

OPTN Data Advisory Committee

Descriptive Data Request

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

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## Background/Purpose

Organ Procurement and Transplantation Network (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, as well as the high volume of changes, 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 policy monitoring and evaluation 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 forms 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 Scientific Registry of Transplant Recipients (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 submit accurate 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:** Policy implementation affected the following eight OMB-approved forms in the OPTN Data 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. **Table 1** below has been provided to summarize conditions that cause a form to generate and 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	At 6-month, 1- and 2-year anniversaries of transplant, or notification of recipient's death or graft failure	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 August 30, 2023, or 365 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 August 30, 2021 (365 days prior to the implementation). All data in this report are current as of September 22, 2023.

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 the treatment of forms remaining in “Expected” status at time of implementation:** When the policy implementation occurred on August 30, 2022 at 8 am EST, 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 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 implementation on August 30, 2022 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. These forms were affected by the policy change, even though they may have been due before August 30, 2022.

## High-Level Summary Findings

In summary, this twelve-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:

- In the first year following implementation, a total of 69,894 unlocking events occurred, averaging 1318.8 unlocking events per week.
- Unlocking trends in terms of most and frequently unlocked forms, most common unlock reasons given, and temporal trends in unlocking activity in specific times of the year were similar at one year to those noted in the 6-month report previously provided to the DAC.
- 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 (all but RHS) now have national timely completion rates above 90% post-policy, compared to only three pre-policy. Two of the eight (DDR and TCR) now have timely completion rates above 95%, compared to only one pre-policy (DDR).
- 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.
- There was, however, a notable spike in TCR and TRR unlocking activity in October and April, potentially corresponding with the data review period that precedes the release of the biannual Program-Specific Reports (PSRs) by the SRTR.
- 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.
- While most institutions unlock a form one time in the majority of cases, there are some notable outliers who appear to unlock the same form multiple times, and enter the same reason each time. While that might make sense as a rare event for a given form at any institution, for the average at more than one institution across all forms to be that high suggests further analysis of the causes is warranted.
- While some data elements on DDR and kidney (KI) TCR forms more than 90 days past their expected dates appear to be changed less often post-policy per 10,000 forms, the majority of fields that were changed at all were changed more often post-policy. Given that some of these field changes are perhaps driven by SRTR reporting cycles, assessments of the cadence of these changes may be particularly sensitive to the timing of an analysis; this factor should be considered in future reporting on this metric.

## Detailed Results

### Post-implementation Detailed Data on Form Unlocking

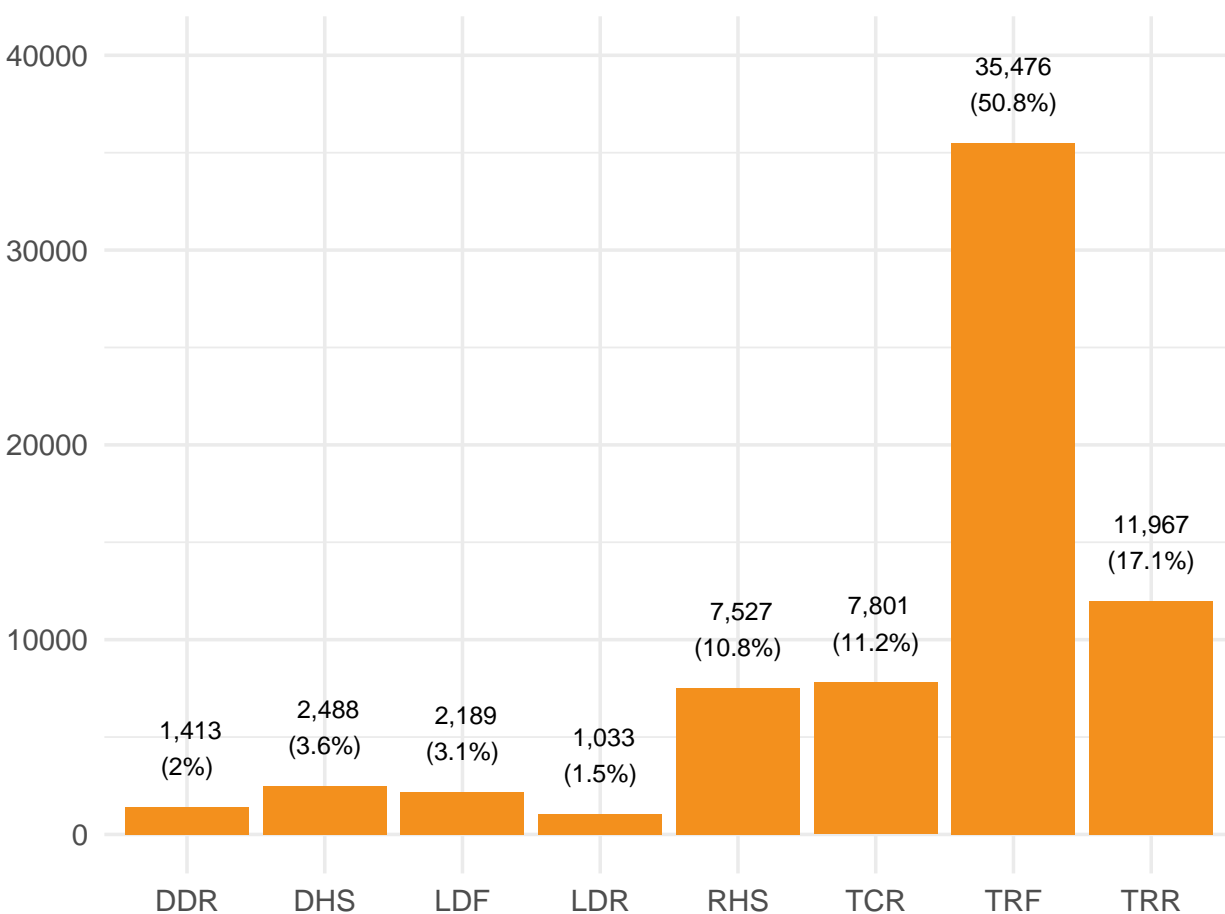
#### Unlocking event frequency summary

At a summary level, **Figures 1 through 5 and Tables 2 through 3** 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 patterns in 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.

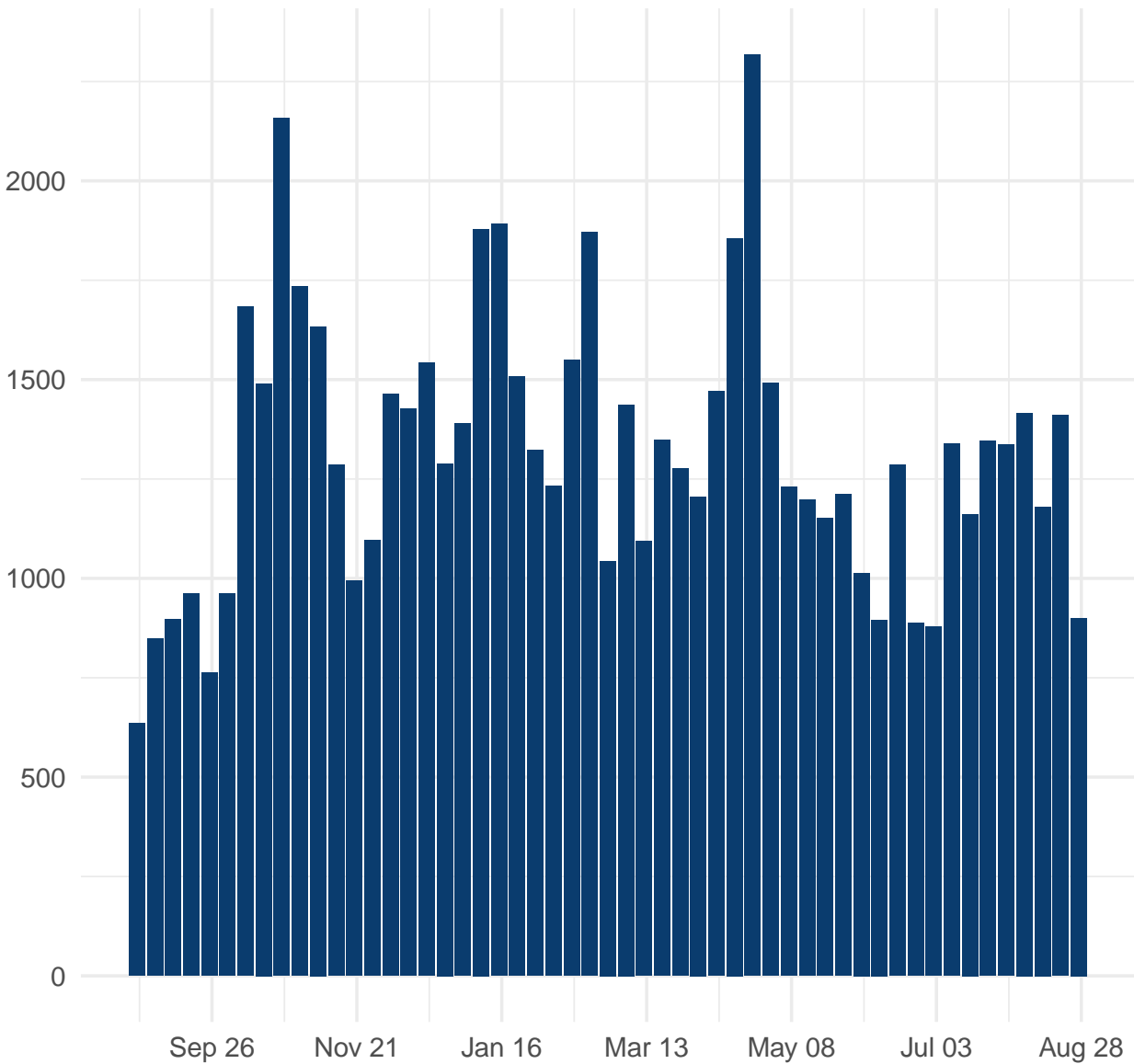
**Figure 1** displays the number of unlocking events by OPTN Data System form type. Through February 26, 2023, 69,894 total unlocking events have occurred. The most commonly-unlocked form to date has been the TRF, accounting for 35,476 (50.8%) of all unlocked forms as of that date. Donor forms of all types have been unlocked much more rarely, though among them, the Donor Histocompatibility form (DHS) was the most frequently unlocked.

**Figure 1. Number of unlocking events by form type.**



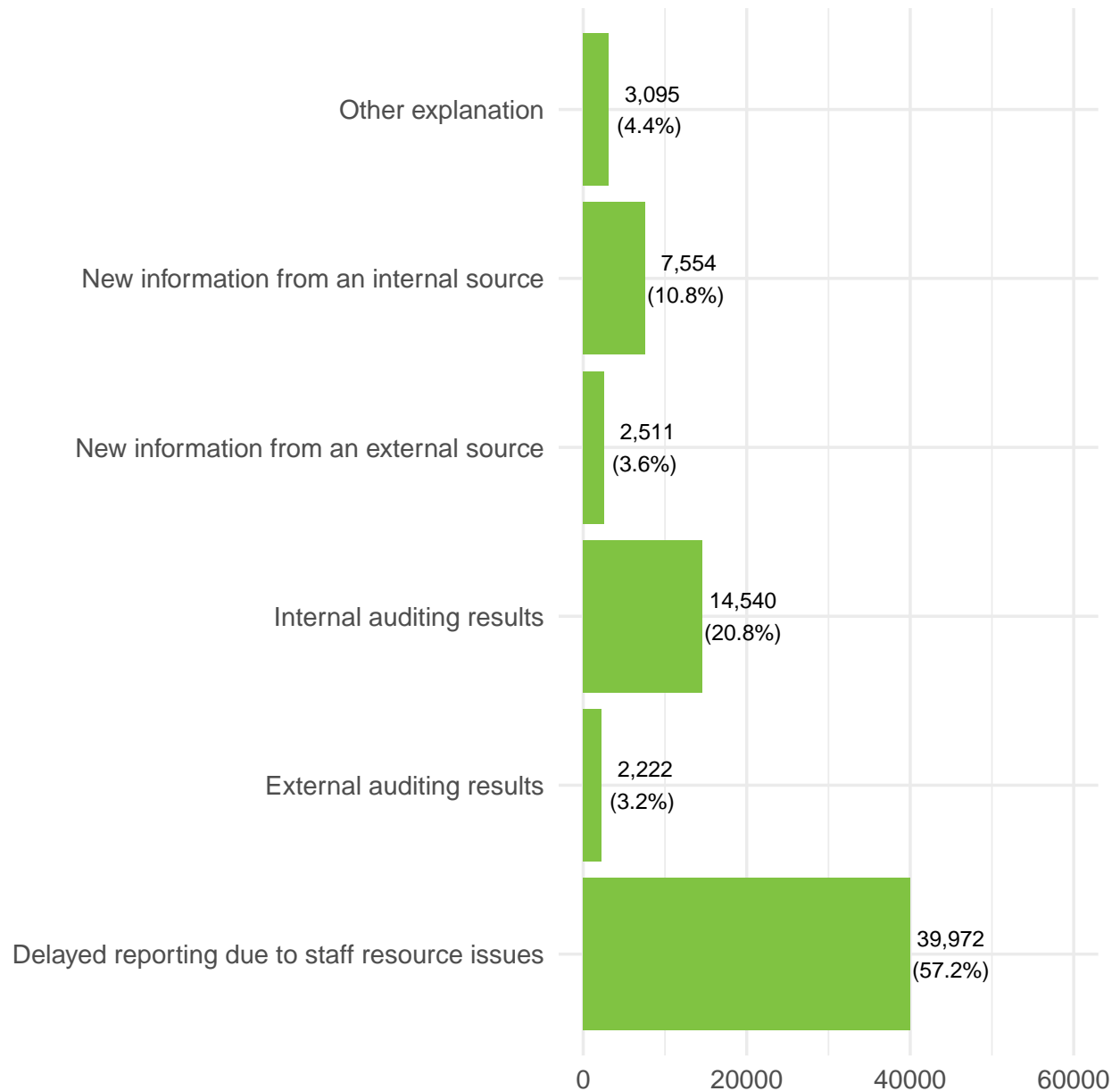
**Figure 2** displays the number of unlocking events per week since the implementation of the policy revision. The largest number of form unlocking events by week to date occurred during the week beginning April 23, 2023, with 2,318 unlocking events. The average number of unlocking events per week in the first year was 1318.8. The first week of policy enactment had the lowest number of unlocking events to date 636.

**Figure 2. Number of unlocking events by week.**



**Figure 3** displays the number of unlocking events by the reason given. A large portion (57.2%) 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 (3.2%).

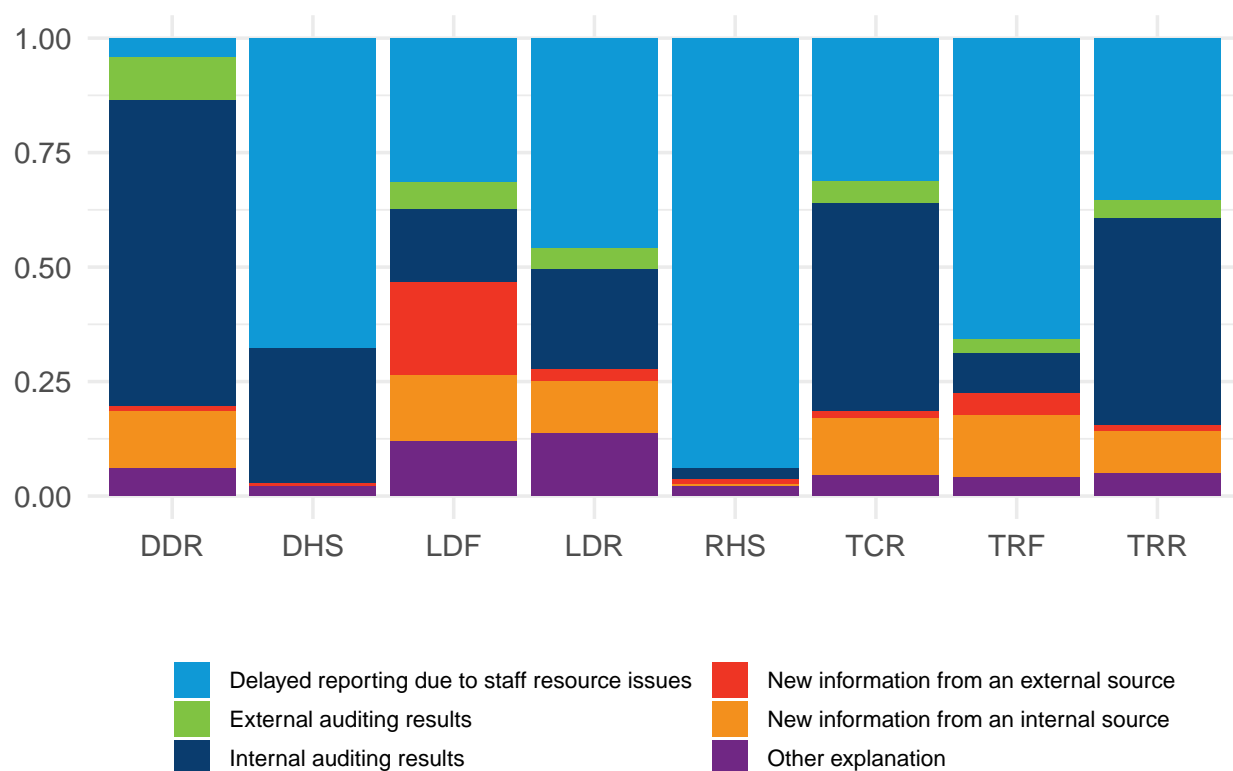
**Figure 3. Number of unlocking events by reason.**





**Figure 4** and **Table 2** display the percent of unlocking events by reason and form type. TCR, DDR, and TRR forms were most commonly unlocked for reasons of “Internal auditing results”, while TRF, RHS and DHS forms were most likely to be unlocked due to “Delayed reporting due to staff resource issues”.

**Figure 4. Percent of unlocking events by reason and form type.**

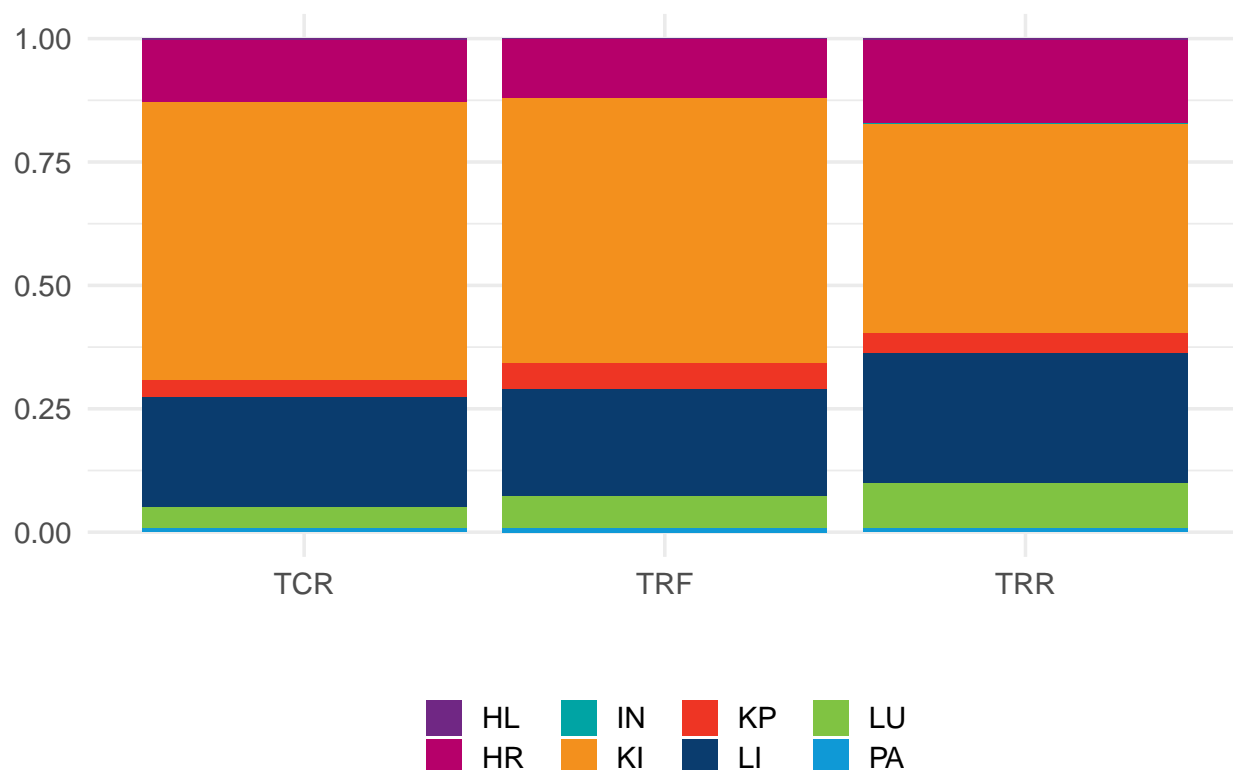


**Table 2. Number and percent of unlocking events by reason and form type.**

Reason	DDR	DHS	LDF	LDR	RHS	TCR	TRF	TRR
Delayed reporting due to staff resource issues	59 (4.2%)	1,686 (67.8%)	688 (31.4%)	474 (45.9%)	7,076 (94.0%)	2,432 (31.2%)	23,325 (65.7%)	4,232 (35.4%)
External auditing results	132 (9.3%)	1 (0.0%)	128 (5.8%)	48 (4.6%)	2 (0.0%)	380 (4.9%)	1,055 (3.0%)	476 (4.0%)
Internal auditing results	944 (66.8%)	731 (29.4%)	352 (16.1%)	225 (21.8%)	170 (2.3%)	3,542 (45.4%)	3,163 (8.9%)	5,413 (45.2%)
New information from an external source	17 (1.2%)	17 (0.7%)	441 (20.1%)	27 (2.6%)	89 (1.2%)	120 (1.5%)	1,651 (4.7%)	149 (1.2%)
New information from an internal source	175 (12.4%)	3 (0.1%)	319 (14.6%)	118 (11.4%)	30 (0.4%)	981 (12.6%)	4,827 (13.6%)	1,101 (9.2%)
Other explanation	86 (6.1%)	50 (2.0%)	261 (11.9%)	141 (13.6%)	160 (2.1%)	346 (4.4%)	1,455 (4.1%)	596 (5.0%)
<b>Total</b>	<b>1,413 (100.0%)</b>	<b>2,488 (100.0%)</b>	<b>2,189 (100.0%)</b>	<b>1,033 (100.0%)</b>	<b>7,527 (100.0%)</b>	<b>7,801 (100.0%)</b>	<b>35,476 (100.0%)</b>	<b>11,967 (100.0%)</b>

**Figure 5** and **Table 3** display the percent distribution of unlocking event frequency by organ and from type for the TCR, TRR and TRF only. Kidney forms were the most frequently unlocked, followed by liver. Given the higher volume of kidney candidates and recipients, this finding was expected.

**Figure 5. Percent of TCR, TRF and TRR unlocking events by organ.**



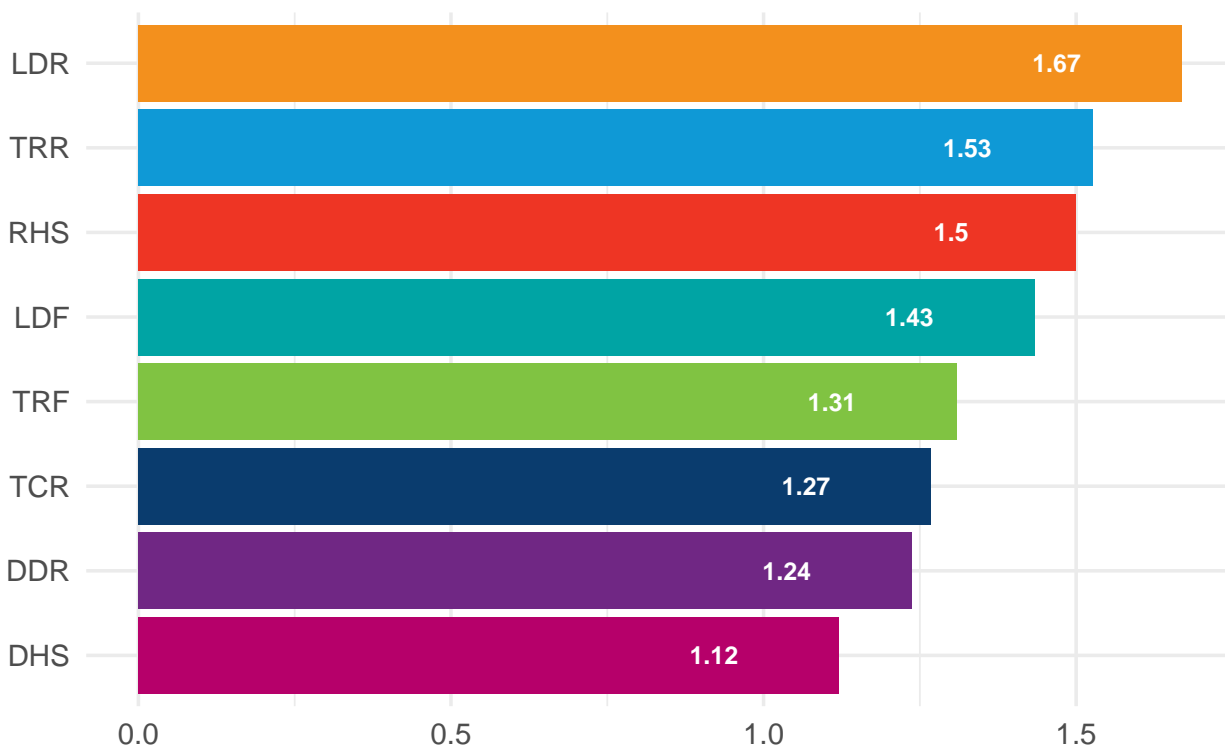
**Table 3. Number and percent of transplant forms unlocked by organ and form type.**

Organ	TCR	TRF	TRR
HL	18 (0.2%)	47 (0.1%)	26 (0.2%)
HR	980 (12.6%)	4,202 (11.8%)	2,011 (16.8%)
IN	15 (0.2%)	57 (0.2%)	46 (0.4%)
KI	4,384 (56.2%)	19,025 (53.6%)	5,071 (42.4%)
KP	271 (3.5%)	1,913 (5.4%)	471 (3.9%)
LI	1,734 (22.2%)	7,696 (21.7%)	3,143 (26.3%)
LU	342 (4.4%)	2,238 (6.3%)	1,114 (9.3%)
PA	57 (0.7%)	298 (0.8%)	85 (0.7%)
Total	7,801 (100.0%)	35,476 (100.0%)	11,967 (100.0%)

### Distinct forms unlocked vs. unlocking events

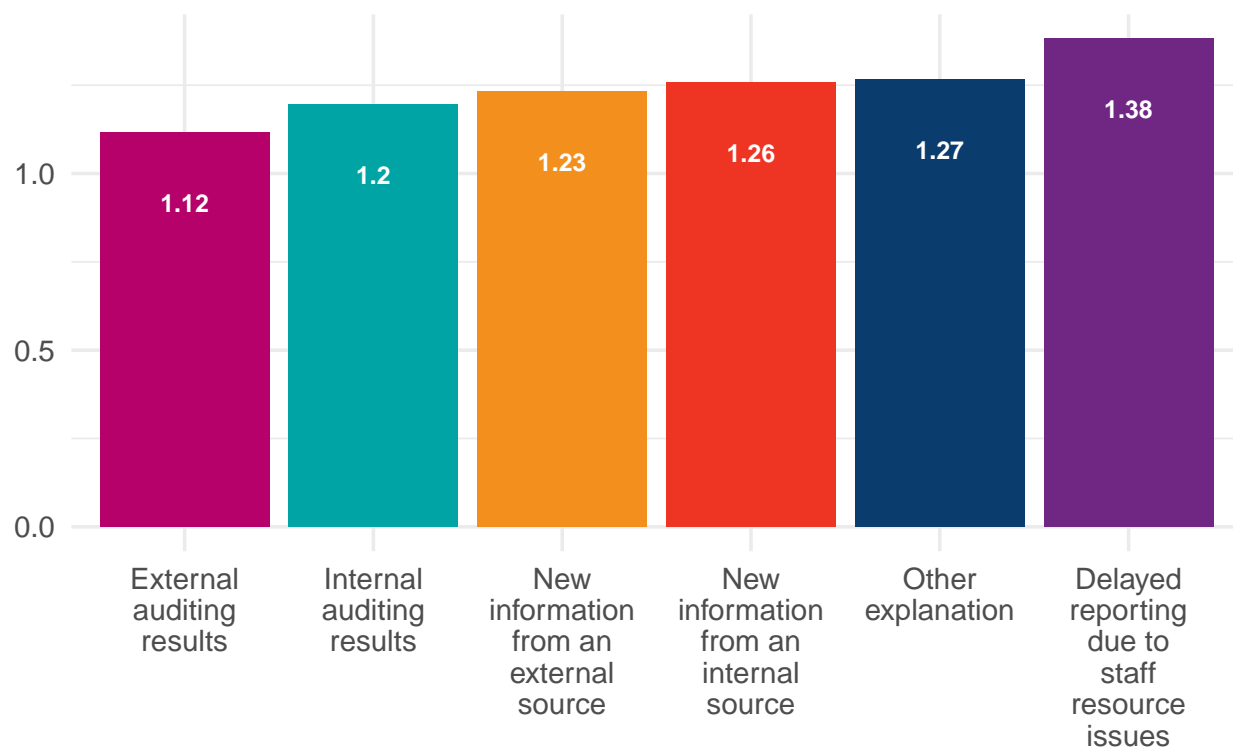
**Figures 6 through 9 and Tables 4 through 7** compare recorded unlocking events since implementation to the de-duplicated, or distinct, number of forms that were ever unlocked over this period. Forms may be unlocked more than once, and this comparison is thus intended to better highlight the actual 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 6. Number of unlocking events per distinct form by form type.**



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

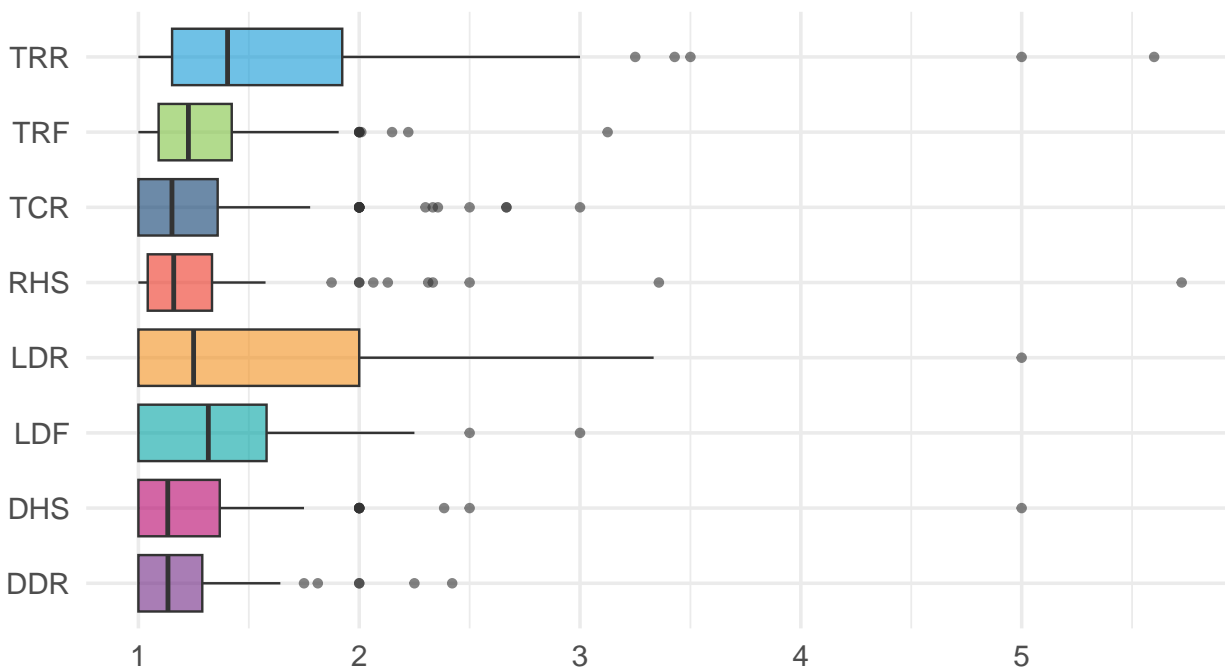
Form Type	Number of Unlocking Events	Distinct Forms Unlocked	Events/Distinct Form
LDR	1,033	619	1.67
TRR	11,967	7,841	1.53
RHS	7,527	5,017	1.50
LDF	2,189	1,527	1.43
TRF	35,476	27,085	1.31
TCR	7,801	6,151	1.27
DDR	1,413	1,142	1.24
DHS	2,488	2,220	1.12

**Figure 7. Number of unlocking events per distinct form by reason given.****Table 5. Number of unlocking events per distinct form by reason given.**

Reason for Unlocking	Number of Event Reasons	Distinct Forms Unlocked	Reasons/Distinct Form
Delayed reporting due to staff resource issues	39,972	28,935	1.38
Other explanation	3,095	2,443	1.27
New information from an internal source	7,554	6,008	1.26
New information from an external source	2,511	2,038	1.23
Internal auditing results	14,540	12,158	1.20
External auditing results	2,222	1,988	1.12

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 8 and Table 6** below. TRRs have notably the highest mean and median number of unlocking events per distinct form across institutions.

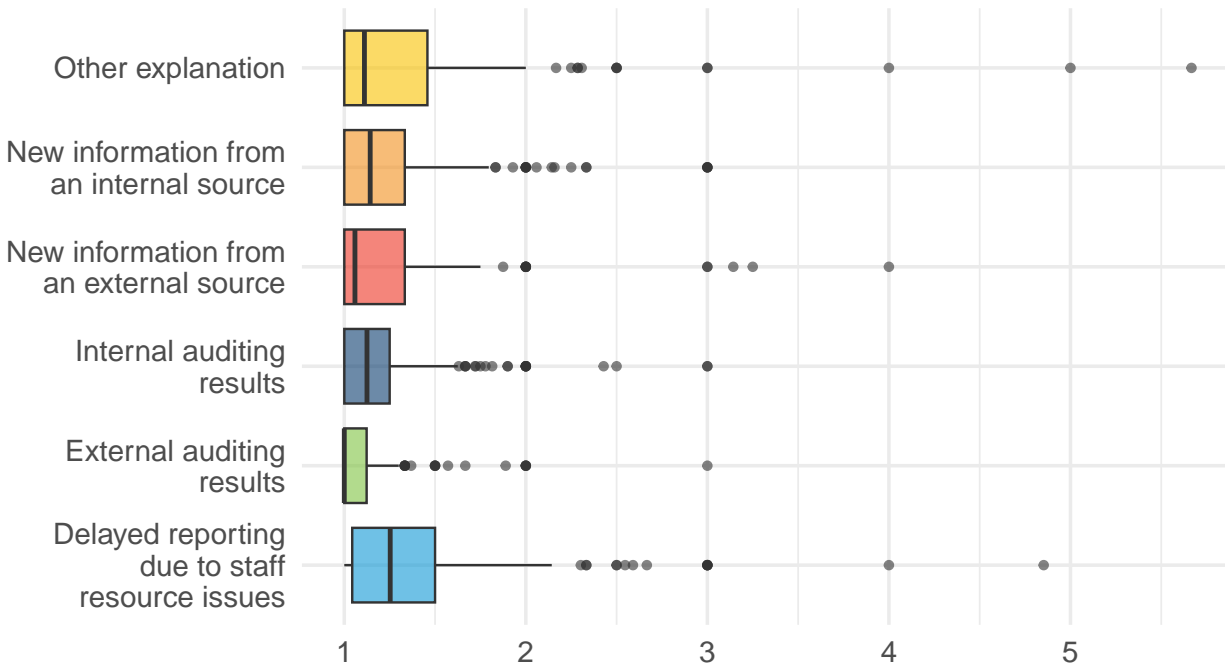
**Figure 8. Distribution of institution-level average number of unlocking events per distinct form by form type (blinded).**



Vertical bar inside box is median value; width of box indicates spread between 25th and 75th percentiles; dots depict outliers.

**Table 6. Distribution of institution-level average number of unlocking events per distinct form by form type (blinded).**

Form Type	Mean (SD)	Median (IQR)
DDR	1.25 (0.35)	1.13 (1, 1.29)
DHS	1.34 (0.61)	1.13 (1, 1.37)
LDF	1.39 (0.4)	1.32 (1, 1.58)
LDR	1.53 (0.72)	1.25 (1, 2)
RHS	1.36 (0.69)	1.16 (1.04, 1.33)
TCR	1.27 (0.35)	1.15 (1, 1.36)
TRF	1.3 (0.29)	1.23 (1.09, 1.42)
TRR	1.61 (0.67)	1.4 (1.15, 1.92)

**Figure 9. Distribution of institution-level average number of unlocking events per distinct form by reason (blinded).****Table 7. Distribution of institution-level average number of unlocking events per distinct form by reason (blinded).**

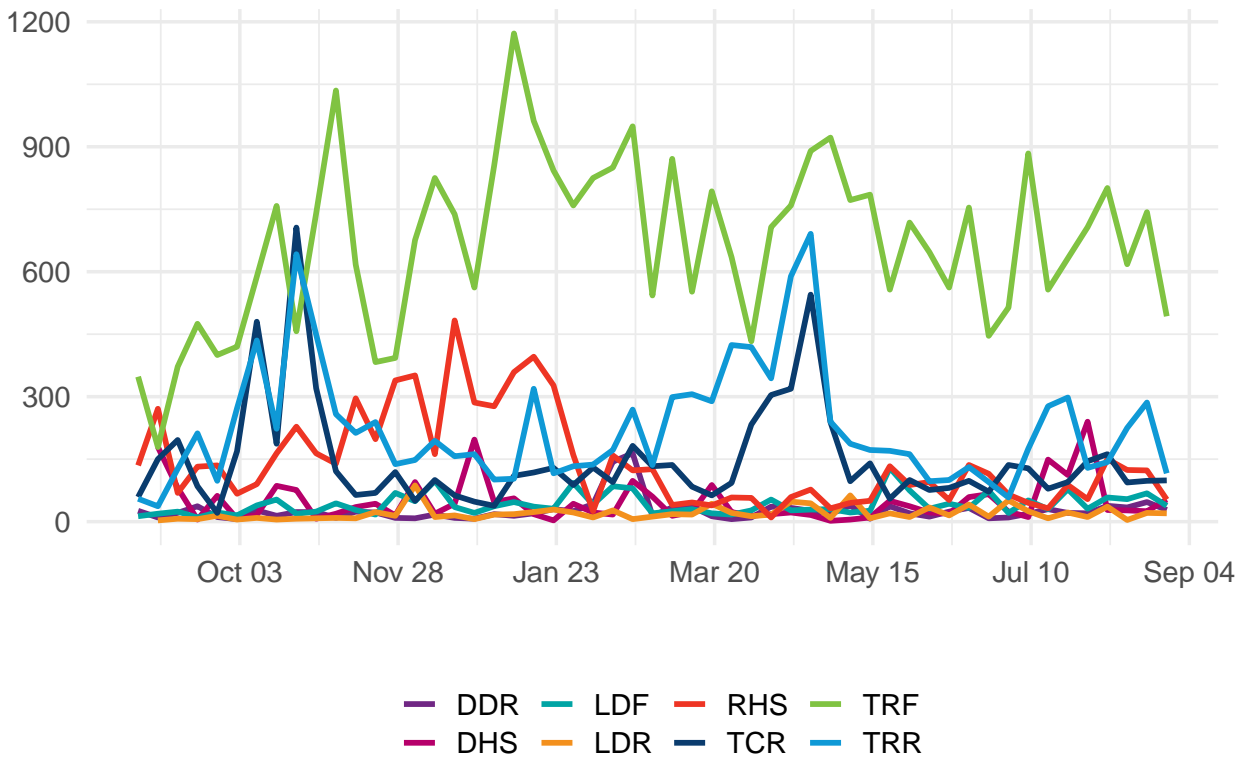
Reason	Mean (SD)	Median (IQR)
Delayed reporting due to staff resource issues	1.4 (0.51)	1.25 (1.04, 1.5)
External auditing results	1.12 (0.27)	1 (1, 1.12)
Internal auditing results	1.2 (0.3)	1.12 (1, 1.25)
New information from an external source	1.24 (0.43)	1.06 (1, 1.33)
New information from an internal source	1.26 (0.38)	1.14 (1, 1.33)
Other explanation	1.33 (0.57)	1.11 (1, 1.46)

**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 10 through 11**.

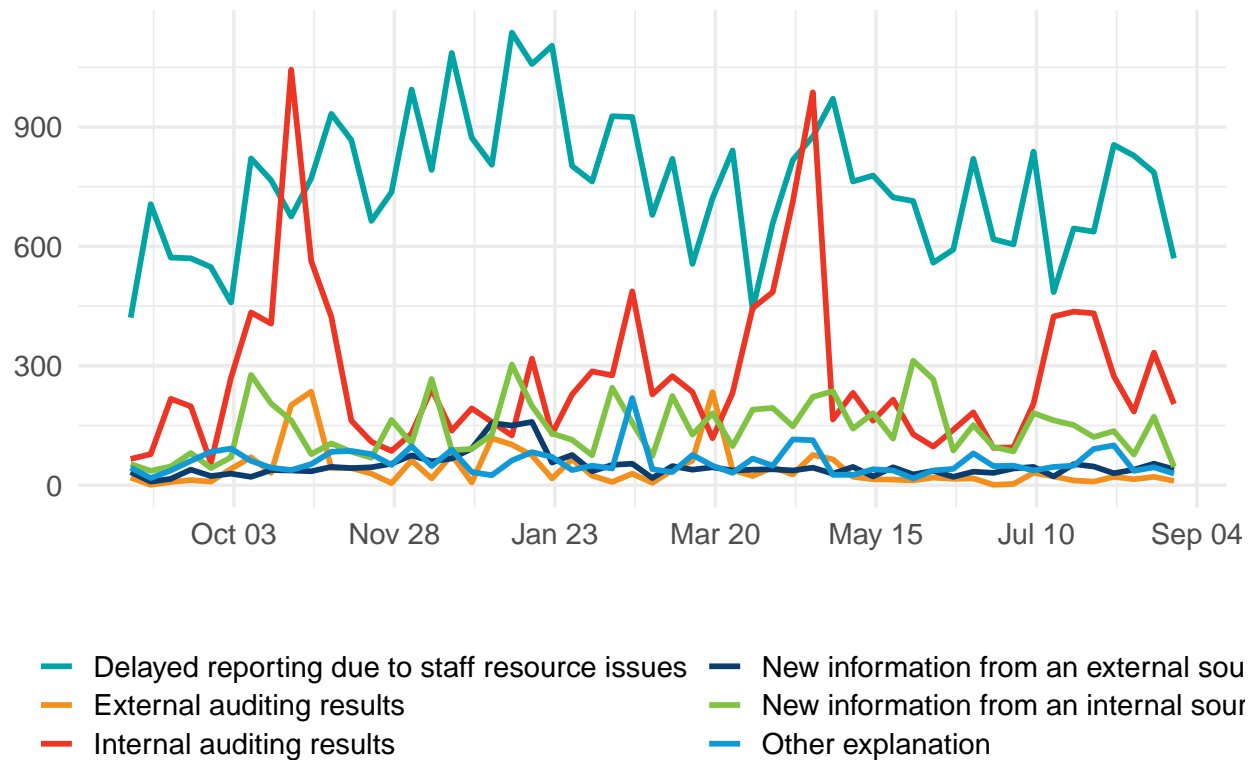
TCR and TRR unlocking activity notably peaked in October 2022 and April 2023, corresponding roughly to the data review period prior to the publication of biannual PSRs by the SRTR. TRF unlocking activity varied over time but was high throughout the entire monitoring period generally.

**Figure 10. Trends in form unlocking by form type and week.**



Reasons given for unlocking also varied considerably by week, with notable spikes in October and April for “Internal auditing results” and persistently high levels of “Delayed reporting due to staff resource issues”.

**Figure 11. Trends in unlocking events by reasons given and week.**



## Pre-/Post-implementation Comparison

### Timely form submission rates by policy era

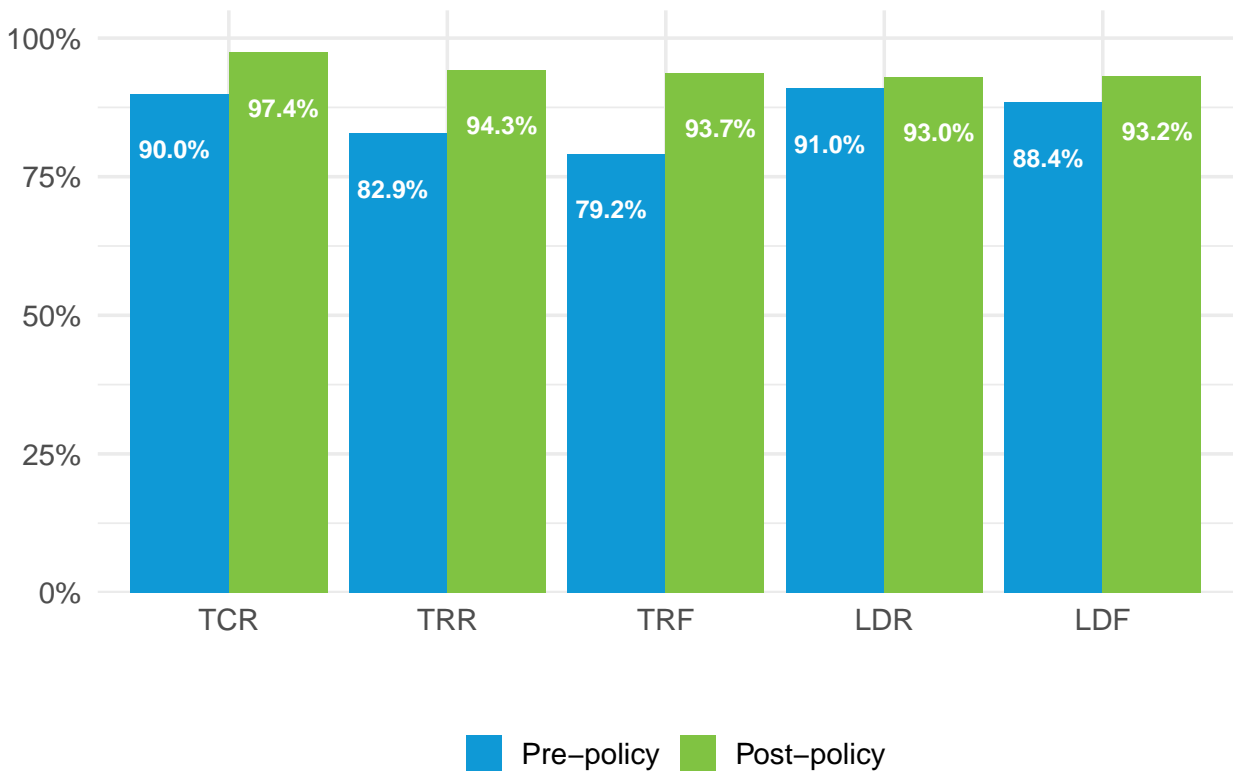
Transplant centers, organ procurement organizations (OPOs), and histocompatibility laboratories (labs) are required to submit OPTN data by the expected dates (due dates) specified in **OPTN Policy 18: Data submission requirements**. **Figure 12** displays data submission rates by form type, for OPTN Data System forms expected from currently active transplant centers during twelve months before and after the policy change (i.e. “Pre-policy” vs. “Post-policy”) (N=# A tibble: 1 x 1, n, , 1 1006495 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=373,223) for the Transplant Recipient Follow-up form (TRF), to 91.0% (N=5,884) for the Living Donor Registration form (LDR).

After implementation, the percentage of forms submitted by the due date ranged from 93.0% (N=6,696) for the Living Donor Registration form (LDR), to 97.4% (N=62,174) for the Transplant Candidate Registration form (TCR).



Figure 12. Forms submitted by transplant centers by expected date pre- and post-policy.

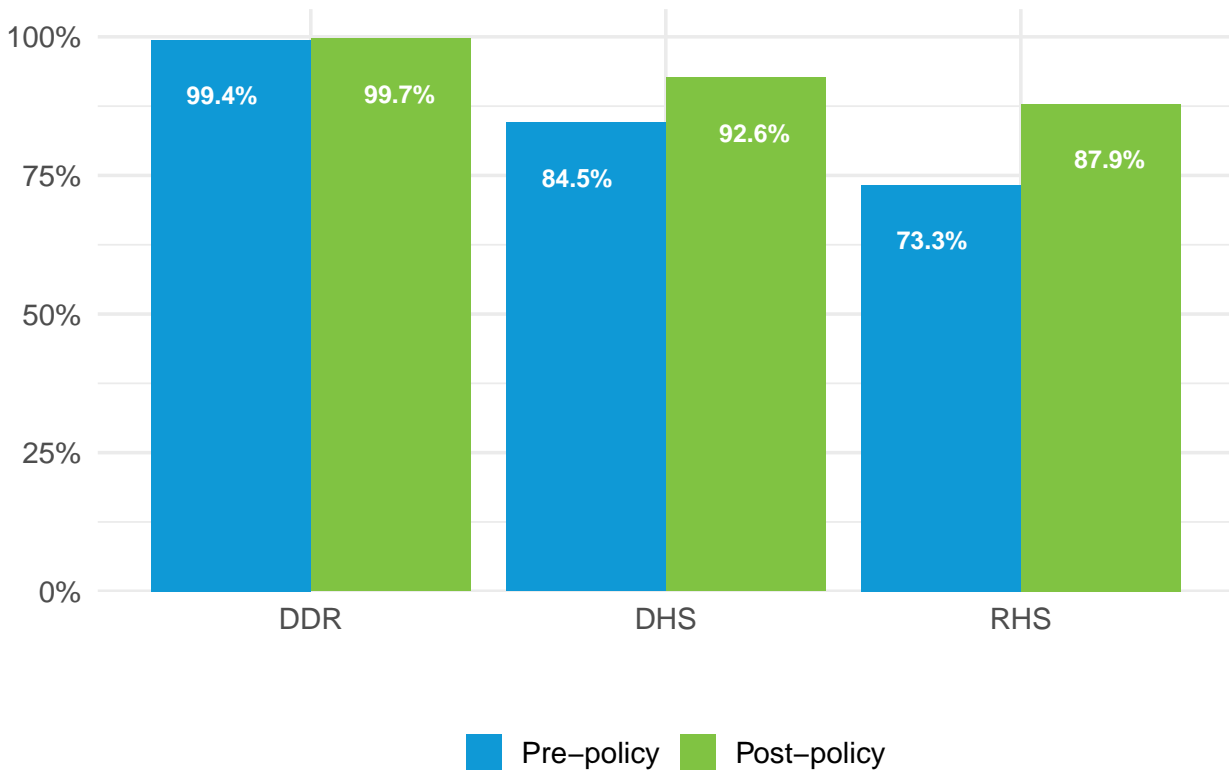


**Figure 13** displays data submission for forms expected from OPOs (N=28,715 forms) and histocompatibility labs (N=115,868 forms), during pre- and post-policy eras.

OPOs submitted 99.4% 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 73.3% (N=33,616 forms) for the Recipient Histocompatibility (RHS) form and 84.5% (N=18,574 forms) for the Donor Histocompatibility (DHS) form.

OPOs submitted 99.7% 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 87.9% (N=41,271 forms) for the RHS form and 92.6% (N=22,407 forms) for the DHS form.

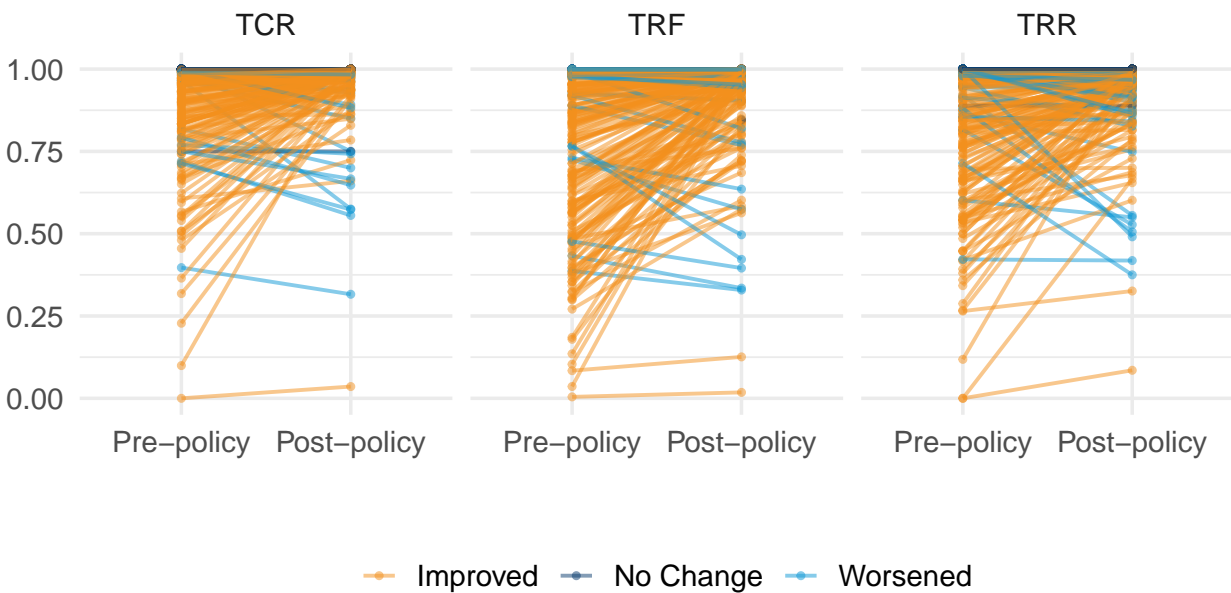
**Figure 13. Forms submitted by OPOs and histocompatibility labs by expected date pre- and post-policy.**



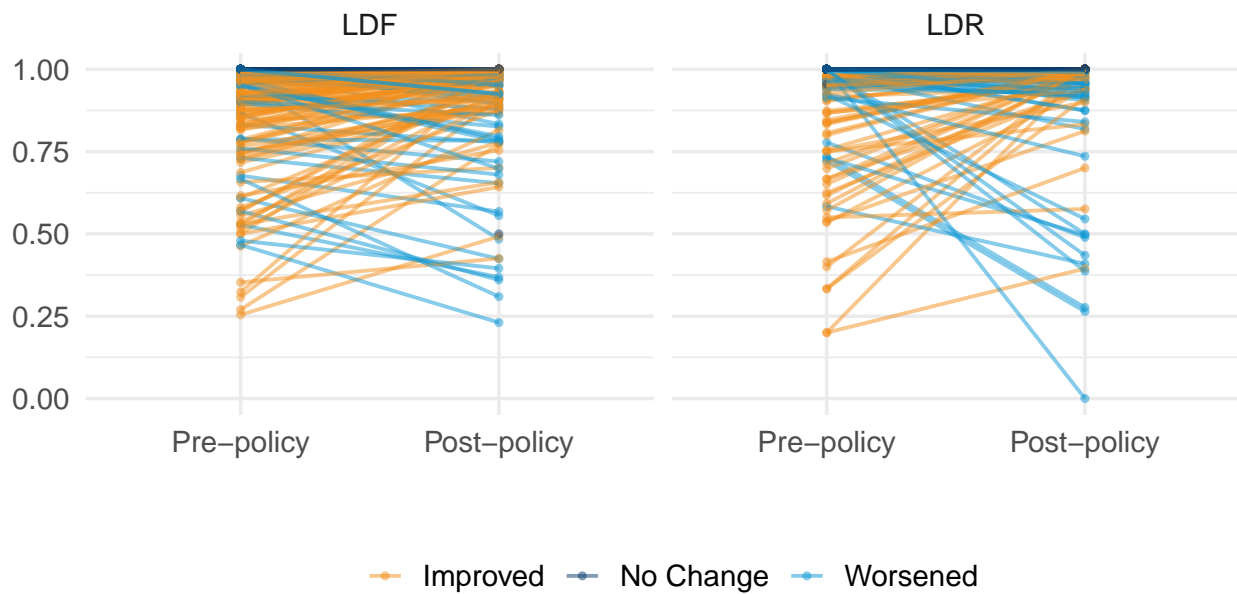
**Timely form submission rates by policy era at institutional level (blinded)**

**Figures 14 through 16** 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.

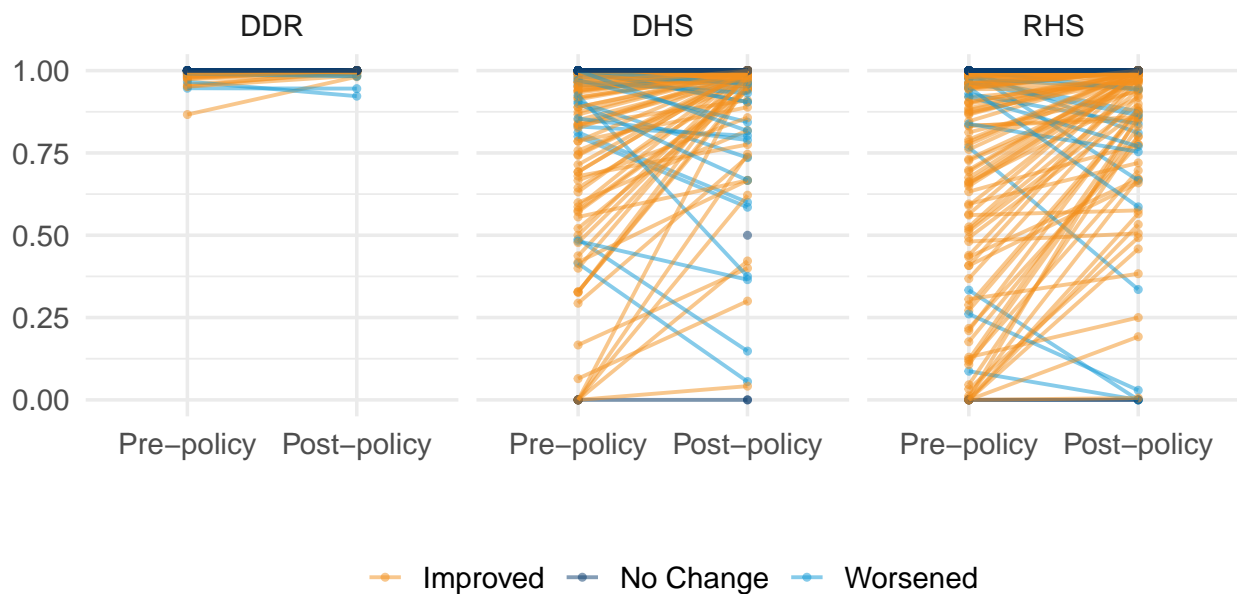
**Figure 14. Center-level rates of transplant form completion by expected date, pre- and post-policy.**



**Figure 15. Center-level rates of living donor form completion by expected date, pre- and post-policy.**



**Figure 16. OPO- and lab-level rates of donor and histocompatibility form completion by expected date, pre- and post-policy.**



**Selected OPTN field-level change frequency by policy era**

At the request of the DAC, in this report, we further examined selected variables on the DDR and Kidney (KI) TCRs, calculating the number of field-level changes per 10,000 forms that occurred more than 90 days after their expected date and characterizing those changes as occurring before ('Pre-policy') and after data lock implementation ('Post-policy') on August 30, 2022.

Summary data on this analysis is presented in Figures 17 through 22 below. Blue bars in the figures below depict the size of the increase in the rate of field change per 10,000 forms after the policy implementation vs. before. Orange bars depict the size of the decrease in the rate of field change per 10,000 forms after the policy implementation vs. before. Note that the scale of these net differences varies across the figures, though the rates calculated are all per 10,000 DDR or TCR forms.

**Figure 17. Change in number of medical history field changes per 10,000 DDR forms 90+ days after expected date by field pre- and post-policy.**

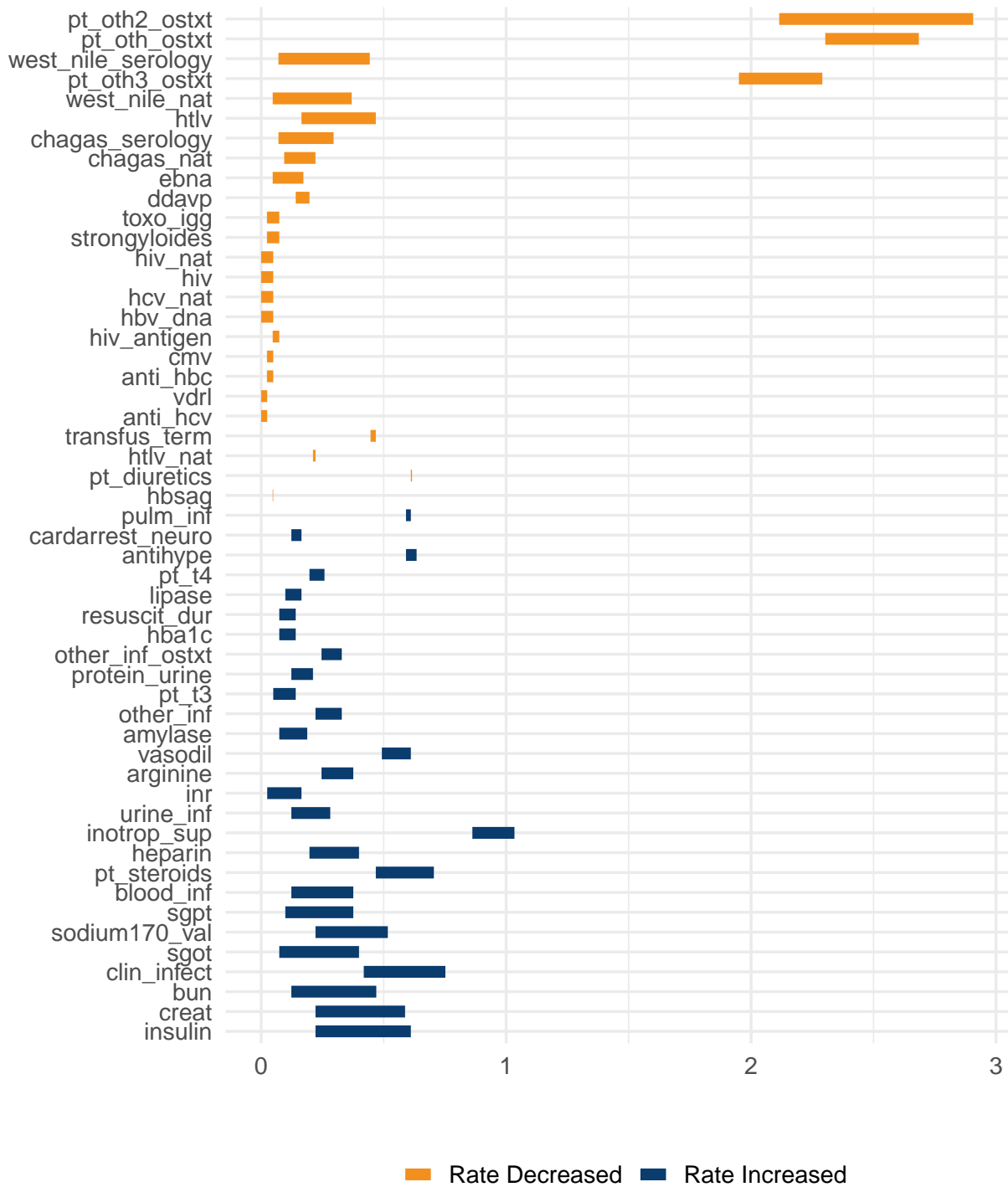


Figure only includes fields where any change was made 90+ days after expected date in either era

**Figure 18. Change in number of social history field changes per 10,000 DDR forms 90+ days after expected date by field pre- and post-policy.**

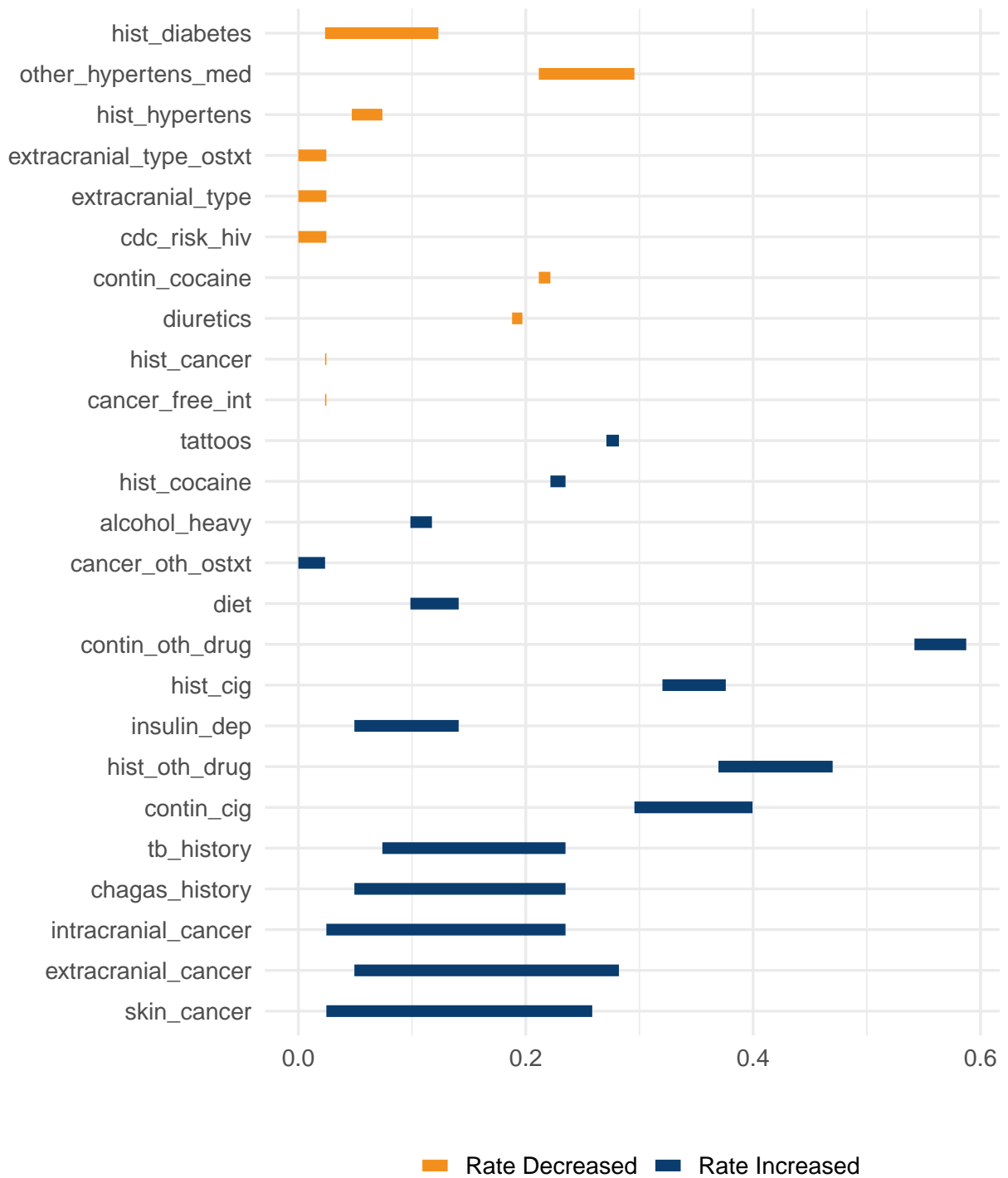


Figure only includes fields where any change was made 90+ days after expected date in either era

**Figure 19. Change in number of organ-specific field changes per 10,000 DDR forms 90+ days after expected date by field pre- and post-policy.**

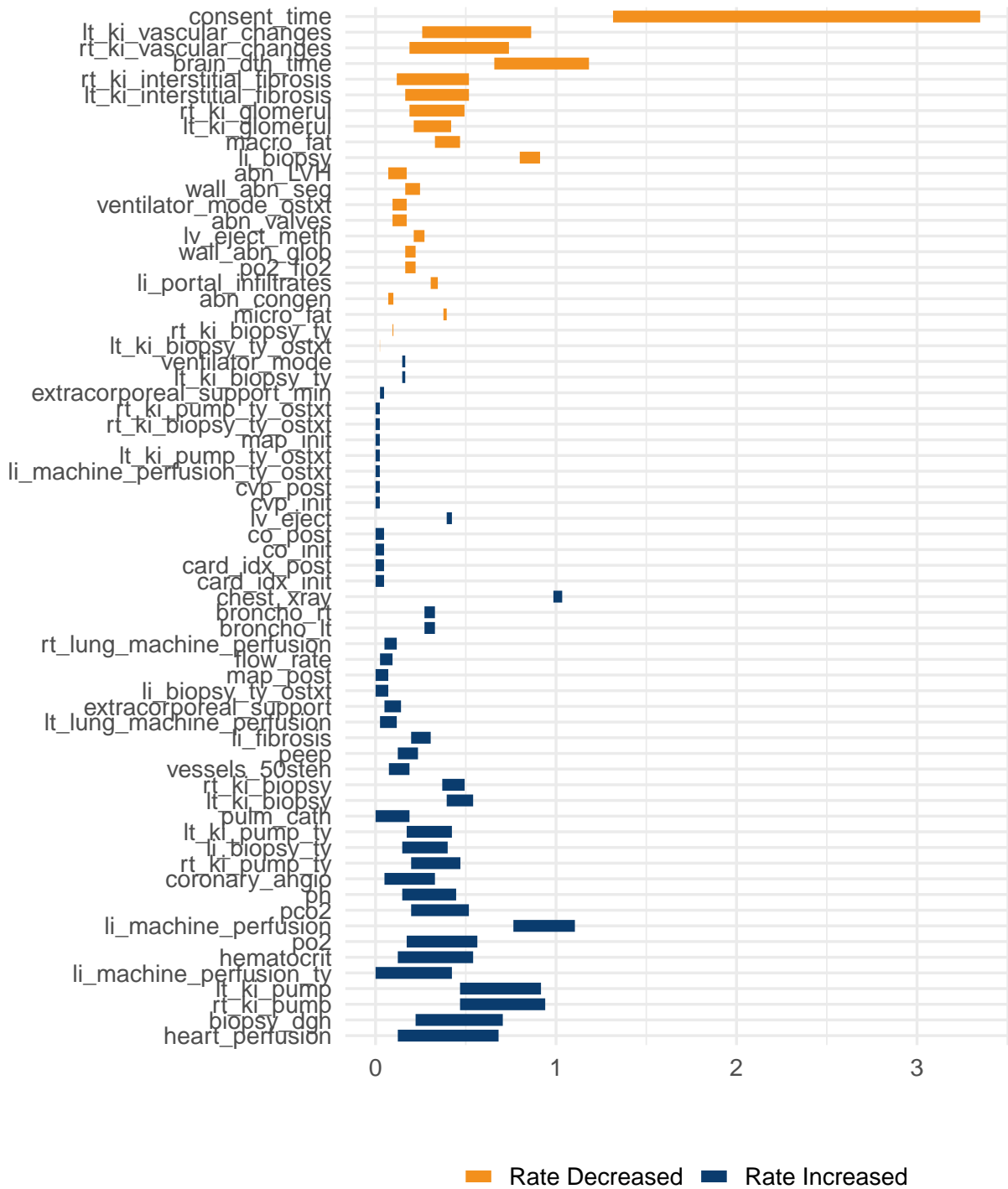


Figure only includes fields where any change was made 90+ days after expected date in either era



**Figure 20. Change in number of KI TCR demographic field changes per 10,000 forms 90+ days after expected date by field pre- and post-policy.**

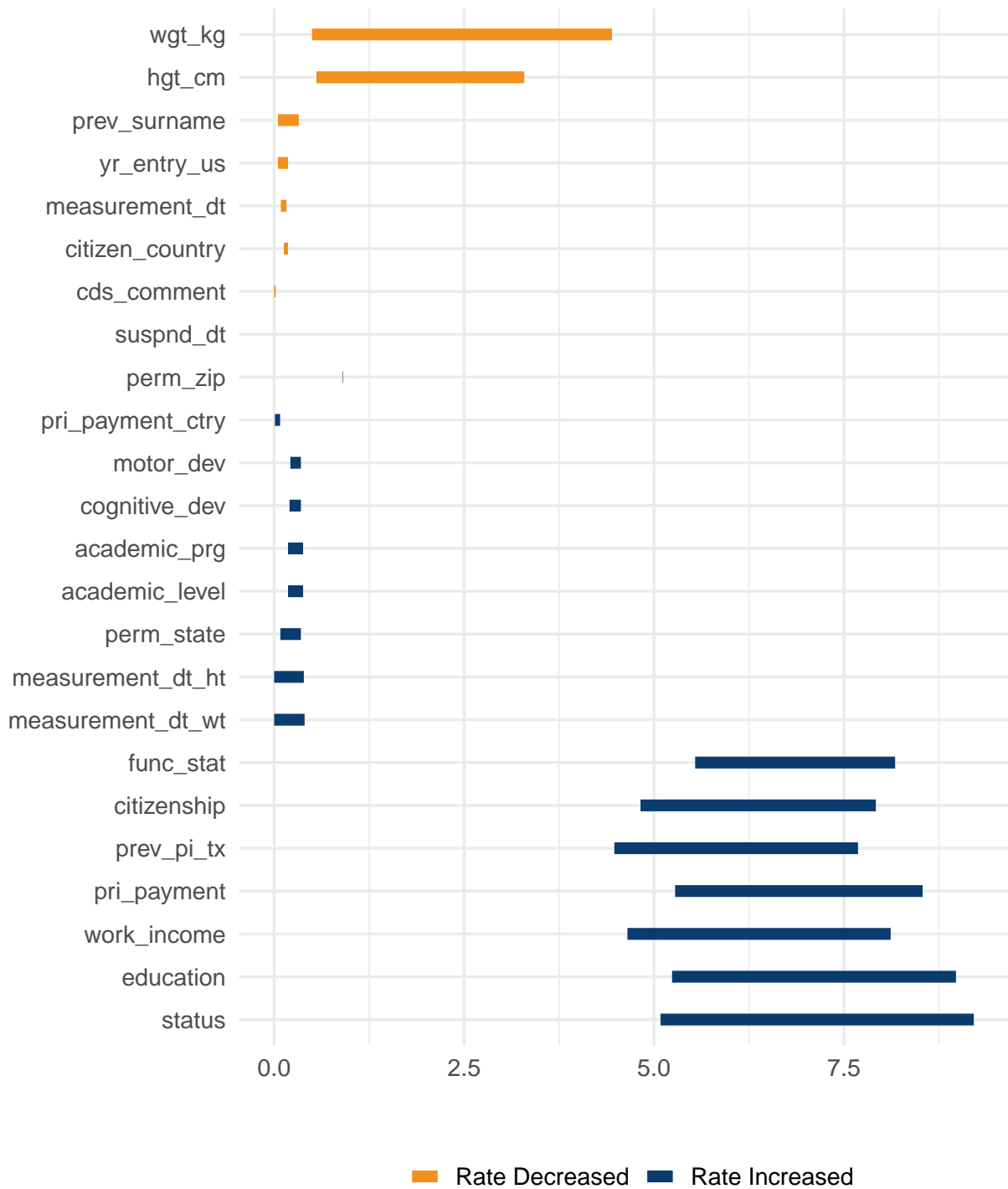


Figure only includes fields where any change was made 90+ days after expected date in either era

**Figure 21. Change in number of KI TCR clinical field changes per 10,000 forms 90+ days after expected date by field pre- and post-policy.**

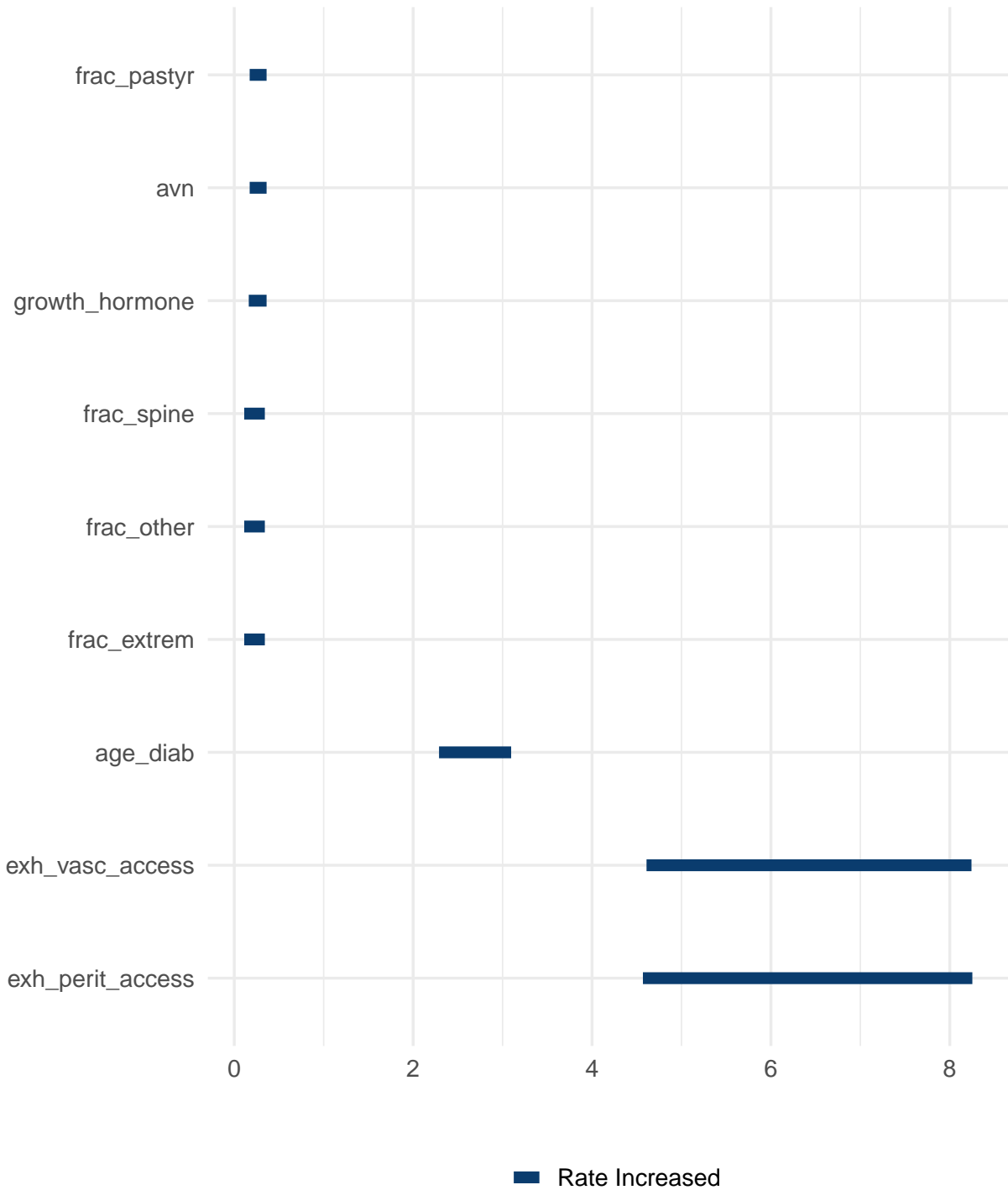


Figure only includes fields where any change was made 90+ days after expected date in either era

**Figure 22. Change in number of KI TCR medical history field changes per 10,000 forms 90+ days after expected date by field pre- and post-policy.**

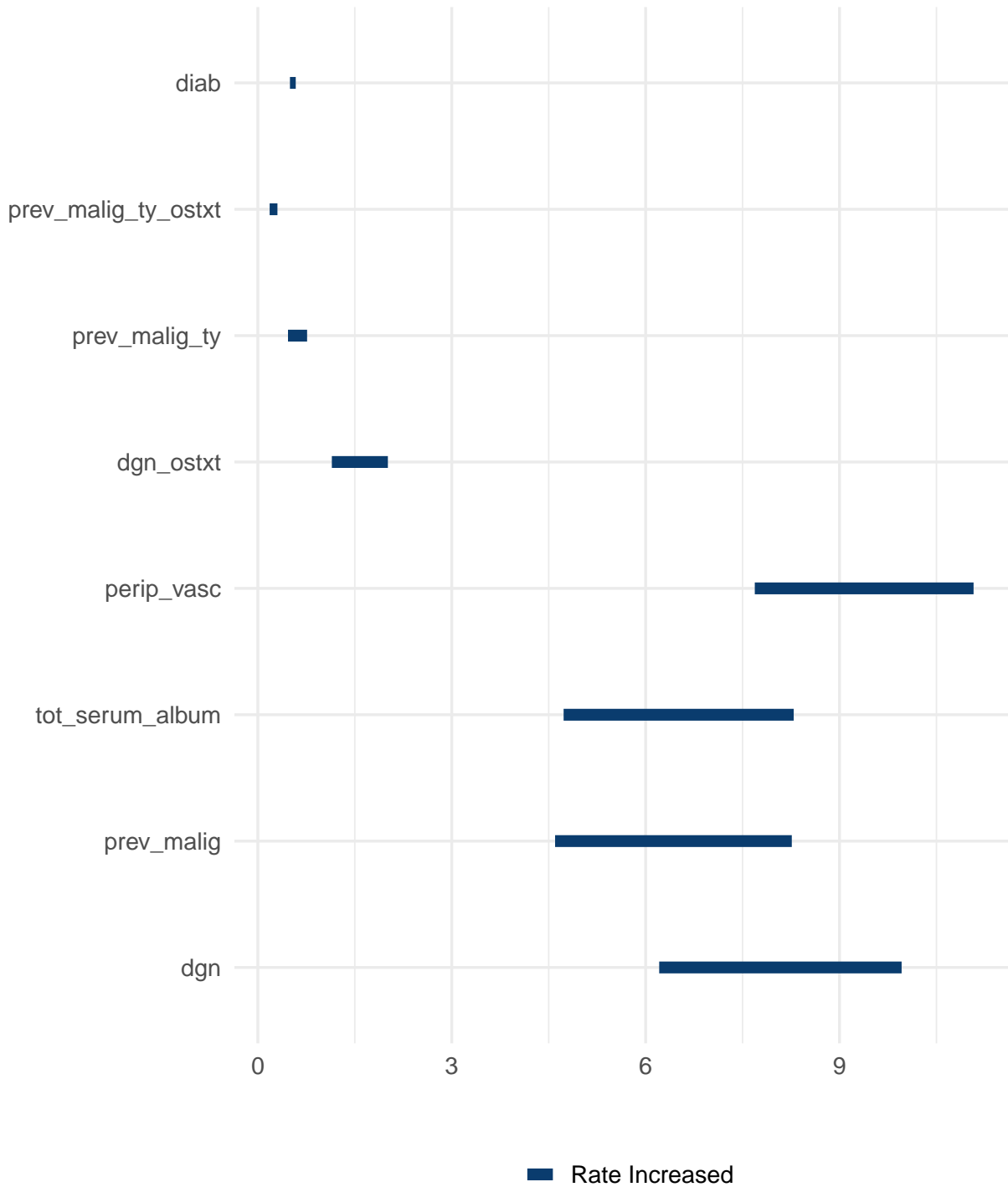


Figure only includes fields where any change was made 90+ days after expected date in either era

## Conclusion

The next scheduled monitoring report for this policy will occur following the 24-month anniversary of the implementation on August 30, 2024 and will be available in early fall 2024. Findings from this monitoring will also become a permanent section in the Annual Data Quality Report to the OPTN Board going forward. Additionally, we plan to assess the rate of field changes across additional forms subject to Policy 18 in future analyses. DAC has specifically expressed ongoing interest in whether there have been meaningful changes in the cadence of edits to data elements that are critical to the modeling of transplant program outcomes reported on the PSRs published by the SRTR.