

OPTN Data Advisory Committee

Descriptive Data Request

# Updates to Policy 18, Data Submission Requirements Six-Month Monitoring Report

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## Background/Purpose

OPTN members are expected to submit accurate, high-quality data. Nonetheless, OPTN members and other data users have raised concerns in the past about the integrity of submitted data. They pointed to different data submission deadlines in policy as a problem. They also pointed out the ability of members to change data indefinitely after submission and the high volume of changed data as reasons to question the data's accuracy. Data users have raised concerns that the issues may impact program performance evaluations and ultimately patient outcomes.

The Data Advisory Committee (DAC) proposed addressing data quality concerns by modifying initial submission deadlines associated with OPTN Data System forms and reducing members' ability to make changes following submission. Together, the resulting changes were intended to improve OPTN data quality and products such as research analyses and program specific reports.

On August 30, 2022, **OPTN Policy 18: Data Submission Requirements** was updated through this DAC-led project in response to community feedback, public comment and OPTN Board approval to make several changes to OPTN data submission policies for eight Office of Management and Budget (OMB)-approved forms in the OPTN Data System, otherwise known as TIEDI®. This effort made the following policy changes to previous data submission requirements for OPTN members:

- Removal of **OPTN Policy 18.4: Data Submission Standards** from OPTN policies, as it provided data submission requirements that appeared to conflict with **Policy 18.1**,
- Update of **OPTN Policy 18.1**-specified data submission timelines for all eight OPTN Data System forms (enumerated below) to add 30 or 60 days to the previously-specified data submission timelines, such that all forms now have either 60- or 90-day submission deadlines,
- Instituting a new data change process for these forms, such that members complete more steps to make data changes as part of **Policy 18.1** than previously. Specifically, after the form submission deadline of 60 to 90 days passes, members must 'unlock' their data in order to make a correction in the OPTN Data System. Upon requesting the form 'unlock', members must submit an explanation detailing why the data values are being changed, from a list of discrete options, and are required to submit the name of an individual at their institution who has reviewed and provided approval to make the change. This individual should be someone at the transplant program with oversight of data entry and quality for OPTN data submissions.

These policy actions improve the widespread availability of trusted, complete, and accurate data for members seeking to use it for performance improvement. High-quality data will also improve OPTN policy development activities and evaluation of transplant system performance. Additionally, other researchers who study and assess transplant system performance will benefit from data quality improvements. It also aligns with the OPTN Final Rule's requirement that timely and institution-specific performance data be made publicly available in order to appraise the quality of transplantation programs.

## Strategic Plan Goal or Committee Project Addressed

This policy change impacts the following **OPTN Strategic Plan** goals:

- **Improve equity in access to transplants:** Improved data quality may lead to more accurate analysis of problems and better developed solutions that may help the OPTN and SRTR develop policies and practices that lead to more equitable organ allocation.
- **Improve waitlisted patient, living donor, and transplant recipient outcomes:** Outcomes may improve as increased data accuracy and timeliness allow the transplantation community to identify beneficial treatments.
- **Promote the efficient management of the OPTN:** This proposal's focus on assisting OPTN members with their efforts to initially submit accurately and timely data will reduce the need for members to spend time and staffing resources to correct mistakes later.

## Committee Request

The policy change enacted on August 30, 2022 requires reporting the following measures to the DAC after implementation:

1. Data submission compliance rates,
2. Frequencies of data changes following submission, as well as the reported reasons associated with the changes, and
3. Other relevant information identified by the Committee.

UNOS Research will provide monitoring reports at six months, 12 months and 24 months post-implementation. Additionally, the DAC will report to the OPTN Board annually on impacts of this policy change.

## Data and Methods

**Data Sources:** The “data lock” policy implementation affected the following eight OMB-approved forms in the OPTN Computer System, listed here with their full names and abbreviations, which will be used hereafter in the report for brevity:

- DDR: Deceased Donor Registration
- DHS: Donor Histocompatibility
- RHS: Recipient Histocompatibility
- LDR: Living Donor Registration
- LDF: Living Donor Follow-Up
- TCR: Transplant Candidate Registration
- TRR: Transplant Recipient Registration
- TRF: Transplant Recipient Follow-Up

Among these forms, Organ Procurement Organizations (OPOs) complete the DDR; histocompatibility labs complete the DHS and RHS, and transplant programs complete the LDR, LDF, TCR, TRR and TRF. All analyses in this and future monitoring reports will therefore focus on timely submission, subsequent unlocking, and editing of these eight forms. As a reference, **Table 1** below has been provided to summarize the conditions that cause a form to generate, and its due dates before and after the policy implementation.

**Table 1. OPTN Data System form generation prompts and submission due dates pre- and post-policy implementation.**

OPTN Data System Form	Form Generation Prompt	Pre-Policy Due Dates	Post-Policy Due Dates
DDR	<i>Donor organ disposition (feedback) form</i> is submitted and disposition is reported for all organs	30 days	60 days
DHS	DHS record is generated	30 days	60 days
RHS	Transplant hospital removes candidate from waitlist because of transplant	30 days	60 days
LDR	Hospital submits <i>living donor feedback form</i>	60 days	90 days
TCR	Hospital registers candidate on waitlist	30 days	90 days
TRR	Transplant hospital removes recipient from waitlist at transplant	60 days	90 days
LDF	6 months, 1 year and 2 year anniversaries of donation	60 days	90 days
TRF	Either: 1) 6-month, 1- and 2-year anniversaries of transplant, or 2) notification of recipient’s death or graft failure (longer due date not observed, 14 day reporting requirement)	30 days	90 days

**Cohort:** This report includes data on all form unlocking events recorded in the OPTN Data System from August 30, 2022 to February 26, 2023, or 180 days post-implementation. We have included all recorded unlocking events in that time period. For comparison, some metrics are also calculated using a “Pre-policy” cohort period dating from March 2, 2022 (180 days prior to the implementation).

Form unlocking events covered in this report may include forms that were submitted prior to August 30, 2022 that were subject to reporting requirements outlined in the pre-implementation period at time of submission, but unlocked on or after this date, as well as forms whose due dates fell after policy implementation and were therefore only subject to the newer, post-implementation requirements at the time they were due.

**Notes on implementation and the treatment of forms in “Expected” status:** Of note, when the policy implementation occurred in the OPTN Data System, forms that were expected within 30 or 60 days before the lock implementation (depending on the form and its previous submission timeline) and remained in expected status at time of implementation (even if the due date had passed) were granted an automatic extension of on the implementation date, so that their expected dates now conformed to the newer policy (60 or 90 day timeline, depending on the form). This was done to ease the transition for members between policy eras for forms already in existence at the time of the change. Any forms generated after the change took place (August 30, 2022 at 8 am EST) were subject to the new policy, however, and no time was added to their expected dates. In this report, policy eras presented in text, tables and graphs will consider all forms whose expected dates (revised or otherwise) fell after the implementation as “Post-policy”, even though some of these forms were generated and expected before the change and had time added to their due dates by the policy change. These forms were affected by the policy change, even though they may have been due before the change.

## Results

### Pre-/Post-implementation Comparison

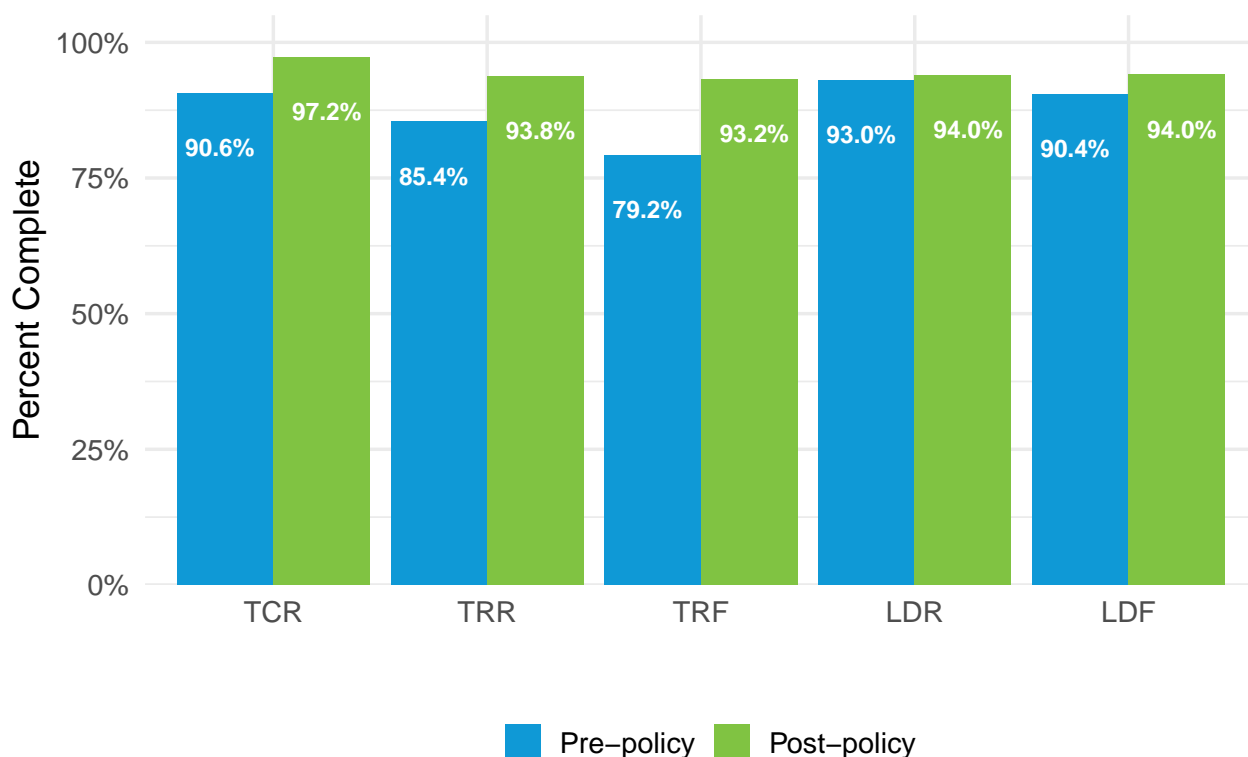
#### Timely form submission rates by policy era

Transplant centers, organ procurement organizations (OPOs), and histocompatibility laboratories (labs) are required to submit OPTN data by the expected dates (due dates) specified in **OPTN Policy 18: Data submission requirements**. **Figure 1** displays data submission by form type, for OPTN Data System forms expected from currently active transplant centers during six months before and after the policy change (i.e. “Pre-policy” vs. “Post-policy”) (N=454,956 forms).

Timely data submission prior to implementation, defined as the percentage of forms submitted by the due date, varied by form type, with the percentage of forms submitted by the due date pre-policy ranging from 79.2% (N=169,687) for the Transplant Recipient Follow-up form (TRF), to 93.0% (N=2,566) for the Living Donor Registration form (LDR).

After implementation, the percentage of forms submitted by the due date ranged from 93.2% (N=169,204) for the Transplant Recipient Follow-up form (TRF), to 97.2% (N=27,306) for the Transplant Candidate Registration form (TCR).

**Figure 1. Forms submitted by transplant centers by expected date pre- and post-policy.**

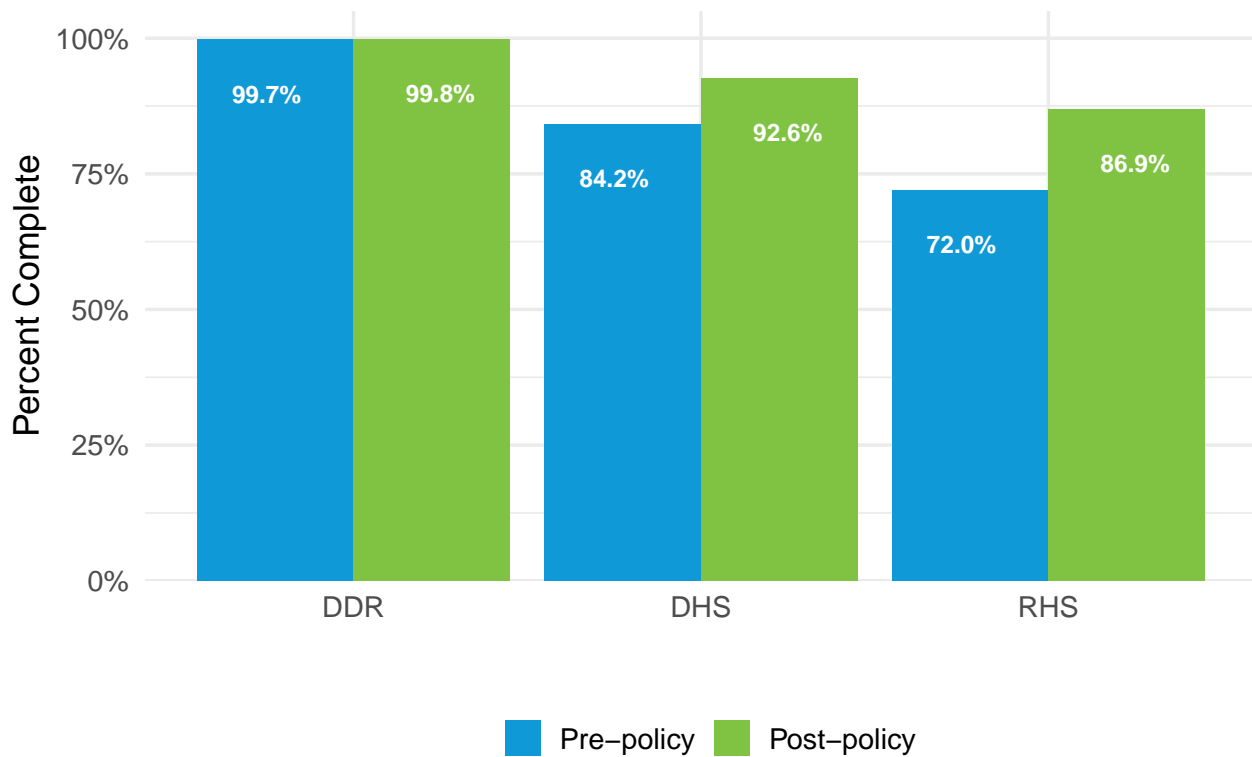


**Figure 2** displays data submission for forms expected from OPOs (N=13,648 forms) and histocompatibility labs (N=55,525 forms), during pre- and post-policy eras.

OPOs submitted 99.7% of the Deceased Donor Registration (DDR) forms by the due date pre-policy. Lab data submission pre-policy varied by form type, with the percentage of forms submitted by the due date ranging from 72.0% (N=16,083 forms) for the Recipient Histocompatibility (RHS) form and 84.2% (N=8,812 forms) for the Donor Histocompatibility (DHS) form.

OPOs submitted 99.8% of the DDR forms by the due date post-policy. Lab data submission post-policy varied by form type, with the percentage of forms submitted by the due date ranging from 86.9% (N=19,821 forms) for the RHS form and 92.6% (N=10,809 forms) for the DHS form.

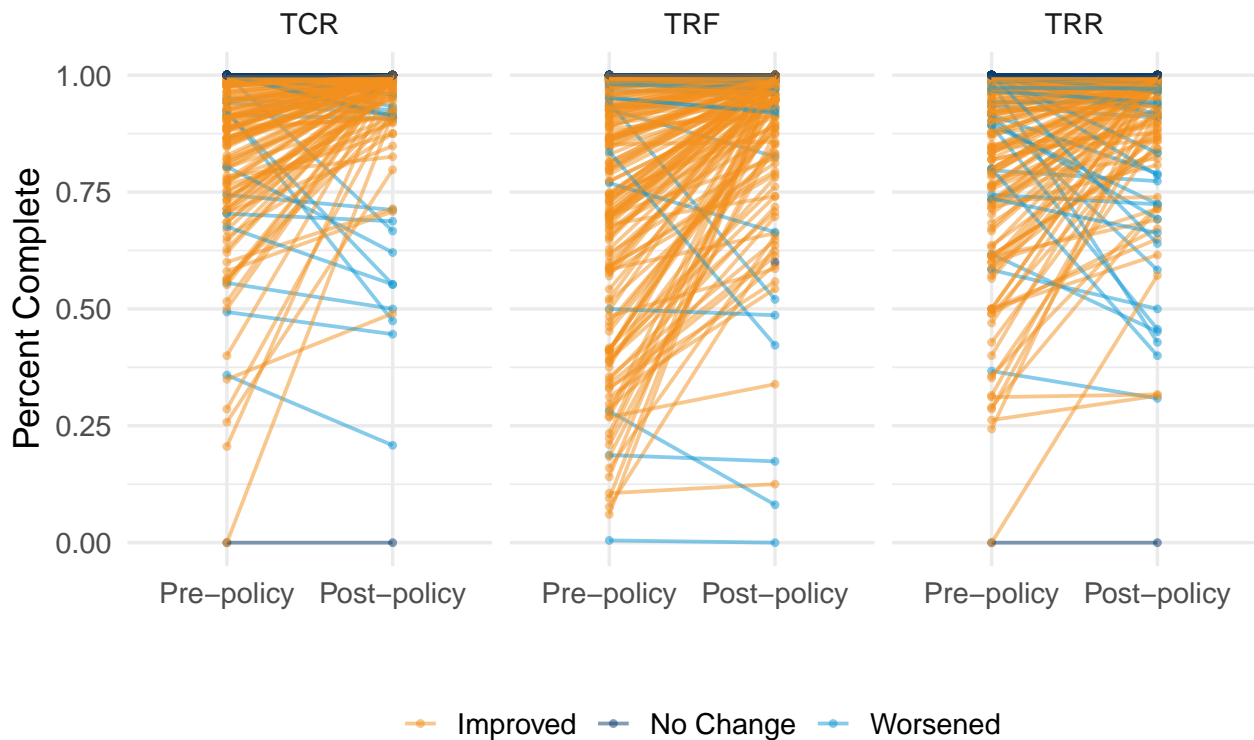
**Figure 2. Forms submitted by OPOs and histocompatibility labs by expected date pre- and post-policy.**



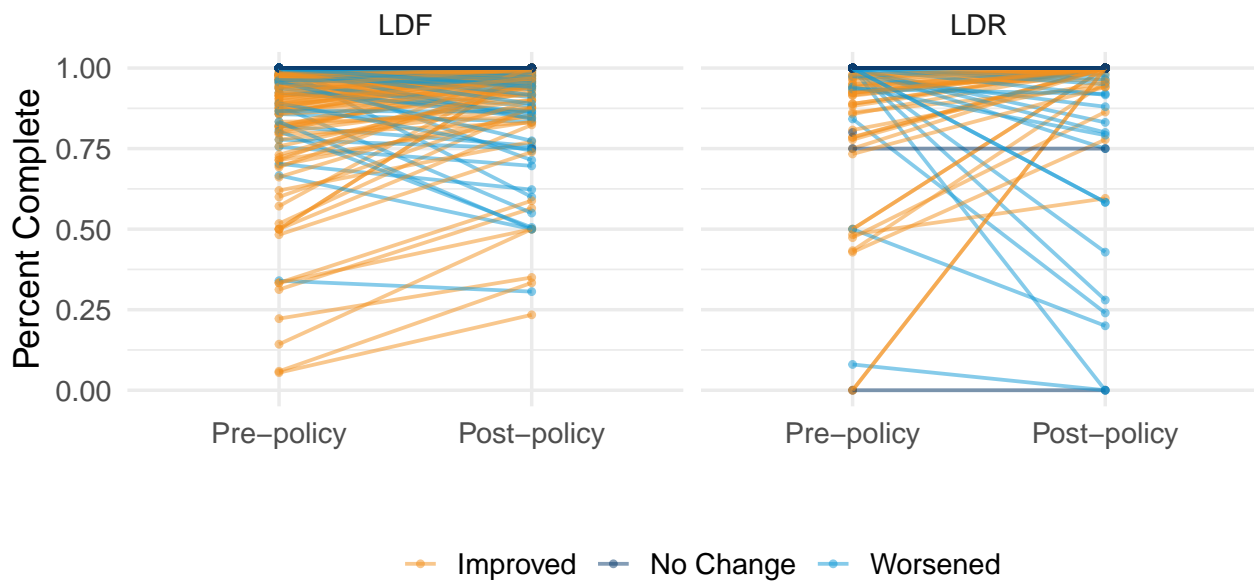
**Timely form submission rates at the institutional level (blinded)**

*Figures 3 through 5* demonstrate institution-level changes in timely form completion in more detail. Institutional identifications have been blinded in these figures, as is OPTN practice for committee reports. However, from the figures, some very notable increases in compliance with timely form submission at the individual institution level are clearly evident. While progress on timely form submission is not uniform, the majority of institutions with lagging form submission prior to August 30, 2022 increased their compliance with policy following the changes to Policy 18: Data Submission Requirements.

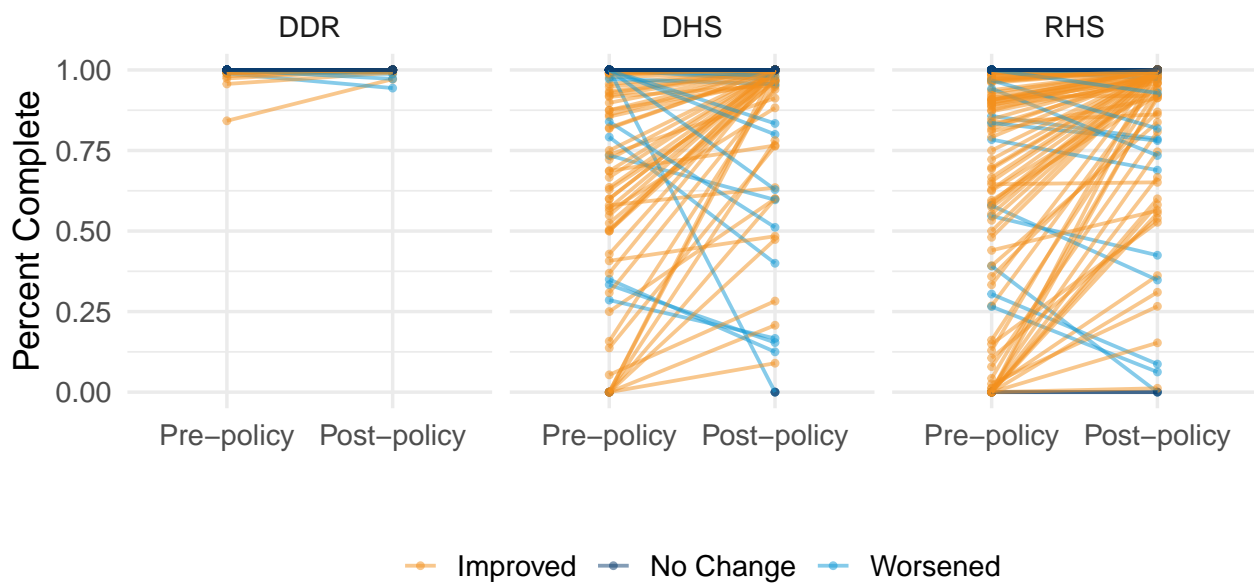
**Figure 3. Center-level rates of transplant form completion by expected date, pre- and post-policy.**



**Figure 4. Center-level rates of living donor form completion by expected date, pre- and post-policy.**



**Figure 5. OPO- and lab-level rates of donor and histocompatibility form completion by expected date, pre- and post-policy.**





## Post-implementation Detailed Data

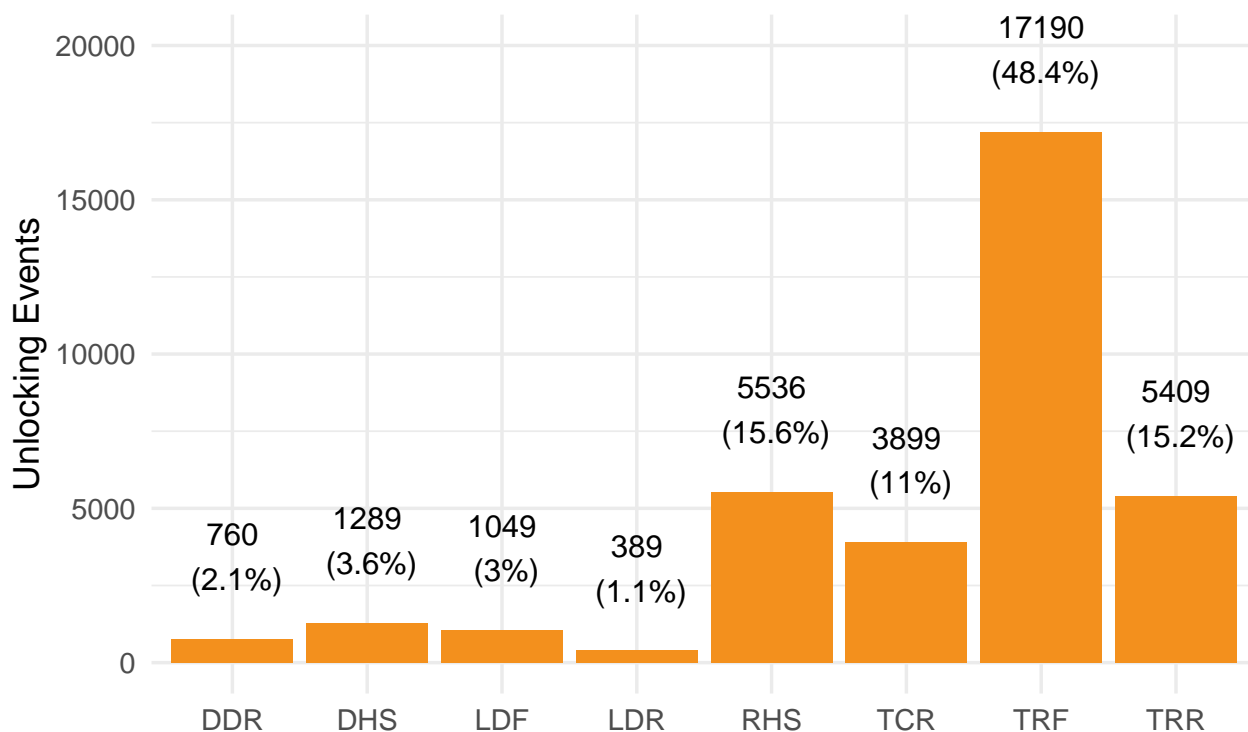
### Unlocking event frequency summary data

At a summary level, **Figures 6 through 10 and Tables 1 through 2** depict the number of form unlocking events to date by form type, week of unlocking, reason given for unlocking, and by organ (for transplant patient-specific forms). We also report summary data on unlocking events by blinded institution.

In subsequent sections, we will delve into more detail about trends and patterns in form- and field-level changes occurring related to these unlock events. These initial graphs and tables however give an indication of overall volume of unlocking since implementation. Note that unlocking events may occur without any field changes or with multiple changes made per unlock session. Note also that the same form, for the same donor, candidate or recipient, may be unlocked multiple times. Thus, the count of unlock events will not correspond with the number of discrete field changes, or the number of distinct forms where data were changed.

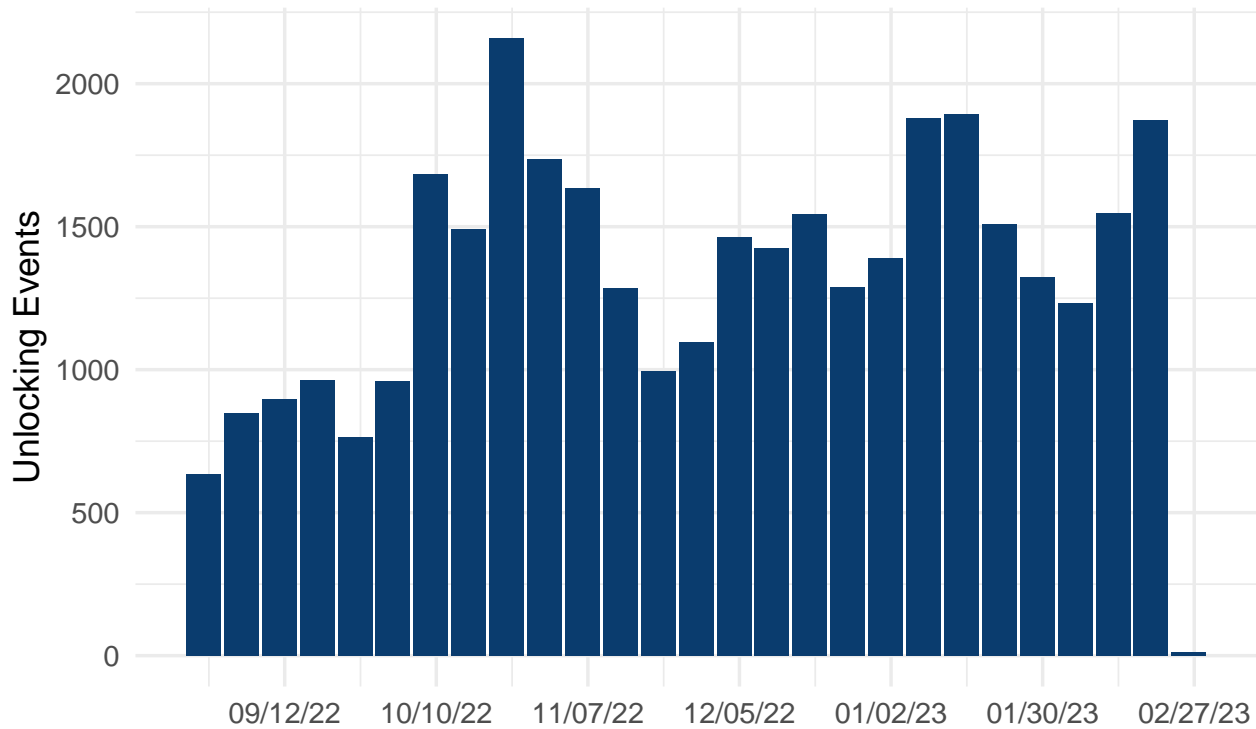
**Figure 6** displays the number of unlocking events by OPTN Data System form type. Through February 26, 2023, 35,521 total unlocking events have occurred. The most commonly-unlocked form to date has been the TRF, accounting for 17190 (48.4%) of all unlocked forms as of that date. Donor forms of all types have been unlocked much more rarely, though among them, the Donor Histocompatibility form (DHS) was the most frequently unlocked.

**Figure 6. Number of unlocking events by form type.**



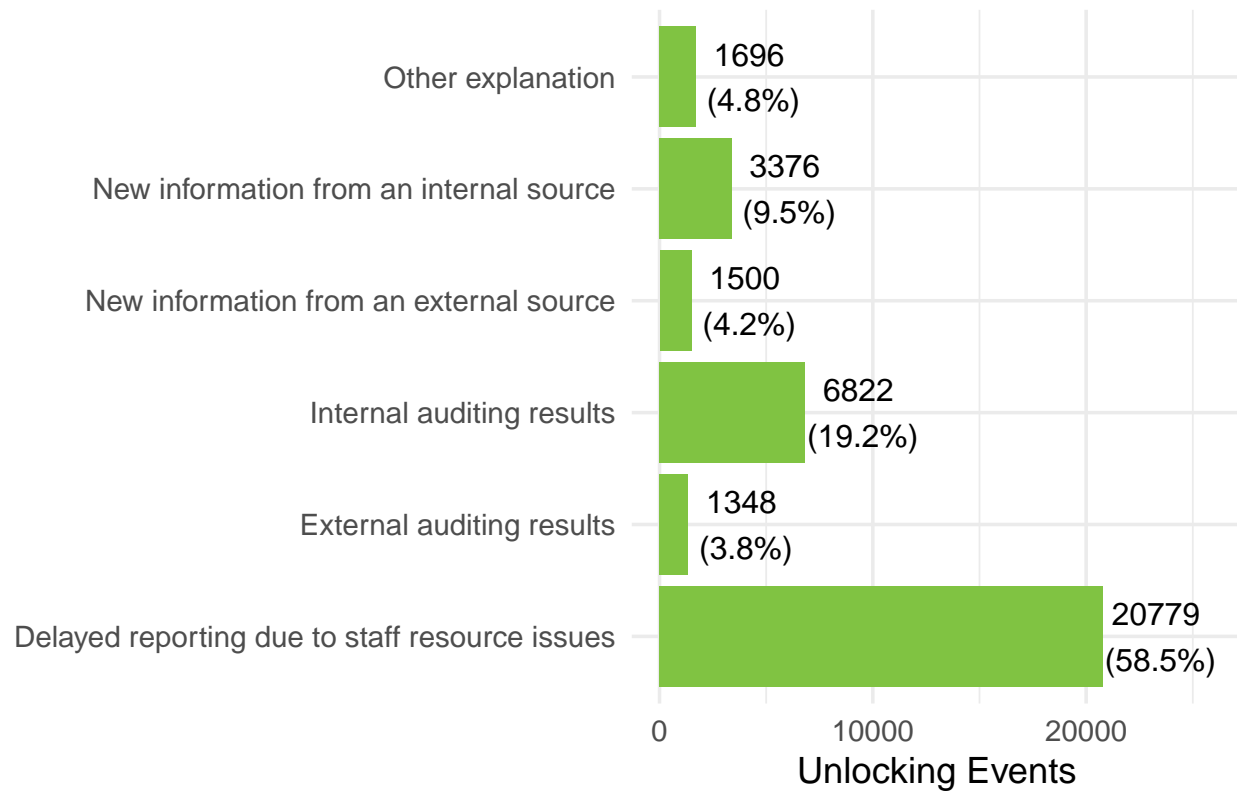
**Figure 7** displays the number of unlocking events per week since the implementation of the policy revision. The largest number of form unlocking events by week to date occurred during the week beginning October 23, 2022. The first week of policy enactment had the lowest number of unlocking events to date. Note that the most current week depicted below was incomplete at the time of report compilation, and therefore the total depicted in the graph may underestimate that week’s complete unlocking volume.

**Figure 7. Number of unlocking events by week.**



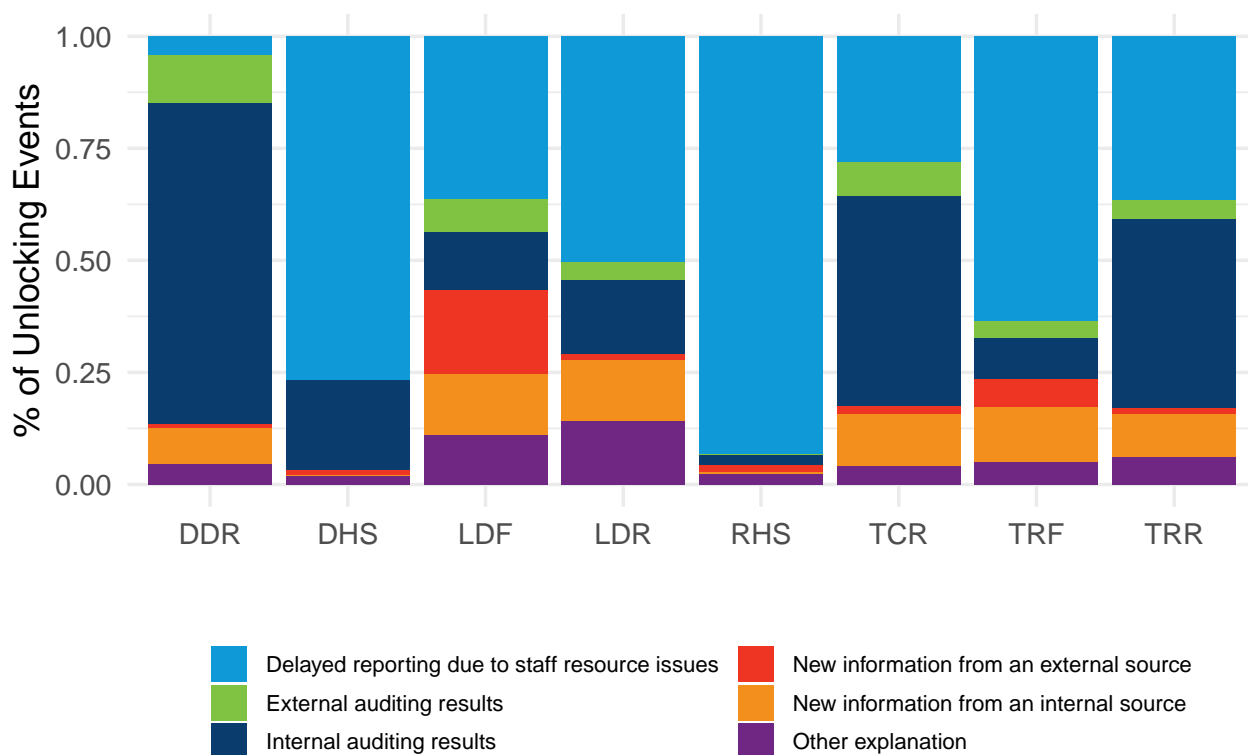
**Figure 8** displays the number of unlocking events by the reason given. A large portion (58.5%) of unlocking events were a result of “Delayed reporting due to staff resource issues”, highlighting resource issues that may persist across members. Note also that “External auditing results” was the least commonly-cited reason for unlocking (3.8%).

**Figure 8. Number of unlocking events by reason.**



**Figure 9** and **Table 2** display the percent of unlocking events by reason and form type. TCR forms were more commonly unlocked for reasons of “Internal auditing results”, while TRF forms were more likely to be unlocked due to “Delayed reporting due to staff resource issues”.

**Figure 9. Percent of unlocking events by reason and form type.**

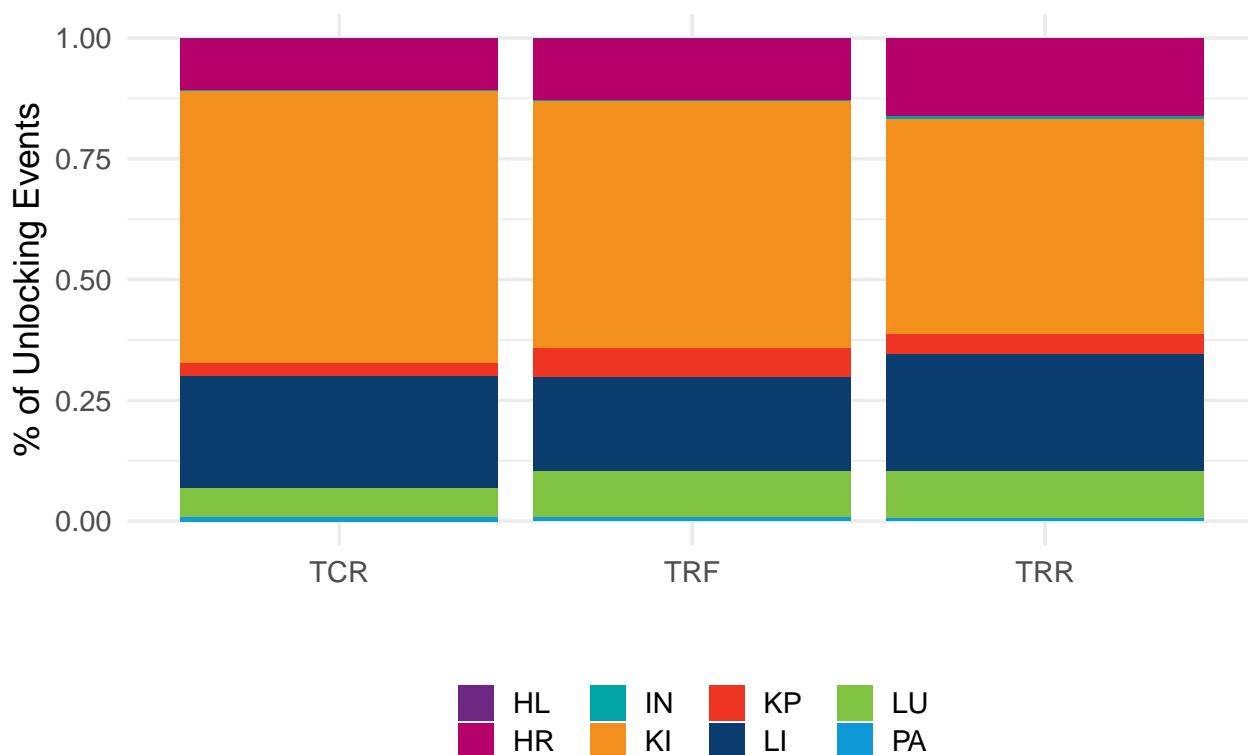


**Table 2. Number and percent of unlocking events by reason and form type.**

Reason	DDR	DHS	LDF	LDR	RHS	TCR	TRF	TRR
Delayed reporting due to staff resource issues	33 (4.3%)	989 (76.7%)	382 (36.4%)	196 (50.4%)	5170 (93.4%)	1097 (28.1%)	10937 (63.6%)	1975 (36.5%)
External auditing results	80 (10.5%)	1 (0.1%)	76 (7.2%)	16 (4.1%)	1 (0.0%)	293 (7.5%)	654 (3.8%)	227 (4.2%)
Internal auditing results	545 (71.7%)	257 (19.9%)	137 (13.1%)	64 (16.5%)	128 (2.3%)	1829 (46.9%)	1573 (9.2%)	2289 (42.3%)
New information from an external source	6 (0.8%)	16 (1.2%)	197 (18.8%)	5 (1.3%)	86 (1.6%)	65 (1.7%)	1057 (6.1%)	68 (1.3%)
New information from an internal source	61 (8.0%)	2 (0.2%)	142 (13.5%)	53 (13.6%)	27 (0.5%)	458 (11.7%)	2111 (12.3%)	522 (9.7%)
Other explanation	35 (4.6%)	24 (1.9%)	115 (11.0%)	55 (14.1%)	124 (2.2%)	157 (4.0%)	858 (5.0%)	328 (6.1%)
Total	760 (100.0%)	1289 (100.0%)	1049 (100.0%)	389 (100.0%)	5536 (100.0%)	3899 (100.0%)	17190 (100.0%)	5409 (100.0%)

**Figure 10** and **Table 3** display the percent of unlocking events by organ and from type for the TCR, TRR and TRF only. Kidney forms were the most frequently unlocked. Given the higher volume of kidney candidates and recipients, this finding was expected.

**Figure 10. Percent of TCR, TRF and TRR unlocking events by organ.**



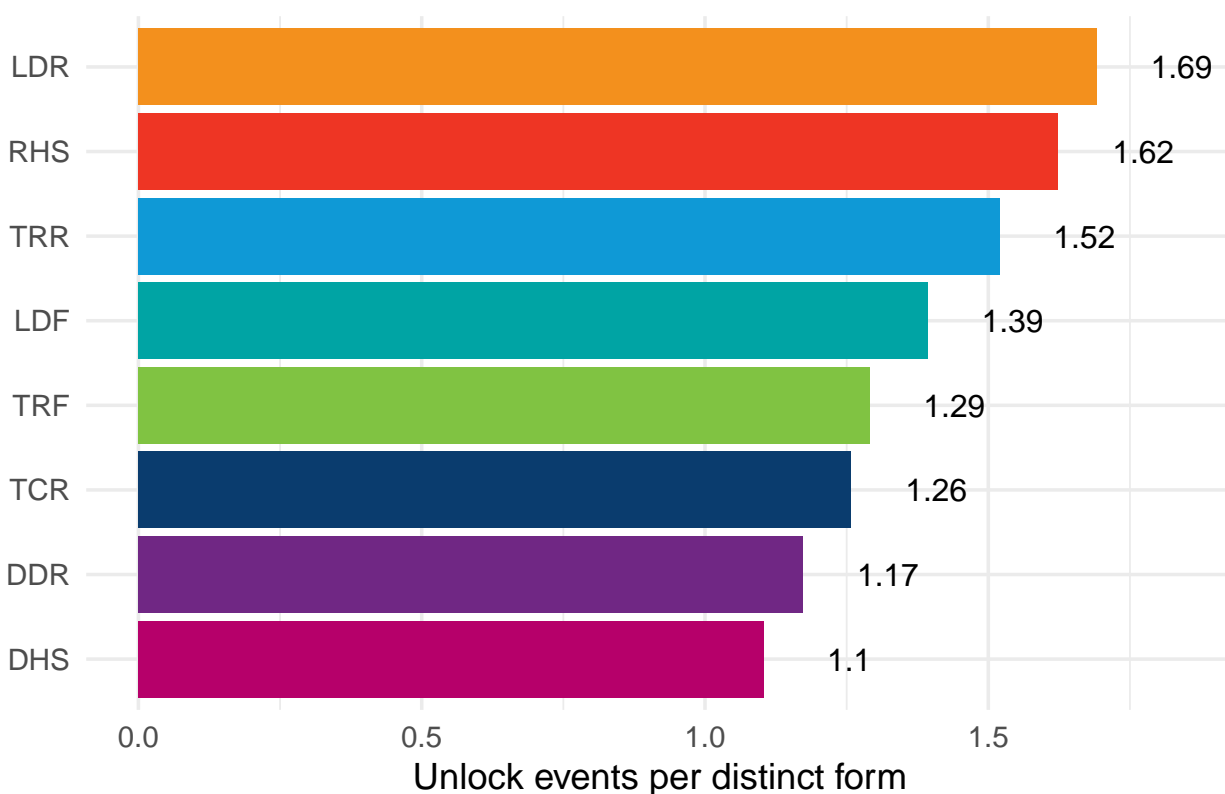
**Table 3. Number and percent of transplant forms unlocked by organ and form type.**

Organ	TCR	TRF	TRR
HL	10 (0.3%)	28 (0.2%)	4 (0.1%)
HR	409 (10.5%)	2188 (12.7%)	876 (16.2%)
IN	5 (0.1%)	39 (0.2%)	30 (0.6%)
KI	2203 (56.5%)	8800 (51.2%)	2412 (44.6%)
KP	102 (2.6%)	1015 (5.9%)	227 (4.2%)
LI	909 (23.3%)	3364 (19.6%)	1300 (24.0%)
LU	228 (5.8%)	1618 (9.4%)	530 (9.8%)
PA	33 (0.8%)	138 (0.8%)	30 (0.6%)
Total	3899 (100.0%)	17190 (100.0%)	5409 (100.0%)

### Distinct forms unlocked vs. unlocking events

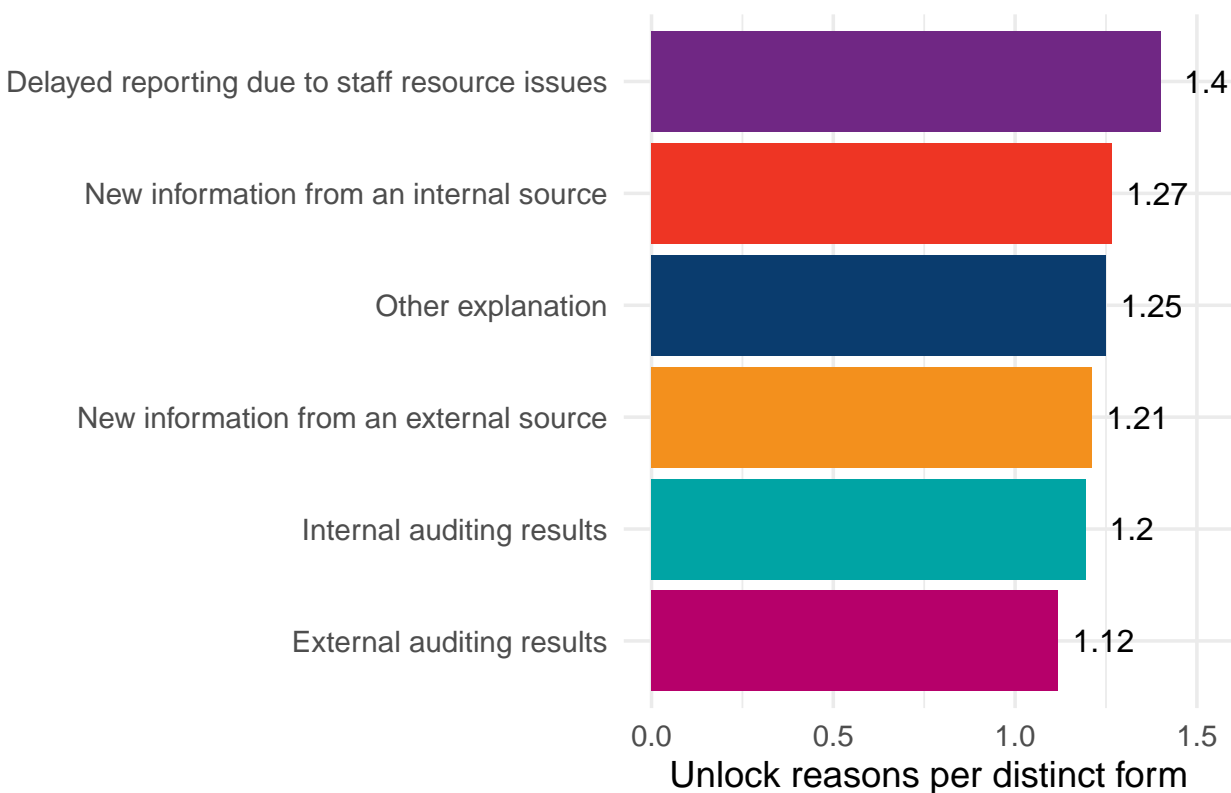
**Figures 11 through 13 and Tables 4 through 5** compare recorded unlocking events since implementation to the de-duplicated, or distinct, number of forms that were ever unlocked over this period. Forms may be unlocked more than once, and this comparison is thus intended to better highlight the actual number of discrete forms where changes could have been made following unlock. Note that an unlocked form may have multiple changes (or no changes) made at the same time, during one unlock session. Therefore, the analysis below does not capture the volume of field changes made upon unlock.

**Figure 11. Number of unlocking events per distinct form by form type.**



**Table 4. Number of unlocking events per distinct form by form type.**

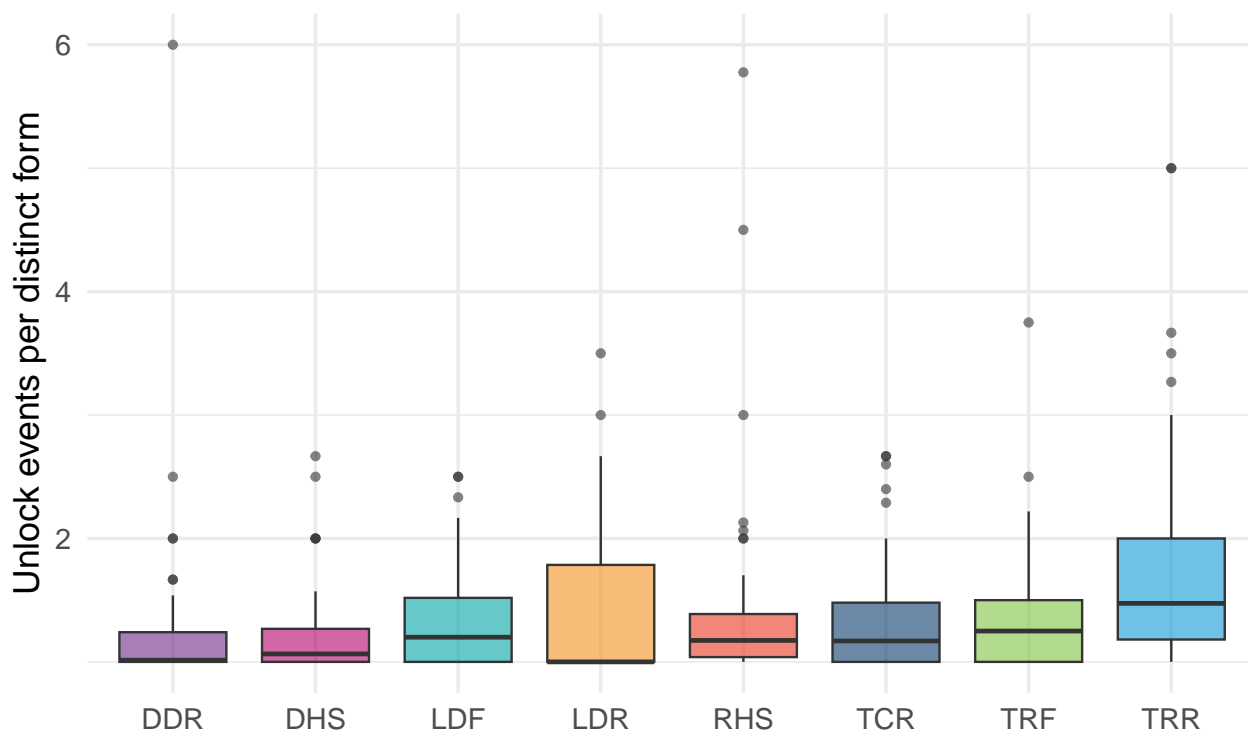
Form Type	Number of Unlocking Events	Distinct Forms Unlocked	Events/Distinct Form
LDR	389	230	1.691304
RHS	5536	3410	1.623460
TRR	5409	3559	1.519809
LDF	1049	753	1.393094
TRF	17190	13324	1.290153
TCR	3899	3099	1.258148
DDR	760	648	1.172840
DHS	1289	1167	1.104542

**Figure 12. Number of unlocking event reasons per distinct form.****Table 5. Number of unlocking event reasons per distinct form.**

Reason for Unlocking	Number of Event Reasons	Distinct Forms Unlocked	Reasons/Distinct Form
Delayed reporting due to staff resource issues	20779	14838	1.400391
New information from an internal source	3376	2666	1.266317
Other explanation	1696	1356	1.250738
New information from an external source	1500	1238	1.211632
Internal auditing results	6822	5703	1.196212
External auditing results	1348	1205	1.118672

Most institutions appear to only unlock the same form once or twice for editing, but there are notable outliers visible for some forms as summarized in **Figure 13 and Table 6** below. TRRs have notably the highest mean and median number of unlocking events per distinct form across institutions.

**Figure 13. Distribution of institution-level number of unlocking events per distinct form by form type.**



**Table 6. Mean, median, p25 and p75 (IQR) of institution-level number of unlocking events per distinct form by form type.**

Form Type	Mean	Median	IQR
TRR	1.64	1.47	1.18, 2
LDR	1.45	1.00	1, 1.79
RHS	1.43	1.17	1.04, 1.39
LDF	1.34	1.20	1, 1.52
TRF	1.33	1.25	1, 1.5
DDR	1.30	1.01	1, 1.24
TCR	1.30	1.17	1, 1.48
DHS	1.25	1.06	1, 1.27

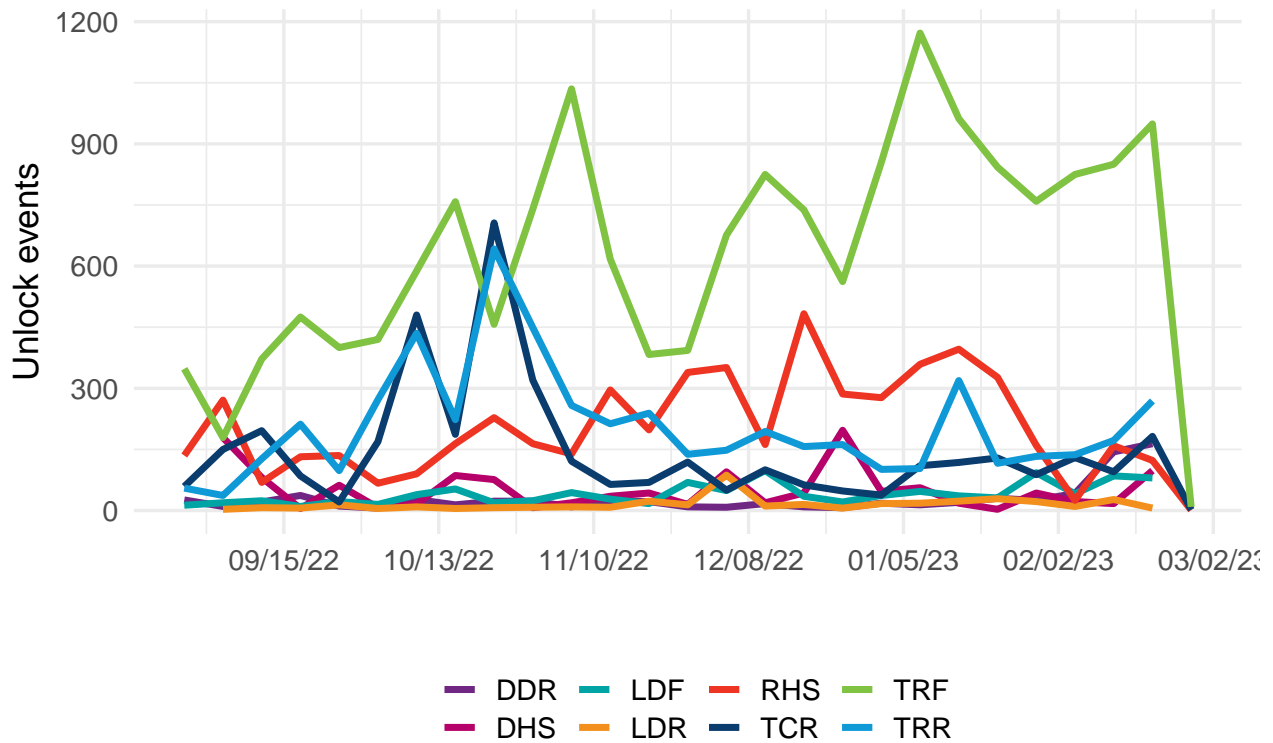


**Temporal trends in unlocking events**

We also examined weekly unlocking volume by form and reason code, to better understand any trends in how often specific forms were unlocked and whether the reasons given for these unlock events varied over time. These data are summarized in **Figures 14 through 15**.

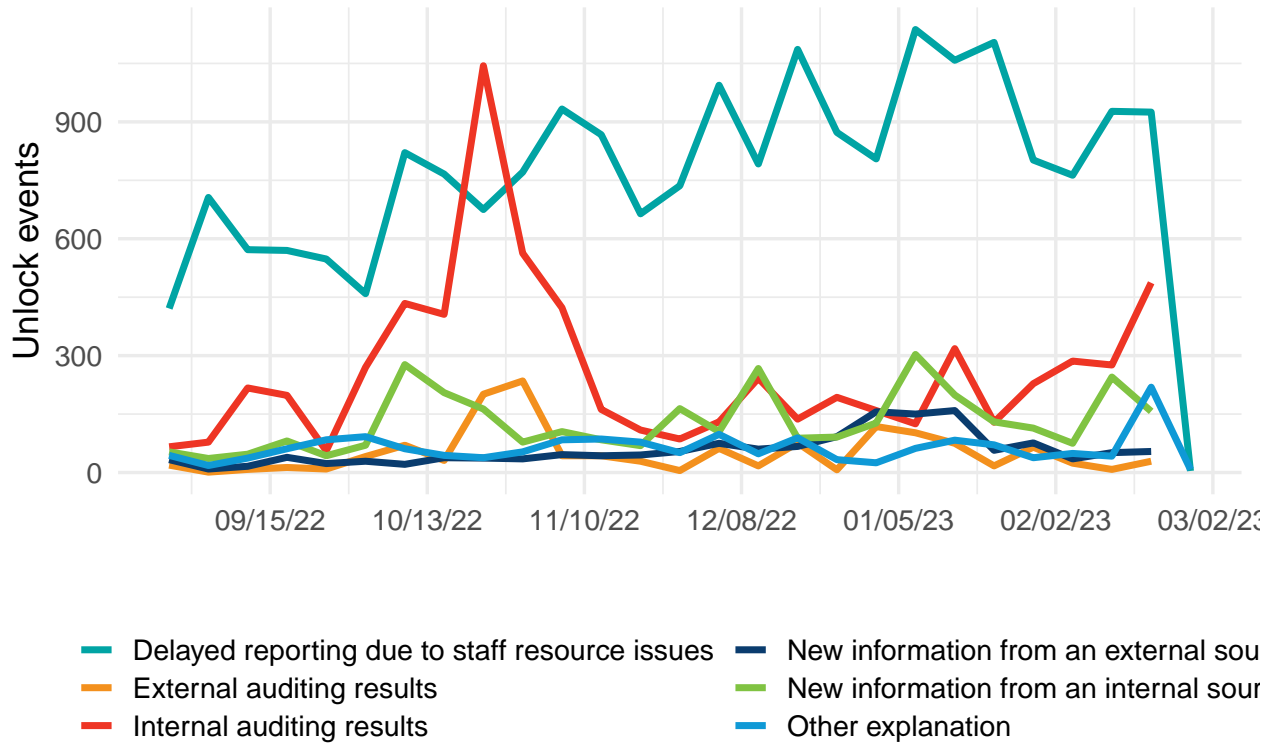
TCR and TRR unlocking activity notably peaked in late October 2022, which may correspond to the data review period prior to the publication of biannual Program-Specific Reports (PSRs) by the Scientific Registry of Transplant Recipients (SRTR). TRF unlocking activity varied over time but was high throughout the entire monitoring period generally.

**Figure 14. Trends in form unlocking by form type and week.**



Reasons given for unlocking also varied considerably by week

**Figure 15. Trends in unlocking events by reasons given and week.**



## Summary Findings

In summary, this six-month post-implementation monitoring report on data accumulated to date following the **Updates to Policy 18, Data Submission Requirements** project found the following general data trends:

- Following the implementation of the 30- or 60-day increases to eight OPTN Data Collection System forms in this policy change, national timely form completion rates rose for all forms
- Timely completion rate increases were highest for histocompatibility forms submitted by labs (i.e. RHS and DHS), and seven of the eight forms have national timely completion rates above 90% post-policy, compared to only one pre-policy. Two of the eight now have timely completion rates above 95%, compared to only one pre-policy.
- The most frequently unlocked form was the TRF. As each recipient has multiple TRF forms generated over the course of their follow up, and as post-transplant follow-up can present challenges for programs, this is not unexpected.
- Form-level unlocking volume was highly variable by week. There was, however, a notable spike in TCR and TRR unlocking activity in late October, potentially corresponding with the data review period that precedes the release of updated transplant program performance monitoring.
- Reasons given for unlocking activity were also highly variable by week. The same spike in TCR and TRR unlocking noted above occurs roughly at the same time that a spike in unlocking attributed to “Internal auditing results” occurs.
- The most common reason given for unlocking a form over the entire period, however, was “Delayed reporting due to staff resource issues”. This speaks to concerns members have reported about having enough staff capacity to maintain timely data entry policy compliance. As the OPTN must routinely weigh data entry burden against the need for adding data elements to existing data collection, this common reason for delayed edits to OPTN data should be considered in future discussions of data quality.

## Conclusion

The next scheduled monitoring report for this policy will occur following the 12-month anniversary of the implementation and will be available shortly after August 30, 2023. In future monitoring reports, we plan to examine whether the number of discrete field changes for DDR, TCR, and TRR forms that are critical to the modeling of transplant program outcomes reported on the PSRs published biannually by the SRTR.

We also plan to determine how frequently unlocks are occurring for forms that were previously validated vs. forms never validated, presumably because the institution had not completed the form before the expected date.

We will also add measures of form volume to some estimates presented here of unlocking volume, to normalize the number of unlocking events to the number of forms the OPTN collects from members and better understand trends in unlocking frequency.