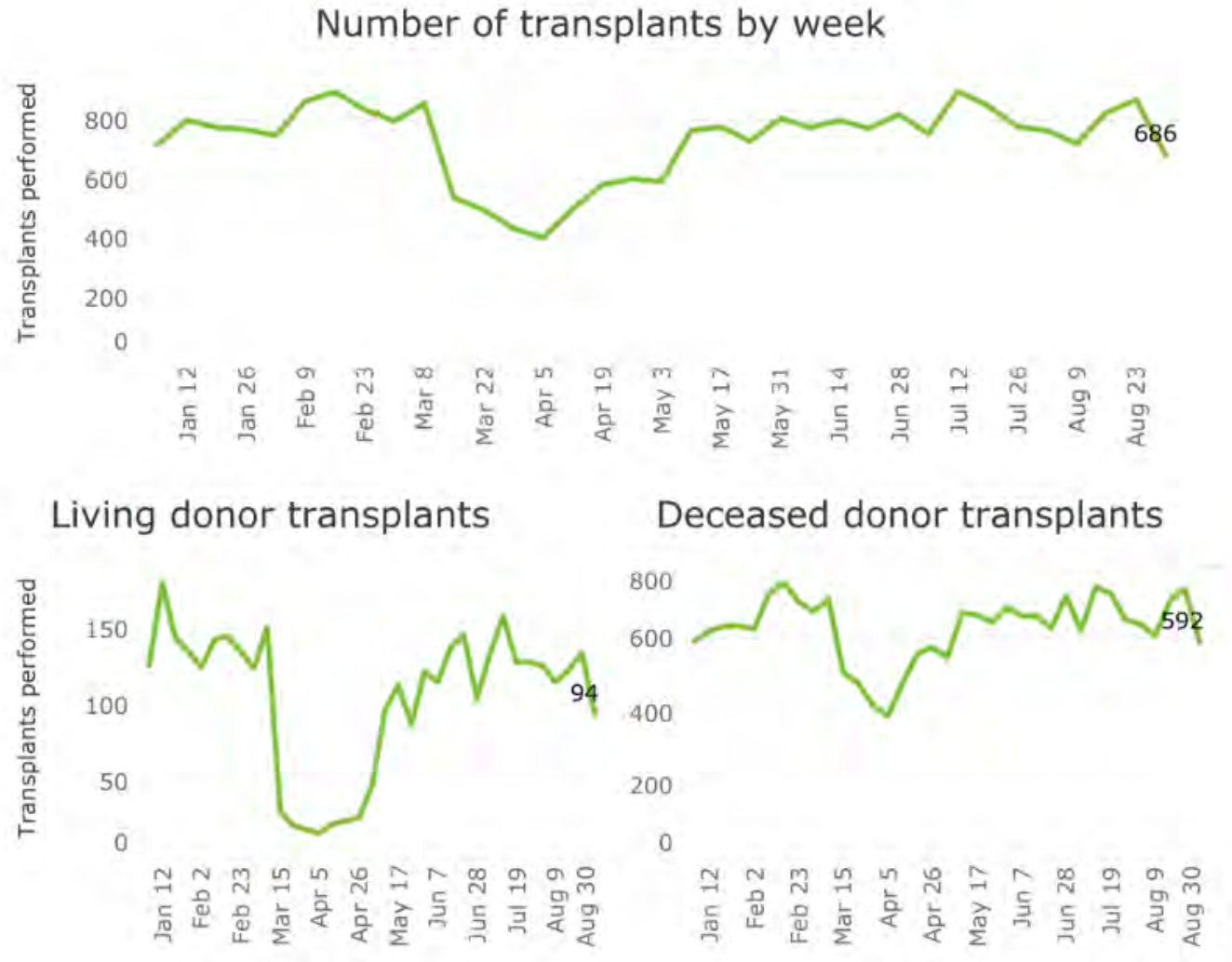


# COVID-19 Emergency Policies and Data Collection

*OPTN Executive Committee*

# COVID-19 impact on transplantation



# COVID-19 impact on transplantation

## Deceased donor transplants



# Authority for emergency actions

## 11.7 Emergency Actions

Policy proposals that meet *at least one* of the following criteria may be adopted by the Board of Directors prior to public comment:

- A proposal that is necessitated by a pending statutory or regulatory change.
- A proposal that is required due to an emergent public health issue or patient safety factors.
- A proposal that is necessitated by a new medical device or technology that affects organ allocation,

Instead, the policy development process for these proposals will require *all* of the following steps:

1. The sponsoring Committee submits the proposal according to *11.2 Submitting Policy Proposals to the Board of Directors*.
2. The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.
3. The policy is distributed for public comment no more than 6 months after approval. This public comment period can be shorter than the normal public comment period but must be at least 30 days.

# OPTN emergency actions in response to community COVID-19 related concerns

| Emergency Action   | Approval date  | Current expiration date |
|--|----------------|-------------------------|
| Updates to Candidate Data During 2020 COVID-19 Emergency       | March 17, 2020 | March 17, 2021          |
| Relax Data Submission Requirements for Follow-Up Forms         | April 3, 2020  | December 31, 2020       |
| Modify Wait Time Initiation for Non-Dialysis Kidney Candidates | April 3, 2020  | December 31, 2020       |
| Incorporate COVID-19 Infectious Disease Testing into DonorNet® | April 3, 2020  | December 31, 2020       |

# Rationale

- Reduce candidate, recipient, and living donor exposure to COVID-19
- Reduce transplant hospital burden during pandemic
- Prevent disadvantaging candidates who are unable to safely access the hospital for pre-transplant lab testing
- Provide OPOs and transplant hospitals efficient communication of COVID-19 testing status and results

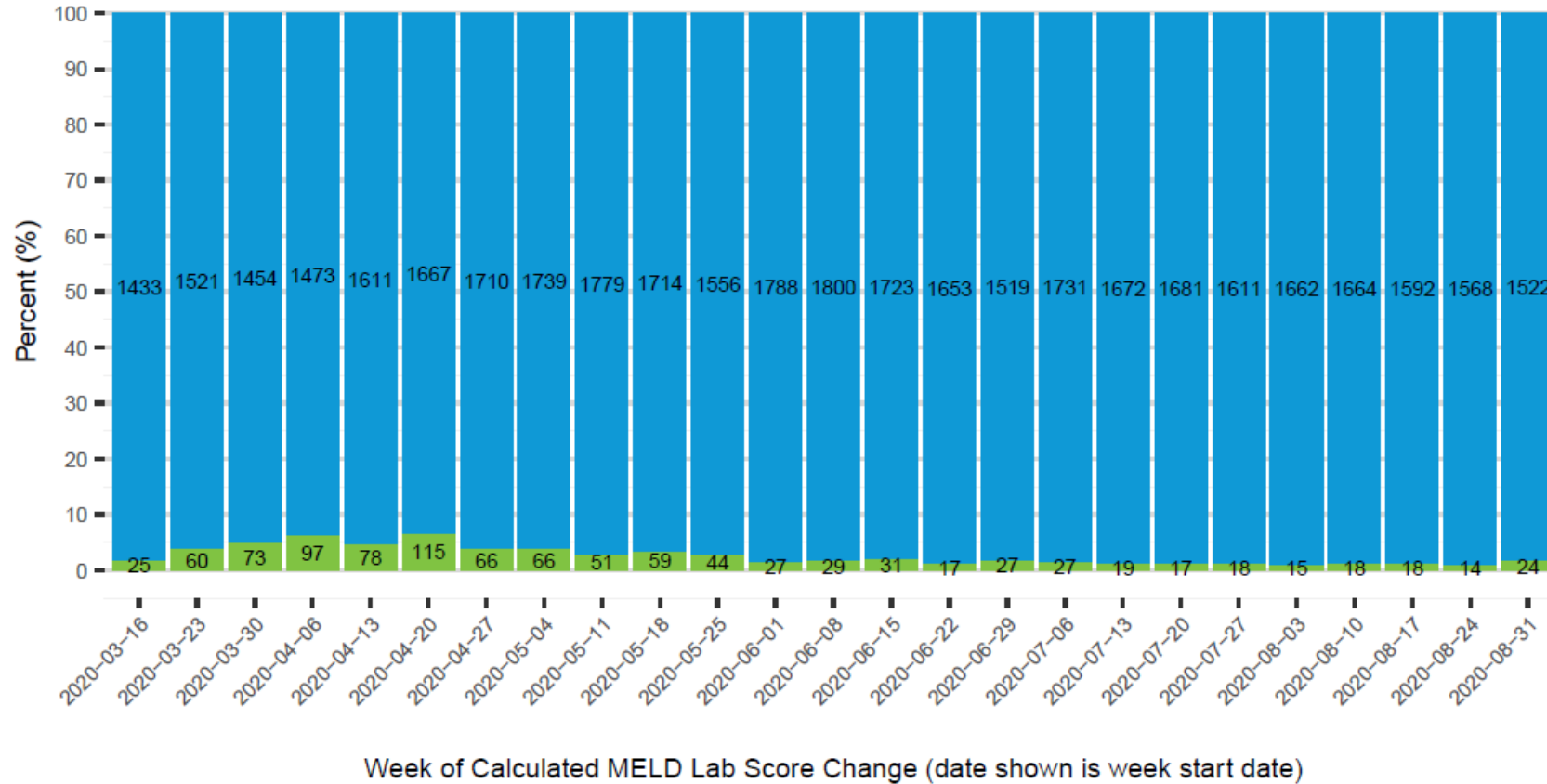
# Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency

- Programs can use a candidate's most recently submitted lab data to maintain medical urgent allocation priority
- Discretion on when to use emergency policy versus bring in a candidate for updated labs left to individual programs
- Primary usage was adult lung, followed by adult liver
- Backdated to declaration of national emergency on March 13, 2020

# Action 1

## Adult Liver

Potential Update to Candidate Data during 2020 COVID-19 via Emergency Policy? ■ No ■ Yes



- Adult liver (left) stable ~1-2% usage week over week
- Adult lung stable at ~5% usage week over week
- Adult heart still has almost no use

*Weeks run Monday-Sunday.*

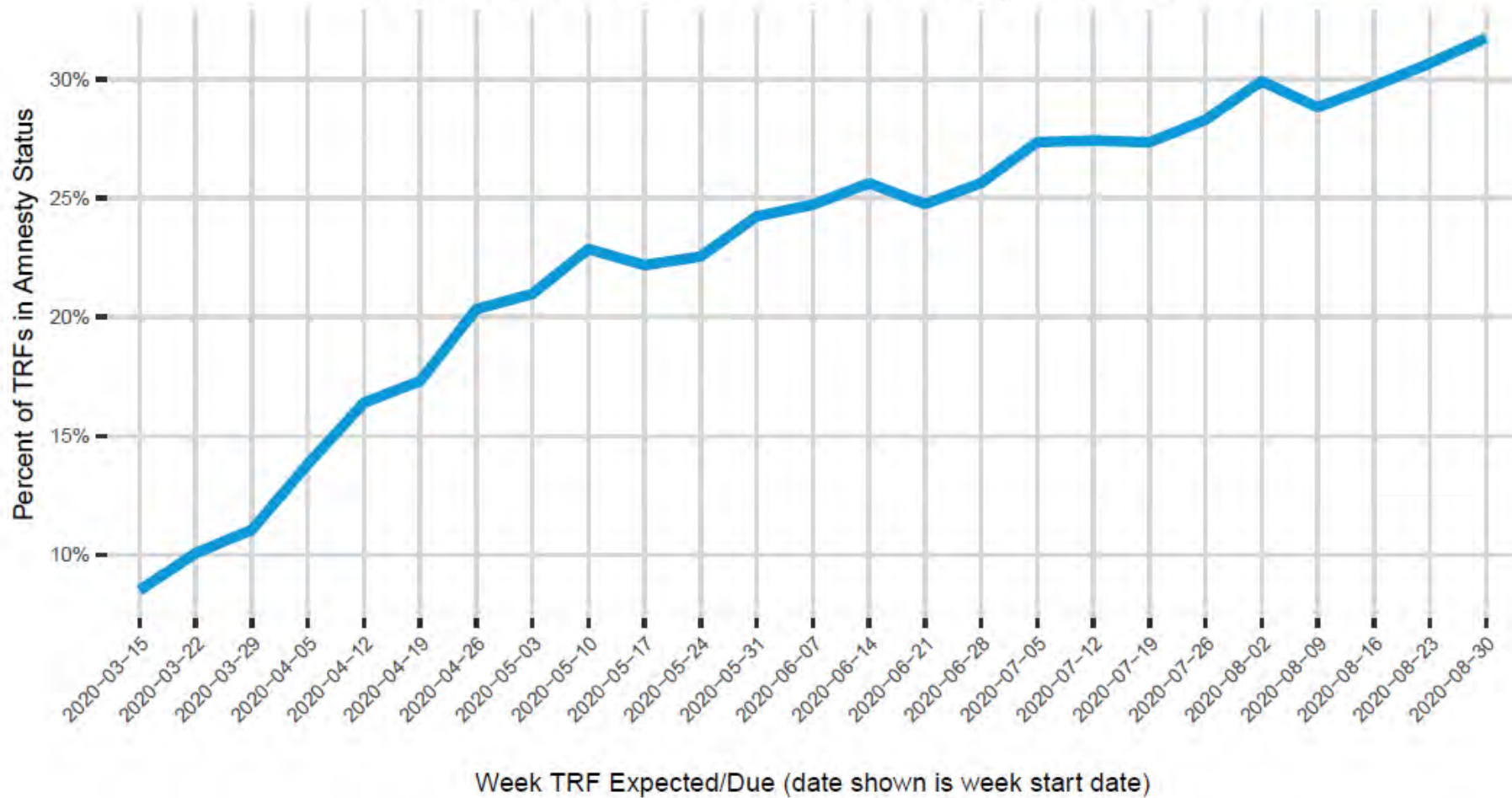


# Action 2: Relax Data Submission Requirements for Follow-Up Forms

- Applies to organ-specific Transplant Recipient Follow-Up (TRF), Living Donor Follow-Up (LDF), and Post-Transplant Malignancy (PTM) forms
- The timeline to report recipient graft failure or death was extended from 14 to 30 days
- If TRF, LDF, or PTM forms are not submitted by their expected date, they are automatically marked in “amnesty” status
- “Amnesty” status implemented April 13, 2020
- Data can still be updated after forms enter amnesty status

# Action 2

Percent of TRF Forms in Amnesty Status by Week Expected

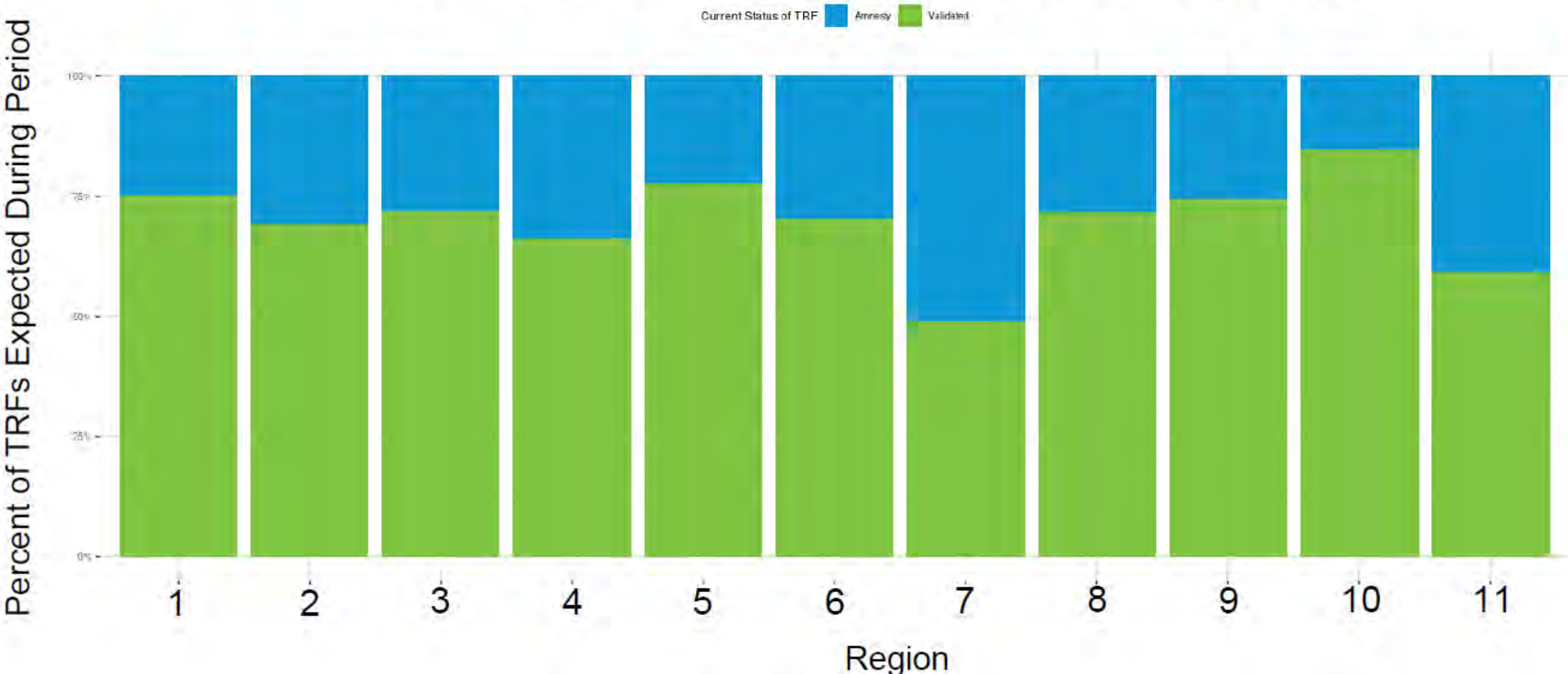


The proportion of TRF forms in Amnesty status continues to slowly increase and is currently over 30%

*Weeks run Sunday-Saturday.*

# Action 2

## Current Status of TRF Forms Expected 6/28-7/25 by Region

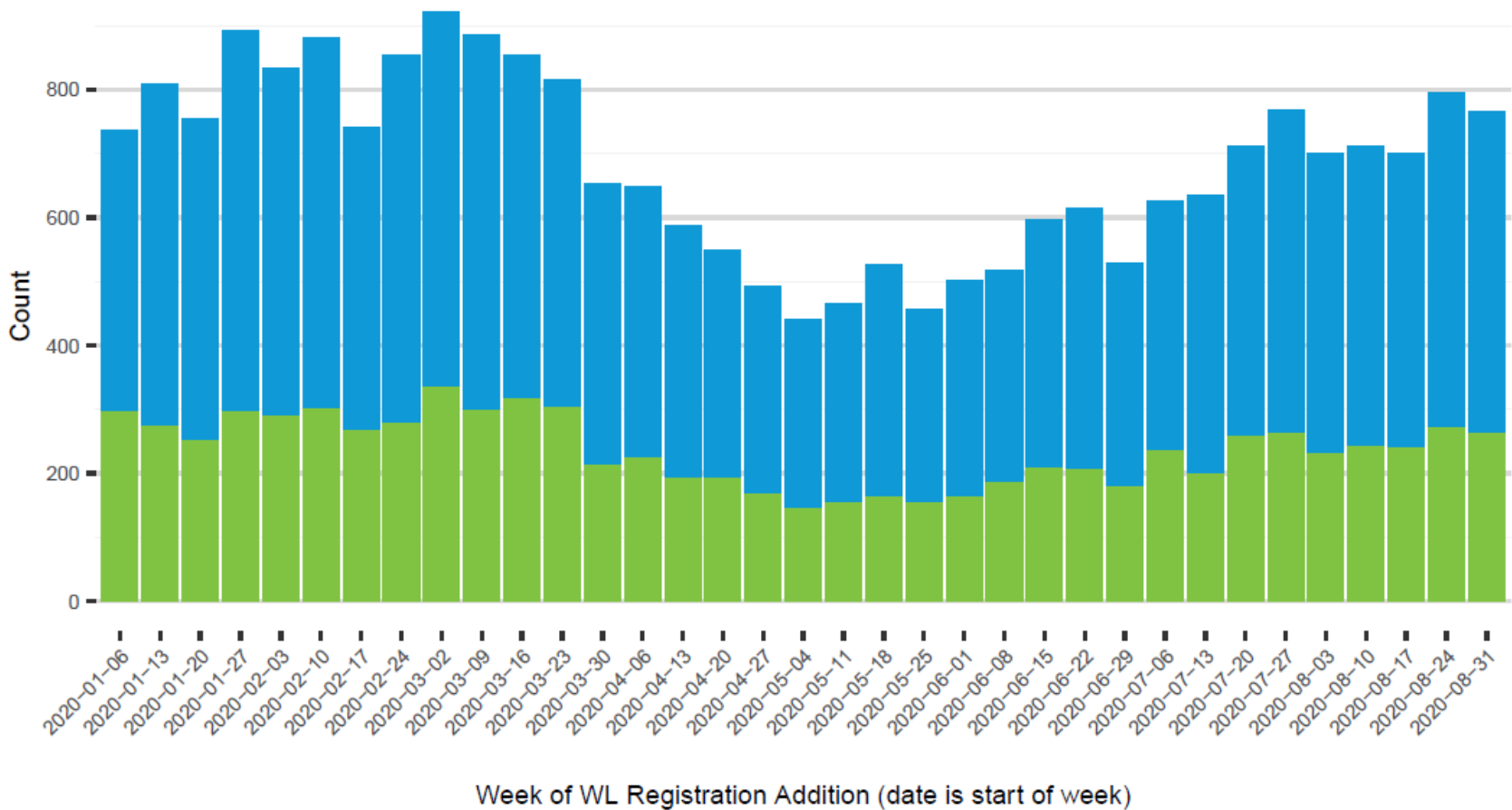


# Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates

- Allows programs to request the initiation of waiting time for non-dialysis kidney candidates to be backdated to the date the program intended to list the candidate for transplant
- Intended to keep candidates from being disadvantaged if they are delayed in completing all required labs for registration
- Modification request form implemented April 10, 2020

# Action 3

Non-Dialysis adult kidney WL additions with no dialysis and CrCl/GFR<=20 at listing? ■ No ■ Yes



Though the number of total waiting time modification forms submitted to the UNOS Organ Center decreased from June, the proportion related to COVID-19 increased to almost 90% in July

Weeks run Monday-Sunday.

# Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet<sup>®</sup>

- Added an optional field to DonorNet to report COVID-19 testing, test type, specimen type, and result
- Implemented April 20, 2020
- Proposed as an optional field for quicker implementation, as well as to minimize disruption to allocation workflow
- 100% of recovered deceased donors have been tested for COVID-19 between April 21, 2020 and August 4, 2020, although only about 75% used the discrete infectious disease testing fields

# Action 4

| Week of      | N Recovered Donors | Results Reported In DonorNet . . . |                     |                     |                     |
|--------------|--------------------|------------------------------------|---------------------|---------------------|---------------------|
|              |                    | Field                              | Text                | Attachments         | Any                 |
| <b>Total</b> | <b>4690</b>        | <b>3601 (76.8%)</b>                | <b>2831 (60.4%)</b> | <b>4552 (97.1%)</b> | <b>4687 (99.9%)</b> |
| Apr 21 2020  | 209                | 130 (62.2%)                        | 153 (73.2%)         | 205 (98.1%)         | 209 (100.0%)        |
| Apr 28 2020  | 210                | 163 (77.6%)                        | 158 (75.2%)         | 203 (96.7%)         | 210 (100.0%)        |
| May 05 2020  | 201                | 148 (73.6%)                        | 135 (67.2%)         | 195 (97.0%)         | 201 (100.0%)        |
| May 12 2020  | 245                | 180 (73.5%)                        | 147 (60.0%)         | 237 (96.7%)         | 245 (100.0%)        |
| May 19 2020  | 230                | 154 (67.0%)                        | 155 (67.4%)         | 223 (97.0%)         | 230 (100.0%)        |
| May 26 2020  | 244                | 173 (70.9%)                        | 144 (59.0%)         | 237 (97.1%)         | 244 (100.0%)        |
| Jun 02 2020  | 258                | 196 (76.0%)                        | 156 (60.5%)         | 249 (96.5%)         | 258 (100.0%)        |
| Jun 09 2020  | 235                | 162 (68.9%)                        | 151 (64.3%)         | 225 (95.7%)         | 235 (100.0%)        |
| Jun 16 2020  | 248                | 189 (76.2%)                        | 155 (62.5%)         | 244 (98.4%)         | 248 (100.0%)        |
| Jun 23 2020  | 263                | 190 (72.2%)                        | 162 (61.6%)         | 253 (96.2%)         | 263 (100.0%)        |
| Jun 30 2020  | 237                | 175 (73.8%)                        | 135 (57.0%)         | 231 (97.5%)         | 237 (100.0%)        |
| Jul 07 2020  | 239                | 184 (77.0%)                        | 138 (57.7%)         | 231 (96.7%)         | 239 (100.0%)        |
| Jul 14 2020  | 284                | 212 (74.6%)                        | 153 (53.9%)         | 279 (98.2%)         | 284 (100.0%)        |
| Jul 21 2020  | 285                | 222 (77.9%)                        | 162 (56.8%)         | 278 (97.5%)         | 285 (100.0%)        |
| Jul 28 2020  | 229                | 184 (80.3%)                        | 130 (56.8%)         | 224 (97.8%)         | 229 (100.0%)        |
| Aug 04 2020  | 247                | 209 (84.6%)                        | 139 (56.3%)         | 239 (96.8%)         | 247 (100.0%)        |
| Aug 11 2020  | 241                | 208 (86.3%)                        | 134 (55.6%)         | 237 (98.3%)         | 240 (99.6%)         |
| Aug 18 2020  | 250                | 218 (87.2%)                        | 142 (56.8%)         | 238 (95.2%)         | 249 (99.6%)         |
| Aug 25 2020  | 253                | 228 (90.1%)                        | 139 (54.9%)         | 243 (96.0%)         | 252 (99.6%)         |
| Sep 01 2020  | 82                 | 76 (92.7%)                         | 43 (52.4%)          | 81 (98.8%)          | 82 (100.0%)         |

# Next Steps

- Board of Directors to consider public comment feedback at their December, 2020 meeting
- Board has multiple options for these emergency actions
  - Extend with a set expiration date and/or grant the Executive Committee authority to nullify when needed
  - Nullify them immediately
  - Allow to expire on the current expiration dates
  - Make the policies and data collection permanent



# Feedback Requested

1. Were the Executive Committee's actions appropriate in the emergency?
2. Should COVID-19 infectious disease testing remain in DonorNet®? Should it be a mandatory field?
3. Should the OPTN require retrospective data entry on follow-up forms given amnesty status under the emergency policies?
4. Is the emergency policy process used by the OPTN the most appropriate way to respond to an emerging health crisis?
5. Are there other things the OPTN should have done, or can still do, to respond to the COVID-19 crisis?

# Summary: COVID-19 Emergency Policies and Data Collection

- Action 1: Updates to Candidate Data During 2020 COVID-19 Emergency
- Action 2: Relax Data Submission Requirements for Follow-Up Forms
- Action 3: Modify Wait Time Initiation for Non-Dialysis Kidney Candidates
- Action 4: Incorporate COVID-19 Infectious Disease Testing into DonorNet®