

# **OPTN Annual Data Quality Report**

DHHS Contract No. 250-2019-00001C Task 3.5.1, Item A123 Date Completed: October 8, 2024

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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 (October 2024)
- 2. Data review report (October 2024)

## 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 Data Advisory Committee, hereafter referred to as DAC, with information necessary to formulate recommendations for improving the quality of official OPTN data. The OPTN Contractor will present these data to the DAC in advance of the November 2024 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 (also known as TIEDI®). 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) Timely data submission,
- 2) Review of key Policy 18 amendment ('Data Lock') metrics to date,
- 3) Summary of findings from members regarding 'Data Lock' trends,
- 4) Changes to fields after forms are locked,
- 5) Comparing OPTN and CMS data on dialysis start dates.

## **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 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 DAC and will incorporate recommendations from the DAC into future versions of the report. As the 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 used 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**

*Timely form completion rates rose between 2021 and 2023*, from: **81.4% to 94.1%** for transplant centers and **78.4% to 88.5%** for histocompatibility labs. Rates stayed roughly the same for organ procurement organizations ranging between **99.4%-99.6%**.

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 2023 as follows:

- 0.053 for transplant centers
- 0.193 for organ procurement organizations, and
- **0.076** for histocompatibility labs.

Form unlocking activity is more common for some forms than others, with the following consistent trends noted:

- Highest unlocking volume to date has been for the **TRF**;
- Seasonal spikes in TRR and TCR unlocking activity occur in October and April;
- Unlocking activity for reported reasons of 'Delayed reporting due to staff resource issues' occurs at a higher level regardless of the time of year;
- **'Internal audit-related reasons'** are cited more commonly in sync with seasonal spikes in TCR and TRR unlocking in April and October.

# The vast majority of the top changes to fields after forms were locked were on forms that were validated after the expected date.

• The only exceptions to this are fields on the **DDR** and the **"Date of Discharge from TX Center"** field on the TRR.

# There were discrepancies between OPTN data and CMS data with regards to dialysis status and dates for kidney and kidney-pancreas candidates.

- 16.1% of registrations listed as not on dialysis in OPTN data were indicated as on dialysis in CMS data.
- 2259 registrations listed as on dialysis in OPTN data had a date discrepancy when compared to CMS data.

- 50% had a date discrepancy of 10 days or less, and
- 13.7% had a date discrepancy of 1 year or more.

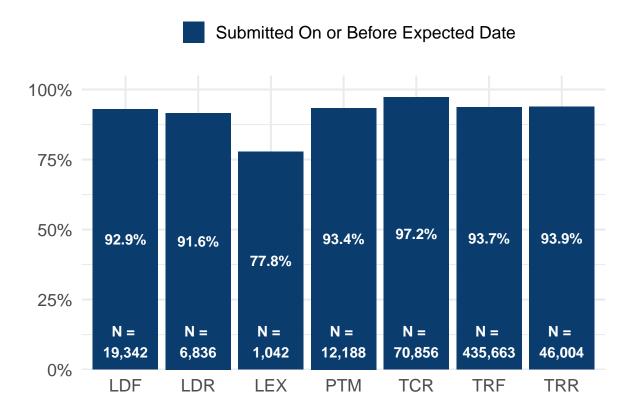
## **Data Quality Assessment Detailed Findings**

### Timely data submission

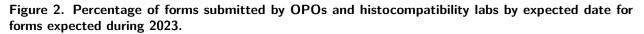
Transplant centers, organ procurement organizations (OPOs), and histocompatibility laboratories (labs) are required to submit OPTN data by the expected dates (due dates) specified in *OPTN Policy 18: Data submission requirements*. *Figure 1* displays timely data submission, defined as the percentage 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 2023 (N=591,931 forms). Timely data submission in 2023 varied by form type, ranging from 77.8% (N=1,042) for the Liver Explant Pathology form (LEX), to 97.2% (N=70,856) for the Transplant Candidate Registration form (TCR).

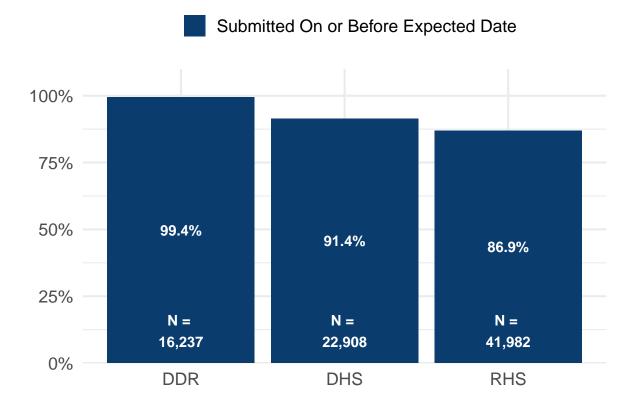
Prior to August 2022, OPTN data submission policy specified both a due date for each individual form in *Policy 18.1*, along with language in OPTN *Policy 18.4 Data Submission Standard* that required members submit 95% of these forms within three months of the due date and 100% within six months of the 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.





*Figure 2* displays data submission for forms expected from OPOs (N=16,237 forms) and histocompatibility labs (N=64,890 forms) during 2023. OPOs submitted 99.4% 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 86.9% (N=41,982 forms) for the Recipient Histocompatibility form and 91.4% (N=22,908 forms) for the Donor Histocompatibility form.

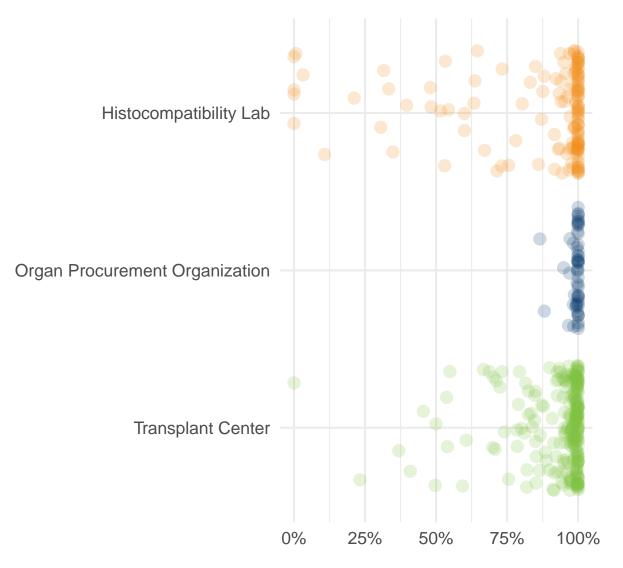




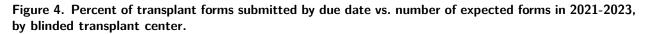


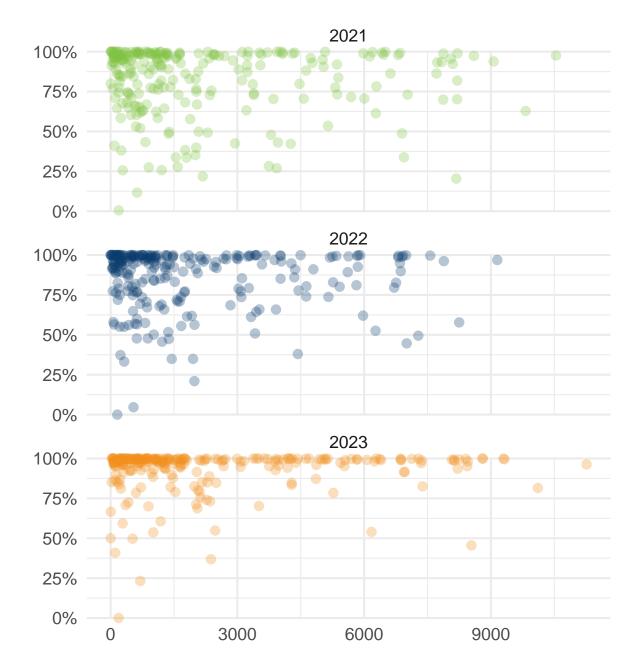
*Figure 3* examines the variation in institution-level form completion rates in 2023 by institution type. For OPTN Data System forms expected during 2023, the median percent of forms submitted by the due date by institution type varies from 98.6% across transplant centers to 100.0% across OPOs. Among all institution types, 100% of forms were submitted by the due date for 33 centers, 37 OPOs, and 67 labs.

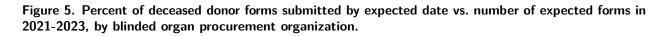
#### Figure 3. Blinded institutional-level timely form completion rates by institution type in 2023.



**Figures 4 through 6** 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 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.







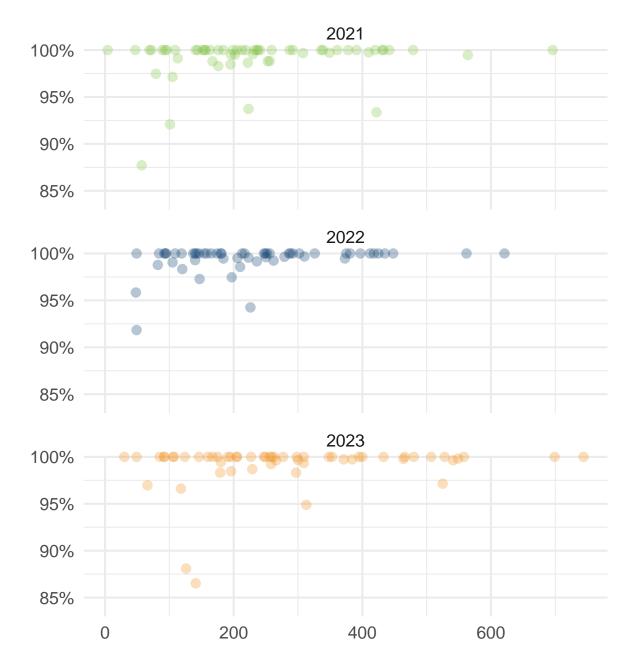
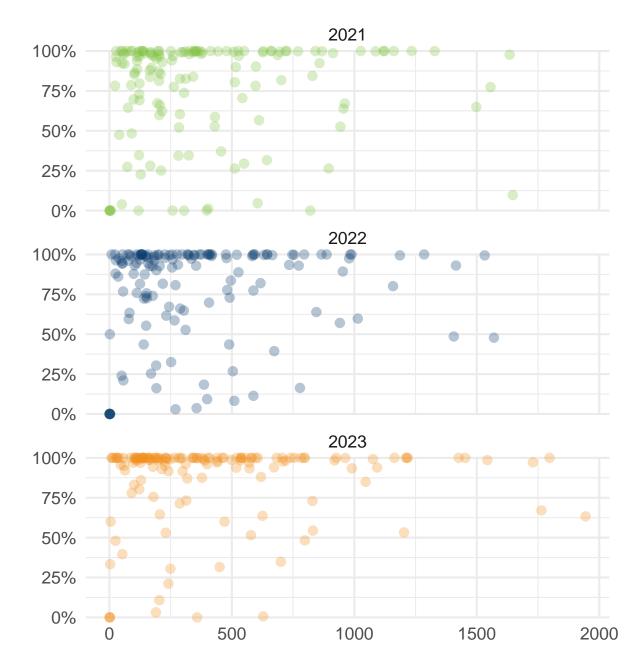
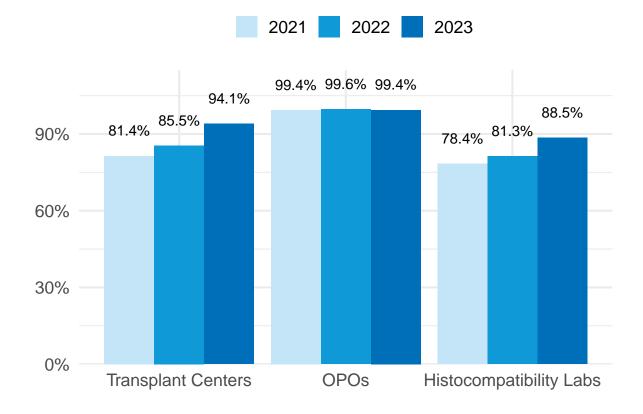


Figure 6. Percent of histocompatibility forms submitted by due date vs. number of expected forms in 2021-2023, by blinded histocompatibility lab.



**Figure 7** displays the percent of OPTN Data System forms submitted by the due date by institution type and year for forms expected 2021 - 2023. 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.



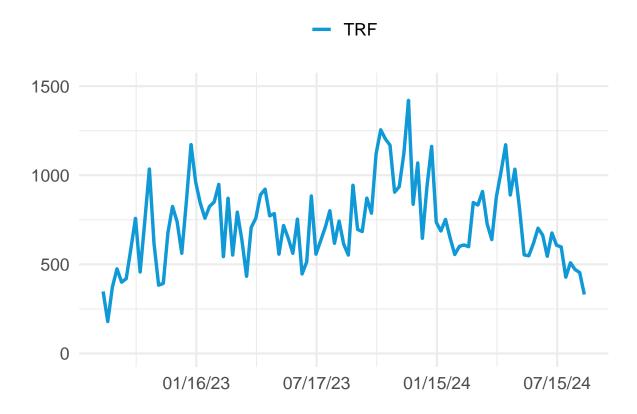


#### Review of key 'Data Lock' trends

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 8 through 11*.

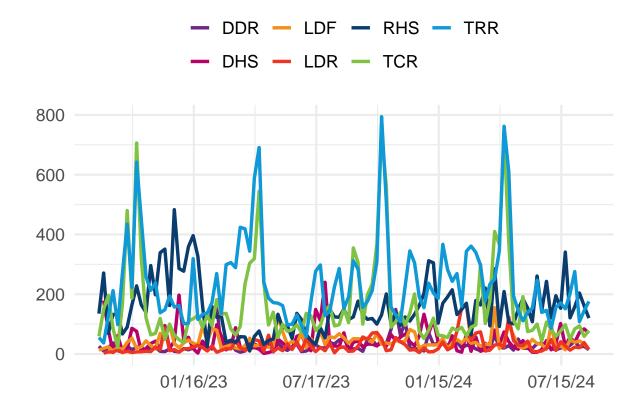
There are notable differences in unlocking volume by form type, with TRF forms having persistently high numbers of unlocking events.

Figure 8. Trends in form unlocking events by form type and week, TRF only.



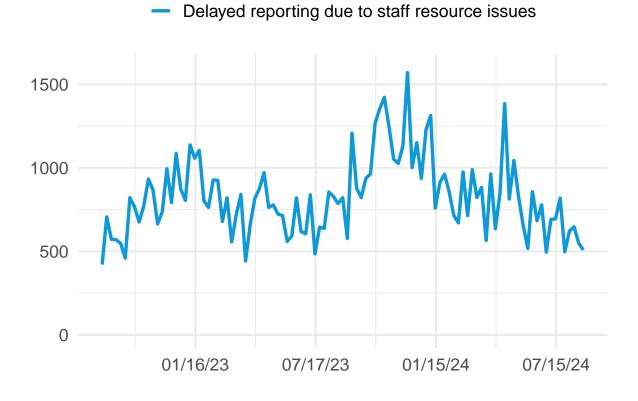
With TRF unlocking volume reported separately in *Figure 8*, the seasonality of TCR and TRR unlocking activity is more obvious in *Figure 9* below. Unlocking activity peaked in October and April, corresponding with the data review period prior to the publication of biannual Program-Specific Reports (PSR) by the SRTR.





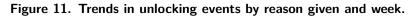
To better highlight different trends in reasons for unlocking events by week, *Figure 10* shows only the number of unlocking events for "Delayed reporting due to staff resource issues".

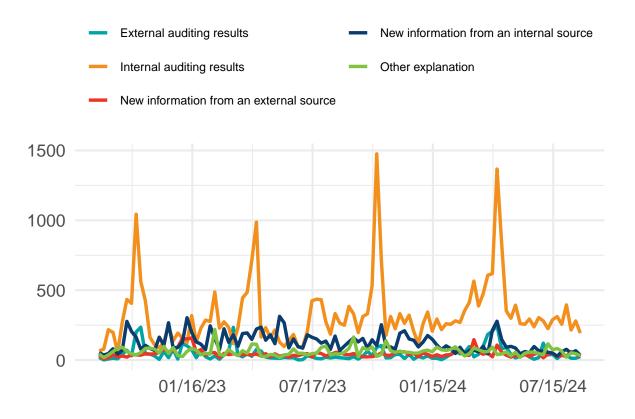
# Figure 10. Trends in unlocking events by reason given and week, "Delayed reporting due to staff resource issues" only.





*Figure 11* shows that compared with "delayed reporting due to staff resource", a lower volume of unlocking events were due to "Internal auditing results". More forms were unlocked due to "Internal auditing results" in October and April, corresponding with the data review period that precedes the biannual publication of the SRTR PSR reports.







To examine the distribution of unlocking frequency given differing form volume levels by institution type, Figure 12 shows the blinded institutional rates of form unlocking events per 100 locked forms.

Figure 12. Blinded institutional level form unlocking events per 100 locked forms by institution type since August 30, 2022.

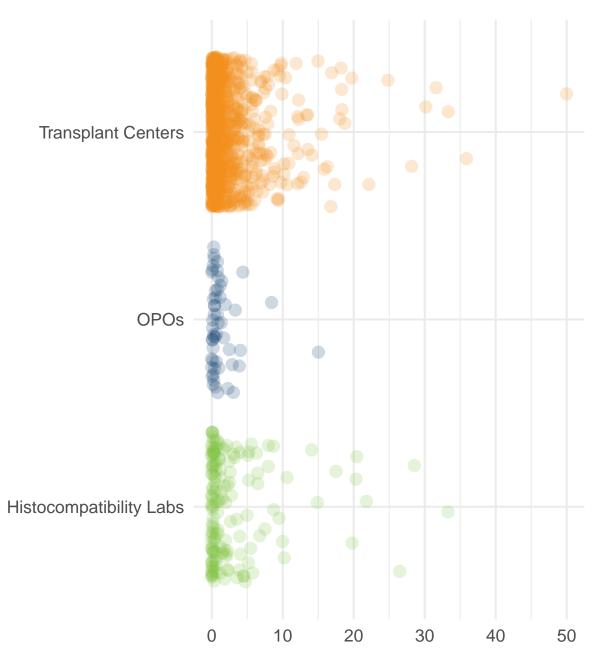
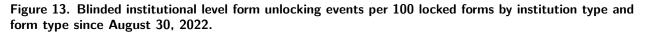
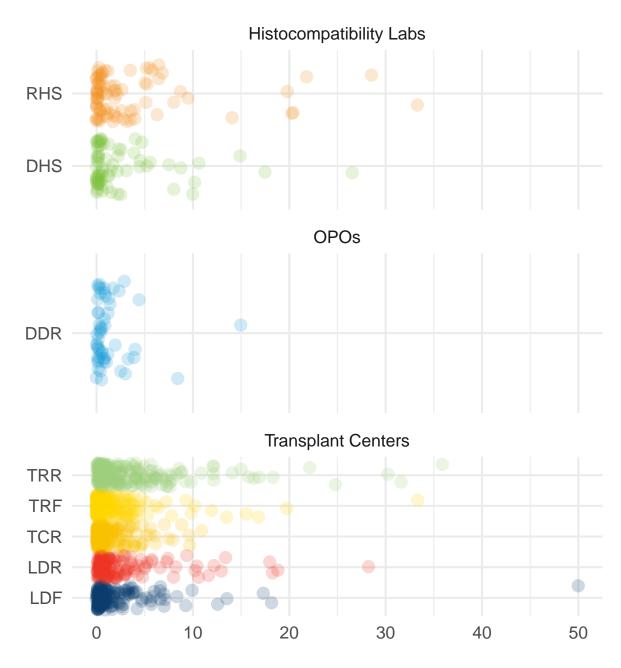


Figure 13 shows the blinded institutional rates of form unlocking events per 100 locked forms by form type.





#### Summary of findings from members regarding 'Data Lock' trends

Since implementation of the revisions to *Policy 18*, OPTN member organizations and members of the DAC have asked whether the changes have improved the quality and timeliness of OPTN data. For instance, DAC members have questioned why forms are frequently unlocked and have requested specifics about OPTN member experiences with the unlocking process. Additionally, DAC members have sought to understand how the unlocking requirement is impacting the electronic submission of data using APIs, and if the two features in tandem have led to better data quality.

To address these and other questions, OPTN contractor staff held two rounds of informal meetings with six OPTN members to gather information about their data lock experiences. The first round of meetings targeted OPTN members responsible for most frequently unlocking forms in the first year following implementation. The second round focused on OPTN members with relatively high levels of unlocking activity and a majority of form submissions through API. One histocompatibility lab and five transplant hospitals were contacted. Short meetings were held between these members and OPTN contractor staff to discuss the DAC's questions. OPOs were excluded due to their low rates of unlocking forms.

The first round of meetings found that high form unlocking rates were often caused by unique circumstances. According to the OPTN members, staffing issues and COVID often led them to miss submission deadlines, and subsequently, required the forms to be unlocked. Missing submission deadlines also may have led to cases of a single form being unlocked multiple times due to the need to frequently unlock the data to pass any validation errors per data element. Despite the identified challenges, none of the OPTN members interviewed raised concerns about potentially implementing a 'hard data lock" which would be set to one year post form creation date. Conversations also revealed a need to promote the existing reports on the Data Services Portal which can assist members in conducting timely review of required data submissions. Half of the OPTN members contacted were unaware of the existence of such tools.

The second round of meetings focused on the challenges of API usage, specifically around the mapping of fields from member's internal Electronic Health Records (EHR) to OPTN forms. Due to multiple factors, some data would not flow accurately, requiring a secondary review of data either prior to submission in the EHR or after submission in the OPTN Data System. It was also found that these API issues were rarely the cause of unlocking a form, as members were very aware of the issues and fixed the problems prior to the form being locked. Many of the OPTN members contacted indicated they were unsure which unlocking explanation to use when API is the reason.

The results of these conversations were presented to the DAC in March and September of 2024. The following recommendations were shared and discussed:

- Expanding the list of unlocking reasons from which OPTN members can select, including reasons specific to API issues and validation errors
- Allowing forms to remain unlocked after the submission deadline if the OPTN member has not completed an initial save of the form
- Pursuing implementation of a 'hard data lock'. The Committee would like to discuss plans for this project and the need to prioritize
- Continuing to educate OPTN members about the existing data lock reports on the Data Services Portal which can assist members in conducting timely review of required data



#### Changes to fields after forms are locked

At the DAC's request, a process was developed to count the number of changes to fields after forms were locked. This analysis includes all forms with field changes after the form was locked from September 1, 2022 to September 1, 2024. *Figures 14 through 19* and *Tables 1 through 6* show the top fields with changes after the form was locked and how many of those changes involve a form that was validated after the expected date. For this analysis, only the top 10 fields are displayed. Forms validated after expected date could indicate that this is the first time that any information was entered into that field, or that the form was previously filled out but not validated before the expected date. The DAC discussed this analysis and is considering next steps.

For all forms except for the DDR, the majority of the top fields changed after the forms were locked were on forms that were validated after the expected date. The exception to this was the "Date of Discharge from TX Center" field on the TRR with 48.6% of changes from forms that were validated after the expected date. Notably, although the TRF had the largest number of fields changed after the form was locked, the vast majority of these changes (97%+) were on forms that were validated after the expected date. Some of the top fields on both the TRR and the TCR are included in the SRTR modeling for the PSRs such as Total Serum Albumin, Education, and Any previous Malignancy. Others are not included in the PSR modeling such as Citizenship, Working for income, and Primary Source of Payment.



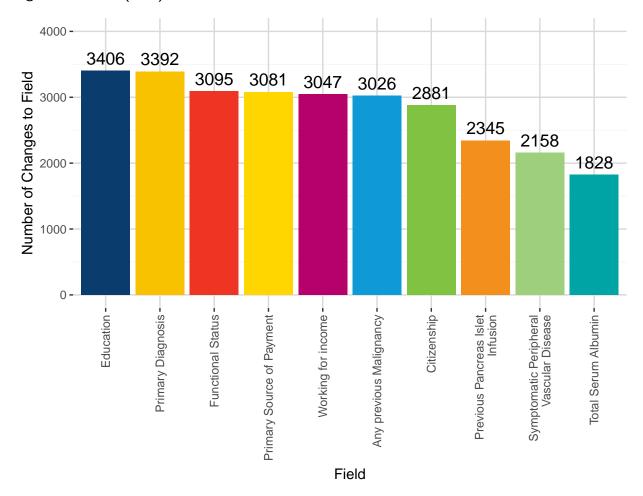


Figure 14. Number of changes per field after the form was locked for the Transplant Candidate Registration Form (TCR).

Table 1. Number of changes per field after the form was locked and percent from forms validated after expected date for the Transplant Candidate Registration Form (TCR).

Field	Changes to Field After Lock	Form Validated After Expected Date
Education	3406	2984 (87.6%)
Primary Diagnosis	3392	2982 (87.9%)
Functional Status	3095	3007 (97.2%)
Primary Source of Payment	3081	2999 (97.3%)
Working for income	3047	2797 (91.8%)
Any previous Malignancy	3026	2971 (98.2%)
Citizenship	2881	2873 (99.7%)
Previous Pancreas Islet Infusion	2345	2303 (98.2%)
Symptomatic Peripheral Vascular Disease	2158	1672 (77.5%)
Total Serum Albumin	1828	1728 (94.5%)

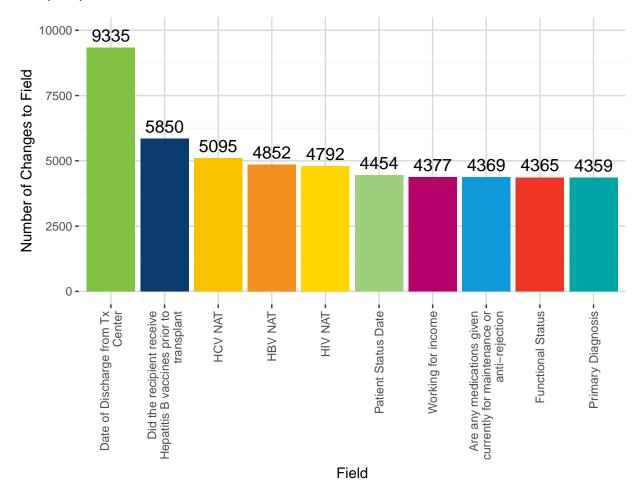


Figure 15. Number of changes per field after the form was locked for the Transplant Recipient Registration Form (TRR).

Table 2. Number of changes per field after the form was locked and percent from forms validated after expected date for the Transplant Recipient Registration Form (TRR).

Field	Changes to Field After Lock	Form Validated after Expected Date
Date of Discharge from Tx Center	9335	4539 (48.6%)
Did the recipient receive Hepatitis B vaccines prior to transplant	5850	4628 (79.1%)
HCV NAT	5095	4302 (84.4%)
HBV NAT	4852	4285 (88.3%)
HIV NAT	4792	4298 (89.7%)
Patient Status Date	4454	4280 (96.1%)
Working for income	4377	3987 (91.1%)
Are any medications given currently for maintenance or anti-rejection	4369	4357 (99.7%)
Functional Status	4365	4153 (95.1%)
Primary Diagnosis	4359	3899 (89.4%)

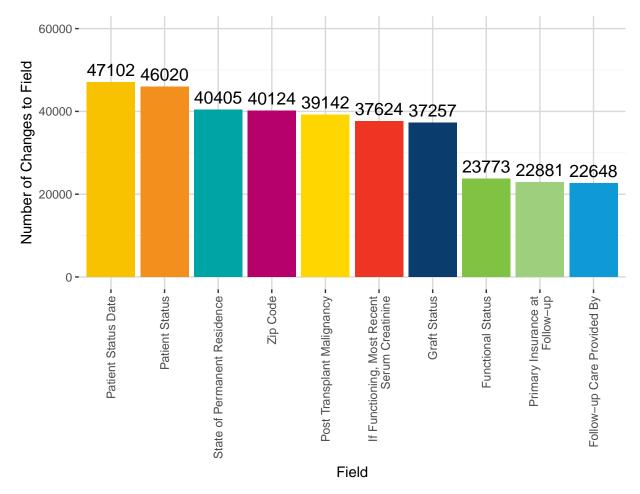


Figure 16. Number of changes per field after the form was locked for the Transplant Recipient Follow-Up Form (TRF).

Table 3. Number of changes per field after the form was locked and percent from forms validated after expected date for the Transplant Recipient Follow-Up Form (TRF).

Field	Changes to Field After Lock	Form Validated After Expected Date
Patient Status Date	47102	46507 (98.7%)
Patient Status	46020	45775 (99.5%)
State of Permanent Residence	40405	40350 (99.9%)
Zip Code	40124	40069 (99.9%)
Post Transplant Malignancy	39142	38545 (98.5%)
If Functioning, Most Recent Serum Creatinine	37624	37283 (99.1%)
Graft Status	37257	37005 (99.3%)
Functional Status	23773	23540 (99%)
Primary Insurance at Follow-up	22881	22404 (97.9%)
Follow-up Care Provided By	22648	22609 (99.8%)

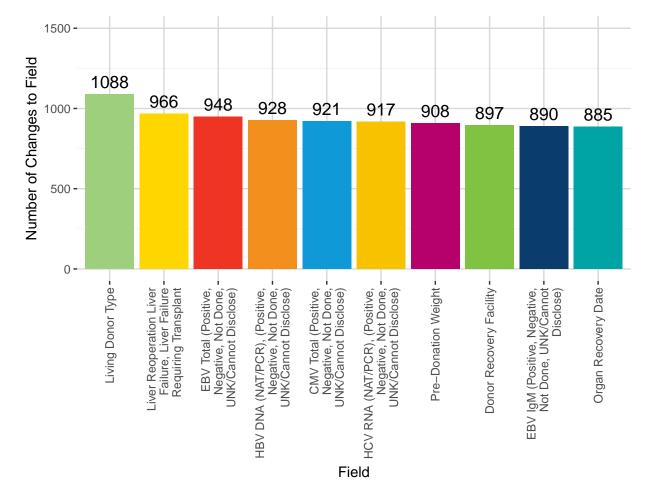


Figure 17. Number of changes per field after the form was locked for the Living Donor Registration Form (LDR).

Table 4. Number of changes per field after the form was locked and percent from forms validated after expected date for the Living Donor Registration Form (LDR).

Field	Changes to Field After Lock	Form Validated After Expected Date
Living Donor Type	1088	899 (82.6%)
Liver Reoperation Liver Failure, Liver Failure Requiring Transplant	966	844 (87.4%)
EBV Total (Positive, Negative, Not Done, UNK/Cannot Disclose)	948	878 (92.6%)
HBV DNA (NAT/PCR), (Positive, Negative, Not Done, UNK/Cannot Disclose)	928	877 (94.5%)
CMV Total (Positive, Negative, Not Done, UNK/Cannot Disclose)	921	881 (95.7%)
HCV RNA (NAT/PCR), (Positive, Negative, Not Done, UNK/Cannot Disclose)	917	876 (95.5%)
Pre-Donation Weight	908	859 (94.6%)
Donor Recovery Facility	897	872 (97.2%)
EBV IgM (Positive, Negative, Not Done, UNK/Cannot Disclose)	890	859 (96.5%)
Organ Recovery Date	885	867 (98%)

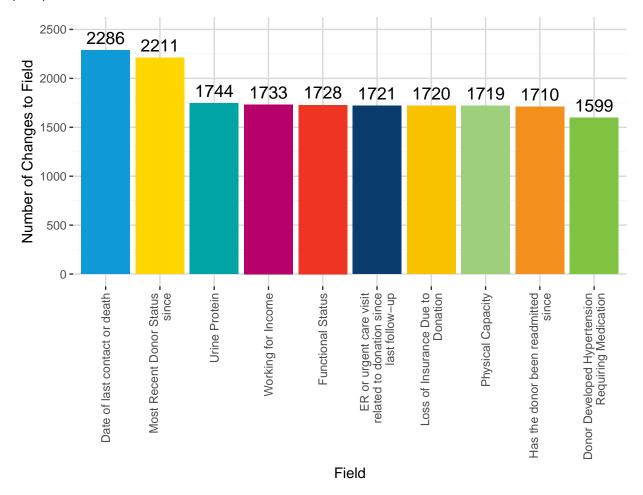


Figure 18. Number of changes per field after the form was locked for the Living Donor Follow-Up Form (LDF).

Table 5. Number of changes per field after the form was locked and percent from forms validated after expected date for the Living Donor Follow-Up Form (LDF).

Field	Changes to Field After Lock	Form Validated After Expected Date
Date of last contact or death	2286	2189 (95.8%)
Most Recent Donor Status since	2211	2175 (98.4%)
Urine Protein	1744	1648 (94.5%)
Working for Income	1733	1702 (98.2%)
Functional Status	1728	1699 (98.3%)
ER or urgent care visit related to donation since last follow-up	1721	1700 (98.8%)
Loss of Insurance Due to Donation	1720	1693 (98.4%)
Physical Capacity	1719	1690 (98.3%)
Has the donor been readmitted since	1710	1686 (98.6%)
Donor Developed Hypertension Requiring Medication	1599	1578 (98.7%)

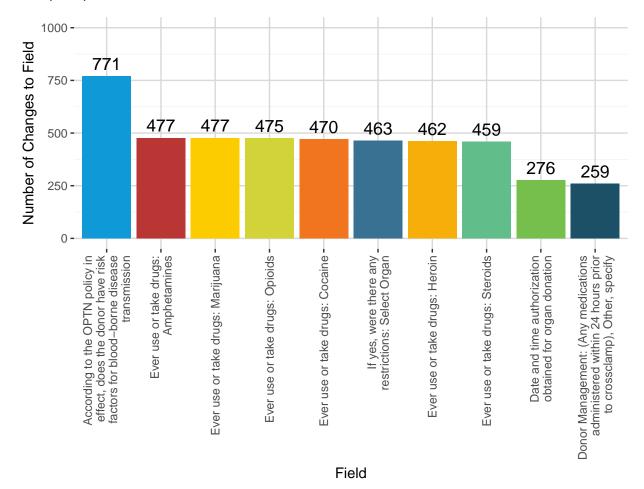


Figure 19. Number of changes per field after the form was locked for the Deceased Donor Registration Form (DDR).

Table 6. Number of changes per field after the form was locked and percent from forms validated after expected date for the Deceased Donor Registration Form (DDR).

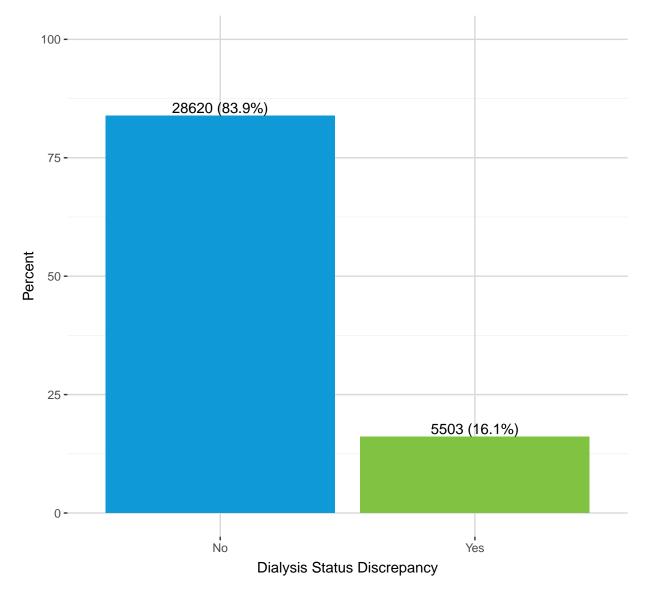
Field	Changes to Field After Lock	Form Validated After Expected Date 54 (7%)	
According to the OPTN policy in effect, does the donor have risk	771		
factors for blood-borne disease transmission			
Ever use or take drugs: Amphetamines	477	58 (12.2%)	
Ever use or take drugs: Marijuana	477	60 (12.6%)	
Ever use or take drugs: Opioids	475	56 (11.8%)	
Ever use or take drugs: Cocaine	470	54 (11.5%)	
If yes, were there any restrictions: Select Organ	463	55 (11.9%)	
Ever use or take drugs: Heroin	462	54 (11.7%)	
Ever use or take drugs: Steroids	459	53 (11.5%)	
Date and time authorization obtained for organ donation	276	88 (31.9%)	
Donor Management: (Any medications administered within 24 hours prior to crossclamp), Other, specify	259	91 (35.1%)	

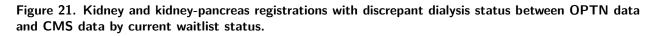
### Comparing OPTN and CMS data on dialysis

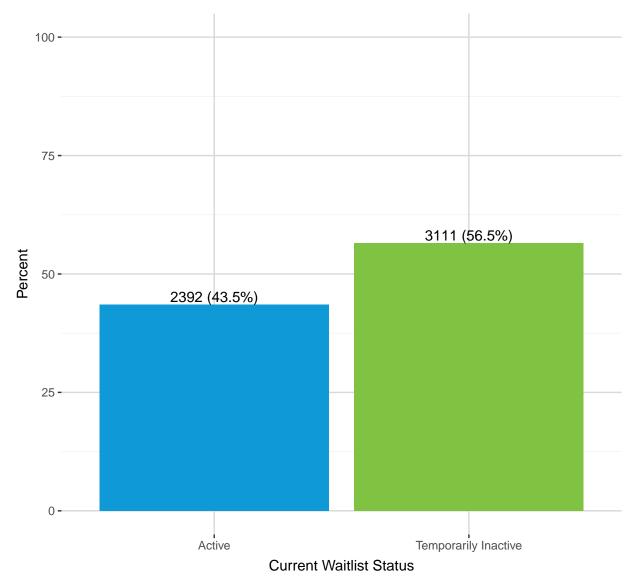
The DAC was interested in comparing OPTN data and CMS data on dialysis status and date to determine if there were discrepancies between the data sources. The DAC has discussed this analysis and is considering next steps.

**Figure 20** and **Figure 21** display the number and percent of kidney and kidney-pancreas registrations listed as not on dialysis in OPTN data with a discrepant dialysis status between OPTN data and CMS data. A total of 5503 (16.1%) registrations had a discrepant status, meaning they were listed as not on dialysis in OPTN data, but were indicated as on dialysis in CMS data. Of those, 2392 (43.5%) are currently listed as active and 3111 (56.5%) are listed as temporarily inactive. As of October 4, 2024, the percent of all kidney and kidney-pancreas candidates who were not on dialysis waiting per center with a discrepant dialysis status had a median of 11.7% with a range of 0.4% to 40.56% and an interquartile range of 5.6% to 21.4%.

# Figure 20. Kidney and kidney-pancreas registrations listed as not on dialysis in OPTN data by whether there is a discrepant dialysis status between OPTN data and CMS data.



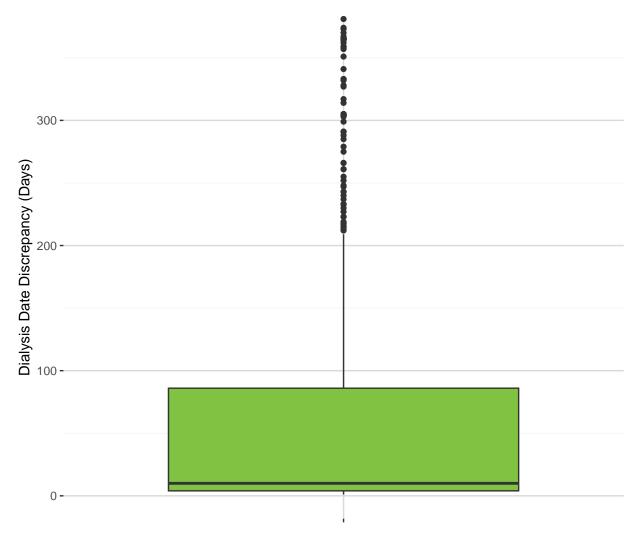






*Figures 22-23* and *Table 7* display the distribution of dialysis date discrepancies between OPTN data and CMS data for kidney and kidney-pancreas registrations listed as on dialysis in OPTN data. 50% of the 2259 registrations with a date discrepancy had a difference of 10 days or less. Approximately 13.7% of registrations with a date discrepancy had a difference of 1 year or more.

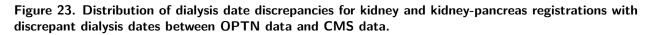
Figure 22. Distribution of dialysis date discrepancies for kidney and kidney-pancreas registrations with discrepant dialysis dates between OPTN data and CMS data.

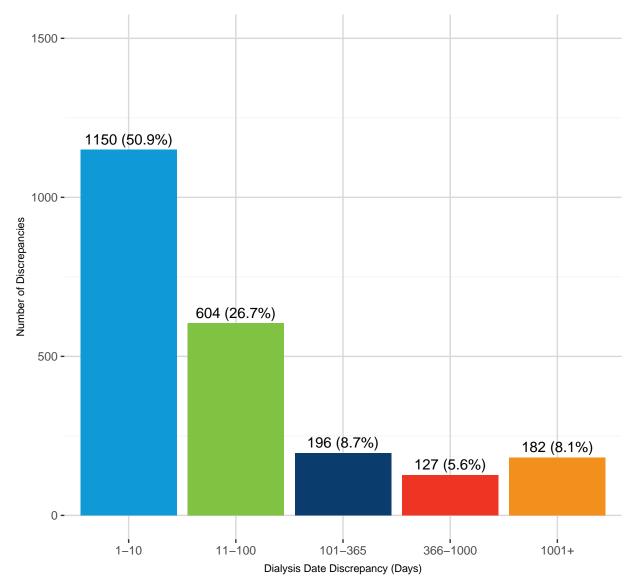


Discrepancies above 365 days were removed from this figure (n=309)

Table 7. Distribution of dialysis date discrepancies for kidney and kidney-pancreas registrations with discrepant dialysis dates between OPTN data and CMS data.

Dialysis Date Discrepancy between OPTN and CMS Data (Days)					
Count	Minimum	25th Percentile	Median	75th Percentile	Maximum
2259	1	4	10	86	8890





## Recommendations

Based on DAC review of findings in this Annual Data Quality Report, review of targeted analyses performed in FY 24, review of the two-year data lock monitoring report, and committee discussions about initiatives that will bring improvements to the OPTN data registry, the DAC recommends the following to the OPTN Board and HRSA:

- Develop and execute a plan, in partnership with the DAC, to achieve greater efficiency by delivering on the OPTN's strategic plan objective "Enhance OPTN data collection: To increase availability of actionable data".
- Develop and prioritize a plan, in partnership with the DAC, to articulate how the OPTN will govern and improve the OPTN's data assets over time. Recommended initiatives:
  - Define OPTN's data strategy
    - \* Improve data collection and architecture as part of OPTN modernization initiative
    - \* Accelerate the use of available government and public data
    - \* Develop a transplant data standard with the federal Office of the National Coordinator (ONC) for Health Information Technology
  - Strengthen data governance
    - \* Establish best practices and set expectations in OPTN policy
      - $\cdot$  Document OPTN's intent for collecting data and improve definitions
      - $\cdot$  Identify, measure and audit most critical data
      - Lock editing of critical data (data lock 2.0)
      - · Re-evaluate transplant follow-up data collection and adjust to reduce burden
    - \* Provide public with a searchable OPTN data dictionary
  - Invest in interoperability
    - \* Adopt clinical data standards to align with the healthcare community
    - \* Collaborate with OPOs to standardize their data collection and processes
    - \* Streamline data collection and exchange methods; align with Network Operations Oversight Committee on plans and investment
  - Adjust stakeholder engagement
    - \* Identify feasibility of engaging and involving government, healthcare members, academic institutions, and EMR and EDR vendors in the data management processes
    - \* Examine issues and challenges involved in expanding the definition of OPTN data to include other supplemental public and government data for use by members and community
- Develop an OPTN fast-track process to identify new data collection and timely approval of necessary changes to ensure the OPTN data registry remains relevant with clinical practices. For example, the data collection for machine perfusion has not kept pace with clinical practices.
- Develop a process to meet more frequently with the Board to approve minor changes to OPTN data collection. This process allows DAC to move expeditiously and efficiently in addressing minor data enhancements for the Board. For example, removal of obsolete data collection to reduce burden.
- Codify the OPTN Board's data champion role in the by-laws so there is clear authority and accountability for the OPTN's data assets. Require the OPTN leadership role to have the appropriate level of skill and expertise to oversee the data and its use. DAC will partner with the Board data champion on identifying and prioritizing OPTN initiatives to improve the OPTN data registry.

ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK