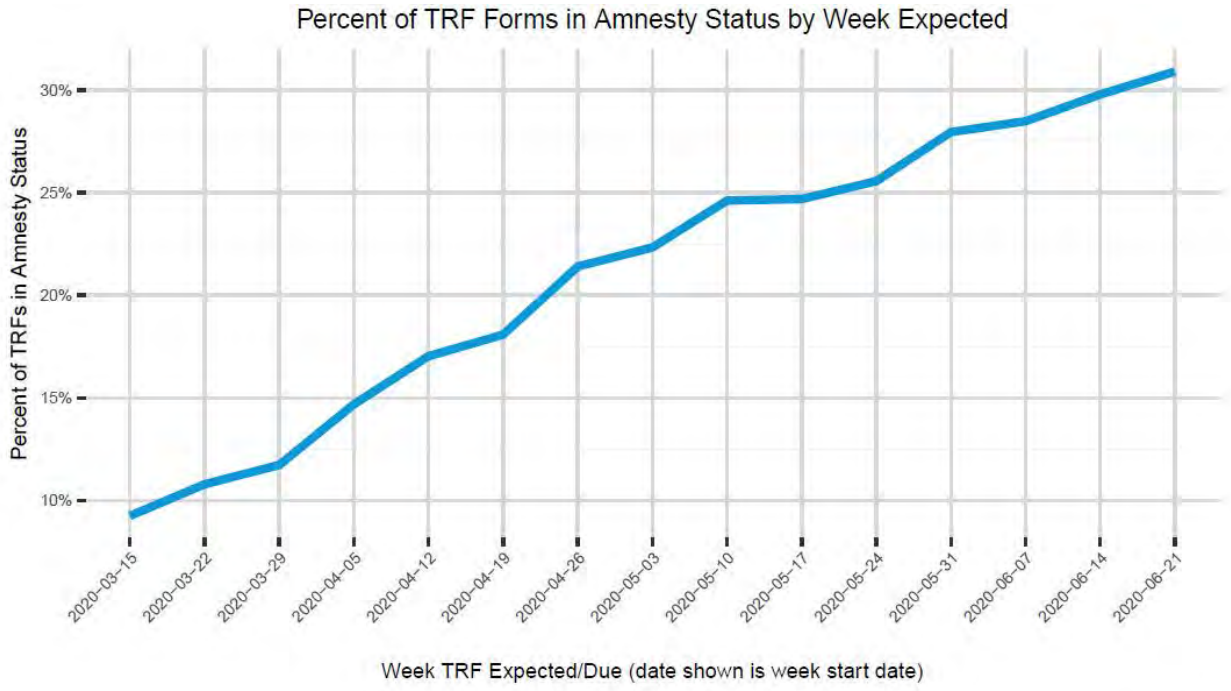


Relax Data Submission Requirements

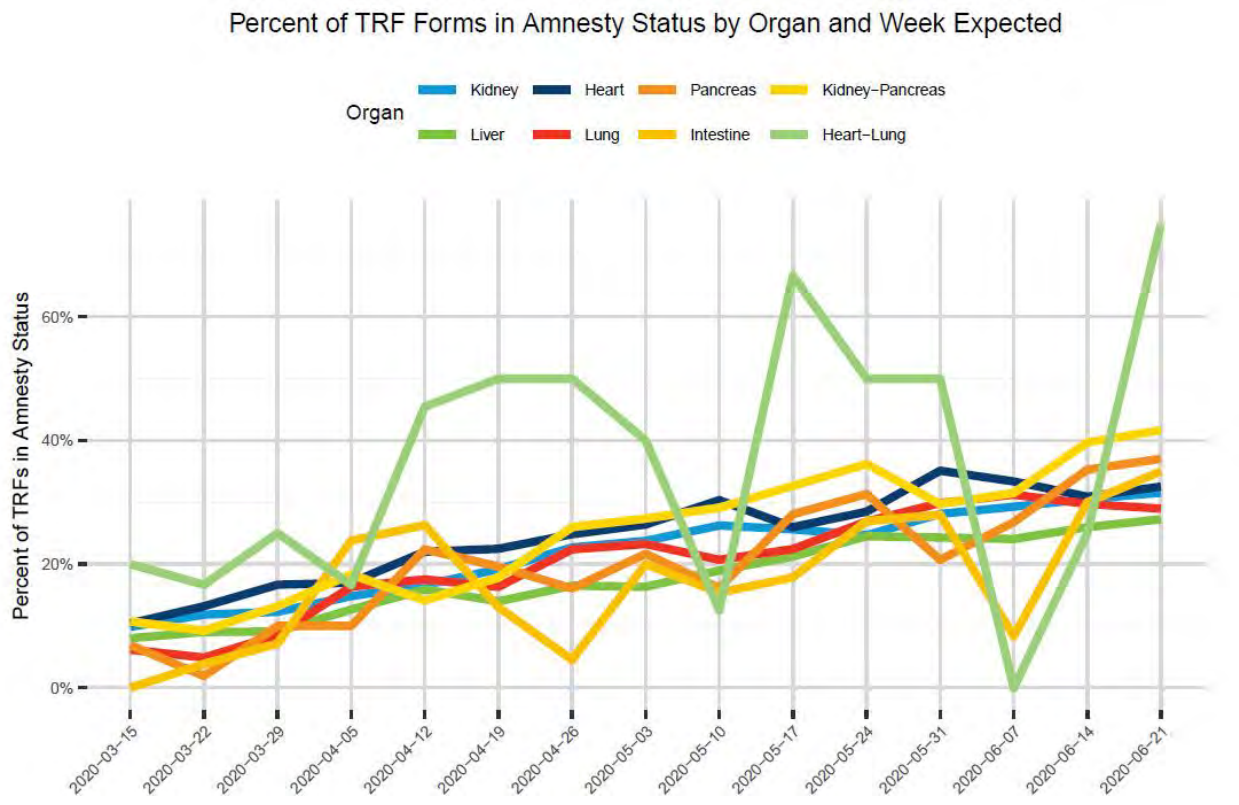
For any form with an expected due date between March 13, 2020 and December 31, 2020, the form will automatically switch into amnesty status if not validated by the due date.

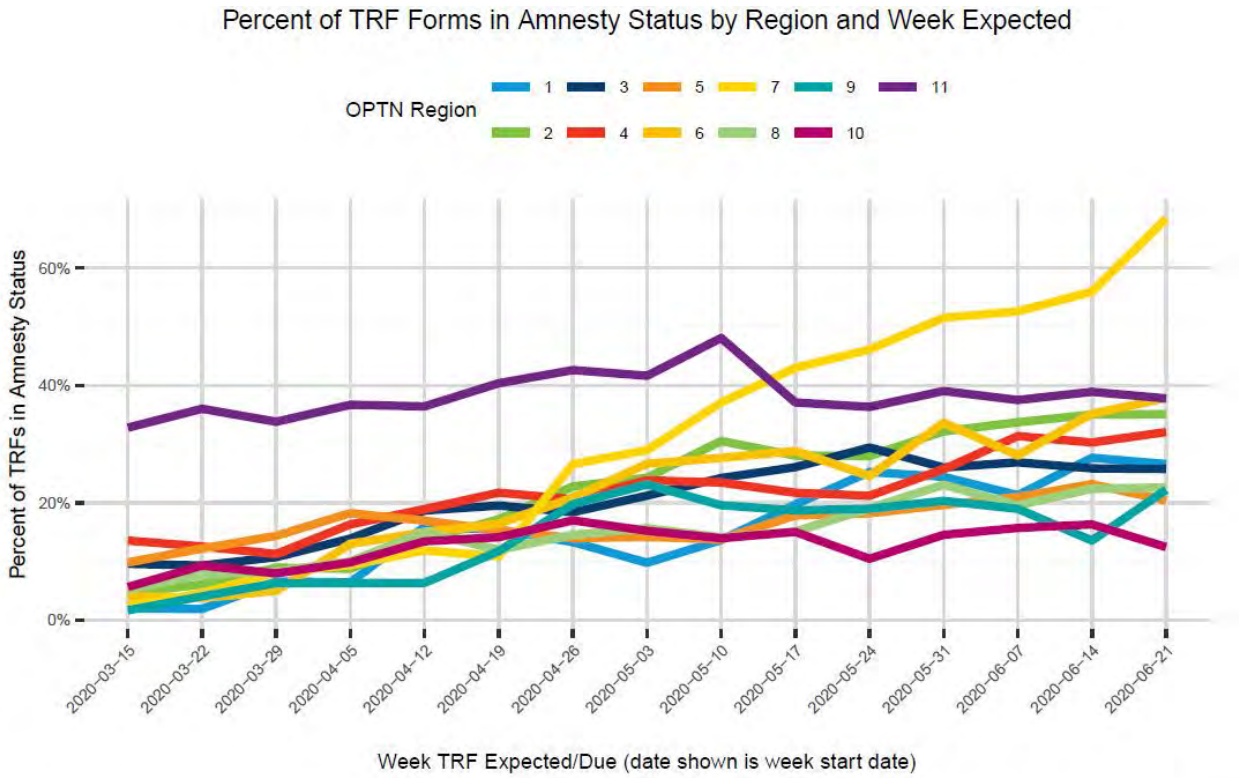
The following set of graphics show the number and percent of transplant recipient follow-up (TRF) forms in amnesty status by week, OPTN region, and organ. The number of forms with expected dates that move into amnesty status is increasing over time since policy implementation.





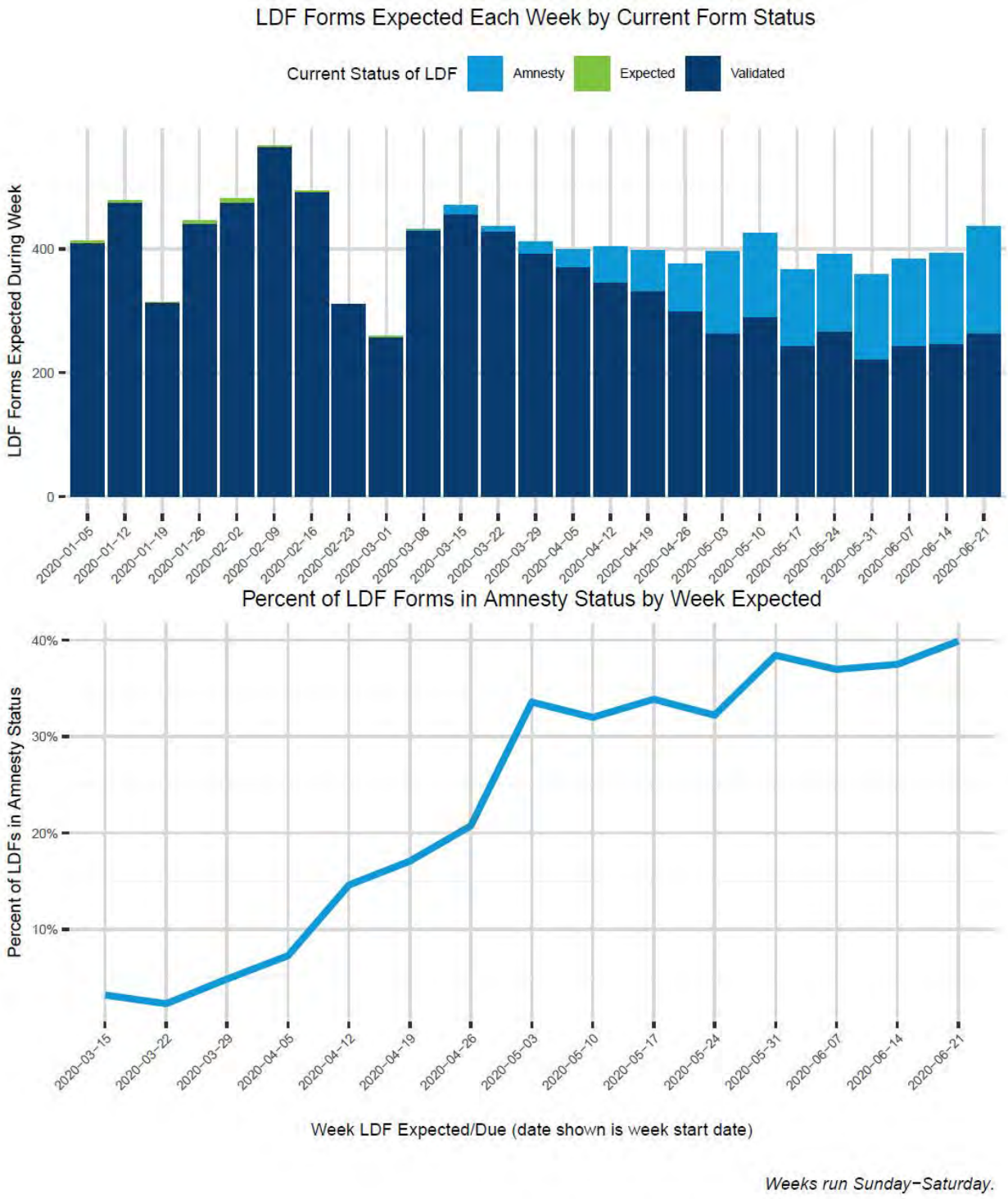
Weeks run Sunday–Saturday.

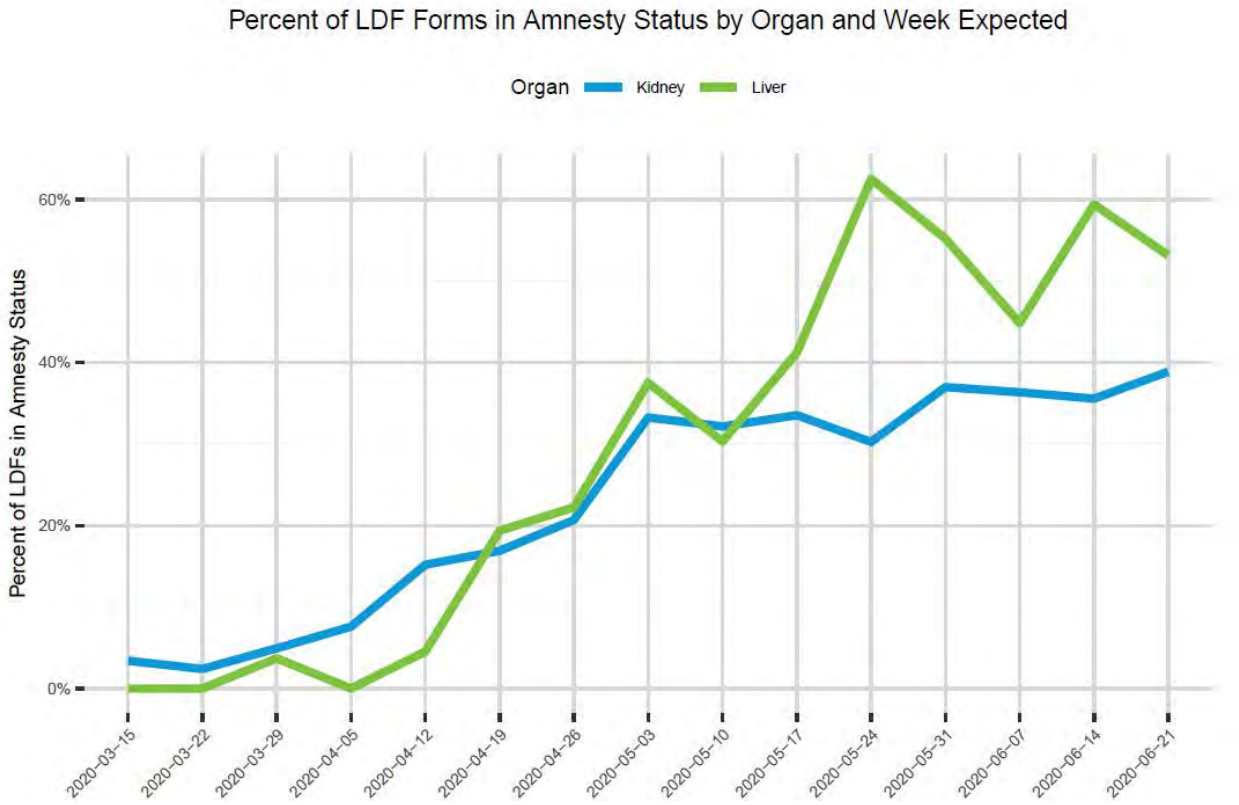


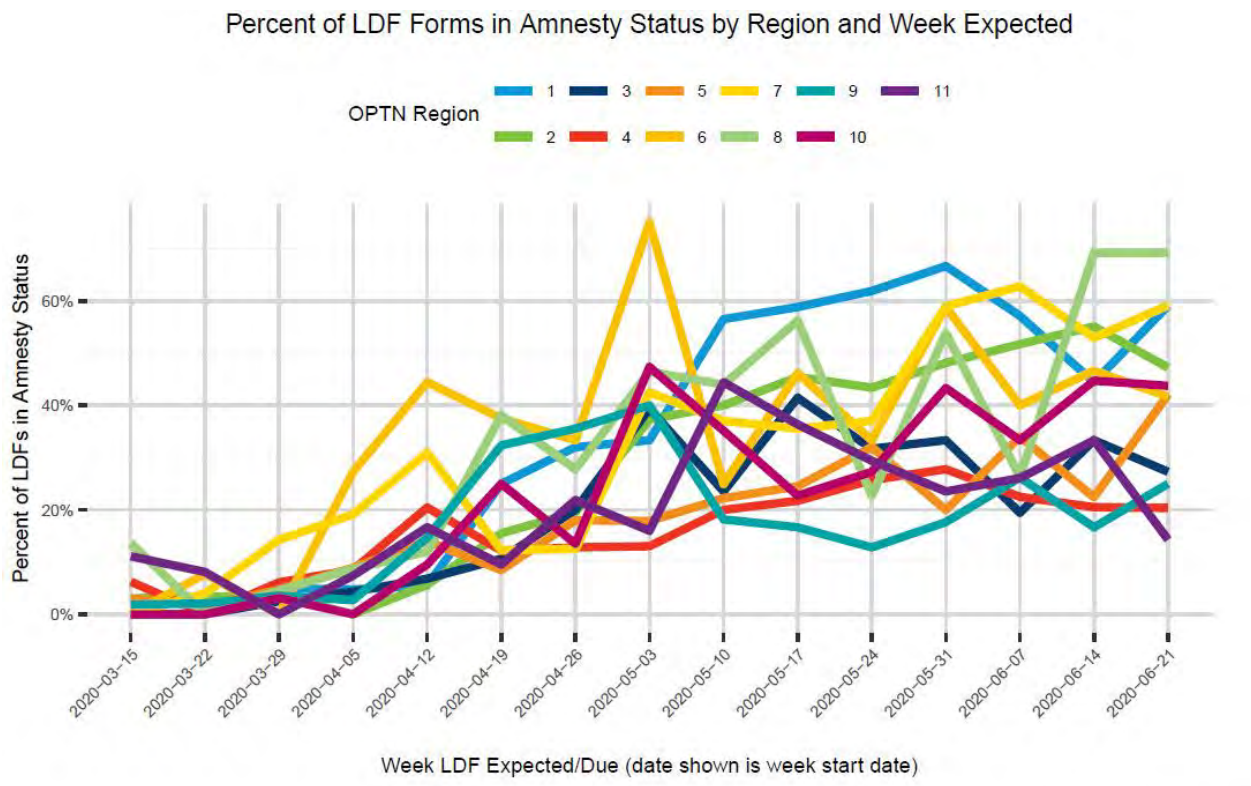


Weeks run Sunday–Saturday.

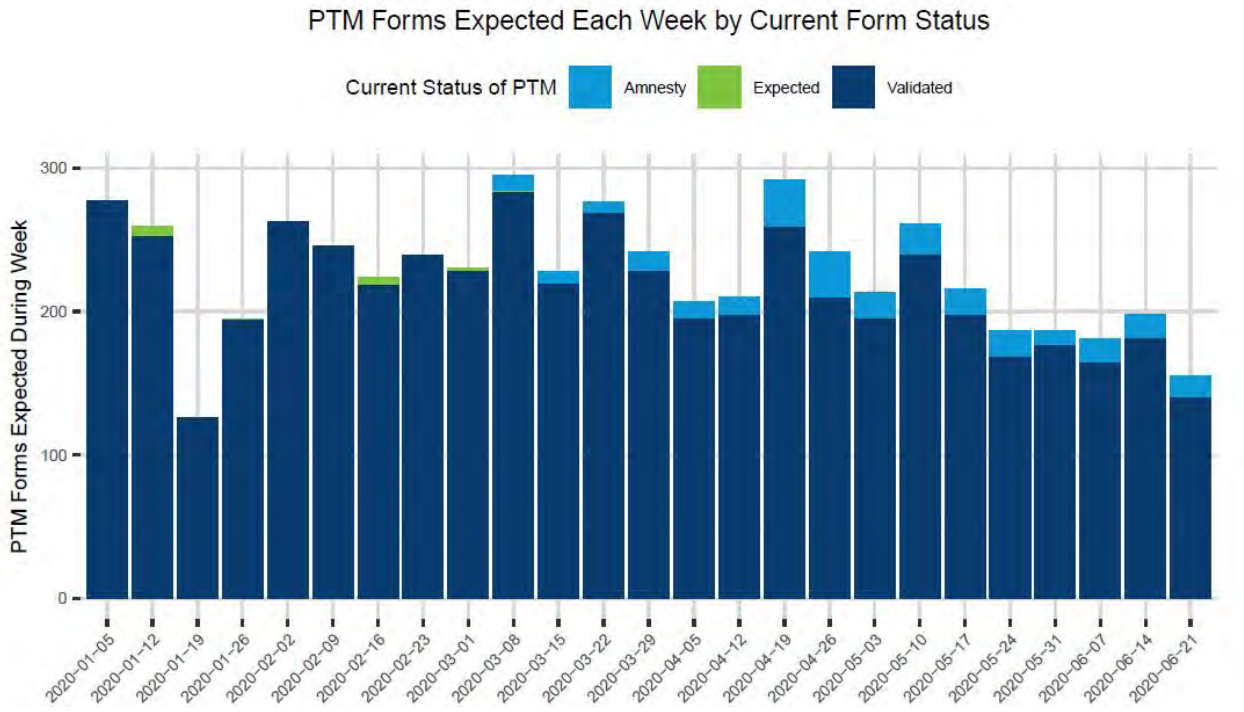
The following set of graphics show the number and percent of living donor follow-up (LDF) forms in amnesty status by week, OPTN region, and organ. The number of forms with expected dates that move into amnesty status is increasing over time since policy implementation.

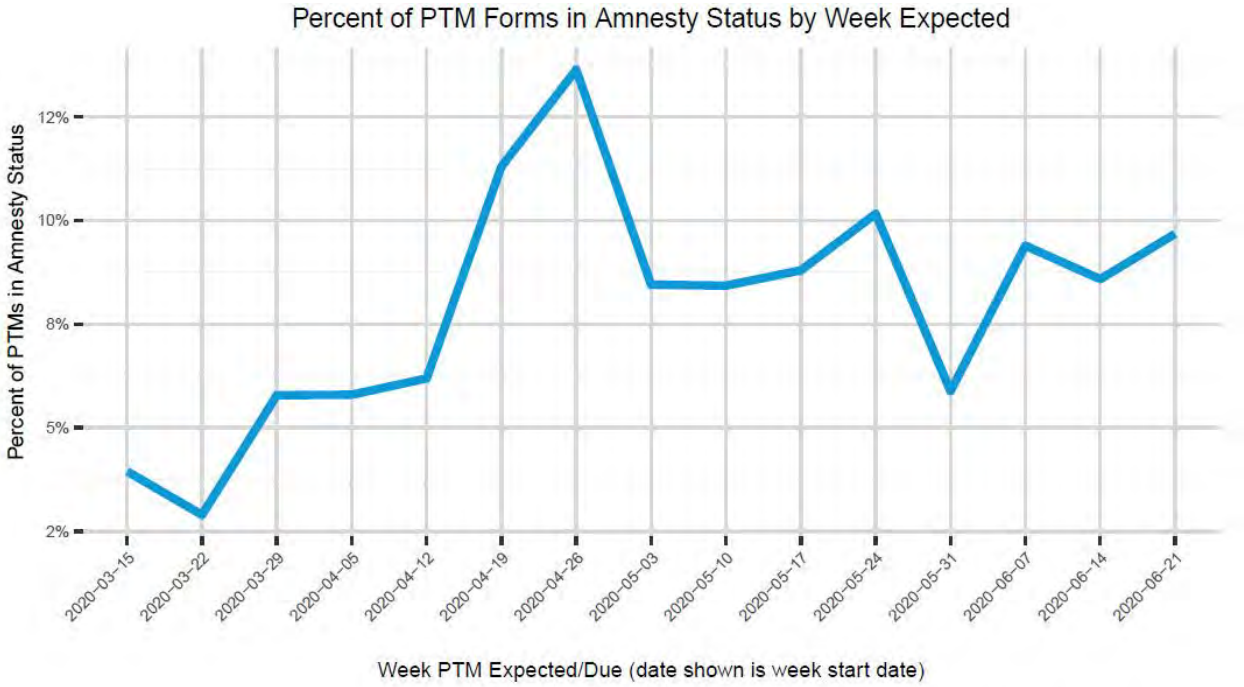



Percent of LDF Forms in Amnesty Status by Organ and Week Expected
Organ
Kidney
Liver
Percent of LDFs in Amnesty Status
60%
40%
20%
0%
2020-03-15
2020-03-22
2020-03-29
2020-04-05
2020-04-12
2020-04-19
2020-04-26
2020-05-03
2020-05-10
2020-05-17
2020-05-24
2020-05-31
2020-06-07
2020-06-14
2020-06-21

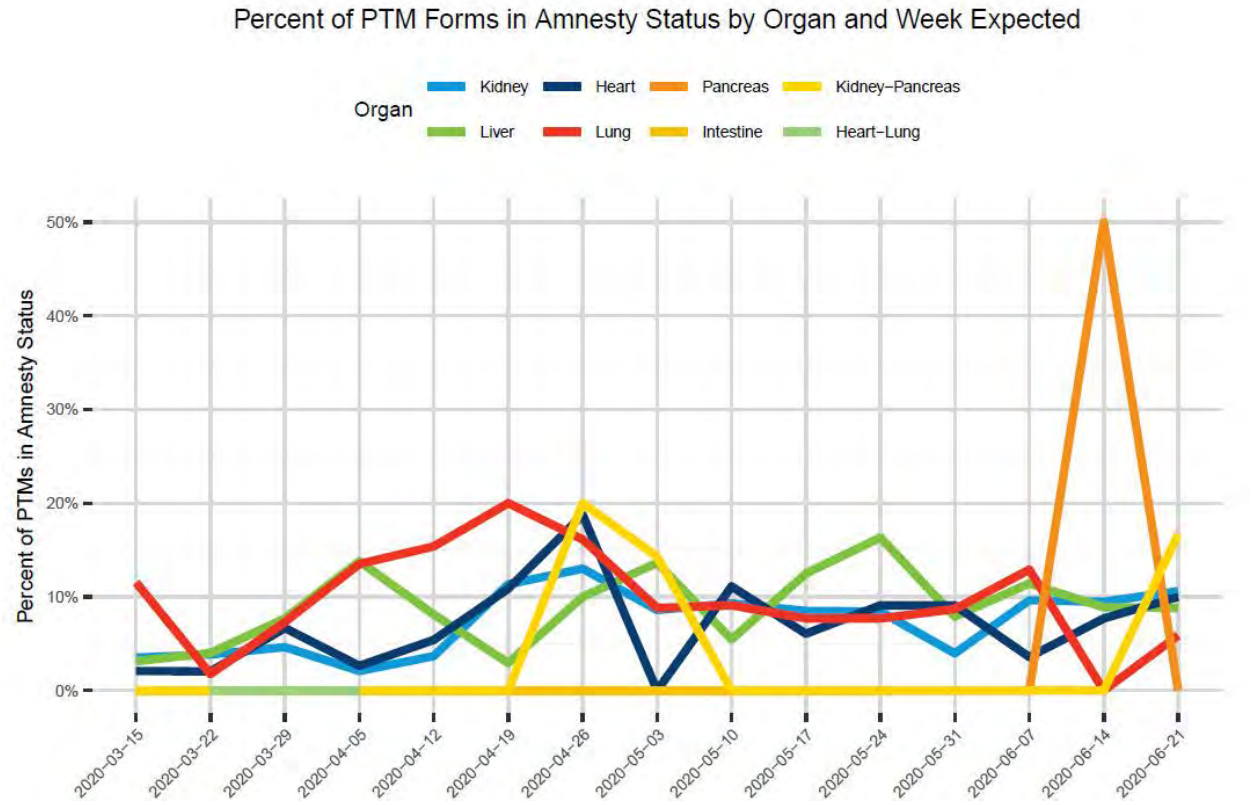


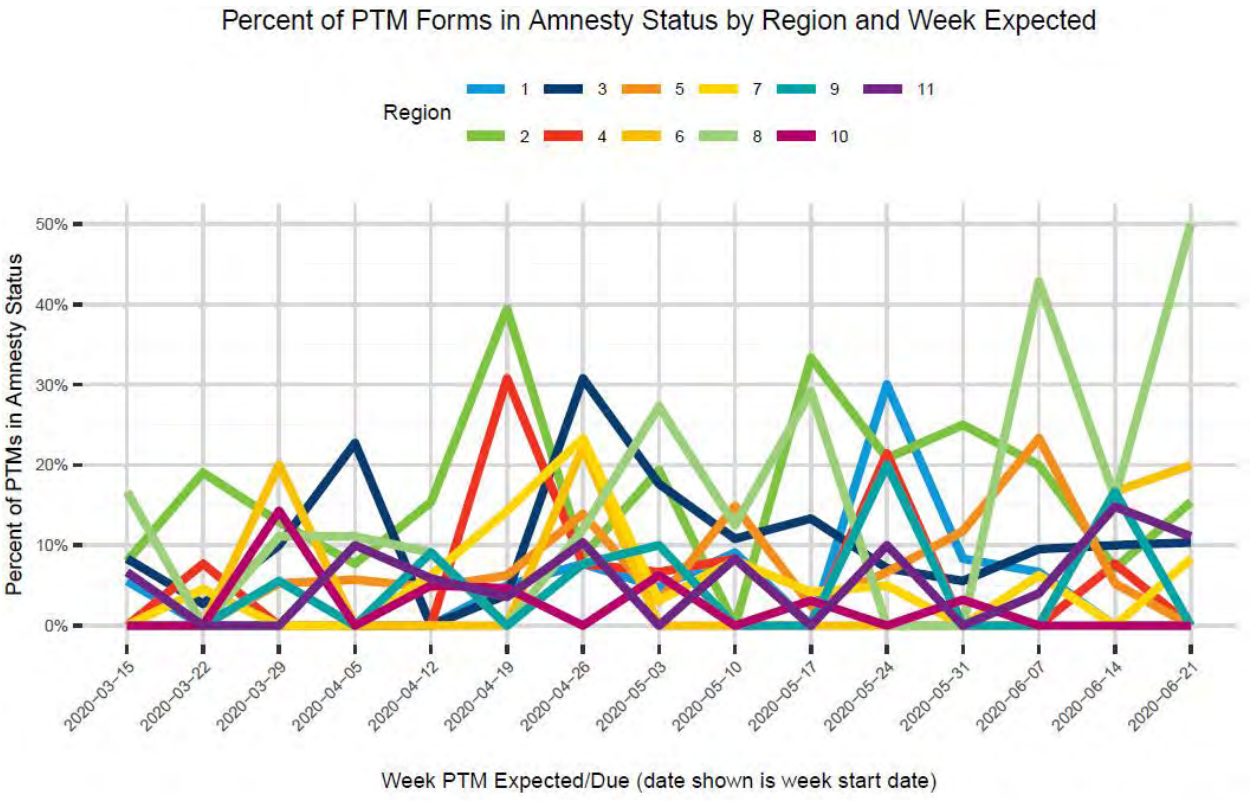
The following set of graphics show the number and percent of post-transplant malignancy (PTM) forms in amnesty status by week, OPTN region, and organ. These forms only generate from an indication of malignancy on the TRF, and the percent of PTM forms in amnesty status has increased slightly during COVID-19.





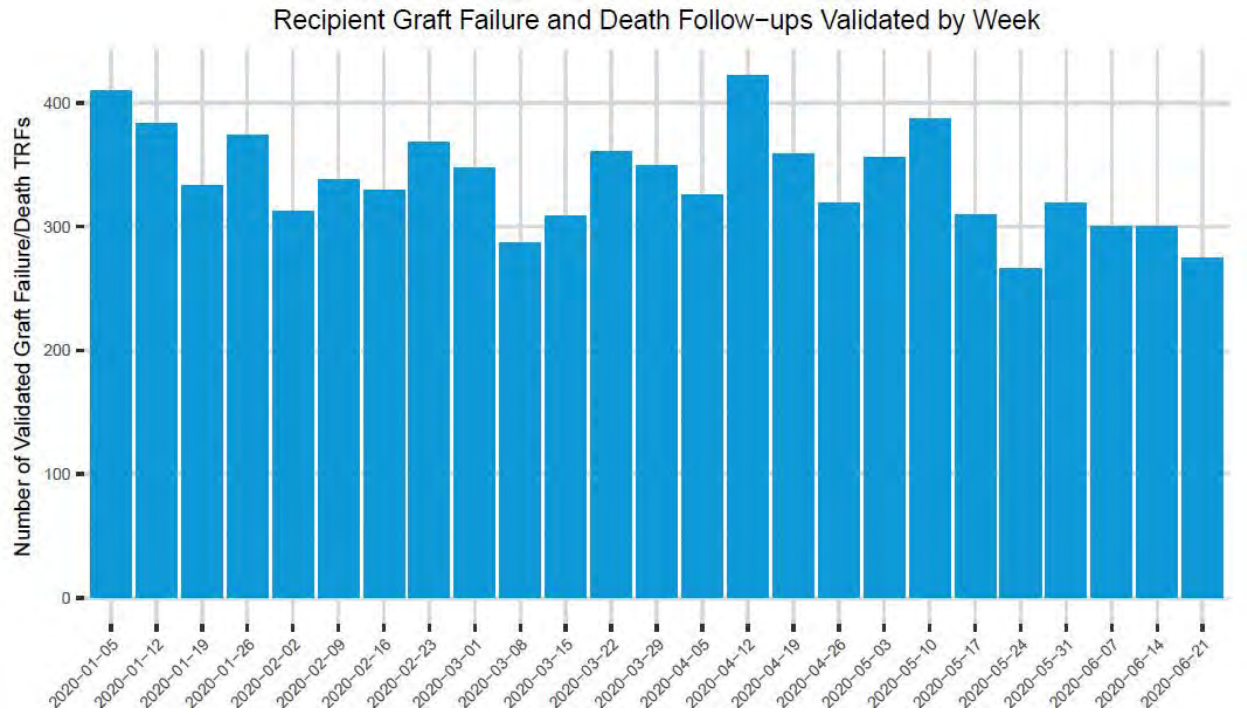
Weeks run Sunday–Saturday.

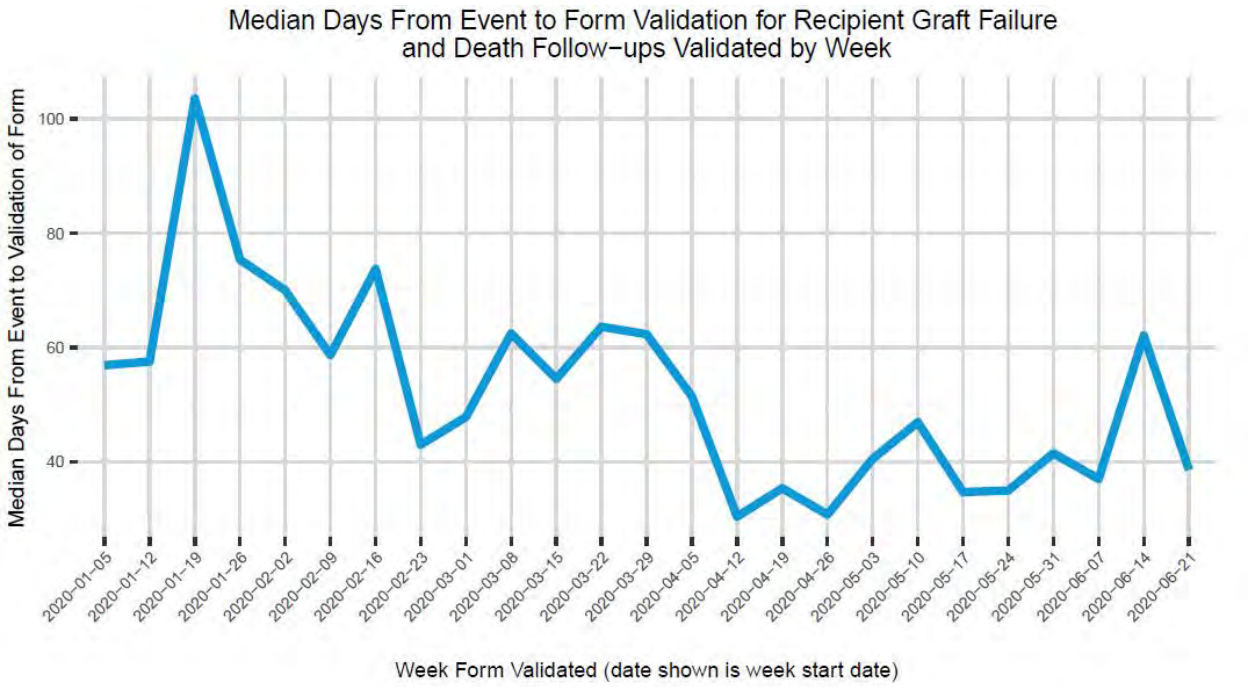




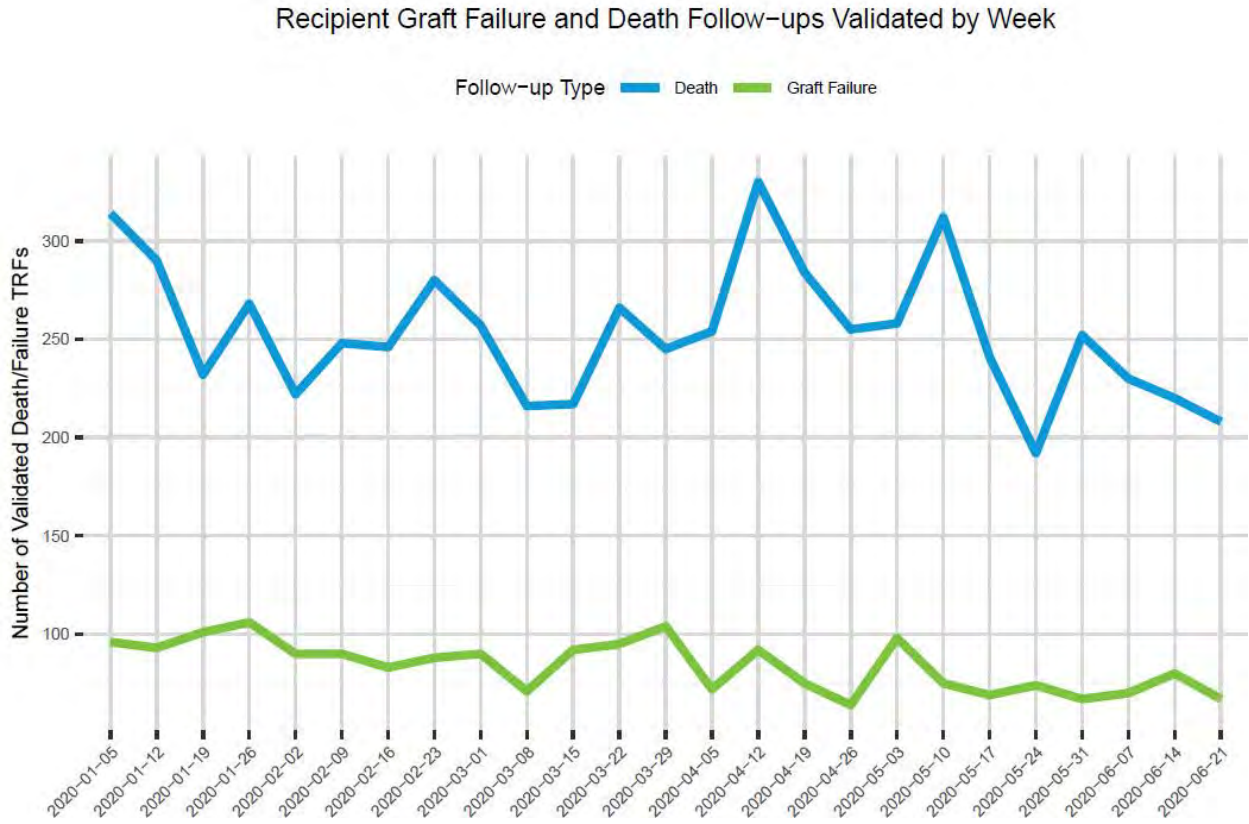
Weeks run Sunday–Saturday.

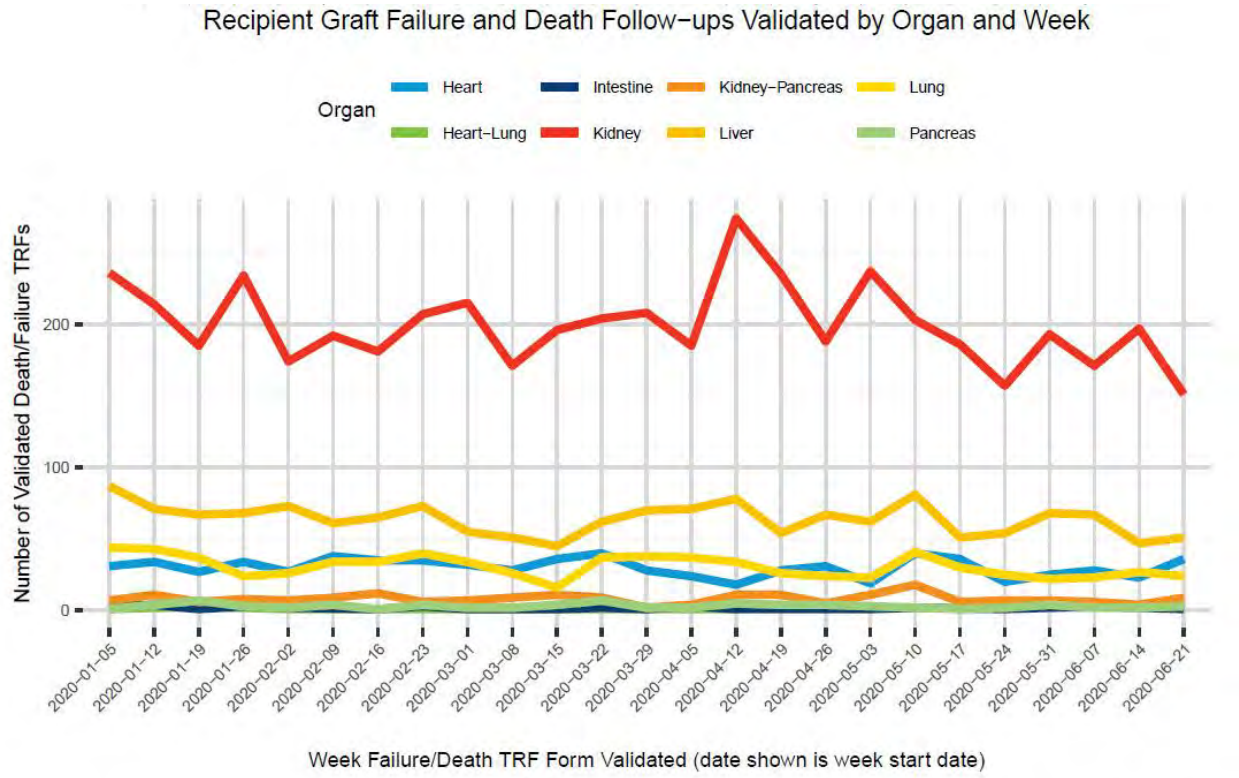
The following set of graphics show the number of graft failure and patient deaths reported on TRF forms by week, OPTN region, and organ. Emergency policy requires these events still be reported, but extended the timeframe from 14 to 30 days. The number of forms indicating these events has remained stable week over week. Recently, there appears to be a decrease in reporting time, which may be indicative of increased communication with patients during COVID-19.



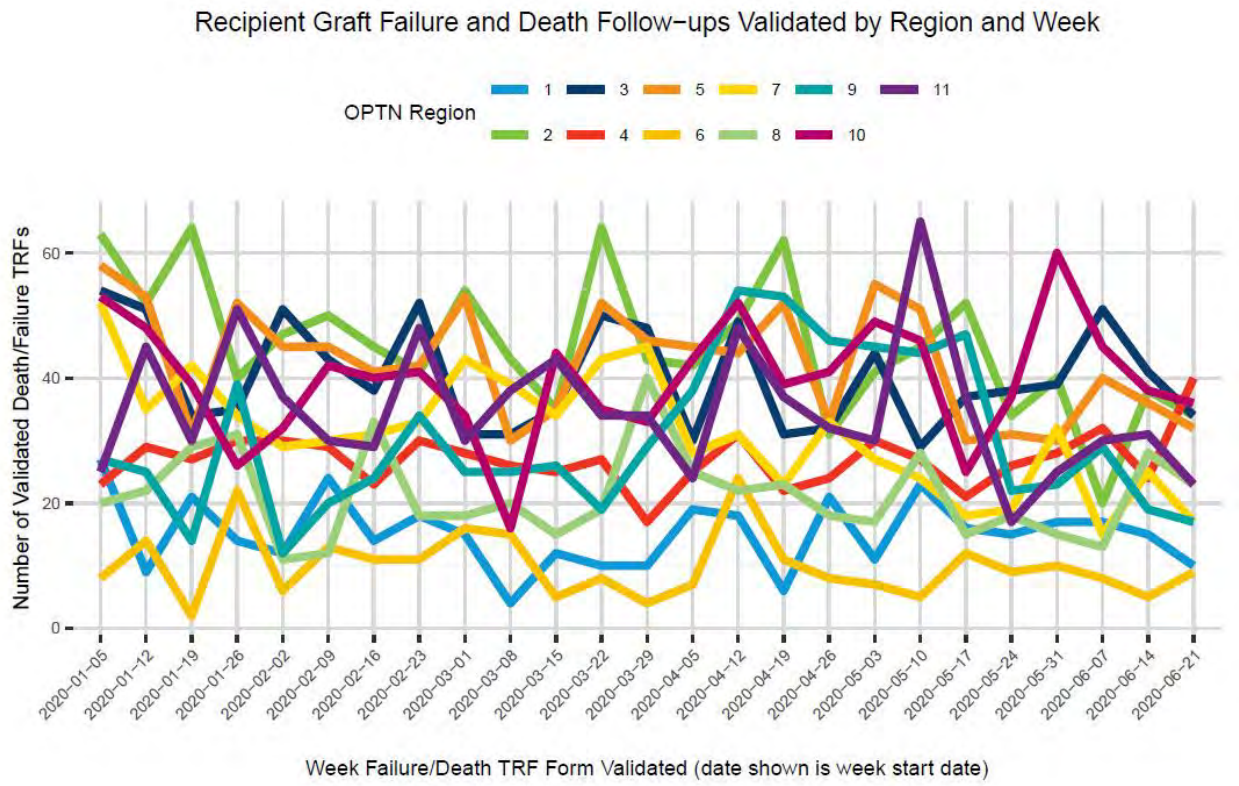


Weeks run Sunday−Saturday.





Weeks run Sunday-Saturday.



Summary and Conclusions

The number and percent of candidates that appear to be taking advantage of carrying labs forward to maintain their waiting list status is small across all organs. Data shown should be the maximum usage; one limitation of the analysis is that there is no way to distinguish in the OPTN database if candidates updated their labs and happened to have the same values from their last labs.

The number of waiting list additions has decreased during COVID-19 (both for dialysis and non-dialysis kidney candidates), but the percentage non-dialysis candidates qualifying for waiting time by eGFR/CrCl has remained fairly stable. As we move further into 2020, it will become known if these candidates will be listed at a later date and use a waiting time modification form to request waiting time back to the date of their qualifying eGFR/CrCl.

The number and percent of TRF, LDF, and PTM forms in 'Amnesty' status have grown throughout the most recent months. For the most part, forms in amnesty status does not appear to be limited to a single organ or OPTN region. This will have analytic implications if transplant programs do not enter the data retrospectively, which is not required by OPTN policy. The number of graft failure and patient death forms have remained stable, and programs are even reporting events faster than previously. This may be due to an increase in provider-patient communications.

Appendix B: Donor Testing for COVID-19

On April 21, 2020, new optional data elements were added to DonorNet® to collect information on testing for COVID-19 in deceased donors. In addition to details on the types of tests, specimens used, and the results, this new data collection includes an initial question to determine the percentage of donors being tested for COVID-19:

- **Was COVID-19 (SARS-CoV-2) testing performed on the donor? (Yes/No/Unknown)**

An analysis of responses provided within the data field as well as an NLP (Natural Language Processing) analysis was completed by the UNOS Data Science team and the results are provided in the table below.

Resu

The below table lists where COVID-19 testing information was provided for donors by week, starting on April 21, 2020.

		Results Reported In DonorNet . . .			
Week of	N Recovered Donors	Field	Text	Attachments	Any
Total	**2297**	**1651 (71.9%)**	**1518 (66.1%)**	**2220 (96.6%)**	**2296 (100.0%)**
Apr 21 2020	209	130 (62.2%)	155 (74.2%)	205 (98.1%)	209 (100.0%)
Apr 28 2020	210	163 (77.6%)	161 (76.7%)	203 (96.7%)	210 (100.0%)
May 05 2020	201	148 (73.6%)	136 (67.7%)	195 (97.0%)	201 (100.0%)
May 12 2020	245	180 (73.5%)	151 (61.6%)	237 (96.7%)	245 (100.0%)
May 19 2020	230	154 (67.0%)	157 (68.3%)	223 (97.0%)	230 (100.0%)
May 26 2020	244	173 (70.9%)	149 (61.1%)	237 (97.1%)	244 (100.0%)
Jun 02 2020	255	194 (76.1%)	159 (62.4%)	246 (96.5%)	255 (100.0%)
Jun 09 2020	234	162 (69.2%)	151 (64.5%)	224 (95.7%)	234 (100.0%)
Jun 16 2020	251	189 (75.3%)	163 (64.9%)	245 (97.6%)	251 (100.0%)
Jun 23 2020	216	156 (72.2%)	135 (62.5%)	203 (94.0%)	215 (99.5%)
Jun 30 2020	2	2 (100.0%)	1 (50.0%)	2 (100.0%)	2 (100.0%)

As of June 30th, there were 2,297 deceased donors reported recovered by U.S. OPOs from April 21-June 30, 2020. Of those 2,297 donors, 71.9% (1651) utilized the new data element for capturing COVID-19 testing results, 66.1% (1518) indicated testing was performed in the one of the large text "highlights" fields in DonorNet®, and 96.6% (2220) attached the COVID-19 testing results as a separate document. UNOS Research reached out to the OPO who had not reported testing for COVID-19 in DonorNet for the week of June 23, 2020, and determined that the donor was tested. **This analysis determined that all deceased donors recovered during this period were tested for COVID-19.**

The table below shows the test results reported in the new DonorNet® data field for donors being tested for COVID-19. The donor below showing a positive COVID-19 result in this report was not an active infection. A UNOS Patient Safety Coordinator spoke with the OPO who confirmed it was a pediatric donor who had a negative COVID-19 PCR result, but did test positive for the antibody. The OPO reports they feel the donor's antibodies resulted from the birth mother who had COVID-19 during pregnancy. All centers knew of these results prior to donation.

Week Donor Recovered	Testing Result				
	Indeterminate	Negative	Positive	Pending	Not Reported
2020-04-19	0	114 (99.13%)	0	1 (0.87%)	0
2020-04-26	0	214 (98.17%)	0	4 (1.83%)	0
2020-05-03	1 (0.47%)	210 (98.13%)	0	3 (1.4%)	0
2020-05-10	1 (0.43%)	229 (97.86%)	0	4 (1.71%)	0
2020-05-17	1 (0.4%)	240 (95.62%)	0	10 (3.98%)	0
2020-05-24	0	256 (96.6%)	0	9 (3.4%)	0
2020-05-31	0	263 (94.27%)	1 (0.36%)	15 (5.38%)	0
2020-06-07	2 (0.77%)	245 (94.23%)	0	12 (4.62%)	1 (0.38%)
2020-06-14	0	293 (95.44%)	0	14 (4.56%)	0
2020-06-21	0	269 (97.11%)	0	8 (2.89%)	0
2020-06-28	0	47 (95.92%)	0	2 (4.08%)	0

Note:
Each donor may have multiple tests done

Policy and/or Bylaws Language

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

Policy 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.

18.1 Data Submission Requirements

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

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	*VCA Candidate List*	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	*Donor organ disposition (feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered

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

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Recovery Hospitals	*Living donor follow-up* (LDF)	Either: • 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency.	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs. Non-submission of the full LDF is acceptable during the COVID-19 emergency.
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	Either of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency. • ~~14~~30 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital submits the *recipient feedback* form	Each liver recipient transplanted by the hospital

The following member:	Must submit the following materials to the OPTN:	Within:	For:
Transplant hospitals	*Recipient feedback*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	*Candidate Removal Worksheet*	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	*Recipient malignancy* (PTM)	Either: • 30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form or • As determined possible by the transplant hospital during the COVID-19 emergency.	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital. Non-submission is acceptable during the COVID-19 emergency.
Transplant hospitals	*Transplant candidate registration* (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. **Error! Reference source not found.** sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

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

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first. This does not apply to VCA transplants.
Recovery hospital	*Living donor follow-up* (LDF)	Either: • 60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or • As determined possible by the transplant hospital during the COVID-19 emergency. This does not apply to VCA transplants. Non-submission is acceptable during the COVID-19 emergency.

18.5 Living Donor Data Submission Requirements

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

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

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

18.5.A Reporting Requirements after Living Kidney Donation

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

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

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

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

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

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

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

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

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

1. Serum creatinine
2. Urine protein

18.5.B Reporting Requirements after Living Liver Donation

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

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

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

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

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

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

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

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

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.

ADD: parent question field: “Was COVID-19 (SARS-CoV-2) testing performed on the donor?”

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