



OPTN Annual Data Quality Report

DHHS Contract No. 250-2019-00001C
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OPTN Contract Performance Work Statement Excerpt:**3.5.1 Maintain a data repository of all official OPTN data.**

The Contractor shall ensure that an official OPTN data collection function and member support for OPTN data collection is available 24 hours/day, 7 days/week, every day of the year. The Contractor shall develop and implement procedures to ensure accuracy of data entry, monitor completeness and timeliness of data submission, and specify the time period during which data corrections and revisions can be performed.

The Contractor shall submit to the COR an annual data quality report on the accuracy and quality of the data at the end of each contract performance period, and this report shall be reviewed and assessed by the OPTN Data Advisory Committee (DAC).

Schedule of Deliverables and Milestones

1. Annual official OPTN data quality report (*December 2023*)
2. Data review report (*December 2023*)

Purpose

This Annual Data Quality Report will provide a foundational assessment of current Organ Procurement and Transplantation Network (OPTN) data quality, and in concert with the OPTN data review report, will provide the OPTN DAC with information necessary to formulate recommendations for improving the quality of official OPTN data. The OPTN Contractor will present these data to the OPTN DAC in advance of the December 2023 OPTN BOD meeting.

Approach

This report will focus on data provided to the OPTN on Office of Management and Budget (OMB) approved forms in the OPTN Data System. The OPTN Contractor will provide data related to three dimensions of data quality: timeliness, availability, and accuracy. As an assessment of data quality within these dimensions, this report focuses on four areas:

- 1) Potential discrepancies in dialysis dates in OPTN data,
- 2) Timely data submission,
- 3) Review of key *Policy 18* amendment (“data lock”) metrics to date, and
- 4) Analysis of cadence of changes to key data fields pre- and post-data lock implementation

Anticipated Challenges

Evaluating data submission practices is challenging for a variety of reasons. A single user profile that submits official OPTN data does not exist. Even within an institutional member type (e.g. transplant hospital), there is variety in the roles (including level of clinical expertise) and processes used to submit official OPTN data. Another challenge is the use of unknown or unavailable as an option for a variety of data elements including numeric fields (e.g. lab values, ischemic times, etc.) and other fields like education level and working for income. By allowing the reporting of unknown or unavailable as an option, it impacts the completeness of these “required” fields. The OPTN contractor will work with the OPTN DAC to discuss these challenges and revise data quality measures over time. Additionally, the OPTN community continues to make progress on the overall goal of moving to electronic data exchange. This effort will enhance data quality across many of the focus areas of this report.

Review & Revision

The OPTN contractor will review the data provided in this report with the OPTN DAC and will incorporate recommendations from DAC into future versions of the report. As DAC's activities evolve over time, we expect to revise the focus areas for assessing data quality in this report. We will also need to reconsider quality measures as data submission practices change, and be responsive to changes such as increased adoption of seamless data exchange methods (e.g. Application Programming Interfaces (APIs)), integration of industry standards for data collection (e.g. ICD codes for diagnoses), and processes for making changes to data after final submission (i.e. "data lock policy").

List of Form Names and Abbreviations

The following is a comprehensive index of OPTN Data System Form names and the corresponding abbreviations we use throughout the report:

OPTN Data System Form Name	Abbreviation
Deceased Donor Registration	DDR
Donor Histocompatibility	DHS
Living Donor Follow-Up	LDF
Living Donor Registration	LDR
Liver Explant Pathology	LEX
Post-transplant Malignancy	PTM
Recipient Histocompatibility	RHS
Transplant Candidate Registration	TCR
Transplant Recipient Follow-Up	TRF
Transplant Recipient Registration	TRR

Selected Highlights

Among kidney recipients with TRRs expected in 2022:

Dialysis status reported on the OPTN Waitlist vs. the TRR **conflicted 9.1%** of the time, and

Dialysis dates reported on the OPTN Waitlist vs. the TRR **conflicted 18.5%** of the time.

Timely form completion rates rose between 2020 and 2022, from:

74.2% to 85.4% for transplant centers,

99.3% to 99.6% for organ procurement organizations, and

76.4% to 81.3% for histocompatibility labs.

Form volume at the institution-level appears to have, at best, either no direct relationship with timely form completion rates, or only a weak positive one (indicating that as form volume increased at an institution, so did timely completion rates), with the correlation coefficients for 2022 as:

-0.024 for transplant centers

0.297 for organ procurement organizations, and

0.116 for histocompatibility labs.

Form unlocking activity is more common since the August 30, 2022 policy implementation for some forms than others, with the following consistent trends noted:

Highest unlocking volume to date has been for the **TRR**,

Seasonal spikes in **TRR and TCR** unlocking activity **occur in October and April**, corresponding to PSR data review periods,

Unlocking activity for reported reasons of **'Delayed reporting due to staff resource issues'** occurs at a **higher level regardless of the time of year**, while

'Internal audit-related reasons' are cited more commonly in sync with seasonal spikes in TCR and TRR unlocking in April and October.

Following the implementation of the data lock in August 2022,

Changes to selected fields on KI TCRs critical to the PSR reports more than 90 days after the forms were added to the system are occurring **more frequently rather than less frequently**, highlighting a continuing gap in accurate, complete and timely reporting.

Data Quality Assessment Detailed Findings

Discrepancies in reported dialysis fields for kidney recipients

Accuracy can be challenging to assess without direct access to the source data from the electronic health record. However, within the OPTN Computer System, there are some data elements collected at multiple time points as a patient progresses from candidate to recipient. Comparing values collected for an individual at multiple time points could identify data discrepancies or potentially inaccurate values.

This section will focus on dialysis status and dialysis dates reported for kidney recipients. Below, **Figure 1** provides the overall rate of discrepancies in information by field type for all recipients with KI TRR forms expected in 2022, while **Figures 2 and 3** characterize the direction of these discrepancies, based on a total of 22,843 deceased donor kidney transplant recipients with TRRs expected during 2022.

While the majority of recipients did not have discrepant dialysis status or date values when comparing between data collection systems, 18.5% do not align by date and 9.1% do not align by status. While dialysis status does often change while a candidate is waiting, we are comparing here the last update to the dialysis information captured in the OPTN Waitlist Data System. This value is expected to be updated as status changes, unlike the information that would be reported on the TCR at time of listing. Furthermore even if OPTN Waitlist and TRR report the same status at time of transplant, the dates of dialysis initiation reported in both places may not align. **Figure 2** excludes recipients whose dialysis status at both points was the same and calculates the percentage of all discrepant statuses by type out of total recipients with a dialysis status discrepancy, while **Figure 3** excludes recipients whose dialysis status at both points was “No”.

Among recipients with discrepant dialysis dates, the most prevalent discrepancy found was that the date of dialysis initiation reported on the OPTN Waitlist was earlier than the date reported on the TRR. As kidney allocation is based on wait time accrued, and as dialysis initiation dates are a critical piece of information that determines when candidate wait time begins for allocation purposes, accuracy in the recording of dialysis initiation dates is critical to equitable allocation.

Figure 1. Percent of KI transplant recipients with discrepant dialysis status or date values between the OPTN Waitlist and the TRR, for KI recipients with TRR forms expected during 2022.

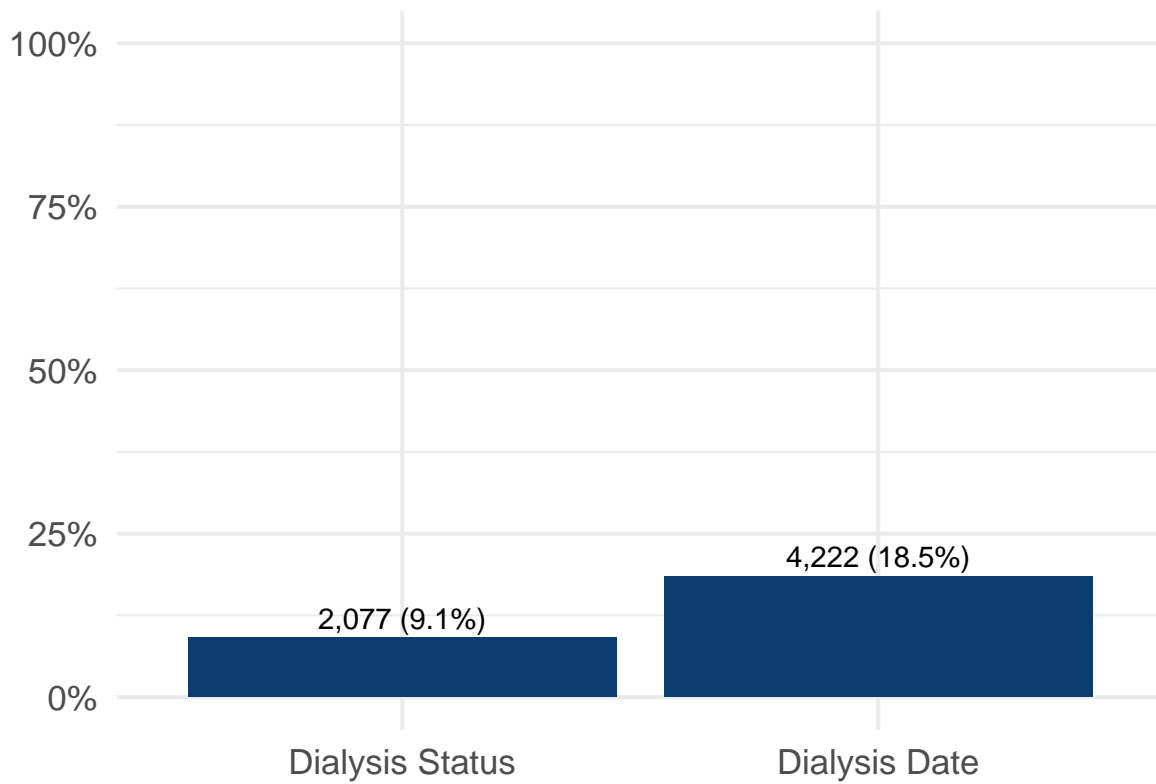


Figure 2. Type of dialysis status reporting discrepancy between OPTN Waitlist and TRR, for KI recipients whose TRR forms were expected during 2022.

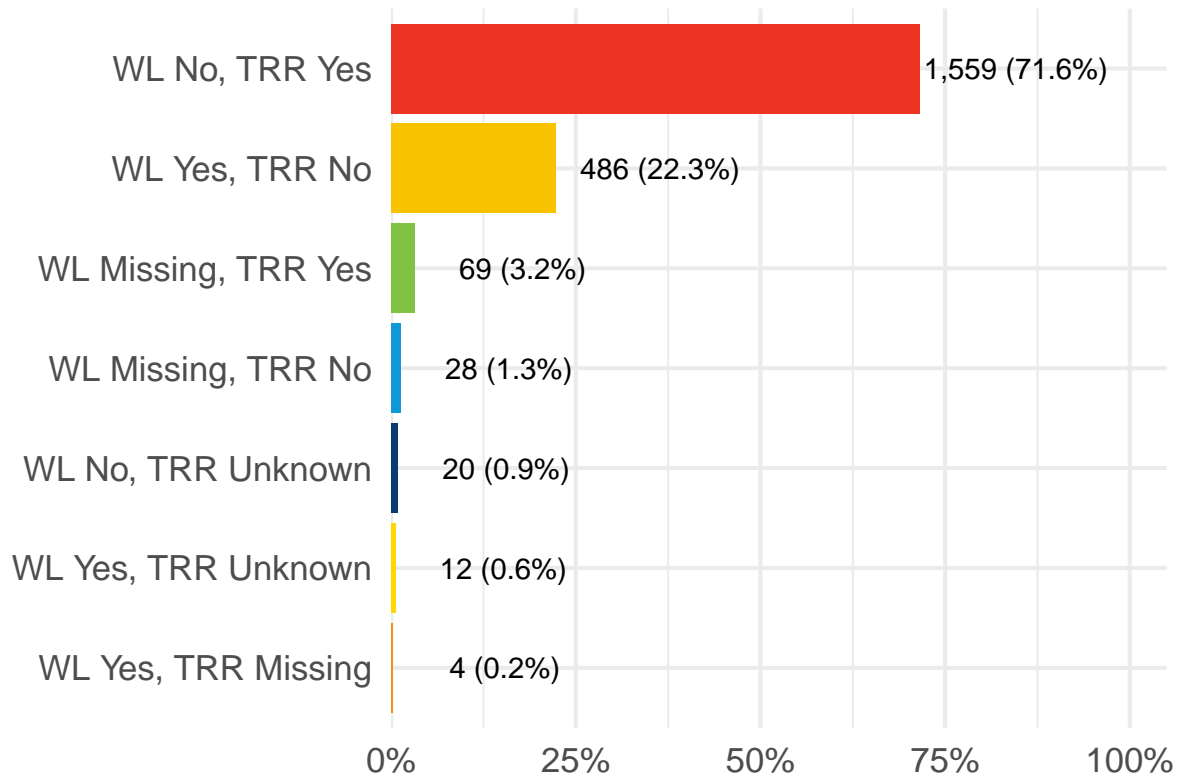
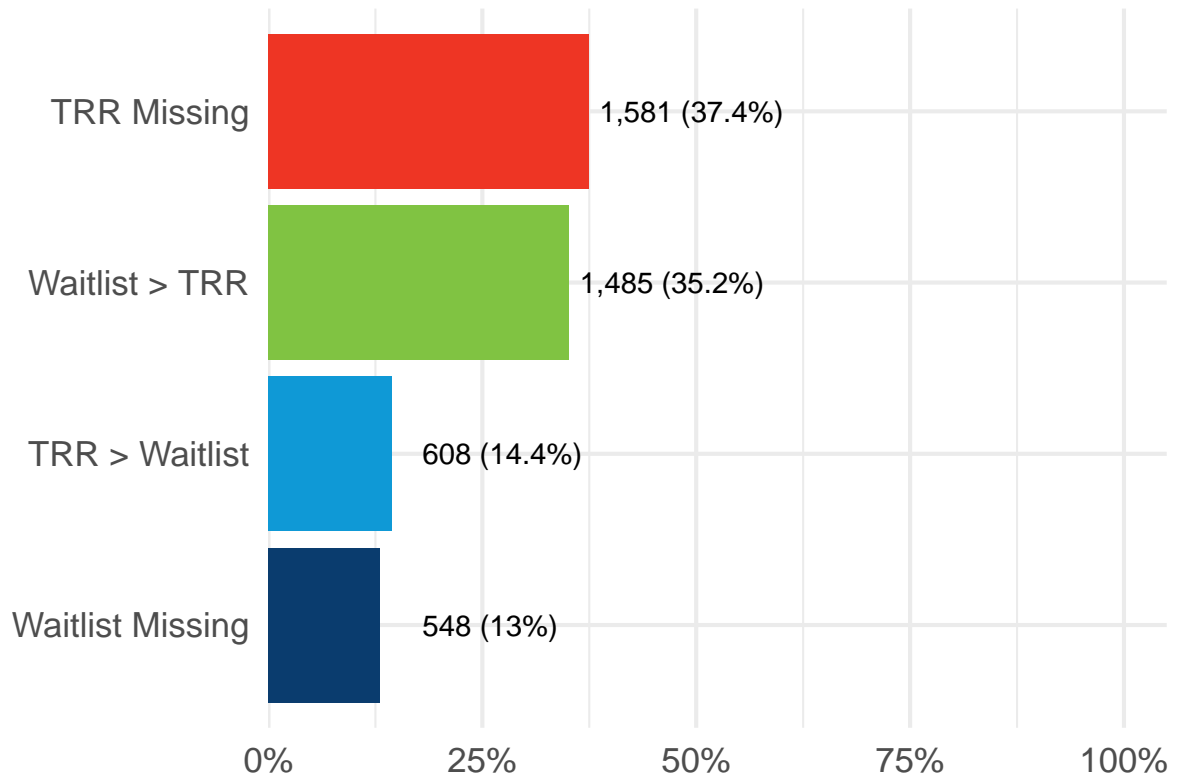


Figure 3. Direction of dialysis date discrepancy between OPTN Waiting List and TRR, among recipients whose TRR forms were expected in 2022.



Timely data submission

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 4** displays timely data submission, defined as the percentage of forms submitted by the expected date among all forms expected that year, by form type, for OPTN Data System forms expected from currently active transplant centers during 2022 (N=480,341 forms). Timely data submission in 2022 varied by form type, ranging from 73.7% (N=1,072) for the Liver Explant Pathology form (LEX), to 93.0% (N=5,875) for the Living Donor Registration form (LDR).

Prior to August 2022, OPTN data submission policy specified both a due date for each individual form in *Policy 18.1*, along with language in *OPTN Policy 18.4 Data Submission Standard* that required members submit 95% of these forms within three months of the due date and 100% within six months of the due date. *OPTN Policy 18.4* was removed with the implementation of the new data submission policy on August 30, 2022, eliminating the confusion of multiple data submission requirements. Data shown here for 2022 includes data from both policy periods. Completion rates presented in **Figure 4** therefore also show percentage of forms submitted up to 90 days after the expected date. The 90 days was used rather than three months as during this period it was the time point required by the Centers for Medicare & Medicaid Services (CMS) for 95% of forms to be submitted by transplant centers for certification. At least 90.5% of each form type were submitted by transplant centers by the expected date or within 90 days after the expected date for that form.

Figure 4. Percentage of forms submitted by transplant centers by expected date and within 90 days of expected date, for forms expected during 2022.

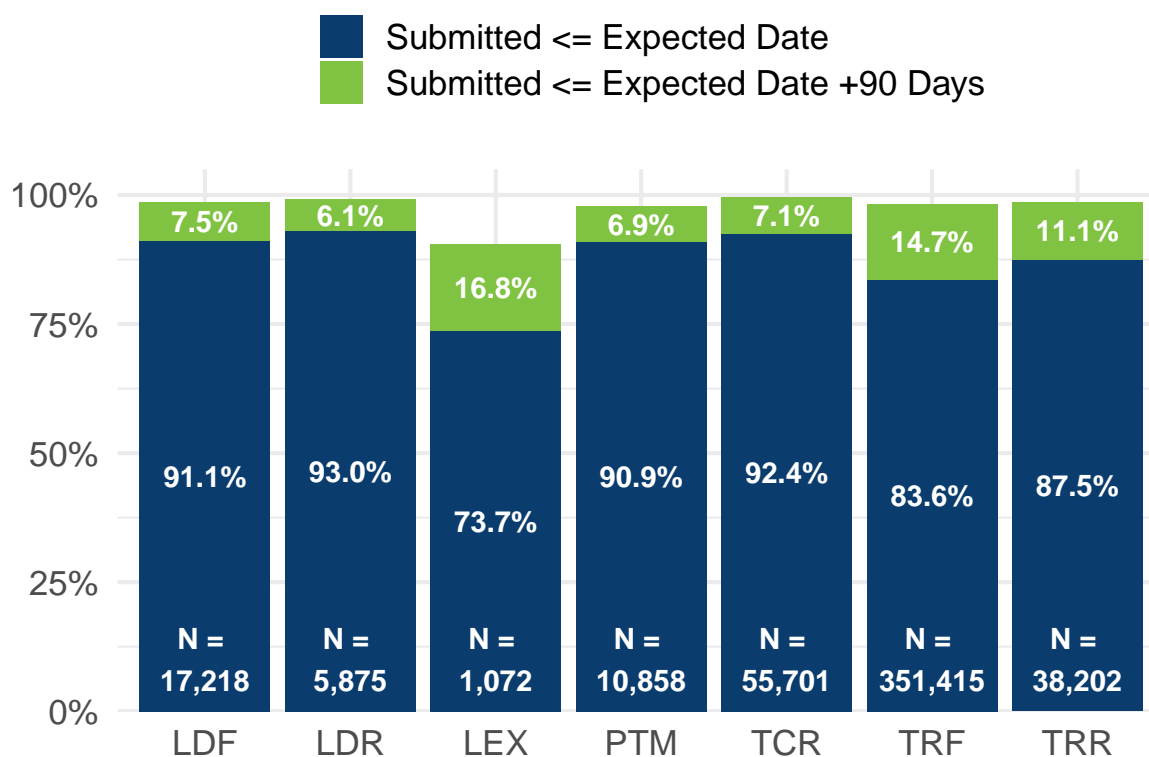
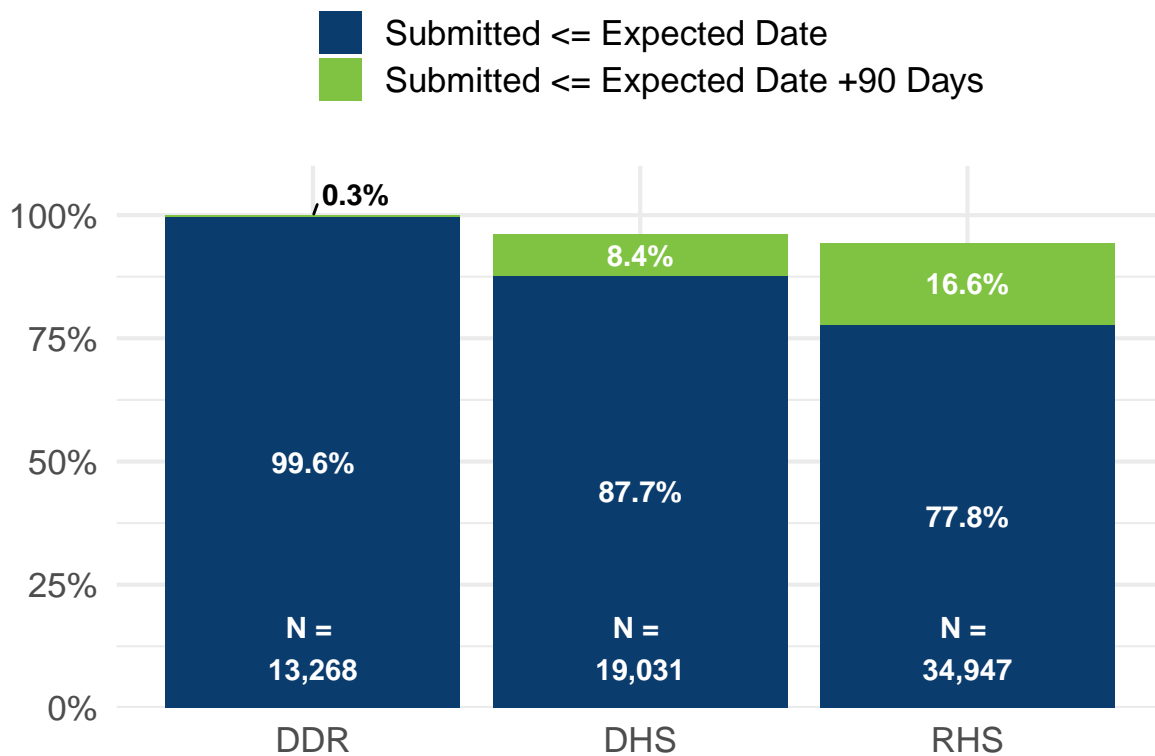


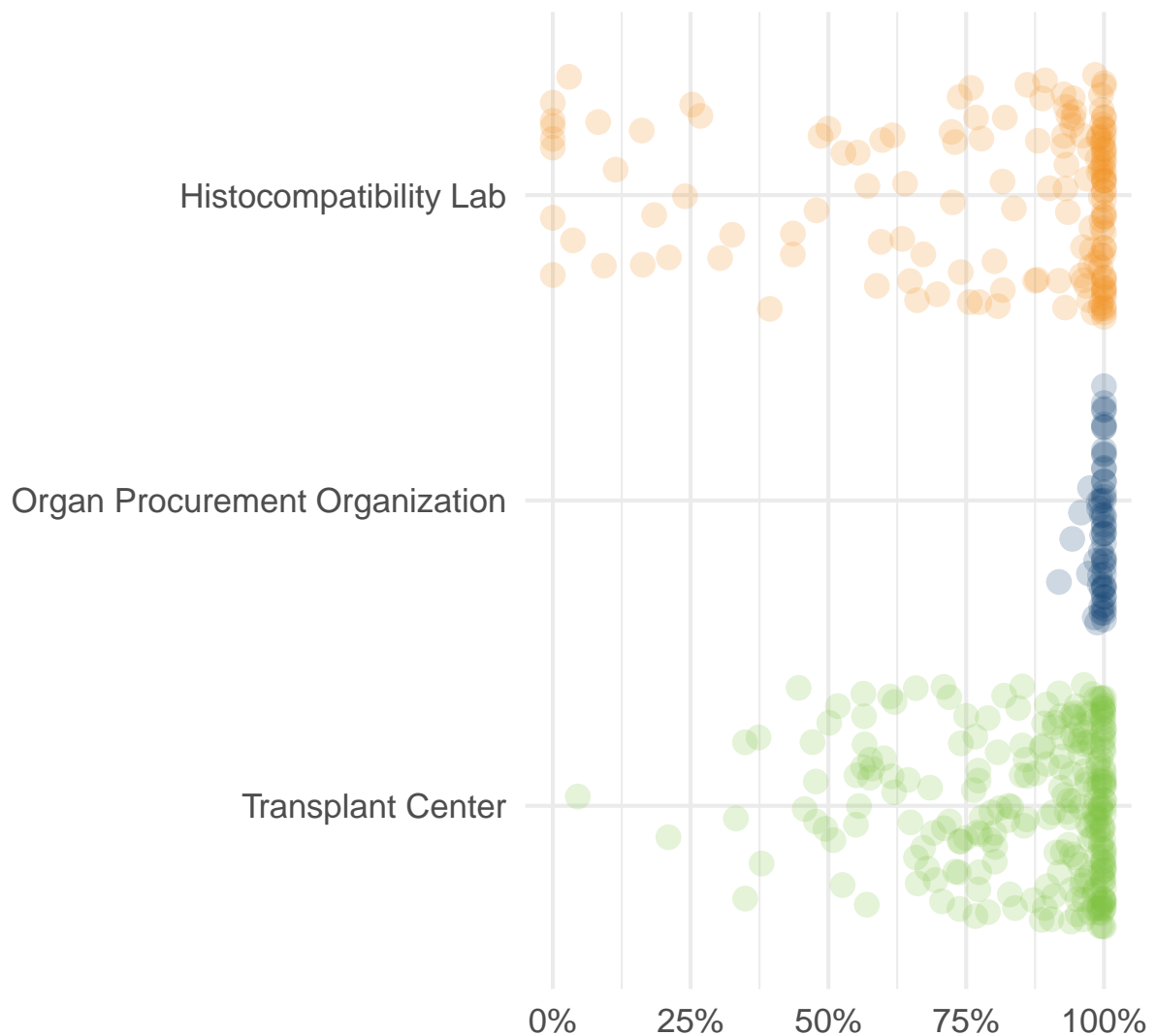
Figure 5 displays data submission for forms expected from OPOs (N=13,268 forms) and histocompatibility labs (N=53,978 forms) during 2022. OPOs submitted 99.6% of the Deceased Donor Registration (DDR) forms by the due date. Lab data submission varied by form type, with the percentage of forms submitted by the due date ranging from 77.8% (N=34,947 forms) for the Recipient Histocompatibility form and 87.7% (N=19,031 forms) for the Donor Histocompatibility form. When looking at the percentage of all forms submitted within 90 days of the due date, the results were 94.3% for the Recipient Histocompatibility form and 96.0% for the Donor Histocompatibility form.

Figure 5. Percentage of forms submitted by OPOs and histocompatibility labs by expected date and within 90 days of expected date, for forms expected during 2022.



The next figure (**Figure 6**) examines the variation in institution-level form completion rates in 2022 by institution type. For OPTN Data System forms expected during 2022, the median percent of forms submitted by the due date by institution type varies from 94.2% (minimum: 4.5%, maximum: 100.0%) across transplant centers to 100.0% (minimum: 91.8%, maximum: 100.0%) across OPOs. Among all institution types, 100% of forms were submitted by the due date for 25 centers, 38 OPOs, and 38 labs. It is important to note that transplant centers were responsible for half a million forms expected in 2022, compared to 13,268 for OPOs and 53,978 for labs during the same time period. Additionally, as mentioned previously, the OPTN data submission policy in effect prior to August 30, 2022 specified both a due date for each individual form in *Policy 18.1*, along with language in OPTN *Policy 18.4 Data Submission Standard* that required members to submit 95% of these forms within three months of the due date and 100% within six months of the due date. These differing requirements in policy contributed to confusion about timely data submission.

Figure 6. Blinded institutional-level timely form completion rates by institution type in 2022.



Figures 7 through 9 below depict scatter plots of the volume of expected forms (x-axis) vs. the timely form completion rate (y-axis) by individual institution and year, with each institution type in separate figures. These graphs allow examination of any potential relationship between form volume and completion rates by institutions. Given that some institutions have many more forms to submit than others, we wanted to be able to determine if form volume alone might account for lower timely completion rates at institutions. No clear relationship between increased form burden and decreased timely completion rates is apparent for any institution type.

Figure 7. Percent of transplant forms submitted by due date vs. number of expected forms in 2020-2022, by blinded transplant center.

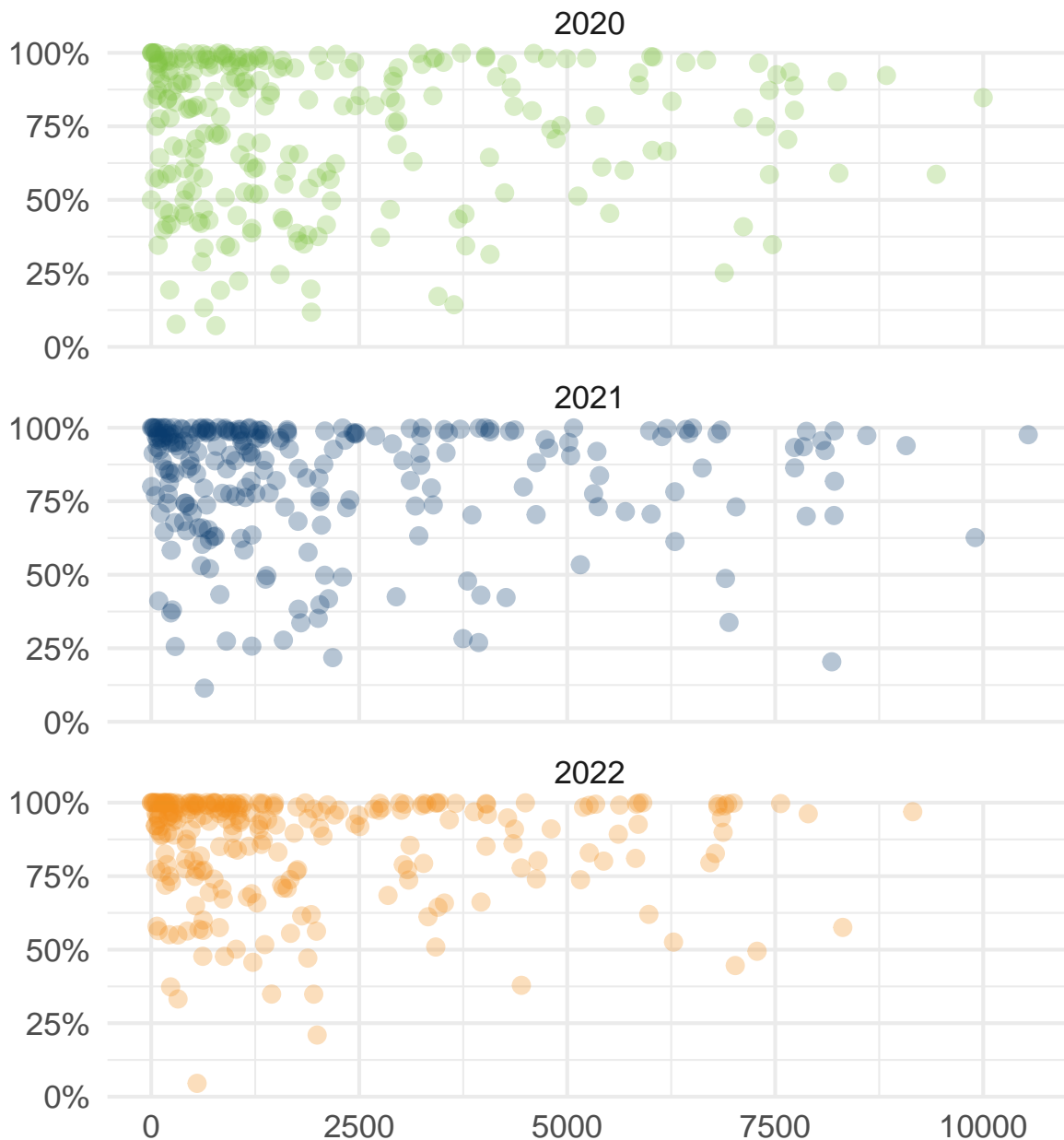


Figure 8. Percent of deceased donor forms submitted by expected date vs. number of expected forms in 2020-2022, by blinded organ procurement organization.

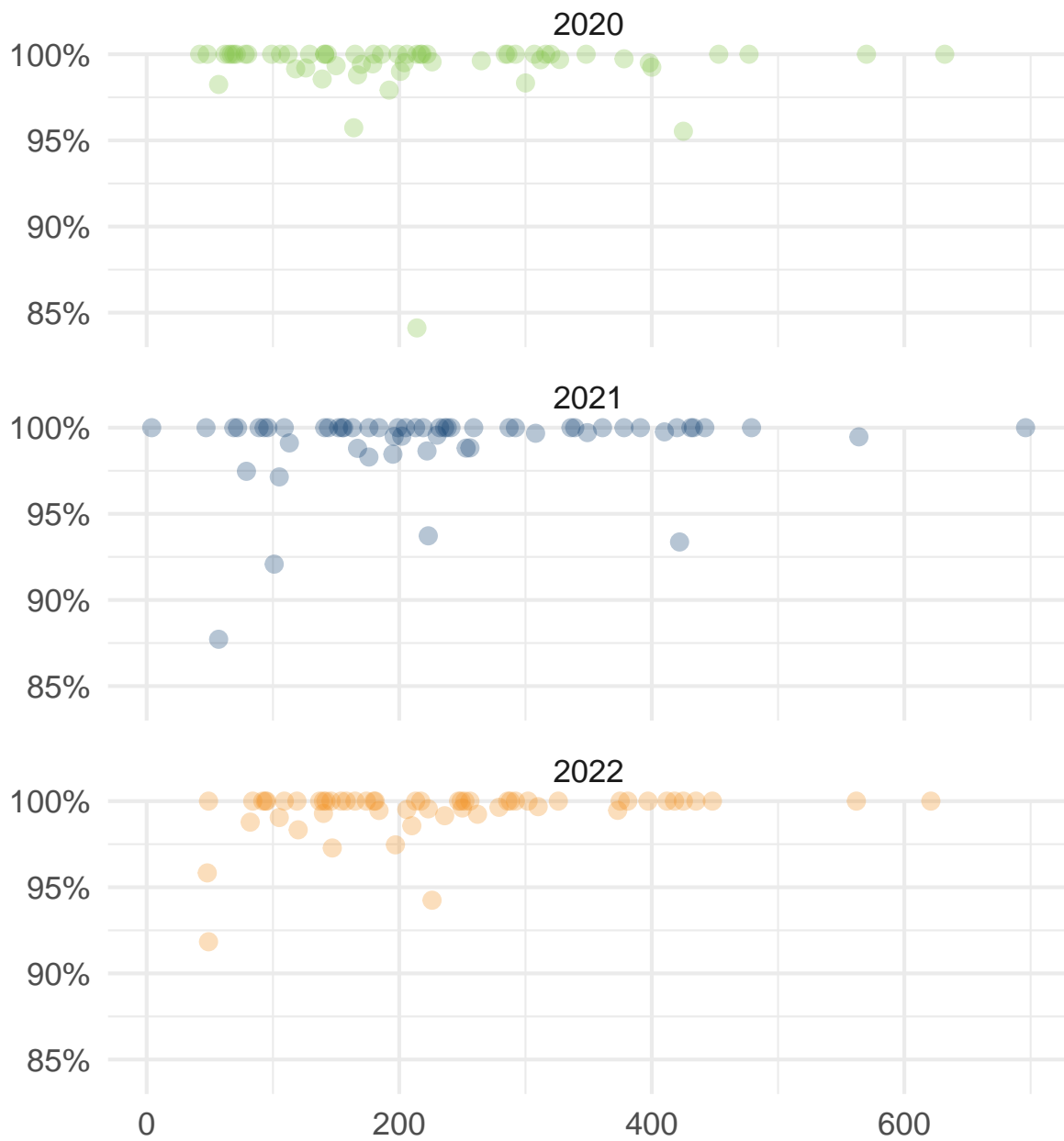


Figure 9. Percent of histocompatibility forms submitted by due date vs. number of expected forms in 2020-2022, by blinded histocompatibility lab.

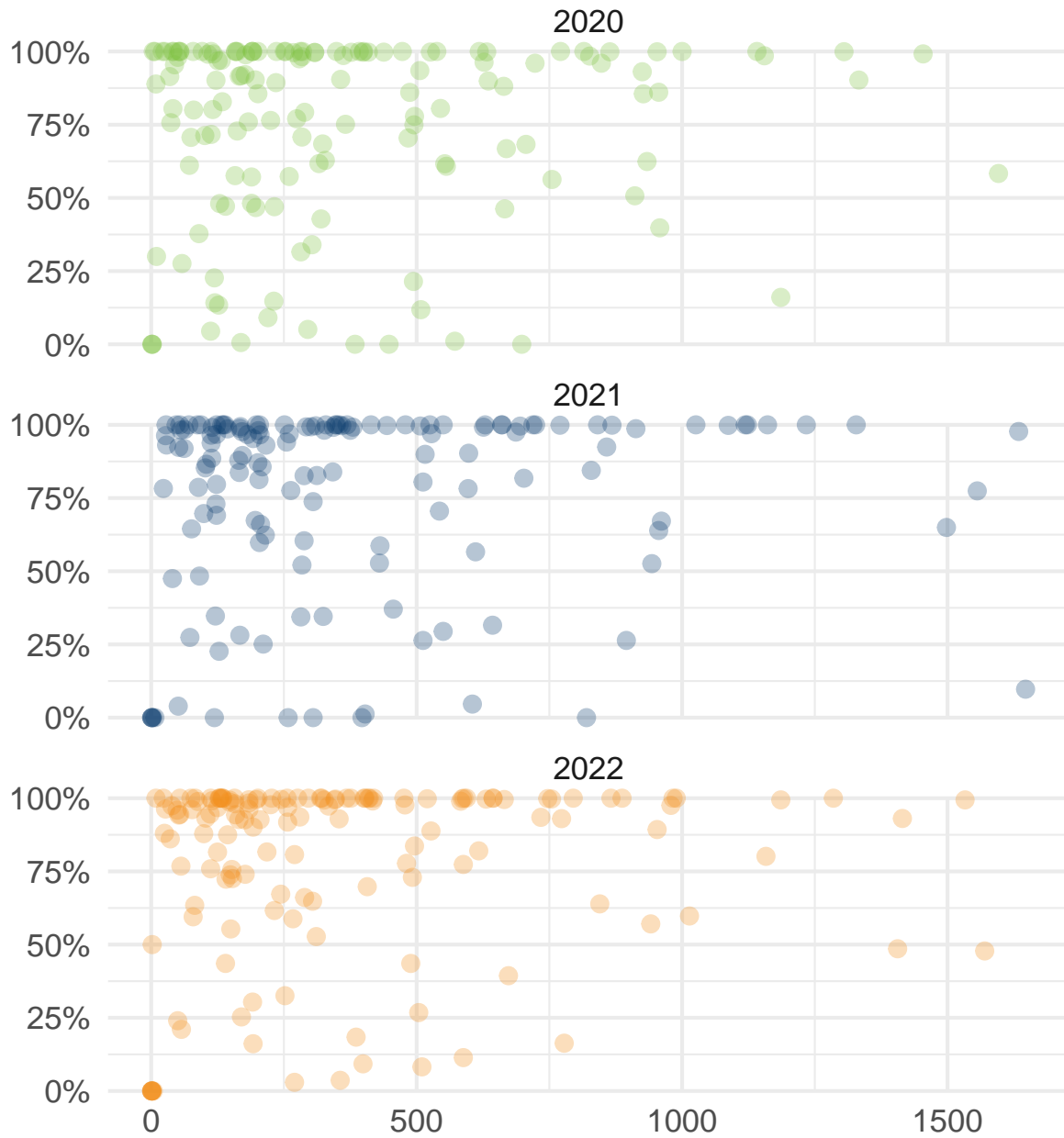
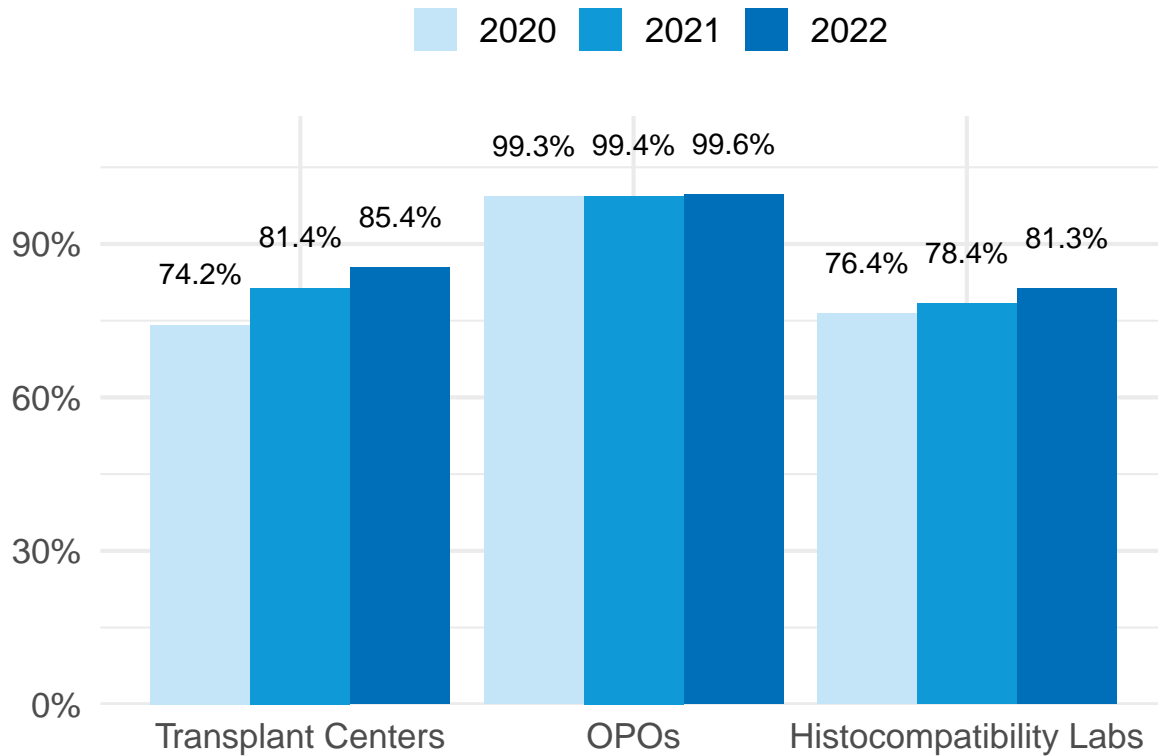


Figure 10 displays the percent of OPTN Data System forms submitted by the due date by institution type and year for forms expected 2020 - 2022. Form completion rates have trended up over this period for all institution types. As increasing timeliness of reporting across forms and institution types was a goal of the amendment to *Policy 18* occurring on August 30, 2022, if this increasing trend continues in the future it further supports that policy effort by the DAC.

Figure 10. Percent of expected submitted by expected date, by year expected and institution type.

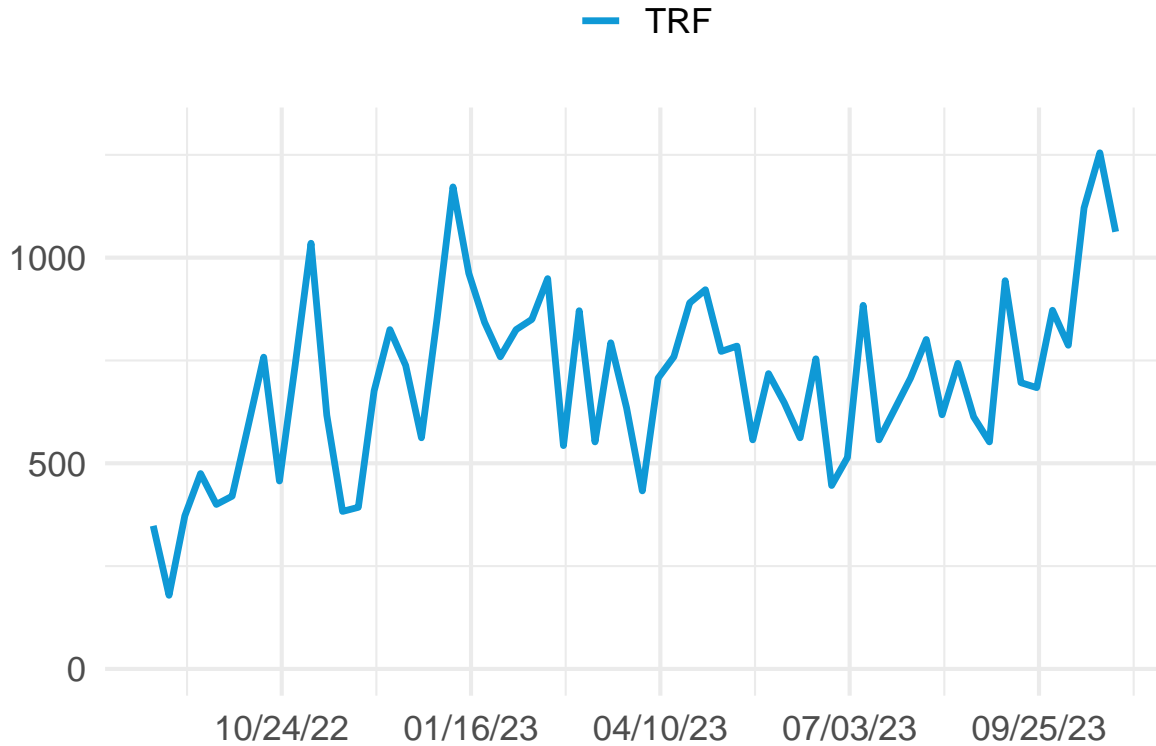


Review of key 'Data Lock' trends

As a component of post-implementation policy monitoring of the *Policy 18* project fully implemented on August 30, 2022, we 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 11 through 14** below.

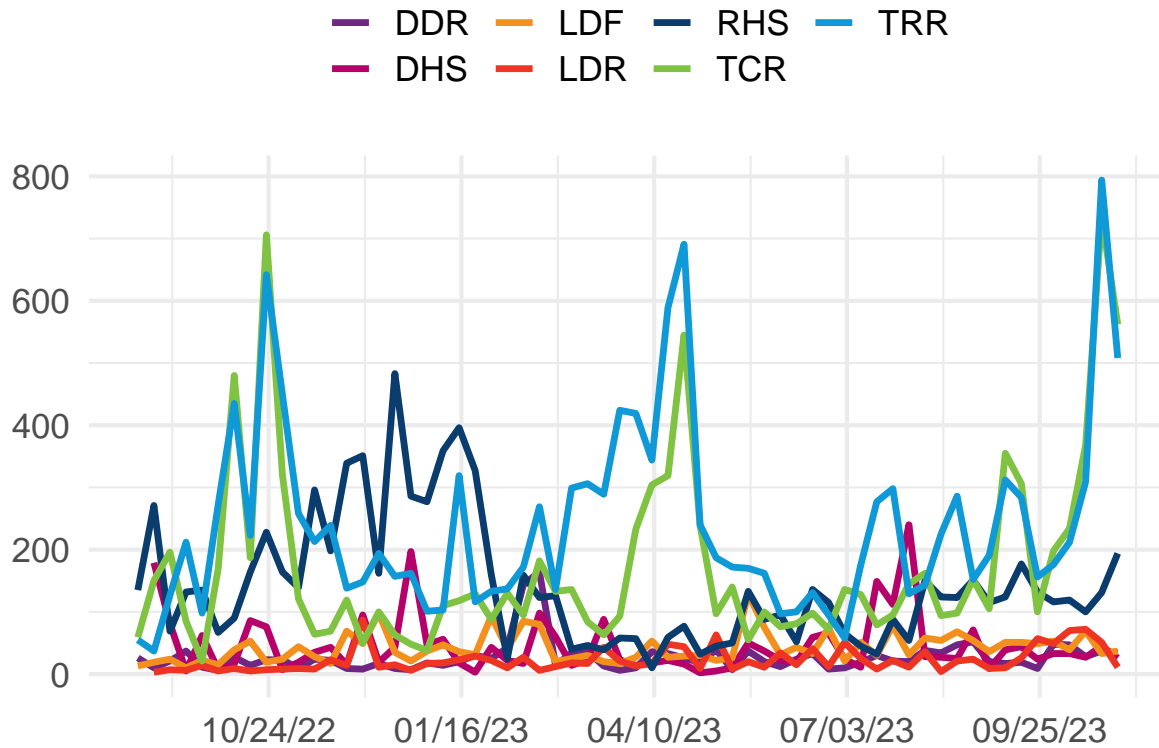
There are notable differences in unlocking volume by form type, with TRF forms having persistently high numbers of unlocking events, as visible in **Figure 11** below.

Figure 11. Trends in form unlocking events by form type and week, TRF only.



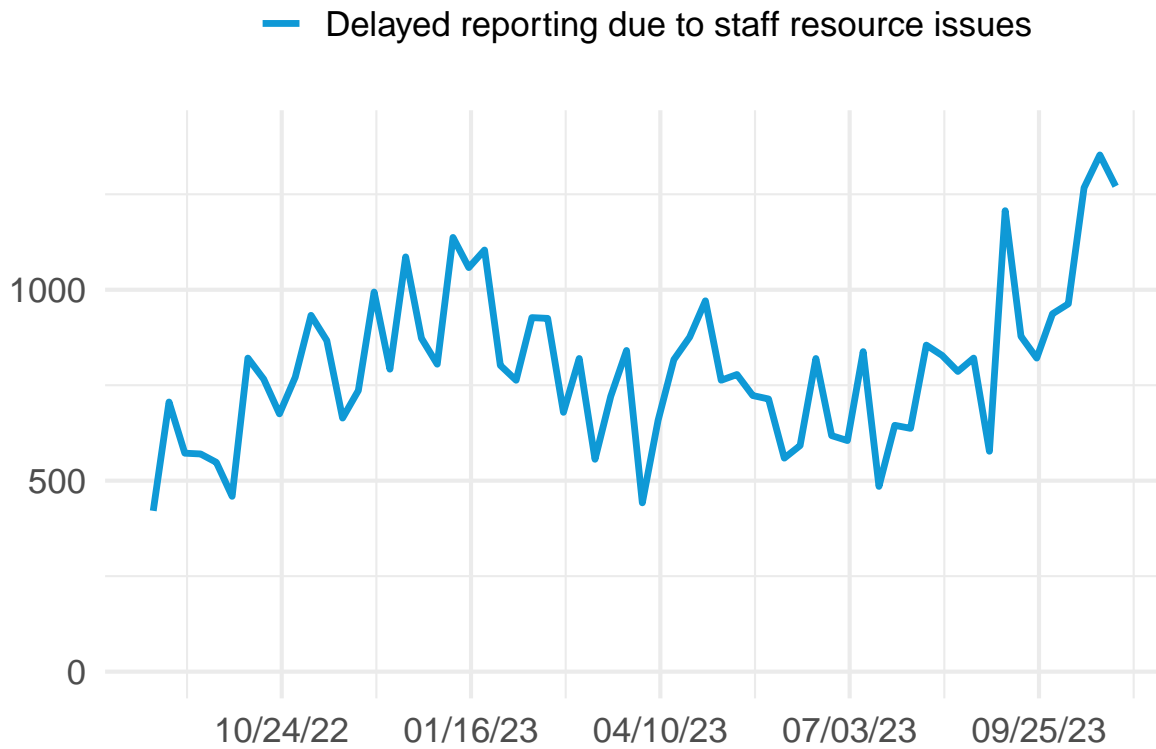
With TRF unlocking volume reported separately in **Figure 11**, the seasonality of TCR and TRR unlocking activity is more obvious in **Figure 12** below. That unlocking activity peaks in October and April, corresponding roughly to the data review period prior to the publication of biannual PSRs by the SRTR.

Figure 12. Trends in form unlocking events by form type and week, excluding TRF.



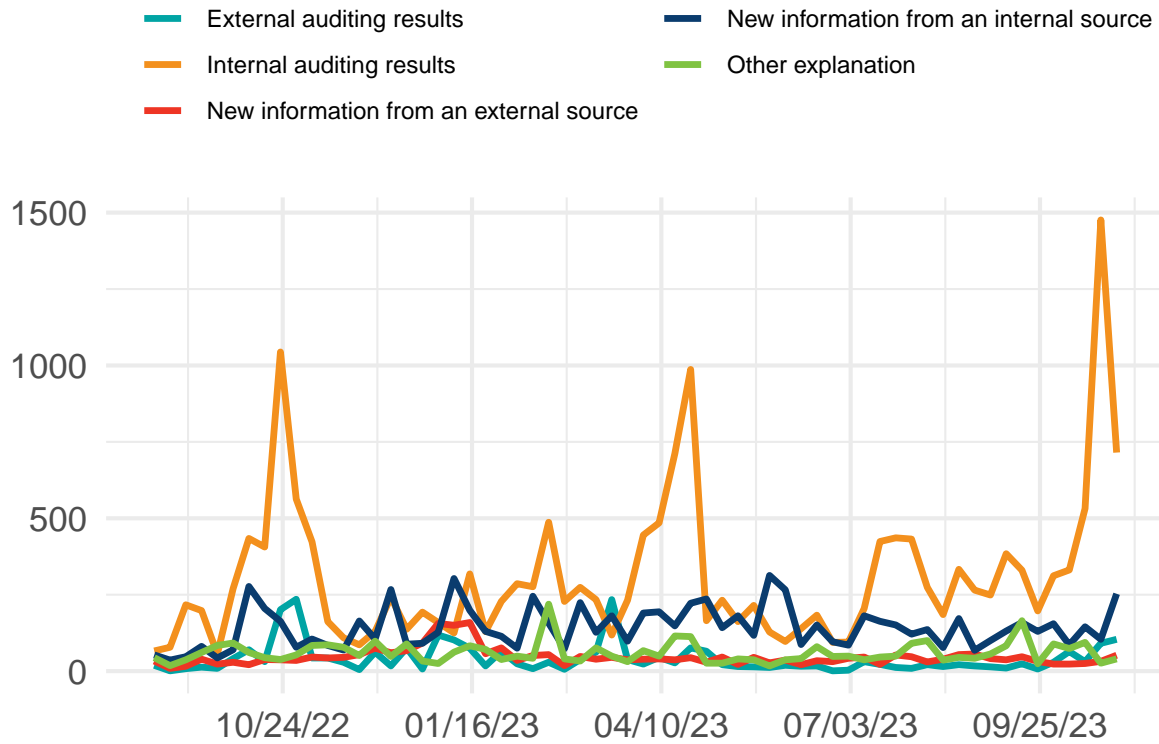
To better highlight different trends seen in reasons given for unlocking events by week, in **Figure 13** below, we separate out all unlocking events for “Delayed reporting due to staff resource issues”. We see a persistently high background level of these unlocking events across time.

Figure 13. Trends in unlocking events by reason given and week, “Delayed reporting due to staff resource issues” only.



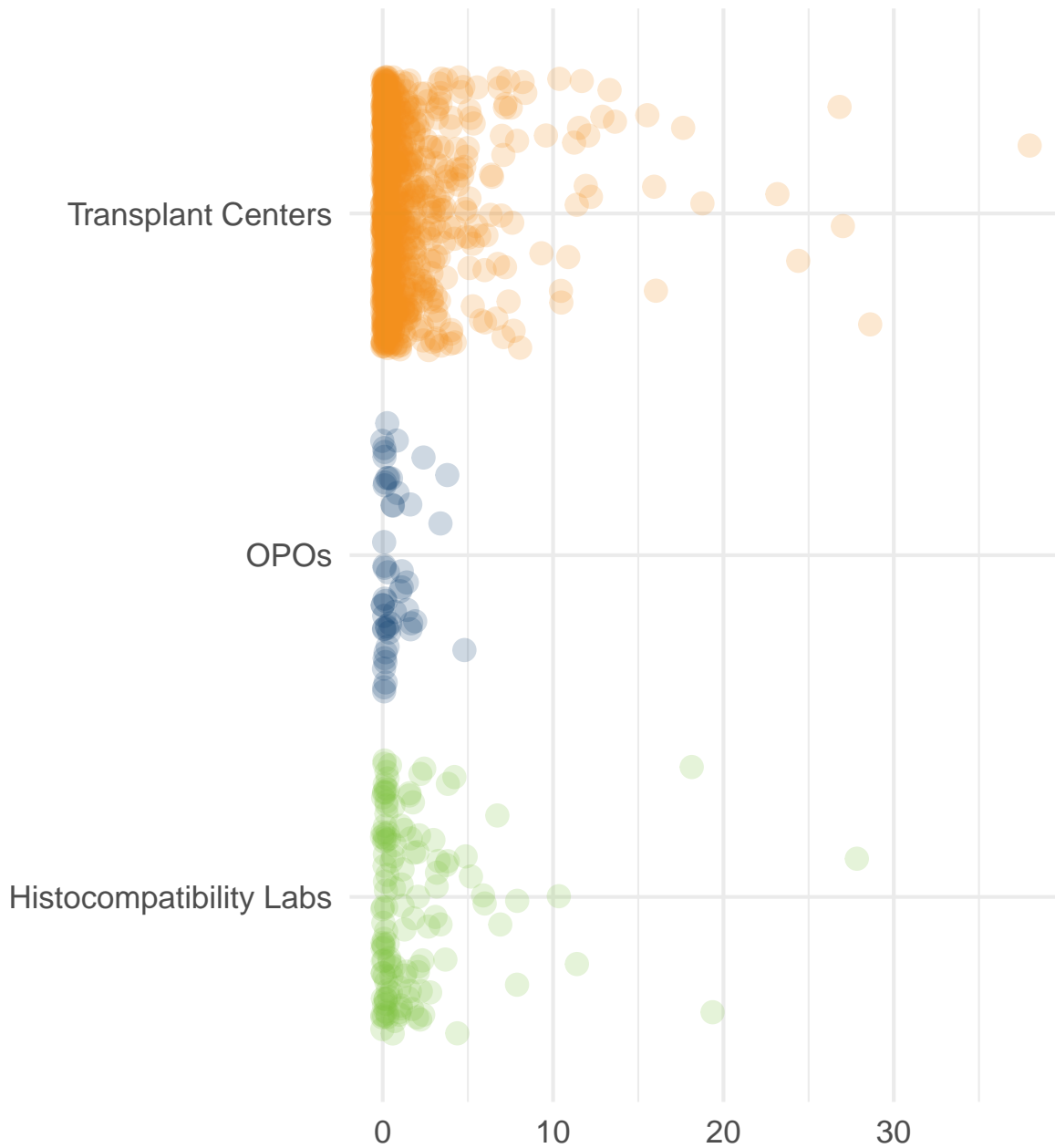
While the unlocking event volume is at a lower scale than for the “Delayed reporting due to staff resource issues” noted in **Figure 13**, an apparently seasonal unlocking trend for the reason of “Internal auditing results” is visible in October and April, corresponding generally to the data review period that precedes the publication of the SRTR PSR reports twice a year.

Figure 14. Trends in unlocking events by reason given and week.



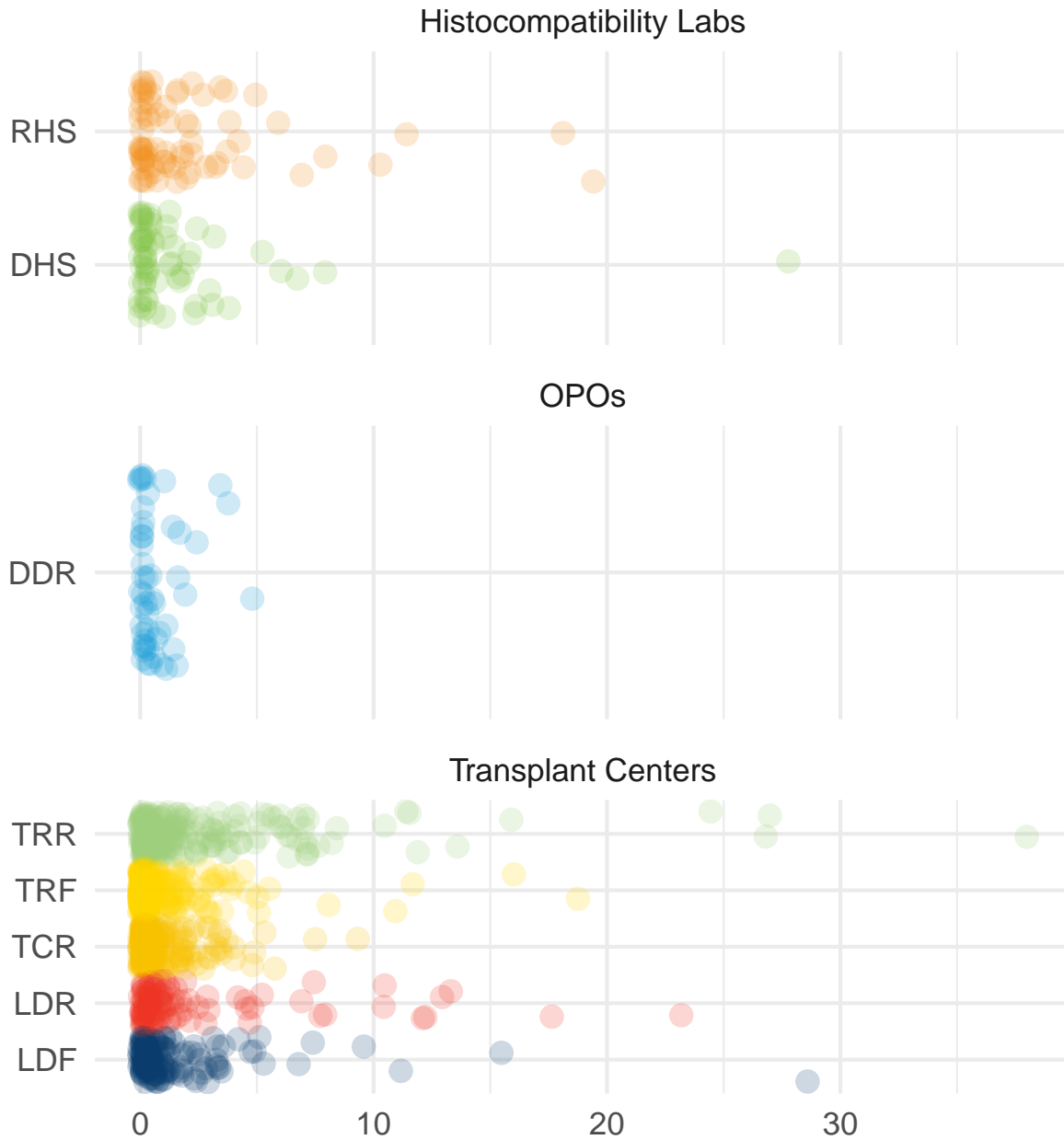
In **Figure 15** below, we plot blinded institutional rates of form unlocking events per 100 locked forms to examine the distribution of unlocking frequency given differing form volume levels by institution type.

Figure 15. Blinded institutional level form unlocking events per 100 locked forms by institution type since August 30, 2022.



In **Figure 16** below, we plot blinded institutional rates of form unlocking events per 100 locked forms by form type to examine the distribution of unlocking frequency given differing form volume levels by institution type.

Figure 16. Blinded institutional level form unlocking events per 100 locked forms by institution type and form type since August 30, 2022.



Cadence of data changes to selected OPTN data system fields pre- and post-data lock

At the request of the DAC, in this report, we further examined selected variables on Kidney (KI) TCRs, calculating the number of field-level changes per 10,000 forms that occurred more than 90 days after their form addition dates and characterizing those changes as occurring before ('Before Policy Change') or after ('After Policy Change') data lock implementation on August 30, 2022. Summary data on this analysis is presented in **Figures 17 through 19** below.

Figure 17. Number of KI TCR demographic field changes per 10,000 forms >90 days after form addition date, pre- and post-policy implementation.

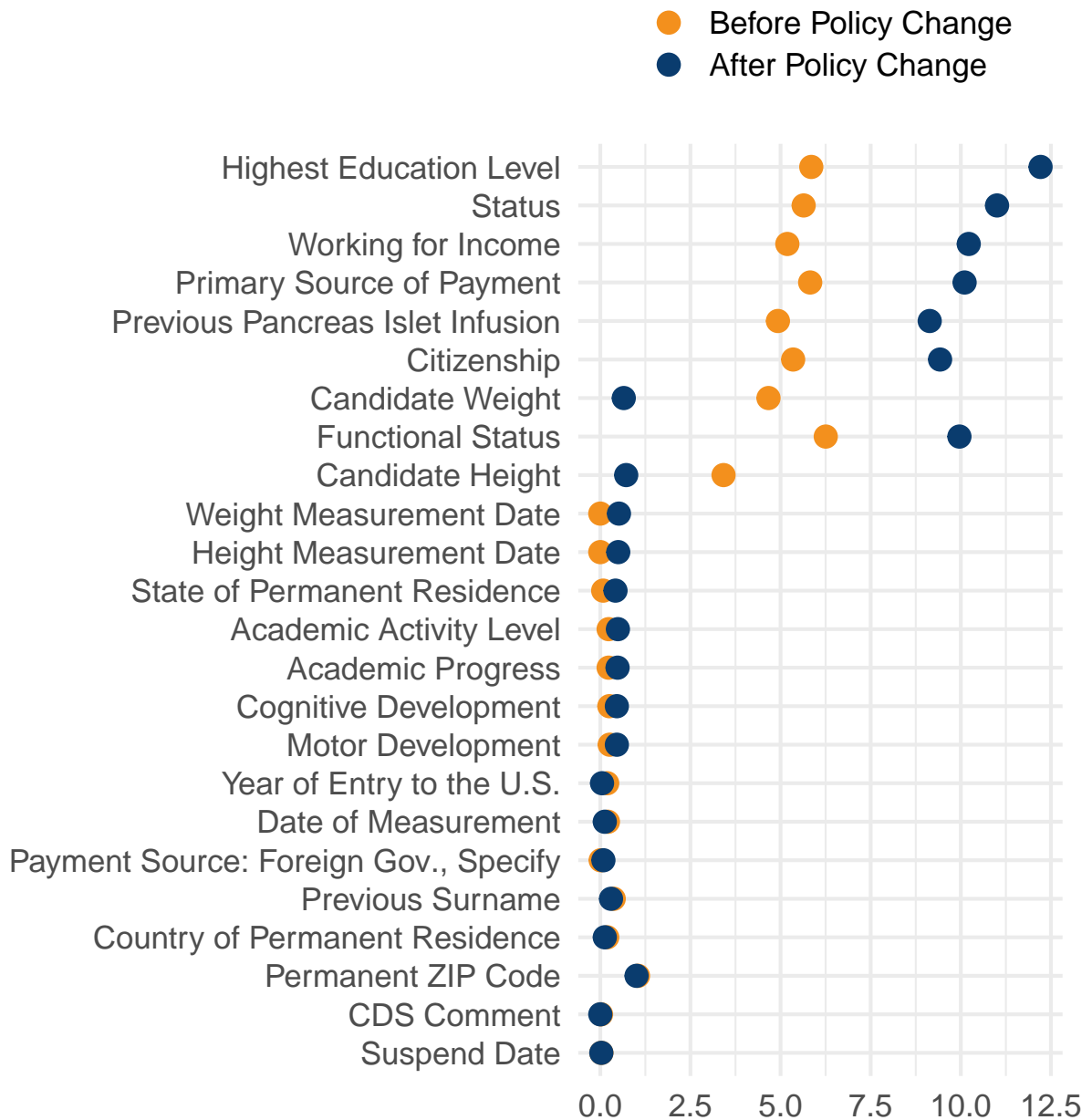


Figure 18. Number of KI TCR clinical field changes per 10,000 forms >90 days after form addition date, pre- and post-policy implementation.

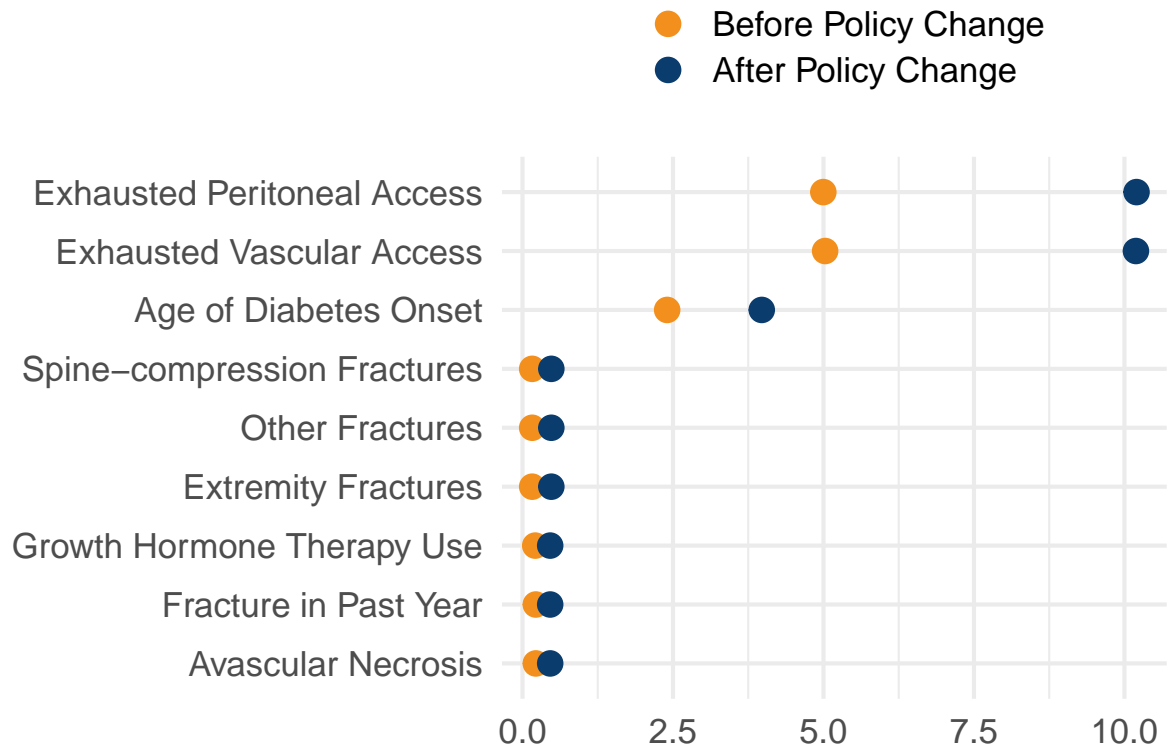
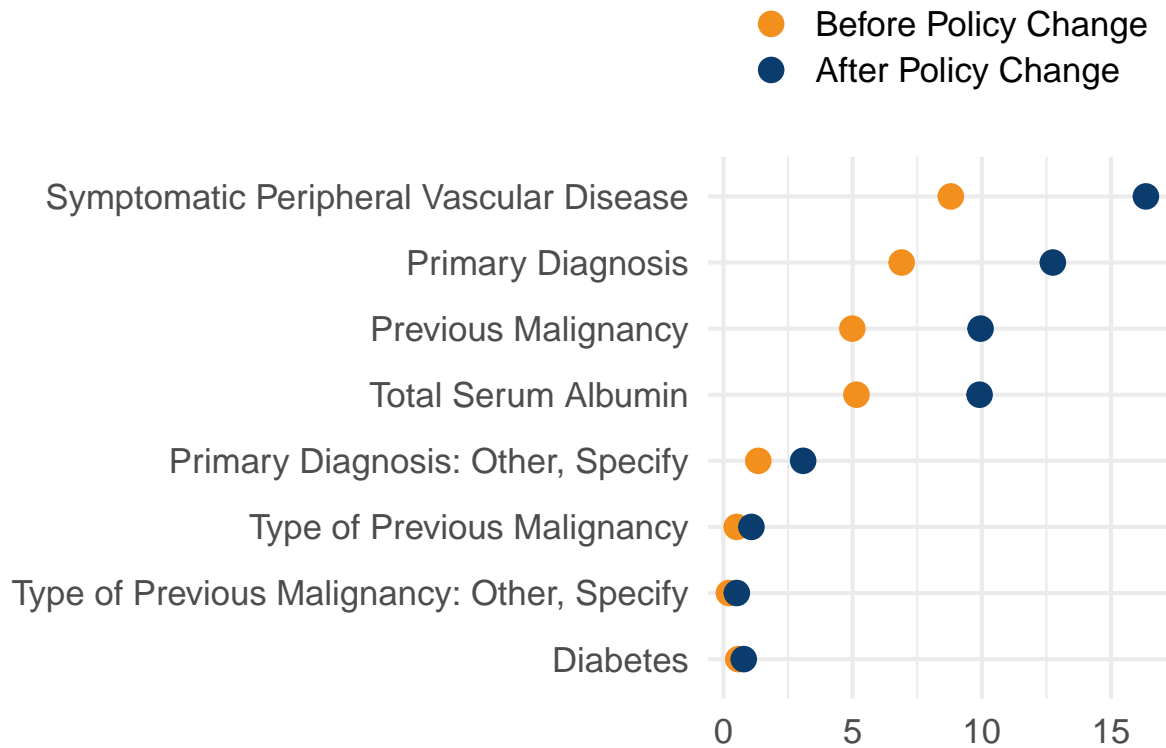


Figure 19. Number of KI TCR medical history field changes per 10,000 forms >90 days after form addition date, pre- and post-policy implementation.



Summary

Based on DAC review of findings in this Annual Data Quality Report, ongoing discussions of monitoring data from the *Policy 18* and Refusal Code projects, and decisions about new approaches to addressing OPTN quality issues, the DAC highlights the following recommended steps that the OPTN should take, supported by the DAC, to ensure the integrity and timeliness of the OPTN Data System:

Short-Term (1-2 years)

1. Review transplant programs that are unlocking/editing data at higher rates to determine what action is needed (e.g., education, additional monitoring, enhancements, etc.)
2. Perform additional analysis to understand the correlation between member data submission approach (electronic or manual) and form unlocking activities
3. Monitor and work with programs that have high rates of inconsistencies in dialysis dates and dialysis statuses between the OPTN Waitlist and the TRR to identify opportunities to reduce error rates
4. Enhance *OPTN Policy 18* to identify committee ownership and oversight for OPTN data, as well as expectations for monitoring, measuring and managing data quality
5. Review and update the OPTN Data Collection Principles

Long-Term (2-3 years)

6. Support HRSA and the OPTN Board committing resources for the OPTN Contractor to implement and sustain clinical data standards within the OPTN Computer System