HRSA
Health Resources & Services Administration

Task Order 3

Historical Complaint Data Analysis

July 11, 2024

Prepared for HRSA under the contract of HRS308634
75R60223D00001/75R60223F34003

Patient Safety: Contents

Executive Summary

The project team reviewed all 1,324 patient safety complaints from the Master Case List (MCL) received between 1/1/2022 and 3/30/2024 to analyze trends in historical OPTN patient safety data. A complaint can be a case, referral, or turndown. A case is a complaint that warrants further investigation by the Patient Safety team, a referral is a complaint that warrants further investigation by another functional area of UNOS, such as Allocations, Site Survey, Patient Relations, or IT, and a turndown is complaint that falls out of scope of OPTN authority and is therefore closed by the Patient Safety team.

Complaint Volume	Of the 1,324 complaints, **1,007 were cases (76%),** 80 were referrals (6%) and 237 were turndowns (18%).
Complaint & Case Closure Timeline	On average, it takes **81.7 days to close a complaint and 86.8 days to close a case**. It takes an average of approximately 132 days to submit the MPSC packet to the UNOS Compliance Operations Analyst (COA).
HRSA Notification	**88% of HRSA notifications occur within one day, meeting HRSA requirements**. **HRSA was notified of 3.8% (50) of total complaints.** Half of these notifications pertained to criteria #6: any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety, and criteria #5: suspected or confirmed HIV transmission from a deceased or living donor to a recipient.
Complaint Reporter Type	**Most complaints were reported by Transplant Centers (41%), while 16% were identified via UNOS automated reporting and 14% were submitted by OPOs**. Most complaints were submitted via the Patient Safety Portal (64%).
Complaint Subject Member Type	**Almost 80% of complaints are about Transplant Centers and OPOs (42% and 37% respectively).** Labs accounted for 2% of complaints, and non-OPTN members accounted for 1% of complaints. The remaining 18% did not have a subject member type provided.
Self-reports	24% of all complaints were self-reported; **40% of complaints submitted by TXCs, OPOs, and labs were self-reported**.

Executive Summary, cont.

Complaint Classification	**Five types of complaint classifications accounted for two-thirds of all complaints**: organ & extra vessels (14%), deceased donor organ procurement (13%), identification of transmissible disease (12%), "other" (13%), and "N/A" (15%).
Complaint Risk Level	**More than 88% of complaints and cases had a risk rating of "common"**; however, risk level is subject to change throughout the investigative process and the MCL does not denote whether a risk level has been modified since intake.
Anonymous Complaints	**Two percent of total complaints were submitted by anonymous reporters**. Of the 32 anonymous complaints, **13 (41%) resulted in an elevated risk rating** (1-exceptional and 2-priority); this suggests the importance of anonymous reporting mechanisms in identifying serious patient safety issues.
Complaint Substantiation	Excluding complaints with an "N/A" or "unknown" substantiation status, **59% of complaints and 68% of cases were substantiated**. Substantiation occurs when an investigation proves the complaint to be true.
Policy & Bylaw Violations	Of the 1,324 patient safety complaints**,** 300 of these had policy or bylaw violations. These 300 complaints resulted in **343 policy and bylaw violations** (81% and 7%, respectively). Almost half **(49%) of policy violations pertained to OPTN Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage**. **91% of policy violations were referred or are pending referral to MPSC.**
MPSC Investigations	**Of the 1,324 patient safety complaints, 312 (24%) were referred to MPSC for further investigation.** Almost half of these referrals pertained to organ and extra vessels; living donation; and deceased donor organ procurement. An additional 13% are pending referral to MPSC.
State Complaint Volume	**Five states account for approximately 40% of total patient safety complaints**: California, New York, Texas, Florida, and Ohio. When evaluating state complaint rate (state complaint volume divided by the state transplant volume), five states had a rate greater than 2.6%: Alabama (3.4%), Iowa (3%), Kansas (2.8%), Nevada (2.8%), Kentucky (2.7%), and Nebraska (2.7%).

Abbreviations & Glossary of Terms

Abbreviation	Term
COA	Compliance Operations Analyst
DT	Disease Transmission (UNOS-designated team)
MCL	Master Case List
MPSC	Membership & Professional Standards Committee
OPO	Organ Procurement Organization
OPTN	Organ Procurement & Transplantation Network
TXC	Transplant Center
UNOS	United Network for Organ Sharing

Term	Definition
ABO	Refers to the ABO blood group system
Case	A complaint that warrants further investigation by the UNOS Patient Safety Team
Complaint	A notification of a potential patient safety incident
Functional Areas Within UNOS	UNOS has functional areas that each focuses on a specific set of activities or responsibilities. The most referenced UNOS functional areas within patient safety include: — Patient Relations — Allocations — Site Survey — IT
Master Case List	The primary document used to house patient safety incident data
Referral	A complaint that warrants further investigation by another functional area of UNOS, such as Allocations, Site Survey, or IT
Subject Member	The OPTN member for whom the complaint pertains to
Substantiation	Substantiation occurs if the UNOS patient safety investigation finds the complaint to be valid and true
Turndown	A complaint that falls out of scope of OPTN authority and is therefore closed by the Patient Safety team

Data Request

Data Request

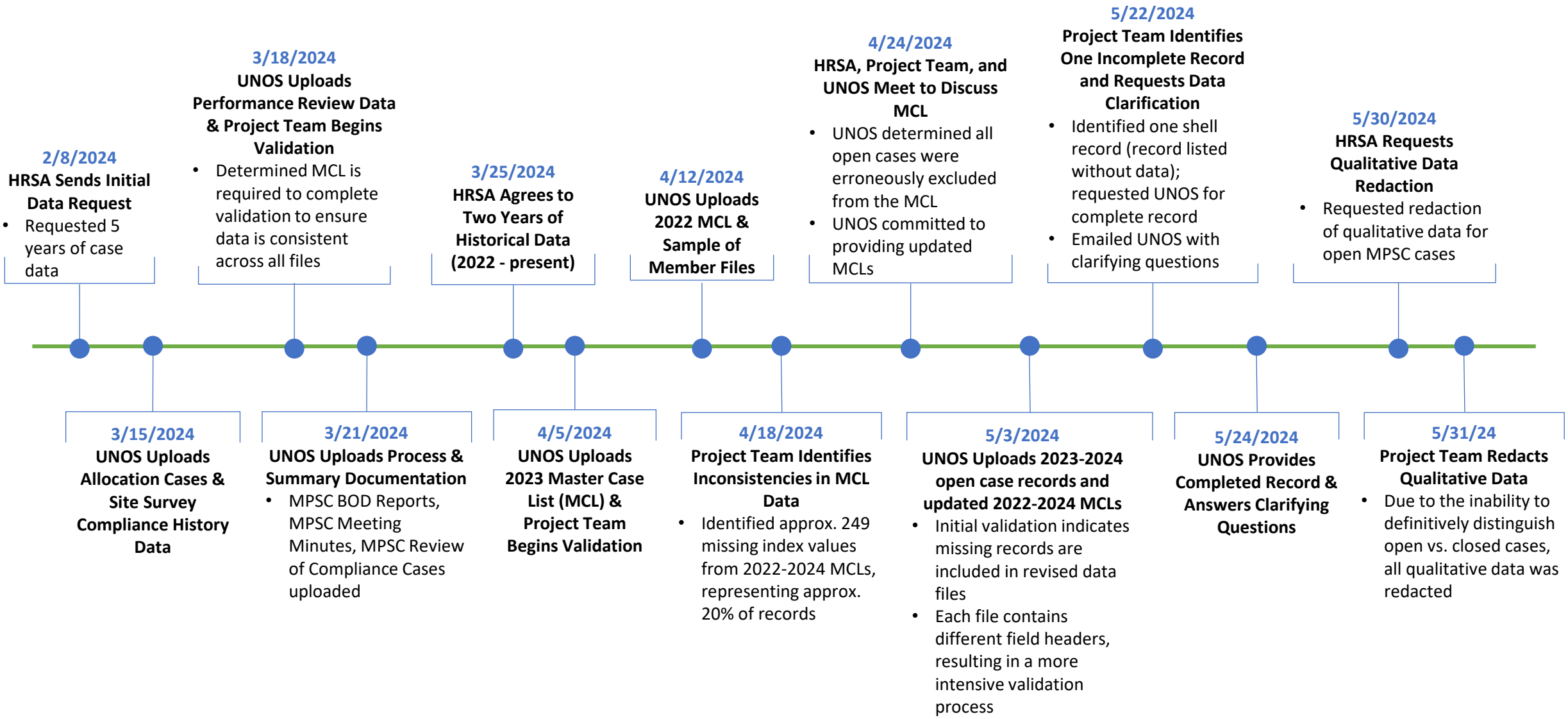
- Data and documents to include, but not limited to, patient safety-related complaints/incidents reported to the OPTN or identified by site visits, media review, etc. and any item reported to the OPTN MPSC by HRSA or CMS directly
- Cases from 1/1/19 – 2/8/24 (later modified to two years: 2022 – 2023)
- All case statuses, outcomes, and resolutions
- Procedures and guidance documents used for the five-year timeframe, and case-specific process tracking with time stamps and monitoring documentation
- Case/event/incident documentation must be characterized, categorized, classified, or otherwise grouped by type
- Data could be compiled in Excel spreadsheets or table format
- **Request sent 2/8/24**

Documents Received

- **Master Case List (2022 – 2024 Q1);** includes case statuses and outcomes from the UNOS patient safety team (excludes MPSC outcomes)
- **MCL Primary & Sub-classifications**; reference document defining primary complaint classifications
- **MPSC Monitoring Effectiveness Report** (March 2024); aggregate data with metrics to monitor effectiveness to monitor OPTN members and identify compliance problems
- **OPTN Monitoring Activity Report** 2023; aggregate data of performance cases, compliance actions, member applications
- **MPSC Report of Investigative Activities** March 2023; aggregate data of volume of patient safety cases
- **UNOS Compliance & Safety Investigation Triage Form**
- **OPTN Record Retention Schedule**
- **MPSC Operational Rules Tracking**
- **MPSC Reference Cards**; reference document outlining MPSC actions
- **Compliance and Safety Investigation Process Flow**

Document list represents documentation post-redaction and deletion of case-sensitive fields and files.

Data Timeline



Overall Volume and Process Timeline

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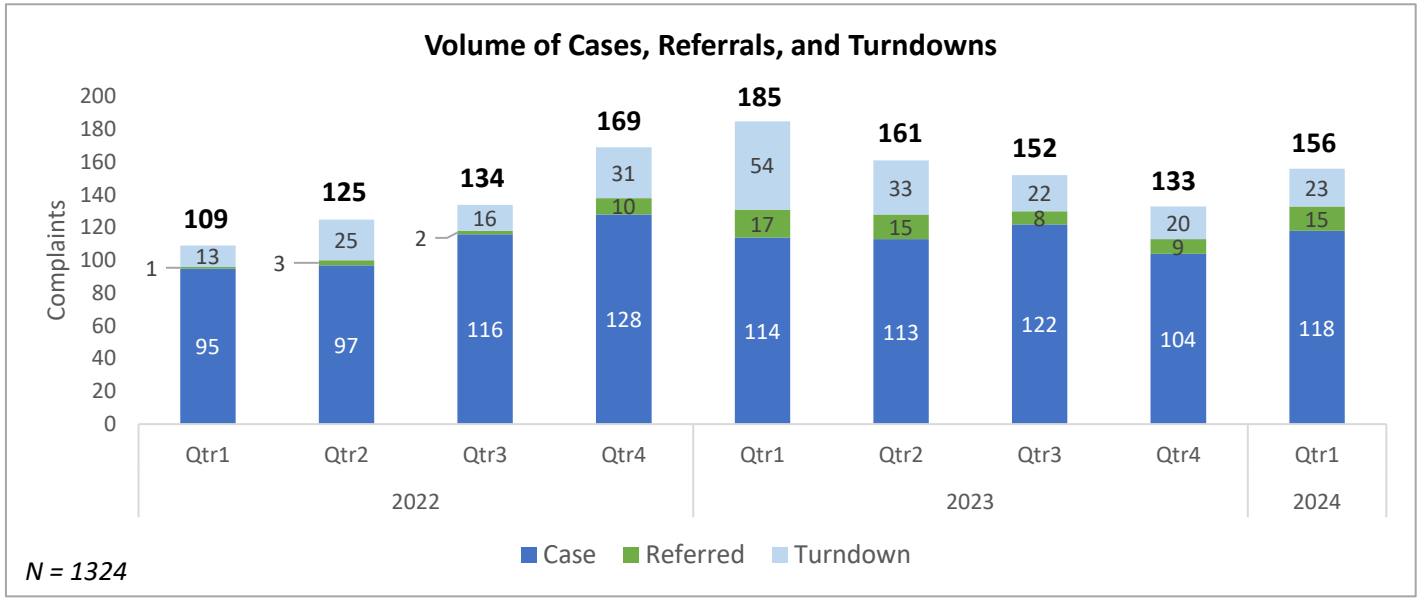
Total Complaint Volume

Of the 1,324 complaints received from 2022 – 2024 Q1, 76% of complaints result in a "case" status, while 6% result in a referral to another functional area of UNOS, and 18% are turned down. Total patient safety **complaint volume increased 17.5% from 2022 to 2023**. However, the proportion of complaints converting to cases decreased from 2022 (81%) to 2023 (72%), while the volume of referrals and turndowns increased from 2022 (19%) to 2023 (28%). The **volume of cases increased 3.9% from 2022 to 2023**, indicating the majority of the volume increase was primarily due to an increase in referrals and turndowns (76.2% increase in referrals and turndowns from 2022 to 2023).



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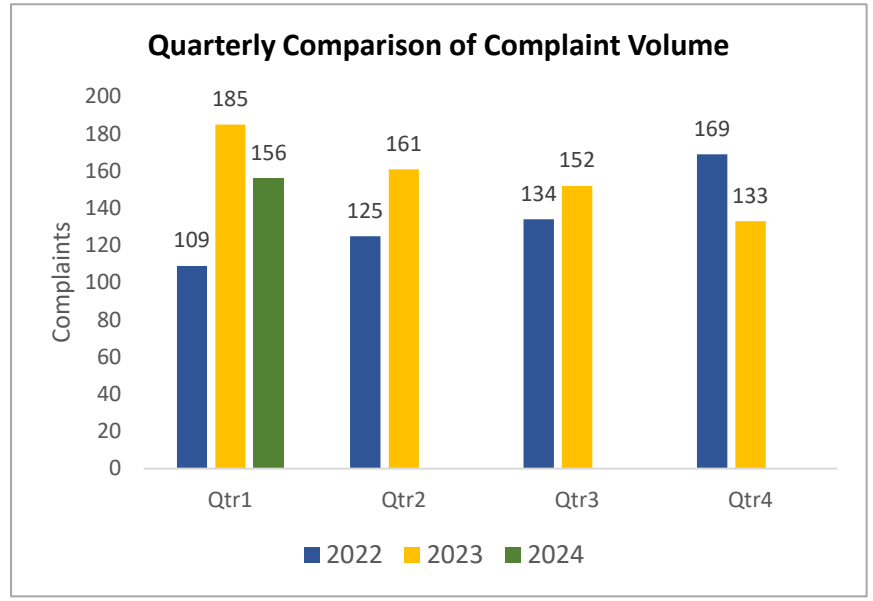

	Case		Referral		Turndown		Total
	Volume	*% of Annual Total*	*Volume*	*% of Annual Total*	*Volume*	*% of Annual Total*	*Volume*
2022	436	81%	16	3%	85	16%	537
2023	453	72%	49	8%	129	20%	631
2024 Q1	118	76%	15	10%	23	15%	156
Total	**1007**	76%	**80**	6%	**237**	18%	**1324**

Volume by Referral Recipient					
	2022	**2023**	**2024 Q1**	**Total**	**% of Grand Total**
Site Survey	5	21	6	32	40%
Allocations	6	18	3	27	34%
Disease Transmission	1	5	2	8	10%
Communications	1	2	0	3	4%
Other*	3	3	4	10	13%
Total	**16**	**49**	**15**	**80**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24

**Other: Help Desk, IT, Member Quality, Membership, MPSC, Patient Services, Privacy, and Research*

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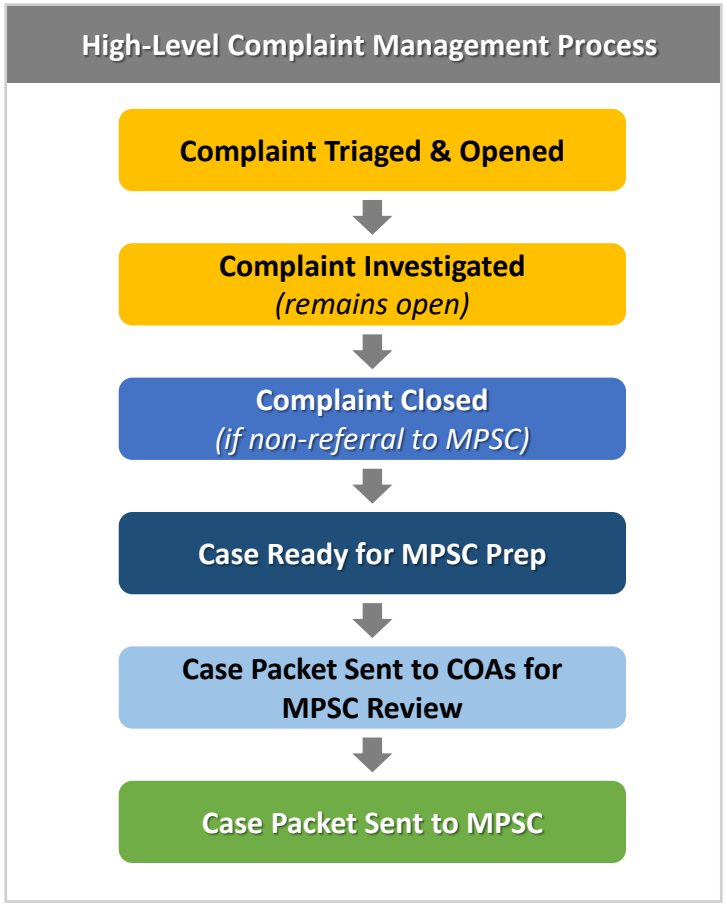
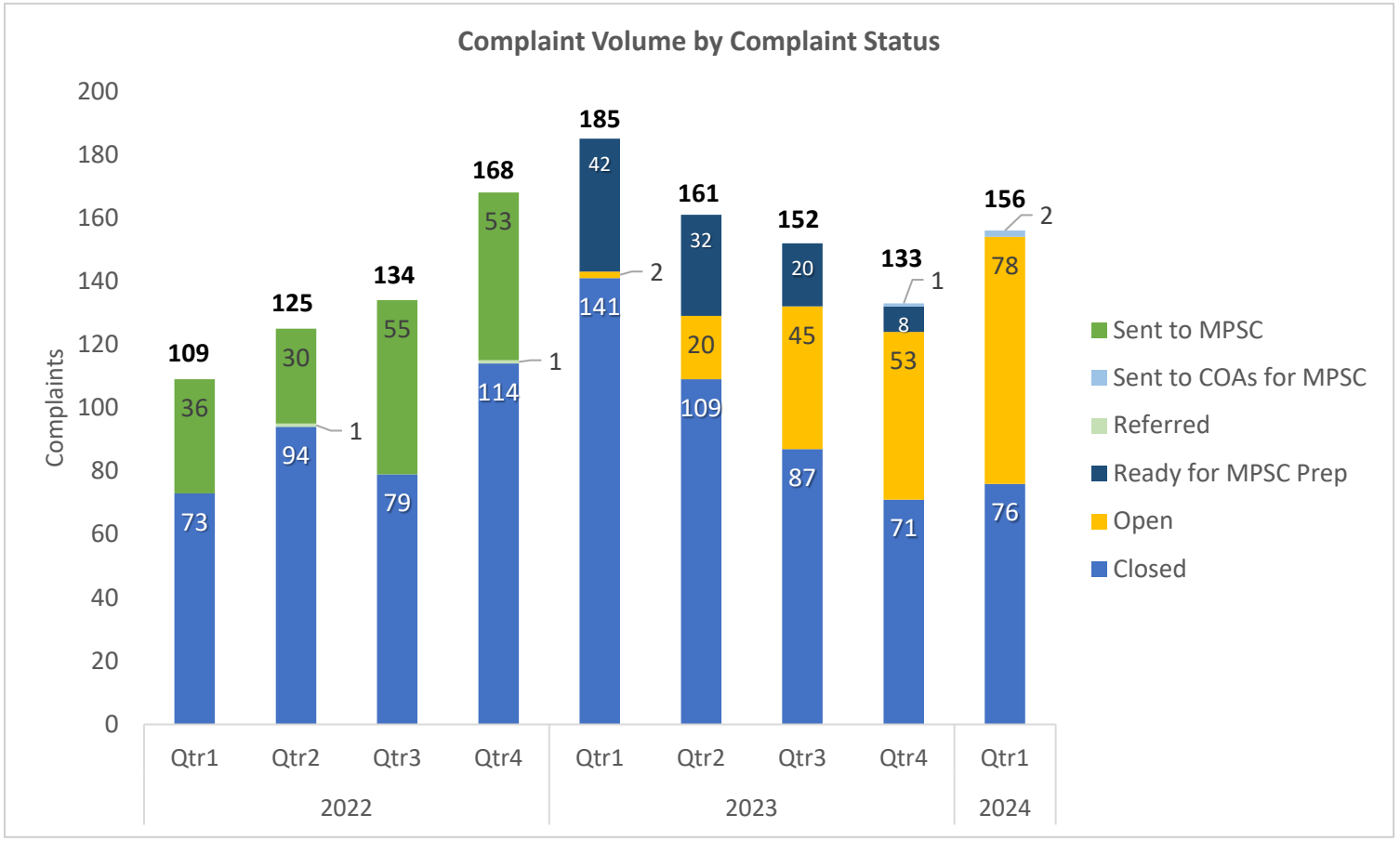
Complaint Volume by Complaint Status

Investigations can take one year to complete, which is why 33% of complaints remain open between 2023 Q2 – 2024 Q1. Due to current documentation practices, it is difficult to discern how many complaints have been sent to MPSC, investigated and subsequently closed. Some cases may be marked as "closed" despite being referred to MPSC for further investigation, while others will be labeled as "Sent to MPSC."





N= 1323; excludes one record with a blank case status

Source: Master Case List, 1/1/22 – 3/30/24
Referral status may indicate referral to another functional area of UNOS or referral to MPSC

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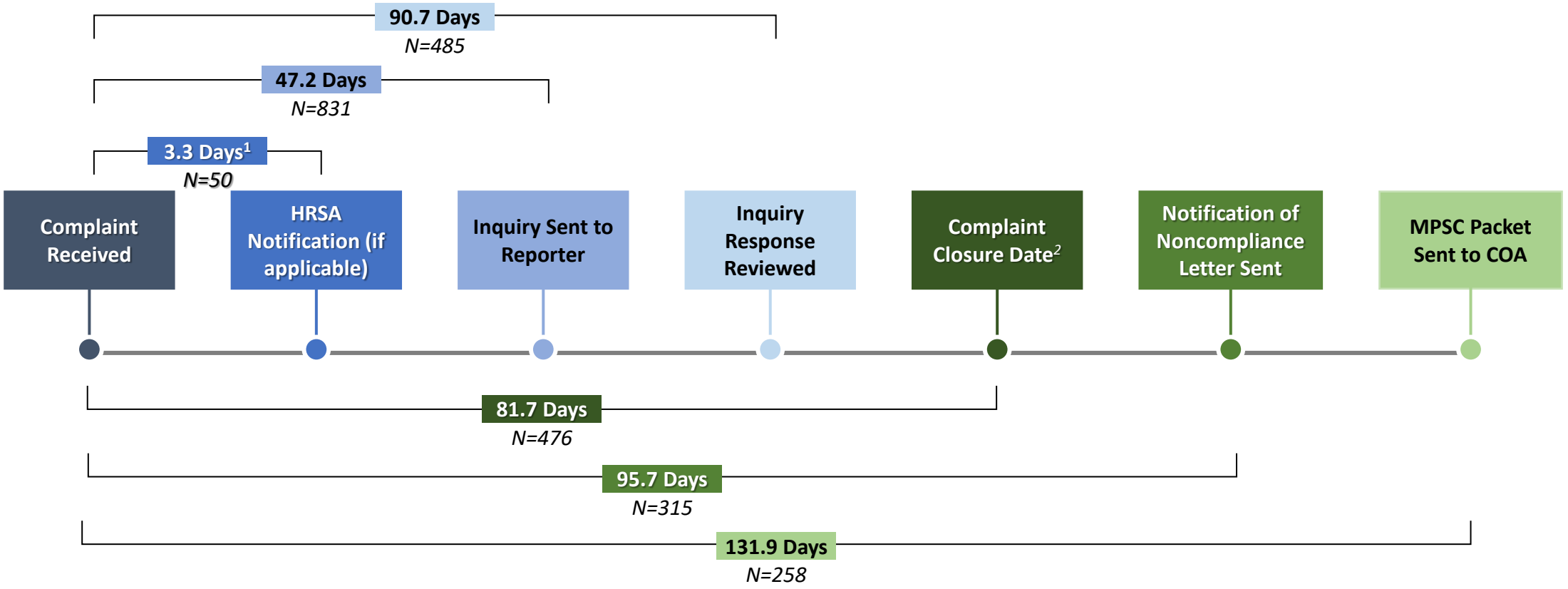
High-level Timeline Analysis – All Complaints

The timeline below indicates the **average timeframe** from event notification to each step in the patient safety process for **all patient safety complaints**. While these averages offer valuable insight, it's essential to note instances where the sequence may seem out of order. For example, while the **average time for complaint closure is 81.7 days**, it may appear longer than the average of 90.7 days to review an inquiry response (which ideally precedes closure). This discrepancy arises because not all complaints will require each step in the investigative process, and some complaints will require the same step multiple times.



[1]*88% of HRSA notifications occurred within 0-1 days, meeting HRSA requirements*
[2]*Complaints may be closed prior to inquiry or without referral to MPSC for further investigation*
Source: Master Case List, 1/1/22 – 3/30/24

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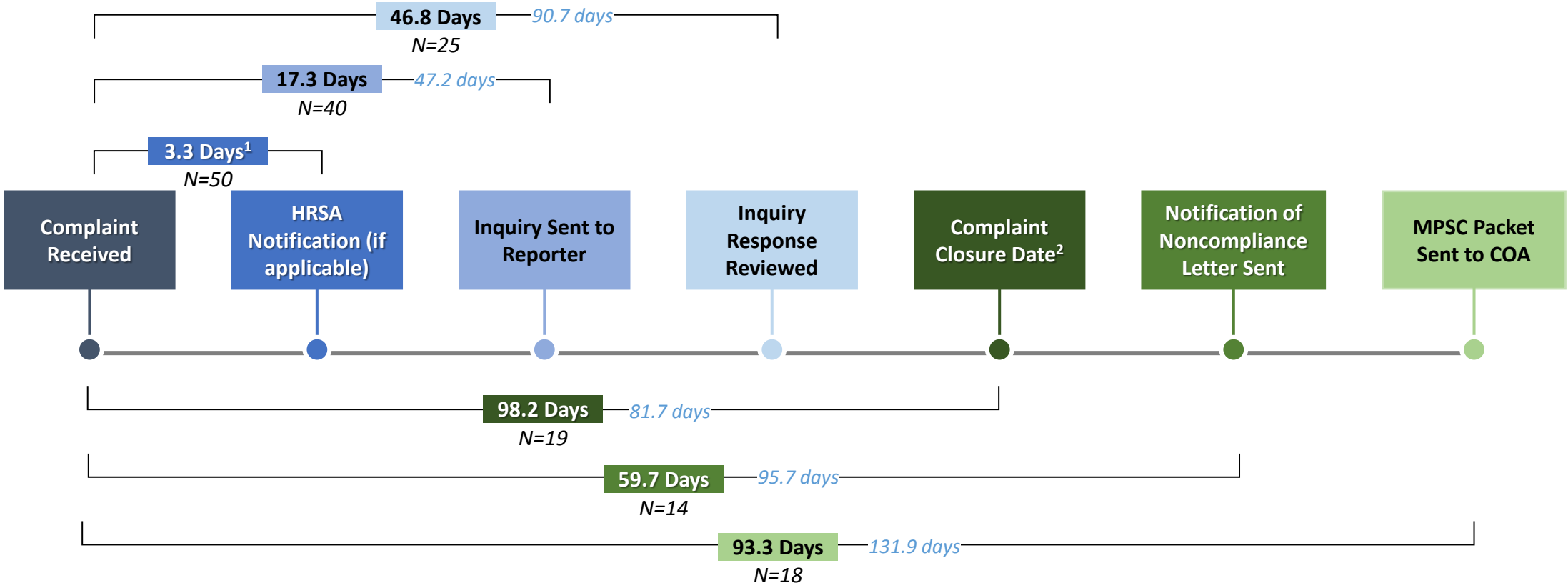
High-level Timeline Analysis – HRSA Notifications

The timeline below indicates the **average timeframe** from event notification to each step in the patient safety process for **patient safety cases requiring HRSA notification**. **The timeline for HRSA-notified events appears to be expedited** when compared with the timeline for all complaints. Initial steps ("Inquiry Sent to Reporter" and "Inquiry Response Reviewed") take approximately half the amount of time compared to the timeline for management of all complaints. "Notification of Noncompliance Letter Sent" and "MPSC Packet Sent to COA" occurred approximately one month faster for HRSA-notified complaints compared to all complaints.

**Blue text indicates timeframe for all complaints for comparison*



[1]*88% of HRSA notifications occurred within 0-1 days, meeting HRSA requirements*
[2]*Complaints may be closed prior to inquiry or without referral to MPSC for further investigation*
Source: Master Case List, 1/1/22 – 3/30/24

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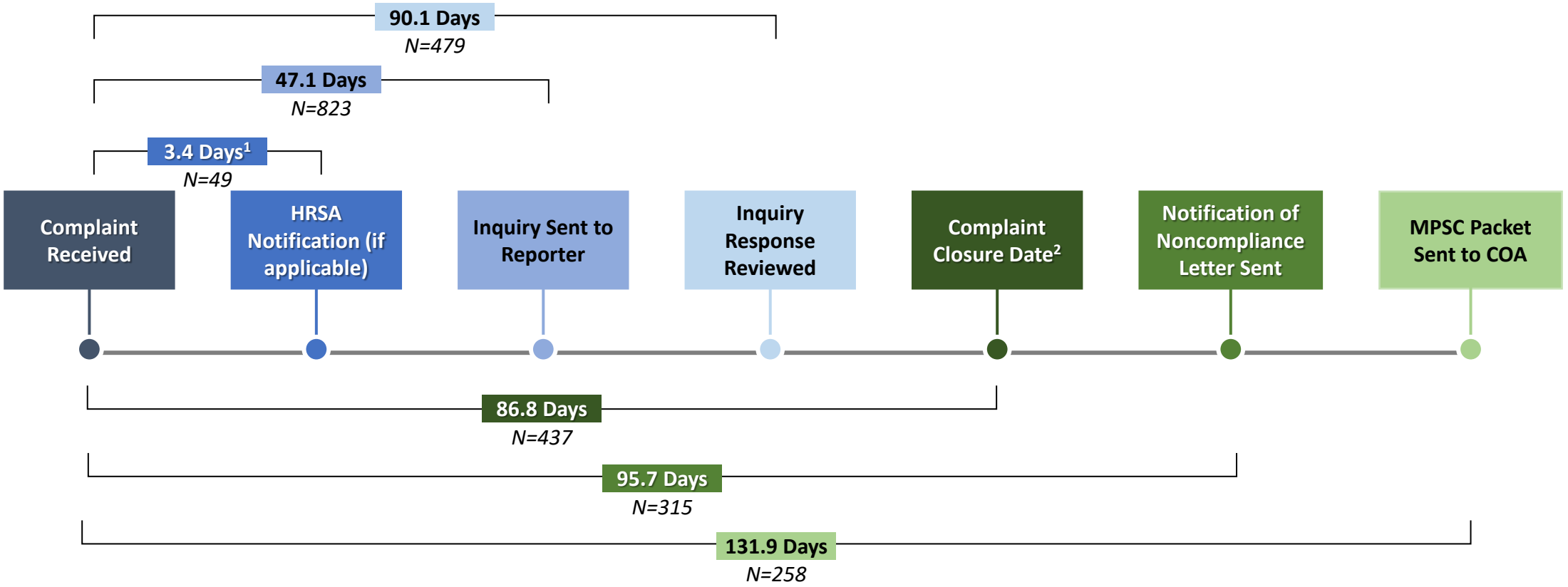
High-level Timeline Analysis – Cases

The timeline below indicates the **average timeframe** from event notification to each step in the patient safety process for **patient safety cases**. While these averages offer valuable insight, it's essential to note instances where the sequence may seem out of order. For example, while the **average time for case closure is 86.8 days**, it may appear longer than the average of 90.1 days to review an inquiry response (which ideally precedes closure). This discrepancy arises because not all complaints will require each step in the investigative process, and some complaints will require the same step multiple times.



[1]*88% of HRSA notifications occurred within 0-1 days, meeting HRSA requirements*
[2]*Complaints may be closed prior to inquiry or without referral to MPSC for further investigation*
Source: Master Case List, 1/1/22 – 3/30/24

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HRSA Notification Requirements

The following table indicates events that require HRSA, MPSC, and UNOS leadership notification:

Number	Description	Timeline for HRSA, MPSC, and UNOS Leadership Notification
1	Transplant of the wrong organ into an organ recipient	Within 24 hours
2	Near-miss transplant of the wrong organ into an organ recipient*	Within 24 hours
3	Transplant into the wrong organ recipient	Within 24 hours
4	Near-miss transplant into the wrong organ recipient	Within 24 hours
5	Suspected or confirmed HIV transmission from a deceased or living donor to a recipient**	Within 24 hours
6	Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule	Within 24 hours
7	Living donor death, regardless of the time period after surgery and regardless of the cause of death	Within 24 hours
8	Failure of a native organ in a living organ donor	Within 24 hours
9	Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records)	Within 24 hours
10	Use of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration	Within 24 hours
11	Any "Never Event," as included in the Centers for Medicare and Medicaid Services' policies for selected hospital-acquired conditions, in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation)	Within 24 hours
12	Suspected or significant potential of non-HIV disease transmission from a donor to a recipient**	Within one business day
13	Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member	Within one business day

**A near-miss occurs when the error is not caught before the recipient is brought to the surgery holding area.*
***"Suspected" means there is ample evidence to suggest that an HIV transmission was likely.*
Source: Compliance and Safety Investigation intake Form_Rev.1Nov23 MPSC

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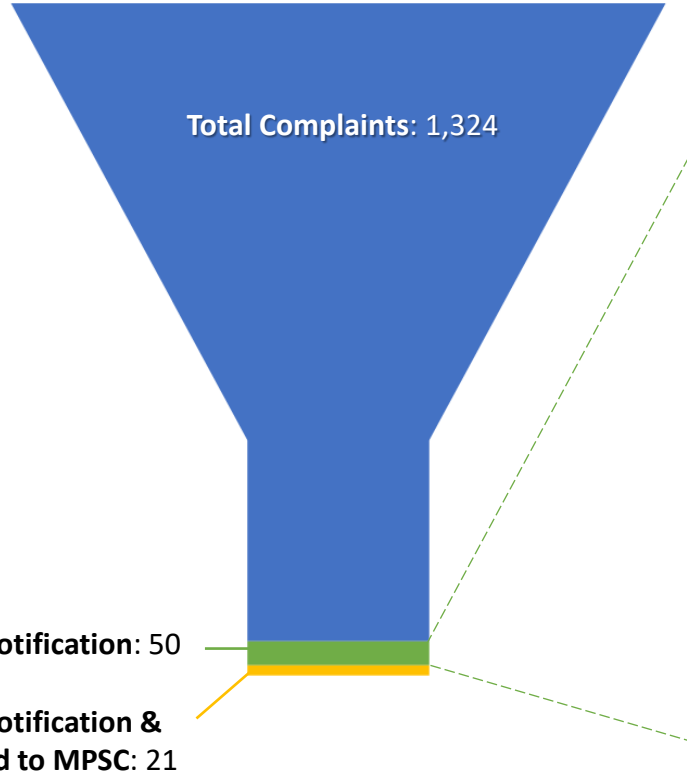
HRSA Notifications – All Complaints

HRSA was notified of 3.8% of all complaints (50/1324). Of these 50 complaints, 49 converted to "case" status. While it was not possible to determine the volume of complaints that should have been reported to HRSA, the low notification rate indicates an opportunity for increased transparency of complaints and cases. Given that HRSA notification requirements correlate with OPTN policies, **it could be encouraged, at minimum, that HRSA is notified any time a policy violation is identified**. Based on the 2022 – 2024 Q1 data set, this would equate to approximately 280 complaints over a two-year period.



Reasons for HRSA Notification (3.8% of Total Complaints)			
#	**Event Description**	**Volume of Complaints**	**% of Total HRSA Notifications**
6	Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule	14	28%
5	Suspected or confirmed HIV transmission from a deceased or living donor to a recipient**	11	22%
7	Living donor death, regardless of the time period after surgery and regardless of the cause of death	9	18%
11	Any "Never Event," as included in the Centers for Medicare and Medicaid Services' policies for selected hospital-acquired conditions, in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation)	4	8%
2	Near-miss transplant of the wrong organ into an organ recipient*	2	4%
3	Transplant into the wrong organ recipient	1	2%
9	Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records)	1	2%
-	Unknown	3	6%
-	Media	3	6%
-	Awareness	2	4%
	Total	**50**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24
**A near-miss occurs when the error is not caught before the recipient is brought to the surgery holding area.*
***"Suspected" means there is ample evidence to suggest that an HIV transmission was likely.*
Source: Compliance and Safety Investigation intake Form_Rev.1Nov23 MPSC

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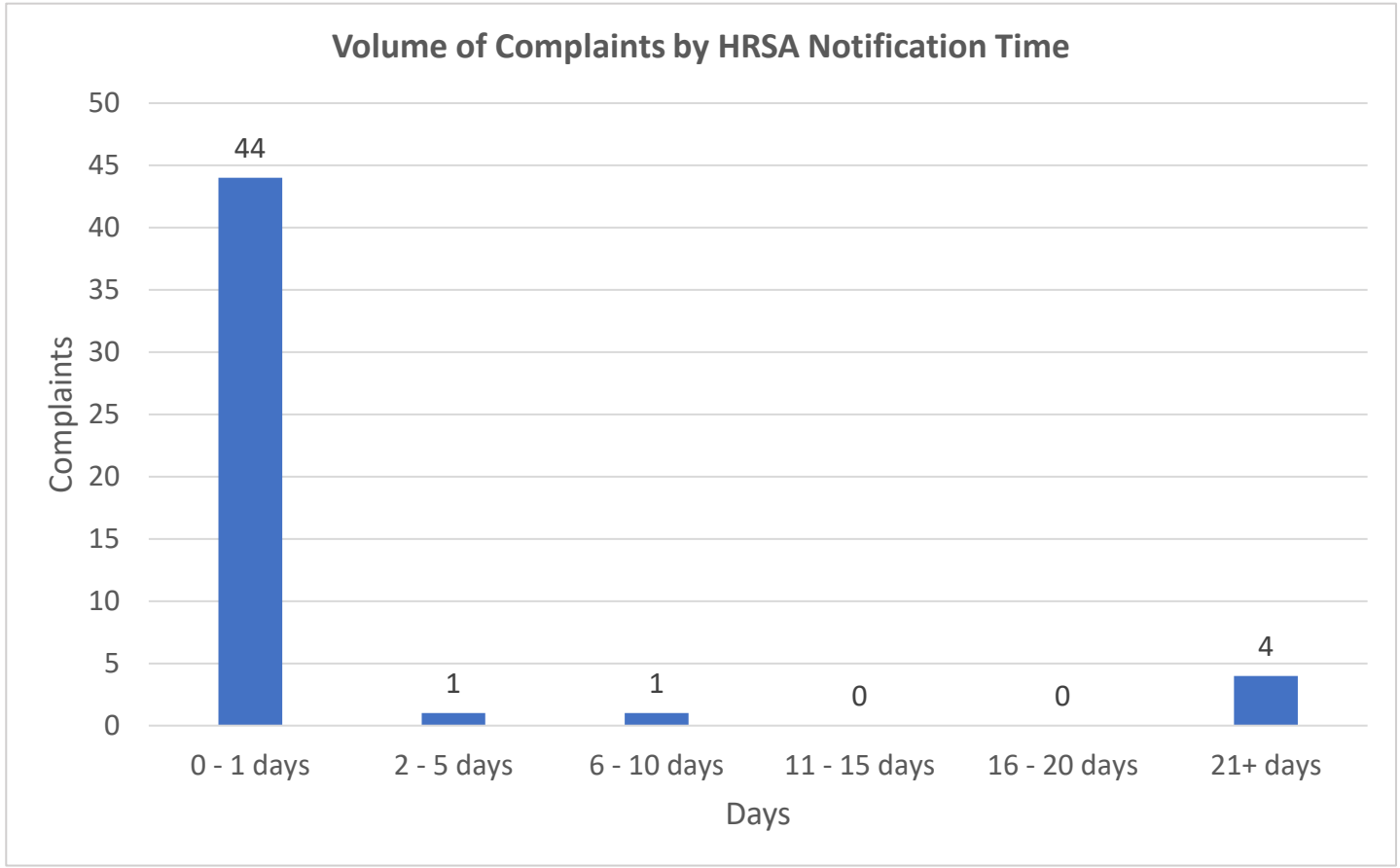
HRSA Notifications – All Complaints Histogram

Although the average time for HRSA notification is 3.3 days, this figure is influenced by a small portion (8%) of complaints that took over 21 days for notification. 88% of complaints that required HRSA notification were addressed within 0-1 days, meeting HRSA requirements. For complaints where HRSA was notified after 0-1 days, it's possible these complaints did not initially meet HRSA notification criteria until later in the investigation.



Day Range	Total	% of Grand Total
0-1 days	44	**88%**
2-5 days	1	**2%**
6-10 days	1	**2%**
11 – 15 days	0	**0%**
16 – 20 days	0	**0%**
21+ days	4	**8%**
Grand Total	**50**	**1324**

Source: Master Case List, 1/1/22 – 3/30/24

Complaint Reporter & Subject Type

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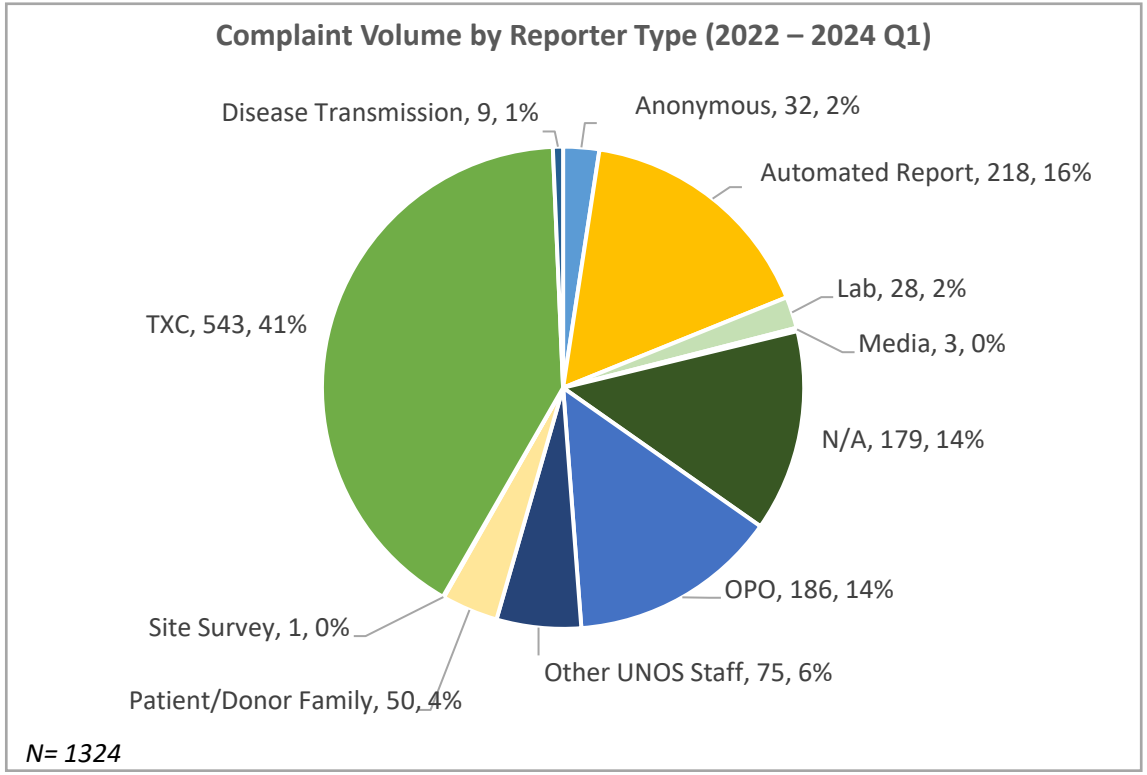
Complaint Volume by Reporter Type

OPTN members are required to report patient safety events per OPTN policy. **The majority (41%) of complaints were reported by Transplant Centers** (TXCs), followed by UNOS automated reporting (16%) and OPOs (14%). The data depicts **82% of complaints submitted by Transplant Centers and 87% of complaints submitted by OPOs result in a "case" status**. Additionally, 50% of complaints identified via automated reporting result in a "case" status. It appears data documentation practices improved following 2022 as indicated by the decrease in reporter type "N/A" values.



Volume of Complaints by Reporter Type					
Reporter Type	**2022**	**2023**	**2024 Q1**	**Total**	**% of Grand Total**
TXC	146	305	92	543	41%
Automated Report	103	110	5	218	16%
OPO	41	103	42	186	14%
N/A	**177**	2	0	179	14%
Other UNOS Staff	26	47	2	75	6%
Patient/Donor Family	17	27	6	50	4%
Anonymous	8	17	7	32	2%
Lab	12	14	2	28	2%
Disease Transmission	7	2	0	9	1%
Media	0	3	0	3	<0%
Site Survey	0	1	0	1	<0%
Grand Total	**537**	**631**	**156**	**1324**	**100%**

Complaints Resulting in Case/Referral/Turndown Status by Reporter Type (2022 – 2024 Q1)					
Reporter Type	**Case**	**Referral**	**Turndown**	**Total**	**% Converted to Case**
TXC	447	50	46	543	82%
Automated Report	108	7	103	218	50%
OPO	162	14	10	186	87%
N/A	144	3	32	179	80%
Other UNOS Staff	62	2	11	75	83%
Patient/Donor Family	28	1	21	50	56%
Anonymous	19	3	10	32	59%
Lab	27	0	1	28	96%
Disease Transmission	8	0	1	9	89%
Media	1	0	2	3	33%
Site Survey	1	0	0	1	100%
Grand Total	**1007**	**80**	**237**	**1324**	**76%**

Source: Master Case List, 1/1/22 – 3/30/24

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Most Common Notification Method Used by Different Reporters

Transplant Centers, OPOs, and Histocompatibility Labs submit the majority of their patient safety complaints via the Patient Safety Portal. Patients/donors and their families submit more than half of complaints to UNOS staff. Unfortunately, the data set does not state who patients/families are connecting with at UNOS and how the UNOS staff are notified. **Anonymous reporters primarily use the Member Reporting Line** (31% of anonymous complaints). The member reporting line is intended for OPTN member use; however, this number is publicly available and could be used by both OPTN members and non-OPTN members.

Reporter Type*	Primary Reporting Mechanism
Transplant Center	Patient Safety Portal *94% of TXC-submitted complaints (511/543)*
Organ Procurement Organization	Patient Safety Portal *92% of OPO-submitted complaints (171/186)*
Histocompatibility Lab	Patient Safety Portal *100% of lab-submitted complaints (28/28)*
Patient, Patient/Donor Family	UNOS Staff *54% of patient/family-submitted complaints (27/50)*
Anonymous	Member Reporting Line *31% of anonymously submitted complaints (10/32)*

**Excludes complaints identified via UNOS staff or UNOS automated reporting;*
Source: Master Case List, 1/1/22 – 3/30/24; 839 complaints submitted by TXCs, OPOs, labs, patients/families, anonymous

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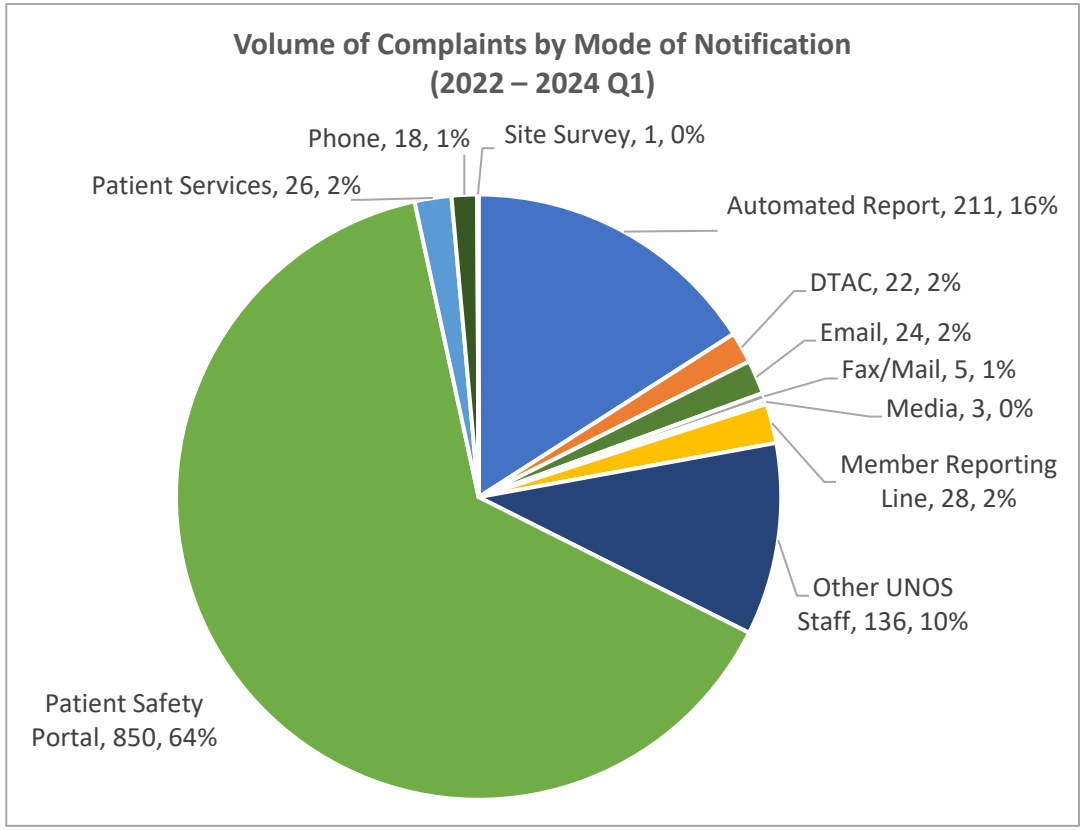
Complaint Volume by Mode of Notification

Most complaints were submitted to UNOS via the Patient Safety Portal (64%), followed by automated report notification (16%) and notification by other staff in other UNOS functional areas (10%). If there is a lower than expected volume in any of the reporting modalities, then this may indicate an opportunity for enhanced education from HRSA and/or Contractor. There may be an opportunity to enhance patient/family engagement in the future with increased transparency of complaint reporting mechanisms.



Volume of Complaints by Mode of Notification					
Mode of Notification	**2022**	**2023**	**2024 Q1**	**Grand Total**	**% of Grand Total**
Automated Report	99	107	5	**211**	16%
DTAC (UNOS)	21	1	0	**22**	2%
Email	3	18	3	**24**	2%
Fax/Mail	4	0	1	**5**	0%
Media	0	3	0	**3**	0%
Member Reporting Line	17	6	5	**28**	2%
Other UNOS Staff	43	80	13	**136**	10%
Patient Safety Portal	324	402	124	**850**	64%
Patient Services (UNOS)	26	0	0	**26**	2%
Phone	0	13	5	**18**	1%
Site Survey (UNOS)	0	1	0	**1**	0%
Grand Total	**537**	**631**	**156**	**1324**	100%

Source: Master Case List, 1/1/22 – 3/30/24

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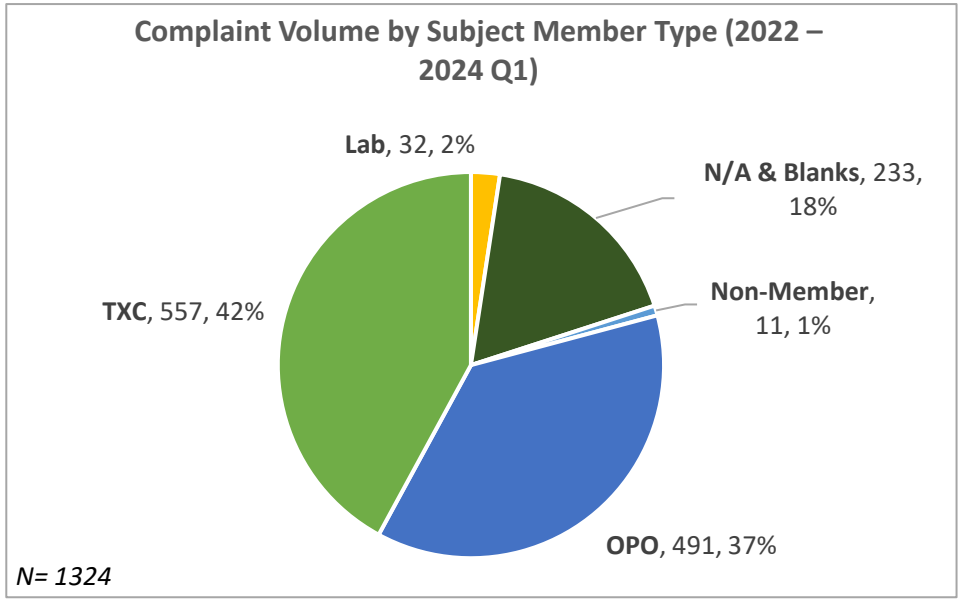
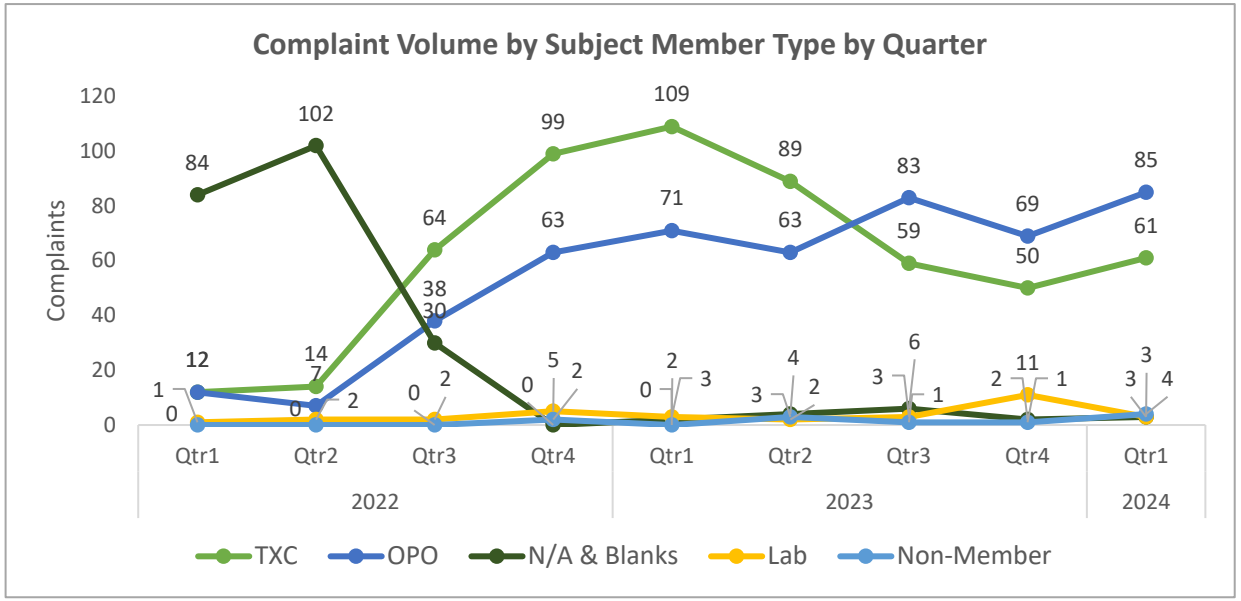
Complaint Volume by Subject Member Type

Approximately **79% of complaints pertain to Transplant Centers and OPOs**, with only **2% of complaints pertaining to histocompatibility labs**. In 2022, approximately 40% of complaints did not have a subject member type indicated, as subject member type does not appear to have been consistently documented until 2023. This impacts the ability to trend data by member type over time between 2022 Q1 – 2024 Q1. However, **it appears the volume of complaints pertaining to Transplant Centers decreased throughout 2023, while complaints pertaining to OPOs increased throughout 2023**.





Volume of Complaints by Subject Member Type					
Subject	**2022**	**2023**	**2024 Q1**	**Total**	**% of Grand Total**
TXC	189	307	61	557	42%
OPO	120	286	85	491	37%
N/A and Blanks*	216	14	3	233	18%
Lab	10	19	3	32	2%
Non-Member	2	5	4	11	1%
Grand Total	**537**	**631**	**156**	**1324**	**100%**

	2022				2023				2024
Subject Member	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**
TXC	12	14	64	99	109	89	59	50	61
OPO	12	7	38	63	71	63	83	69	85
N/A & Blanks	84	102	30	0	2	4	6	2	3
Lab	1	2	2	5	3	2	3	11	3
Non-Member	0	0	0	2	0	3	1	1	4
Total	**109**	**125**	**134**	**169**	**185**	**161**	**152**	**133**	**156**
Annual Total	**537**				**631**				**156**

Source: Master Case List, 1/1/22 – 3/30/24

** It appears "N/A" and blank subject member type values were not consistently recorded until late 2022*

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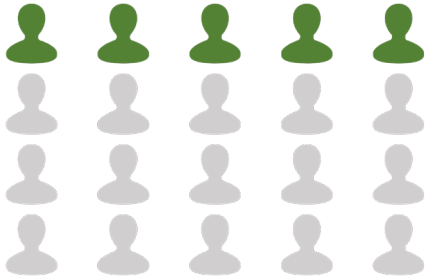
Organization Types Reporting and Receiving Complaints

An analysis of **all patient safety complaints from 2022 – 2024 Q1 found that 24% of complaints were self-reported**. When solely analyzing **complaints submitted by Transplant Centers, OPOs, and histocompatibility labs, 40% of patient safety complaints were self-reported**. Self-reporting is defined as instances where the reporting member code matches the complaint subject member code. When **Transplant Centers file a complaint, 38% of the time the complaint pertains to another Transplant Center and 60% of the time the complaint pertains to an OPO**.

All Complaints

24%

of all patient safety complaints were self reports

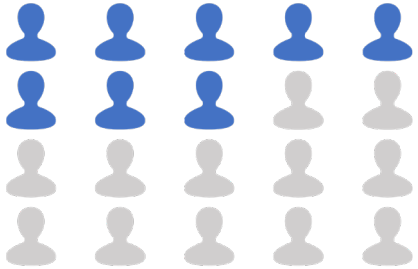


Evaluated all complaints submitted by all reporter types (N=1324)

Complaints Submitted by TXCs/OPOs/Labs

40%

of patient safety complaints submitted by TXCs, OPOs, and histocompatibility labs were self reports



Evaluated complaints submitted by TXCs, OPOs and histocompatibility labs (N=757)

For complaints that contained multiple members per submission, the record was marked as a self-report if at least one of the submitter members was listed in the "subject member code" field
Source: Master Case List, 1/1/22 – 3/30/24

Types of Organizations Reporting and Receiving Patient Safety Complaints*

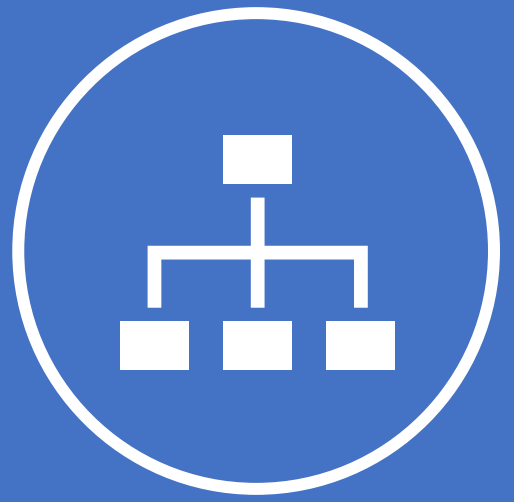
	Complaint Subject Member Type					
Complaint Reporter	**TXC**	**OPO**	**N/A & Blanks**	**Lab**	**Non-Member**	**Grand Total**
TXC	209	326	6	0	2	**543**
Automated Report	175	4	39	0	0	**218**
OPO	60	110	1	11	4	**186**
N/A	0	1	178	0	0	**179**
Other UNOS Staff	47	20	4	4	0	**75**
Patient/Donor Family	42	4	3	0	1	**50**
Anonymous	17	9	2	0	4	**32**
Lab	0	11	0	17	0	**28**
Disease Transmission	7	2	0	0	0	**9**
Media	0	3	0	0	0	**3**
Site Survey	0	1	0	0	0	**1**
Grand Total	**557**	**491**	**233**	**32**	**11**	**1324**

**Includes self-reports*

Volume of Complaints that were Self-reported by Reporter Type

Reporter Type	Self-Reported	Externally Reported	Total Violations by Reporter Type	% Self-Reported
TXC	184	359	**543**	**34%**
OPO	104	82	**186**	**56%**
Lab	13	15	**28**	**46%**
Grand Total	**301**	**456**	**757**	**40%**

Complaint Classification



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Complaint Classification Overview

Primary Classification	Sub-Classifications	Primary Classification Description
ABO	• Conflicting Results, Primary Type • Conflicting Results, Subtype • Data Entry • Incompatible Recipient • Rare Subtype • Typing Requirements, Donor • Typing Requirements, Recipient	• Events related to the testing, determination of, and reporting of donor, candidate, or recipient ABO • Includes issues related to accurate determination of donor, candidate, or recipient subtyping
Allocation	• Bypasses • Late Declines • Actual vs. Intended	• Captures events related to the proper allocation of organs
Candidate Registrations, Modifications, and Removals	• Candidate Referral • Candidate Work-up • Candidate Listing • Waitlist Management	• Typically involves pre-transplant patients or events that occurred prior to or just after transplant • Many cases involve the process of listing a candidate on the waitlist, required information and/or updates to the candidate's waitlist record, and required timelines and information for removing a patient from the waitlist • Incorrect discrepant candidate ABO issues should not be classified in this category
Data Submission Requirements	• Timely Collection of Data • Recording and Reporting Outcomes of Organ Offers • Living Donor Data Submission Requirements	• Events involving timely collection and reporting of required OPTN data, including outcomes of organ offers and required living donor data submission into the OPTN system
Deceased Donor Organ Procurement	• Authorization • Donor Management • Recovery • Surgical Damage	• Events related to the deceased donor organ donation process prior to and in the donor recovery operating room • Events can be related to donor workup, completion of required donor testing, events that occur during the recovery (including surgical damage), communication between recovery teams, and other issues that arise leading up to and during the deceased donor organ recovery process • Most events in this category occurred prior to the organ being packaged/labeled, and/or leaving the donor OR
Histocompatibility	• Data Entry Error • Testing Error	• Events related to inaccurate typing and reporting of HLA

Source: UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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Complaint Classification Overview, cont.

Primary Classification	Sub-Classifications	Primary Classification Description
Identification of Transmissible Diseases	• Testing • Reporting (to OPTN) • Reporting (to other member) • Failed to Report to Anyone	• Events involving the testing, identification, and reporting of infectious disease results • May include events where required infectious disease testing was not completed, not completed according to requirements, or that positive results were not reported to the appropriate entity
Living Donation	• Evaluation • Transplant • Verification • Aborted Procedure • Death >2 Years • Death <2 Years • Native Organ Failure • Redirection • Reporting, Living Donor Events	• Includes all living donor events, as defined in OPTN policy: – Living donor aborted procedures (recovery procedures aborted after the potential donor starts receiving general anesthesia but prior to organ recovery) – Living donor deaths within 2 years of donation – Living donor redirections (a living donor organ is recovered but transplanted into someone other than the original intended recipient) – Living donor non-utilizations (a living donor organ is recovered but not transplanted) – Living donor native organ failure within two years of donation (a prior living donor is added to the wait list for any organ, or a prior living kidney donor begins regularly administered dialysis for ESRD) • May also be issues related to living donor workup and evaluation, concerns reported by pending living donors or prior living donors, and communication issues (usually between the transplant program and the living donor)
Organ and Extra Vessels	• Organ Packaging • Organ Labeling • Organ Shipping • Extra Vessel Packaging • Extra Vessel Labeling • Extra Vessel Shipping • Prohibited Storage • Prohibited Use • Transportation	• Events related to recovered deceased donor organs or vessels • Includes events related to packaging, labeling, and transportation of deceased donor organs and extra vessels and events related to extra vessel storage by the recipient hospital
Organ Offers, Acceptance, and Verification	• Offer Issues • Acceptance Issues • Verification Issues	• Events related to the actual offering, acceptance, or timeliness of organ acceptances or declines • Includes events related to proper review and verification of donor information prior to acceptance • Does not include whether organs were allocated according to policy (these events fall under the “allocation” classification)
Other	• Member-specific • Staffing Culture • Other	• Captures events that cannot be categorized in the other classifications • Events are commonly member-specific and related to the institution culture or events that do not fit into any of the pre-defined categories

Source: UNOS, “Primary and sub classifications_MCL_with Definitions,” 6/11/24

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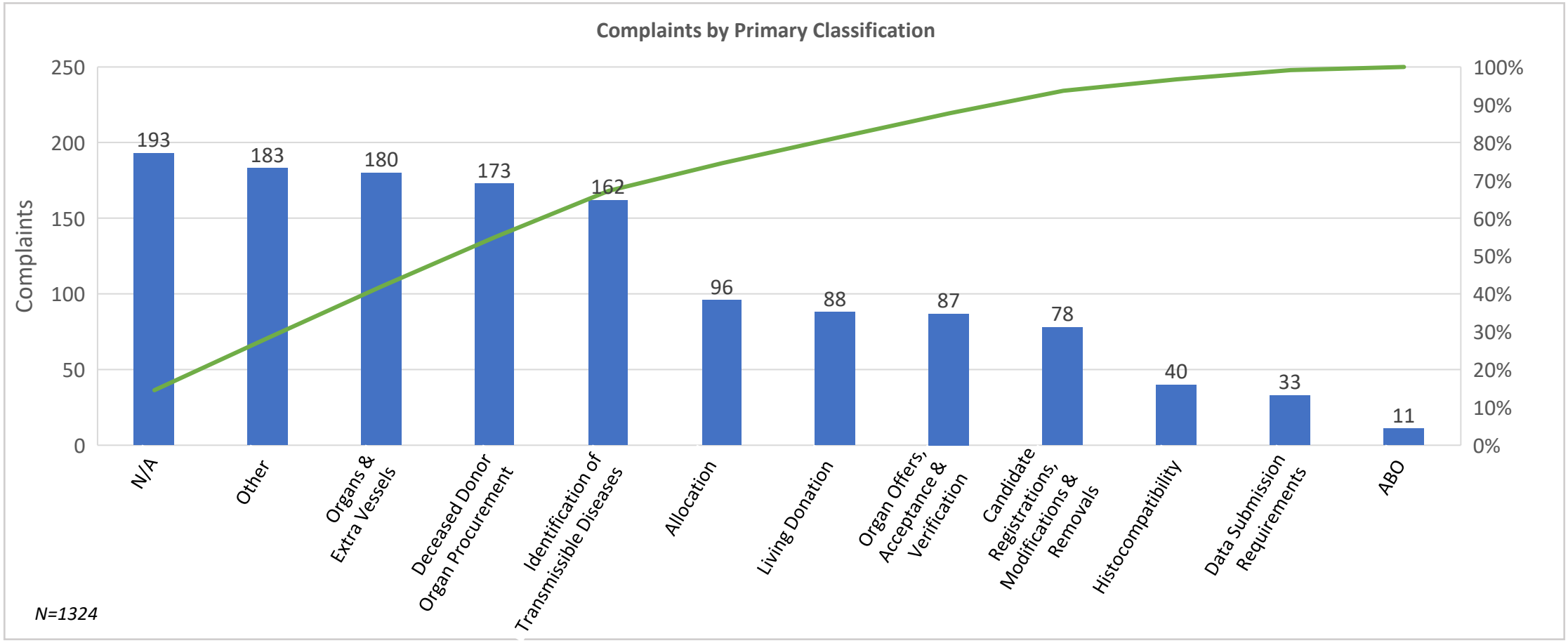
Volume of Complaints by Primary Classification

Five classifications account for 67% of the 1,324 complaints received between 2022 and 2024 Q1: N/A (15%), organ & extra vessels (14%), other (13%), deceased donor organ procurement (13%), and identification of transmissible diseases (12%). The classification of "N/A" was frequently used in the first half of 2022, with consistent documentation of the primary classification field beginning in late 2022. Approximately 1/3 of complaints were classified as "other."



N/A appeared extensively as a primary complaint classification until mid-2022
Source: Master Case List, 1/1/22 – 3/30/24

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Primary Complaint Classification by Subject Member Type

Complaints involving Transplant Centers and OPOs constituted 79% of the 1,324 complaints**. Most complaints about Transplant Centers pertain to the identification of transmissible diseases (22% of TXC complaints); "other" (17%); candidate registrations, modifications, and removals (12%); and organ and extra vessels (11%)**. While 66% of the "other" category did not have additional detail, 11% of "other" complaints pertained to staffing culture and 11% were defined as "member-specific." **The majority of OPO complaints were classified as deceased donor organ procurement (25% of OPO complaints); organ and extra vessels (20%); "other" (14%); and allocation (12%).** While 64% of the "other" category lacked specific detail, 12% of the "other" category pertained to transportation issues.

Primary Complaint Classification by Subject Member Type

Primary Classification	TXC	OPO	Non-Member	N/A & Blanks	Lab	Grand Total	Primary Classification % of Total Complaints
N/A	14	9	0	168	2	**193**	**15%**
Other	92	69	11	4	7	**183**	**14%**
Organ & Extra Vessels	64	97	0	19	0	**180**	**14%**
Deceased Donor Organ Procurement	50	**123**	0	0	0	**173**	**13%**
Identification of Transmissible Diseases	**121**	38	0	3	0	**162**	**12%**
Allocation	25	61	0	10	0	**96**	**7%**
Living Donation	63	2	0	23	0	**88**	**7%**
Organ Offers, Acceptance, & Verification	37	50	0	0	0	**87**	**7%**
Candidate Registrations Modifications and Removals	65	6	0	5	2	**78**	**6%**
Histocompatibility	3	16	0	1	20	**40**	**3%**
Data Submission Requirements	16	16	0	0	1	**33**	**2%**
ABO	7	4	0	0	0	**11**	**1%**
Grand Total	**557**	**491**	**11**	**233**	**32**	**1324**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24

A classification and subject member type of "N/A" appeared extensively as a primary complaint classification until mid-2022

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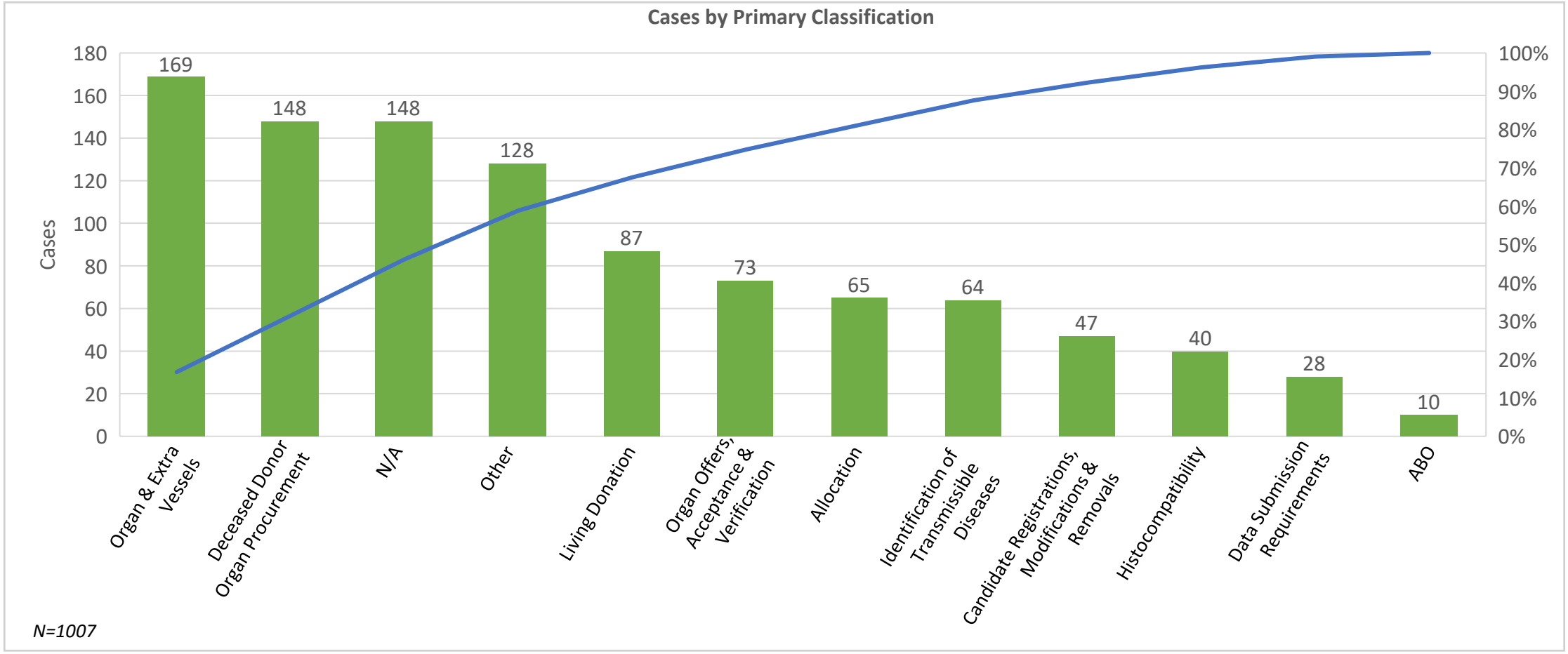
Volume of Cases by Primary Classification

Five classification categories account for 68% of the 1,007 patient safety cases: organ & extra vessels (17%), deceased donor organ procurement (15%), "N/A" (15%), "other" (13%), and living donation (9%). The "N/A" case classification was used extensively through the first half of 2022. The high volume of cases pertaining to organ and extra vessels and deceased donor organ procurement present an opportunity to provide targeted education around OPTN policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage, and policy 2: Deceased Donor Organ Procurement.



N/A appeared extensively as a primary complaint classification until mid-2022
Source: Master Case List, 1/1/22 – 3/30/24

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Primary Case Classification by Subject Member Type

Cases involving Transplant Centers and OPOs constituted 79% of the 1,007 cases reported between 2022 and 2024 Q1. The most common case classifications for cases concerning OPOs were deceased donor organ procurement (27%) and organ & extra vessels (24%). The most common case classifications for cases concerning Transplant Centers were "other" (17%) and living donation (16%).

Primary Case Classification by Subject Member Type

Primary Classification	OPO	TXC	N/A &* Blanks	Lab	Non-member	Grand Total	Primary Classification % of Total Cases
Organ & Extra Vessels	94	56	19	0	0	**169**	**17%**
N/A	8	9	129	2	0	**148**	**15%**
Deceased Donor Organ Procurement	106	42	0	0	0	**148**	**15%**
Other	49	68	3	6	2	**128**	**13%**
Living Donation	2	63	22	0	0	**87**	**9%**
Organ Offers, Acceptance, & Verification	40	33	0	0	0	**73**	**7%**
Allocation	37	21	7	0	0	**65**	**6%**
Identification of Transmissible Diseases	20	42	2	0	0	**64**	**6%**
Candidate Registrations Modifications and Removals	6	39	1	1	0	**47**	**5%**
Histocompatibility	16	3	1	20	0	**40**	**4%**
Data Submission Requirements	15	12	0	1	0	**28**	**3%**
ABO	3	7	0	0	0	**10**	**1%**
Grand Total	**396**	**395**	**184**	**30**	**2**	**1007**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24

A classification and subject member type of "N/A" appeared extensively as a primary complaint classification until mid-2022

Risk Assignment

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Complaint Triage & Risk Levels

Once complaints are received, the UNOS Patient Safety team completes the Compliance and Safety Investigation Triage Form within two hours of receipt if the complaint is received between 8 am – 10 pm seven days per week. **Complaints are triaged as 1-Exceptional, 2-Priority, or 3-Common**. Risk level is assigned based on the outputs of the Triage Form, and only risk level 1-Exceptional has criteria listed in the Triage Form. The risk level is documented in the Master Case List upon triage. However, **risk level is subject to change throughout the investigative process and the MCL does not denote whether a risk level has been modified since intake**. Therefore, this analysis cannot definitively identify whether risk levels reviewed are initial or revised.

Complaint Risk Levels

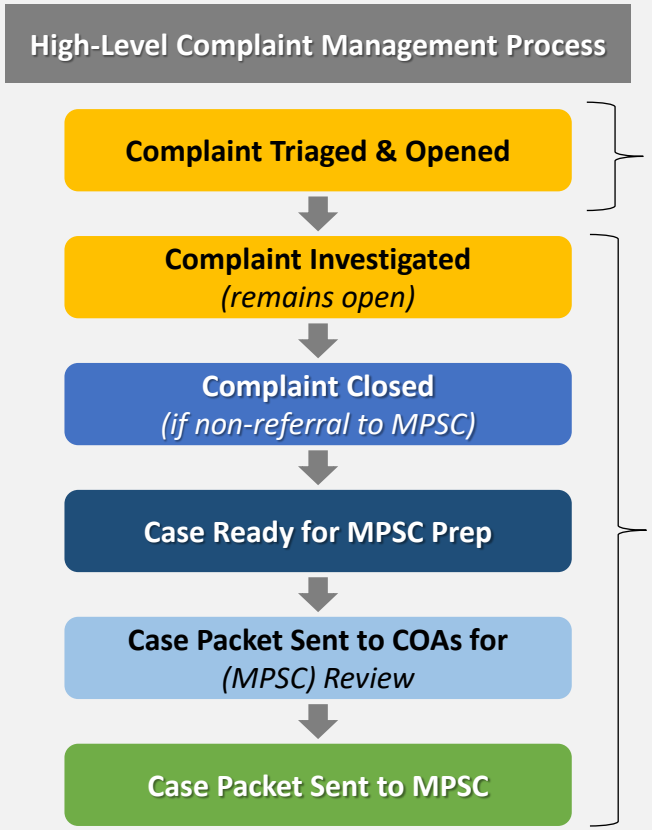
1 Exceptional

- Living donor death within 1 month of donation and related to donation
- Unintentional transplant of the wrong recipient
- Unintentional transplant of the wrong organ
- Unintentional ABO incompatible transplant
- Failure to obtain donor authorization
- Failure to obtain brain death documentation
- Confirmed unintentional HIV transmission from donor to recipient
- An event that poses a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule

2 Priority

3 Common

Complaint Risk Level Documentation



- Risk is initially determined during complaint intake using the UNOS Compliance and Safety Investigation Triage Form
- Risk is documented in the MCL

- Risk is re-evaluated throughout the investigation process and may be modified at any time
- The revised risk may be updated in the MCL, but **the MCL does not indicate if the documented risk level is initial or revised**

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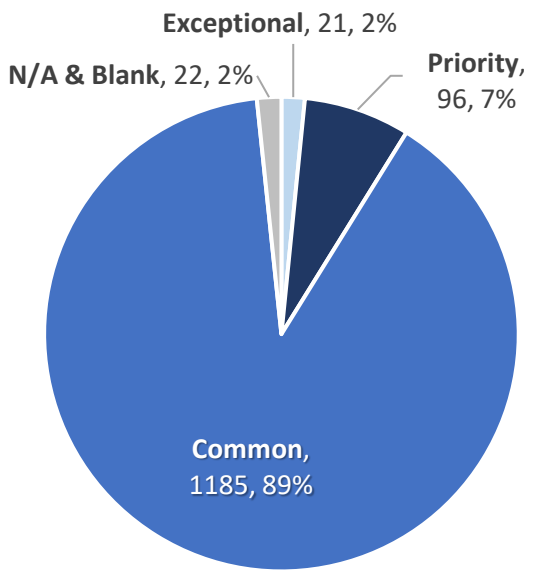
Volume of Complaints by Risk Level and Case/Referral/Turndown Status

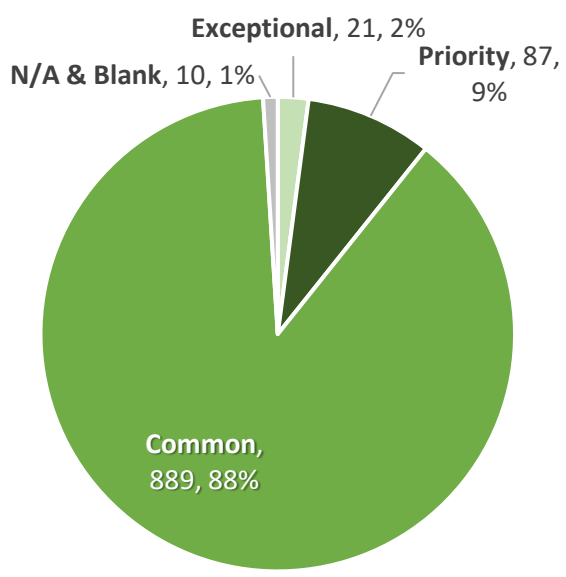
Of the 1,324 complaints between 2022 – 2024 Q1, 89% (1,185) were rated as "common," 7% (96) were rated as "priority," and 2% (21) were rated as "exceptional" risk. Most cases are rated as a "common" risk (88%), while 9% are priority, and 2% are exceptional risk. As stated prior, risk is subject to be modified throughout the investigative process and current documentation does not indicate if risk is initial or revised. Therefore, it is impossible to determine if a higher volume of complaints are initially rated as priority or exceptional and are downgraded as additional information is gathered, or vice versa.

All Complaints by Risk Level



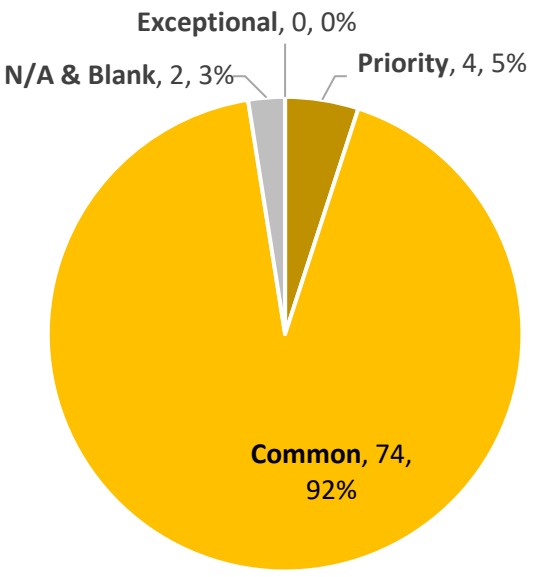
N=1324

Cases by Risk Level



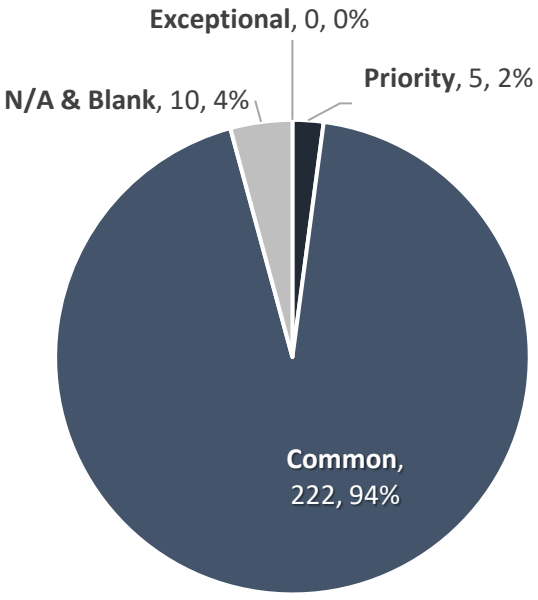
N=1007

Referrals by Risk Level



N=80

Turndowns by Risk Level



N=237

Source: Master Case List, 1/1/22 – 3/30/24

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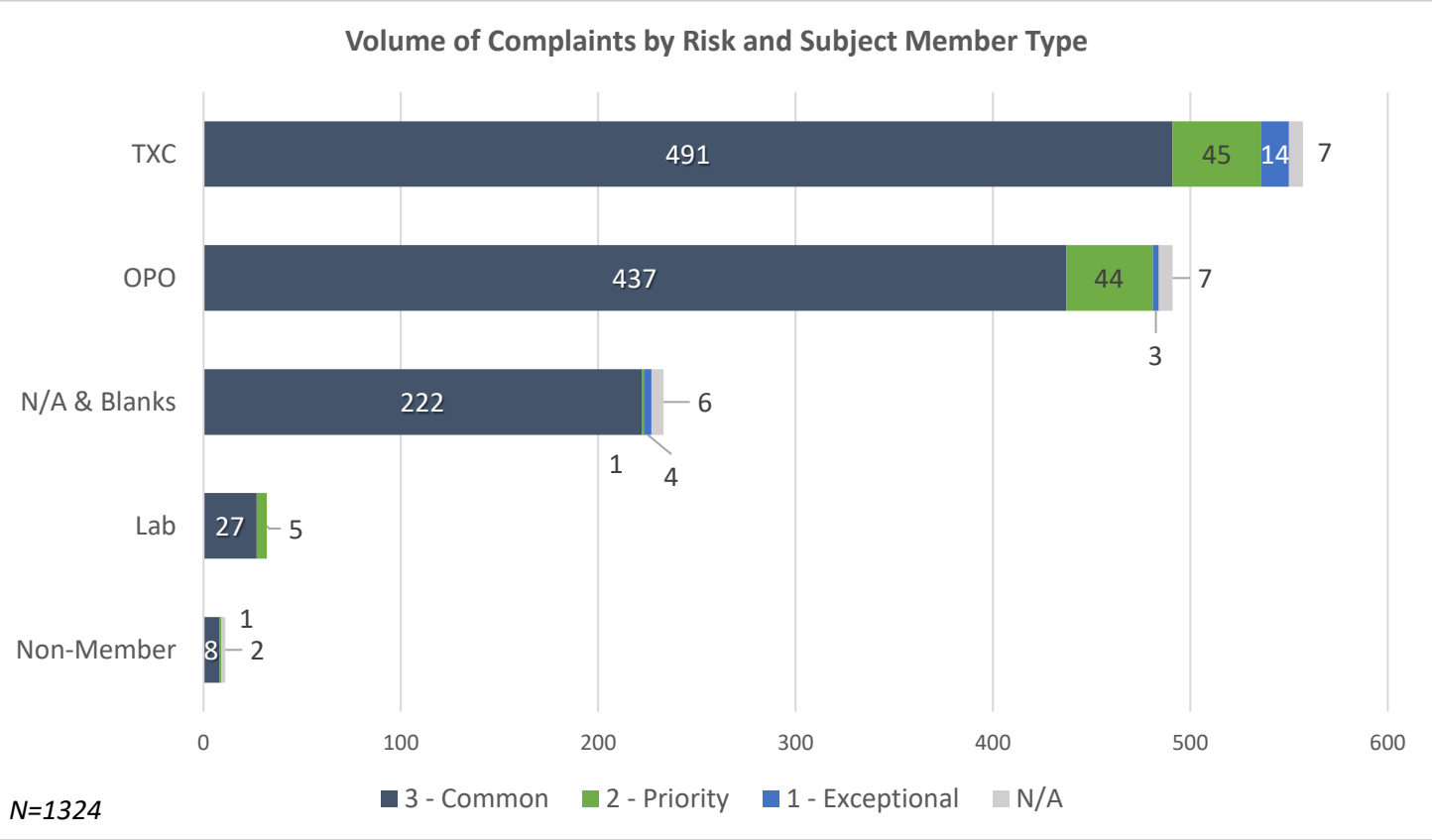
Risk by Subject Member Type

The overwhelming majority of complaints were "common" risk across all subject member types. For complaints pertaining to transplant centers, 88% were rated as "common" risk, while 8% were "priority," and 1% were "exceptional" risk. Complaints pertaining to OPOs followed a similar trend: 89% were rated as "common," 9% were "priority," and less than 1% were "exceptional."



Subject Member Type	Common	Priority	Exceptional	N/A	Grand Total
TXC	491	45	14	7	**557**
OPO	437	44	3	7	**491**
N/A & Blanks	222	1	4	6	**233**
Lab	27	5	0	0	**32**
Non-Member	8	1	0	2	**11**
Grand Total	**1185**	**96**	**21**	**22**	**1324**

Subject member type of "N/A" appeared extensively as a subject member type until mid-2022
Source: Master Case List, 1/1/22 – 3/30/24

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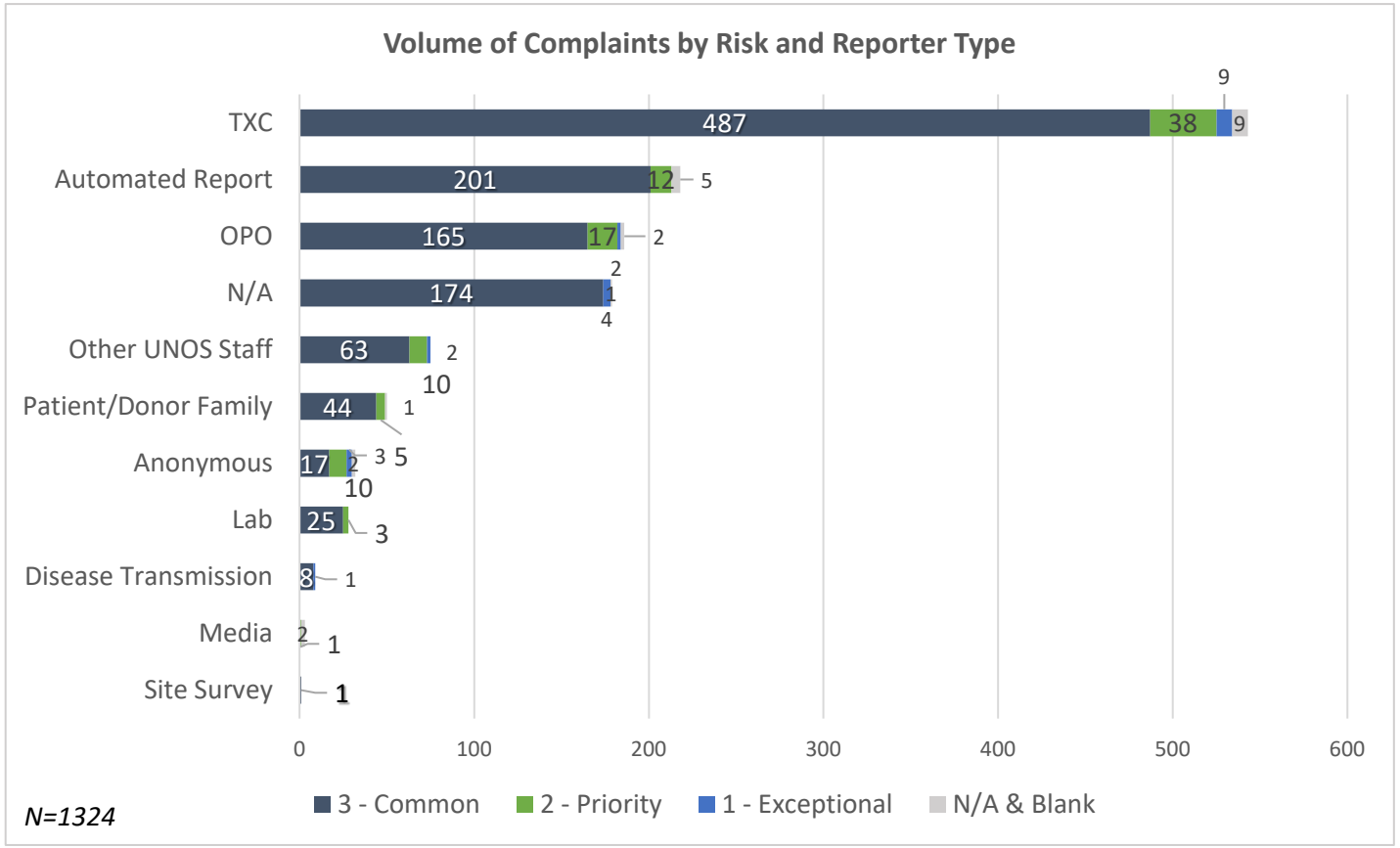
Risk by Complaint Reporter Type

The majority of complaints were rated as common across all reporter types. **Almost half of the exceptional complaints were reported by Transplant Centers (43%). Of the 32 anonymous complaints, 13 (41%) resulted in a priority or exceptional risk rating**. This high percentage suggests the importance of anonymous reporting mechanisms in identifying potentially serious issues. Investing in improving and developing anonymous reporting mechanisms could lead to a higher rate of anonymous reporting and, consequently, improved identification of elevated risk situations.



Subject Member Type	Common	Priority	Exceptional	N/A	Grand Total
TXC	487	38	9	9	**543**
Automated Report	201	12	0	5	**218**
OPO	165	17	2	2	**186**
N/A	174	0	4	1	**179**
Other UNOS Staff	63	10	2	0	**75**
Patient/Donor Family	44	5	0	1	**50**
Anonymous	17	10	3	2	**32**
Lab	25	3	0	0	**28**
Disease Transmission	8	0	1	0	**9**
Media	0	1	0	2	**3**
Site Survey	1	0	0	0	**1**
Grand Total	**1185**	**96**	**21**	**22**	**1324**

Subject member type of "N/A" appeared extensively as a reporter type until mid-2022
Source: Master Case List, 1/1/22 – 3/30/24

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Risk by Complaint Primary Classification

The table below shows the proportion of risk ratings by each complaint primary classification. For most complaints, **greater than 90% of complaints are rated as "common."** However, for **complaints classified as "other," only 78% of complaints are common risk, while 13% are priority, and 4% are exceptional**. Complaints about candidate registrations, modifications, and removals tend to have a higher proportion of complaints with priority risk.

	3 - Common		2 - Priority		1 - Exceptional		N/A		Grand Total	
Primary Classification	**N**	**% of Classification**	**N**	**% of Classification**	**N**	**% of Classification**	**N**	**% of Classification**	**N**	**% of Total**
N/A	186	96%	1	1%	3	2%	3	2%	**193**	**15%**
Other	143	**78%**	24	**13%**	8	**4%**	8	4%	**183**	**14%**
Organ & Extra Vessels	174	97%	2	1%	1	1%	3	2%	**180**	**14%**
Deceased Donor Organ Procurement	156	90%	16	9%	0	0%	1	1%	**173**	**13%**
Identification of Transmissible Diseases	146	90%	13	8%	1	1%	2	1%	**162**	**12%**
Allocation	90	94%	6	6%	0	0%	0	0%	**96**	**7%**
Living Donation	83	94%	1	1%	3	**3%**	1	1%	**88**	**7%**
Organ Offers, Acceptance, & Verification	74	85%	9	10%	3	**3%**	1	1%	**87**	**7%**
Candidate Registrations, Modifications & Removals	64	82%	13	**17%**	1	1%	0	0%	**78**	**6%**
Histocompatibility	34	85%	5	**13%**	1	**3%**	0	0%	**40**	**3%**
Data Submission Requirements	28	85%	5	**15%**	0	0%	0	0%	**33**	**2%**
ABO	7	64%	1	9%	0	0%	3	27%	**11**	**1%**
Grand Total	**1185**	**90%**	**96**	**7%**	**21**	**2%**	**22**	**2%**	**1324**	**100%**

Subject member type of "N/A" appeared extensively as a primary complaint classification until mid-2022
Source: Master Case List, 1/1/22 – 3/30/24

Substantiation and Policy/Bylaw Violations

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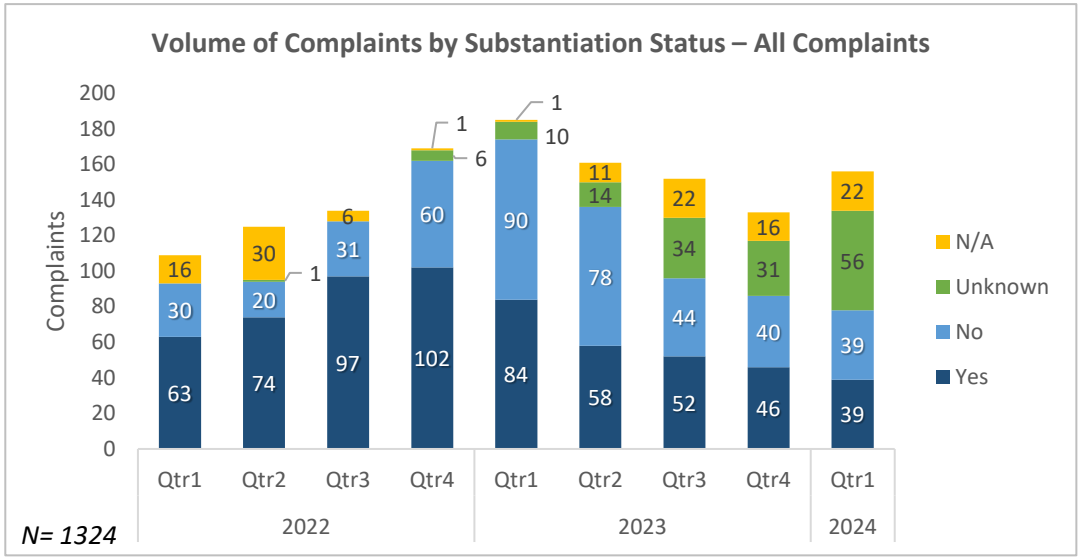
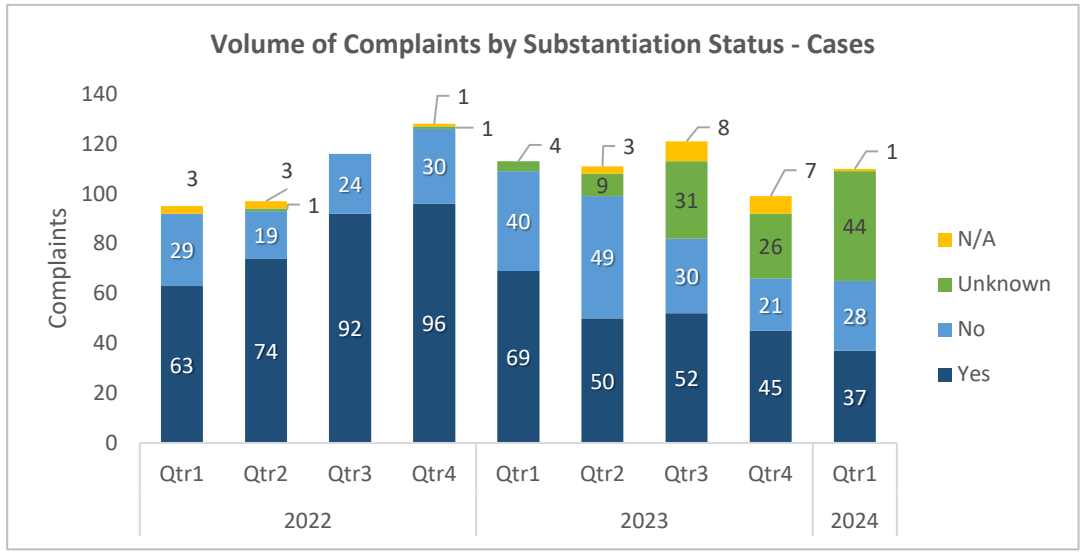
Complaint Substantiation Volume

UNOS determines a complaint meets substantiation if the UNOS patient safety investigation finds the complaint to be valid and true. **Between 2022 and 2024 Q1, approximately 46% of all complaints were substantiated, while 58% of all patient safety cases resulted in substantiation. Excluding "N/A" and "Unknown" substantiation statuses, 59% of complaints and 68% of cases were substantiated.** A complaint or case will often have an "unknown" substantiation status if the complaint or case is still under investigation. 2023 and 2024 Q1 have high volumes of complaints with an "unknown" substantiation status, as investigations can remain open for over one year.





All Complaints (Cases, Referrals, and Turndowns)					
Substantiation Status	**2022**	**2023**	**2024**	**Grand Total**	**% of Grand Total**
Yes	336	240	39	615	46%
No	141	252	39	432	33%
N/A[1]	53	50	22	125	9%
Unknown[2]	7	89	56	152	11%
Grand Total	**537**	**631**	**156**	**1324**	**100%**

Cases					
Substantiation Status	**2022**	**2023**	**2024**	**Grand Total**	**% of Grand Total**
Yes	325	216	37	578	58%
No	102	140	28	270	27%
N/A[1]	7	18	1	26	3%
Unknown[2]	2	70	44	116	12%
Grand Total	**436**	**444**	**110**	**990**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24

[1]*N/A may be used for complaints that were referred or turned down or the substantiation was not documented or able to be captured in the system*

[2]*Unknown status is often used for complaints still under investigation*

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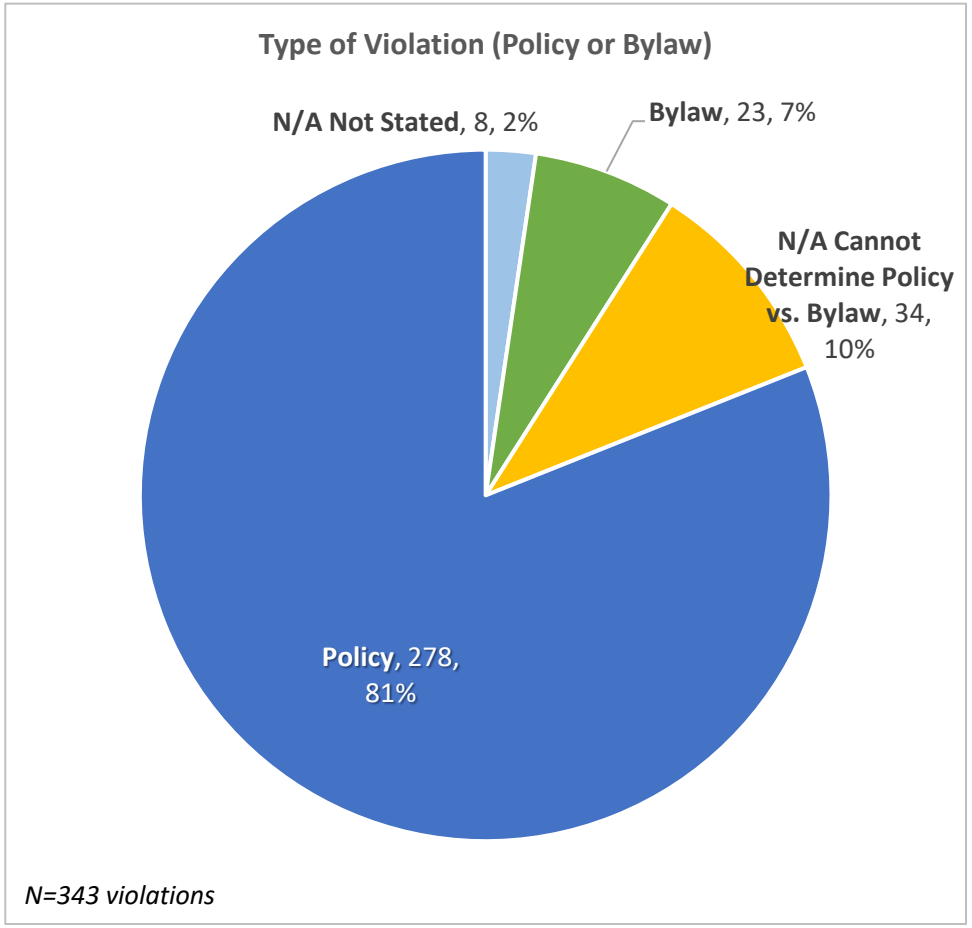
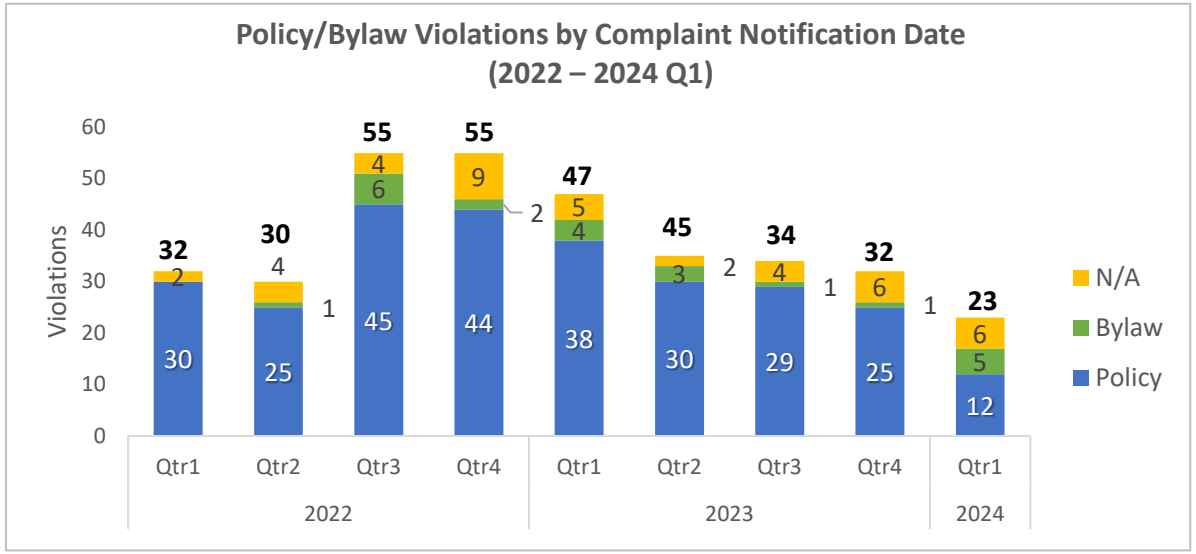
Policy & Bylaw Violations

Of the 1,324 patient safety complaints, **300 had violations, resulting in a total of 343 policy or bylaw violations**. **81% of these were policy violations, and 7% were bylaw violations**. However, 10% could not be categorized because the referenced number exists in both OPTN policy and OPTN bylaws. An additional 2% of violations were unspecified and could not be categorized appropriately. The decline in violations in the latter half of 2023 and beginning of 2024 is likely due to ongoing investigations, which can take over one year to complete.



N=343 violations

Volume of Policy/Bylaw Violations by Subject Member Type (2022 – 2024 Q1)					
Subject Member Type	**Policy Violations**	**Bylaw Violations**	**N/A***	**Total**	**% of Grand Total**
OPO	123	3	16	**142**	**41%**
TXC	103	19	8	**130**	**38%**
Lab	2	1	15	**18**	**5%**
N/A & Blank	50	0	3	**53**	**15%**
			Grand Total	**343**	**100%**



**N/A is indicated for those records marked "N/A" and those whereby it could not be determined if the subject violated a policy or bylaw*

Source: Master Case List, 1/1/22 – 3/30/24; OPTN Policies 5/29/24; OPTN Bylaws 3/30/24

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Summary of OPTN Policies

Parent Policy #	Parent Policy Title	Descriptions Reflect Project Team's Understanding
1	Administrative Rules and Definitions	Provides definitions and general administrative rules applicable to policies and operations of the OPTN
2	Deceased Donor Organ Procurement	Outlines procedures for the procurement of organs from deceased donors, including donor evaluation, consent, and organ retrieval protocols
3	Candidate Registration, Modifications, and Removals	Outlines procedures for registering, modifying and removing candidates from the transplant wait list
4	Histocompatibility	Specifies standards and procedures for histocompatibility testing and reporting to ensure proper matching of donors and recipients
5	Organ Offers, Acceptance, and Verification	Specifies processes for organ offers, acceptance, and verification to ensure proper matching and documentation
6	Allocation of Hearts and Heart-Lungs	Details criteria and procedures for allocating hearts and heart-lung combinations
7	Allocation of Intestines	Outlines criteria and procedures for allocating intestines
8	Allocation of Kidneys	Describes criteria and procedures for allocating kidneys
9	Allocation of Livers and Liver-Intestines	Outlines criteria and procedures for allocating livers and liver-intestines
10	Allocation of Lungs	Details criteria and procedures for allocating lungs
11	Allocation of Pancreas, Kidney-Pancreas, and Islets	Describes criteria and procedures for allocating pancreas, kidney-pancreas, and islets
12	Allocation of Covered Vascularized Composite Allografts	Outlines criteria and procedures for allocating covered vascularized composite allografts
13	Kidney Paired Donation (KPD)	Describes the criteria and procedures for the KPD program
14	Living Donation	Addresses criteria and procedures for living donation, including donor evaluation and informed consent
15	Identification of Transmissible Diseases	Establishes requirements for screening, identifying, and reporting transmissible diseases in organ donors and recipients to ensure the safety or organ transplantation
16	Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage	Outlines standards and procedures for the proper packaging, labeling, shipping, and storage of organs and extra vessels to maintain their viability and integrity during transportation for transplant
17	International Organ Transplantation	Establishes guidelines and procedures for the import and export of organs for transplantation between the United States and other countries, ensuring compliance with regulatory standards and ethical considerations
18	Data Submission Requirements	Specifies the mandatory data submission requirements for transplant programs, including reporting deadlines and data accuracy, to maintain comprehensive and reliable transplant data
19	Data Release	Outlines rules and procedures for the release of transplant data to the public, researchers, and other stakeholders while ensuring patient confidentiality
20	Travel Expense and Reimbursement	Specifies requirements for transplant programs and OPOs to promptly and accurately report all data required by the OPTN
21	Composite Allocation Score Reference	Defines the composite allocation score and outlines its use in organ allocation

Source: OPTN Policies 5/29/24

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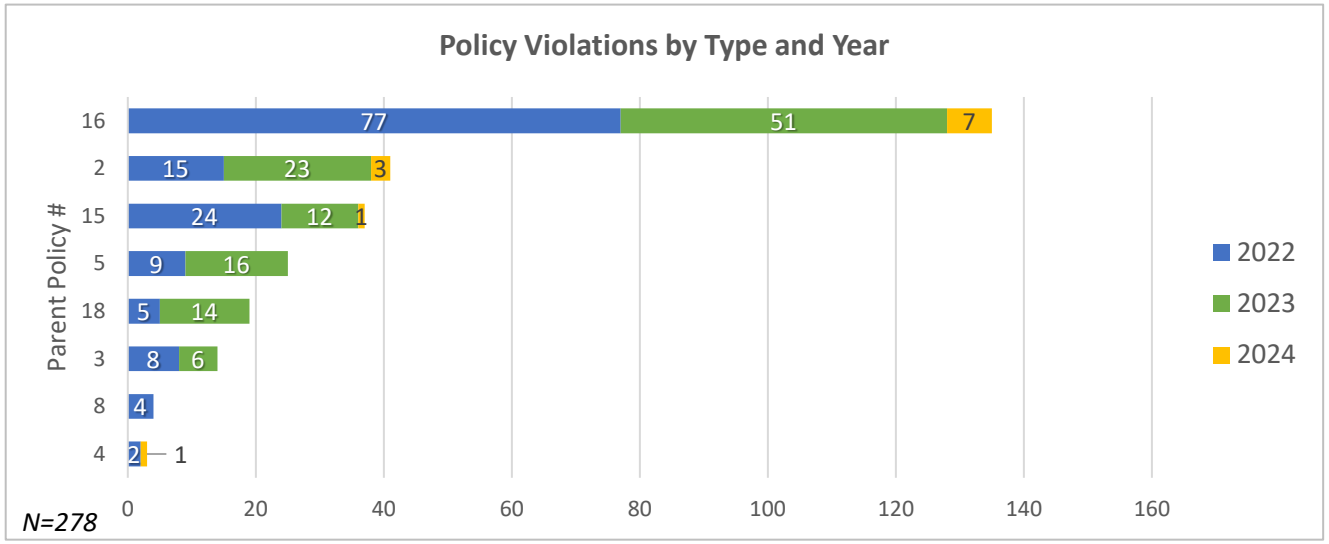
Policy Violation & Reporter Type

Between 2022 and 2024 Q1, **49% of the 278 policy violations pertained to parent OPTN Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage**. Priority should be given to enhancing and monitoring activities pertaining to organ and extra vessel packaging, labeling, shipping and storage. Focused education surrounding these activities could be provided, and education efficacy could be tracked by monitoring and trending the volume of Policy 16 violations. **Transplant Centers reported 45% of policy violations, and 62% of Transplant Center-reported violations pertained to OPOs**. Of the 42 policy violations reported by OPOs, 71% of those complaints pertained to OPOs and 24% pertained to Transplant Centers. **Overall, 39% of policy violations were self-reported by OPOs and Transplant Centers.**



Parent Policy #	Policy Title	Policy Violations (2022 – 2024 Q1)	% of Grand Total
16	Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage	135	49%
2	Deceased Donor Organ Procurement	41	15%
15	Identification of Transmissible Diseases	37	13%
5	Organ Offers, Acceptance, and Verification	25	9%
18	Data Submission Requirements	19	7%
3	Candidate Registrations, Modifications, and Removals	14	5%
8	Allocation of Kidneys	4	1%
4	Histocompatibility	3	1%
	Grand Total	**278**	**100%**

Source: Master Case List, 1/1/22 – 3/30/24; OPTN Policies 5/29/24; OPTN Bylaws 3/30/24

Types of Organizations Reporting and Receiving Policy Violations*

	Complaint Subject Member Type					
Complaint Reporter	**OPO**	**TXC**	**N/A & Blank**	**Lab**	**Reporter Total**	**% of Grand Total**
TXC	77	45	2	0	**124**	**45%**
Automated Report	0	35	10	0	**45**	**26%**
OPO	30	10	1	1	**42**	**15%**
N/A	0	0	35	0	**35**	**13%**
Other UNOS Staff	6	9	2	0	**17**	**6%**
Lab	9	0	0	1	**10**	**4%**
Disease Transmission	0	4	0	0	**4**	**1%**
Anonymous	1	0	0	0	**1**	**<0%**
Grand Total	**123**	**103**	**50**	**2**	**278**	**100%**

**Includes self-reports*

Volume of Policy Violations that were Self-reported

Reporter Type	Self-Reported	Externally Reported	Total Violations by Reporter Type	% Self-Reported
OPO	30	12	**42**	**71%**
TXC	38	86	**124**	**31%**
Lab	0	10	**10**	**0%**
Grand Total	**68**	**108**	**176**	**39%**

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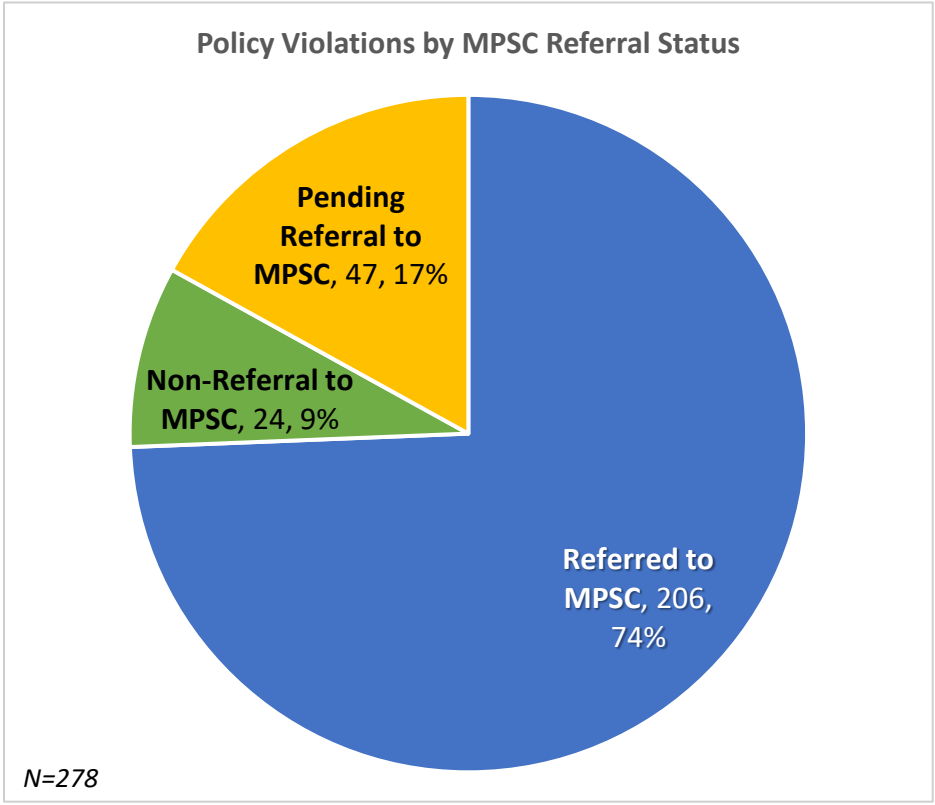
Policy Violations & MPSC Referrals

Of the 278 policy violations identified between 2022 and 2024 Q1, **206 (74%) were referred to MPSC for further investigation, while 47 (17%) are pending referral to MPSC**. Policy 16 (organ and extra vessel packaging, labeling, shipping, and storage) had the most violations (49% of total violations), and 73% of these policy violations were referred to MPSC. Almost all policy violations pertaining to Policy 13: Candidate Registrations, Modifications, and Removals, Policy 8: Allocation of Kidneys, and Policy 4: Histocompatibility were referred to MPSC. Open investigations may be marked as "pending referral to MPSC." Given the data set spans a two-year period and investigations can take one year to complete, a pending referral rate of 17% is not unexpected.

Parent Policy #	Policy Title	Referred to MPSC	Pending Referral to MPSC	Total Violations	% Referred to MPSC
16	Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage	98	24	135	73%
2	Deceased Donor Organ Procurement	31	8	41	76%
15	Identification of Transmissible Diseases	24	7	37	65%
5	Organ Offers, Acceptance, and Verification	21	2	25	84%
18	Data Submission Requirements	13	6	19	68%
3	Candidate Registrations, Modifications, and Removals	13	0	14	93%
8	Allocation of Kidneys	3	0	4	75%
4	Histocompatibility	3	0	3	100%
	Grand Total	**206**	**47**	**278**	**74%**



Source: Master Case List, 1/1/22 – 3/30/24; OPTN Policies 5/29/24; OPTN Bylaws 3/30/24

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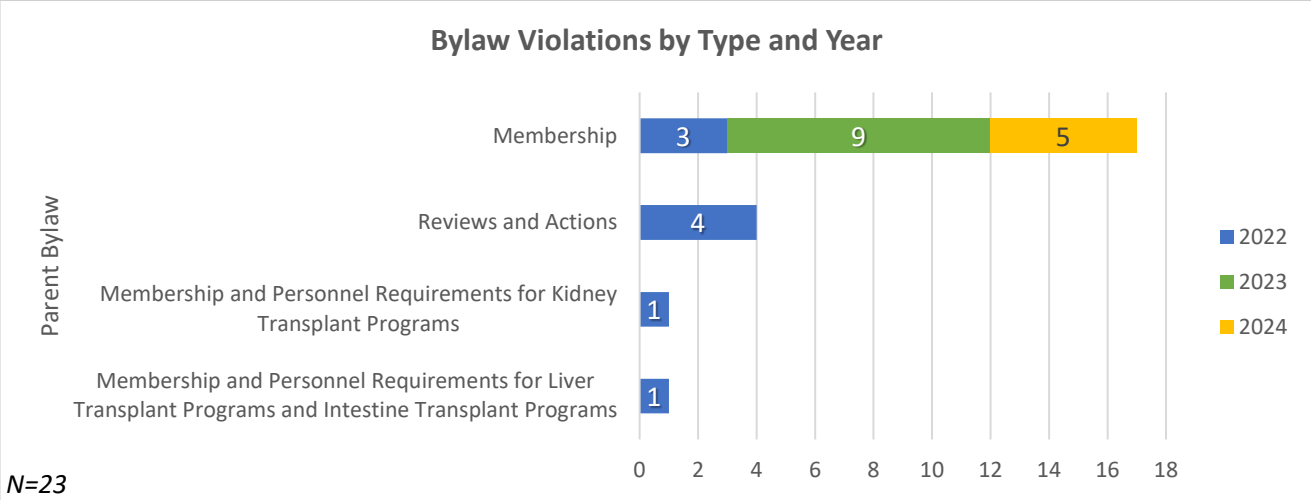
Bylaw Violation & Reporter Type

The data set included both patient safety policy and bylaw violations. From 2022 – 2024 Q1, **23 bylaw violations were identified.** This is not indicative of all OPTN bylaw violations, rather it appears that if a bylaw violation was identified during the patient safety investigation process, it was noted in the MCL. Approximately half of the bylaw violations pertained to Member Compliance. The Member Compliance bylaw states OPTN members agree to comply with OPTN obligations including applicable rules and regulations, acting to avoid risks to patient health or public safety, and fulfilling all requests for information.



Bylaw	Bylaw Violations (2022 – 2024 Q1)	% of Grand Total
Membership	**17**	**74%**
Member Compliance	11	48%
Acting to avoid risks to patient health or public safety	5	22%
Fulfilling all requests for information	1	4%
Reviews and Actions	**4**	**4%**
Investigation of Potential noncompliance with OPTN Obligations	1	4%
Requests to Mitigate Risks	3	13%
Membership and Personnel Requirements for Liver Transplant Programs and Intestine Transplant Programs	**1**	**4%**
Membership and Personnel Requirements for Kidney Transplant Programs	**1**	**4%**
Total	**23**	**100%**

Types of Organizations Reporting and Receiving Bylaw Violations*

	Complaint Subject Member Type				
Complaint Reporter	**TXC**	**OPO**	**Lab**	**Reporter Total**	**% of Grand Total**
OPO	3	3	1	7	**30%**
TXC	6	0	0	6	**26%**
Other UNOS Staff	3	0	0	3	**13%**
Anonymous	3	0	0	3	**13%**
Automated Report	2	0	0	2	**9%**
DT	1	0	0	1	**4%**
Patient/Donor Family	1	0	0	1	**4%**
Grand Total	**19**	**3**	**1**	**23**	**100%**

**Includes self-reports*

Volume of Bylaw Violations that were Self-reported

Reporter Type	Self-Reported	Externally Reported	Total Violations by Reporter Type	% Self-Reported
OPO	3	4	**7**	**43%**
TXC	5	1	**6**	**83%**
Grand Total	**8**	**5**	**13**	**62%**

Source: Master Case List, 1/1/22 – 3/30/24; OPTN Policies 5/29/24; OPTN Bylaws 3/30/24

MPSC Investigations

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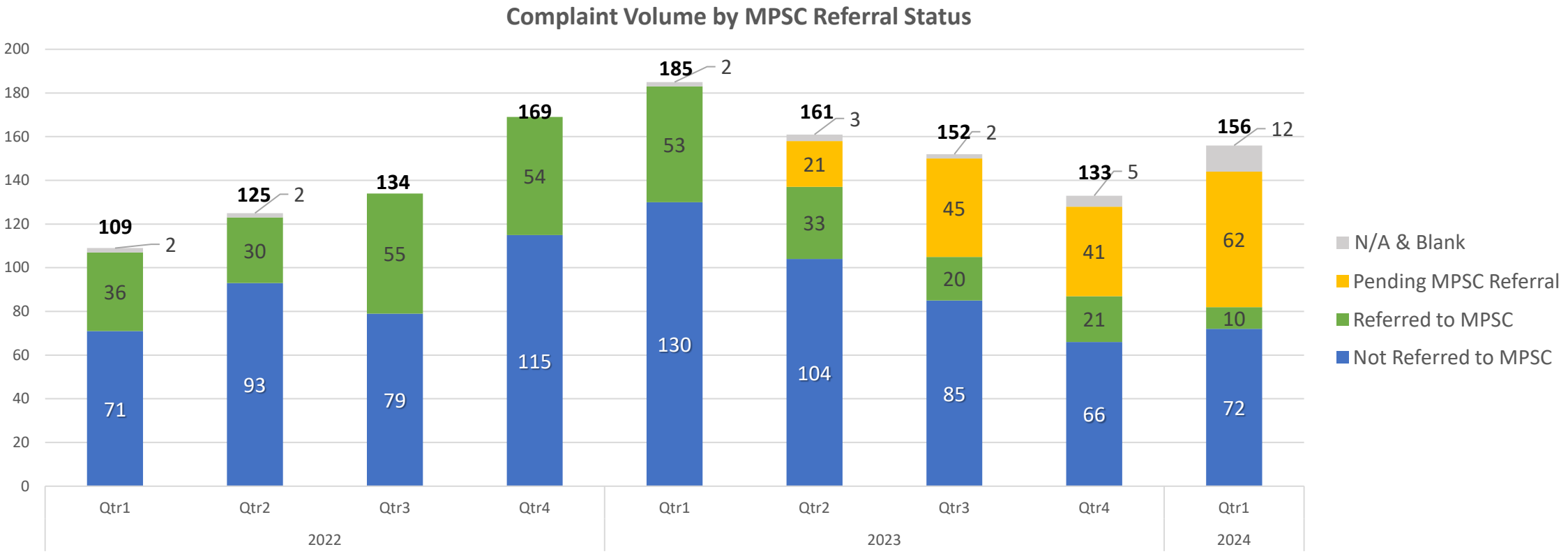
MPSC Performance, Compliance, and Case Activity 2018 - 2023

Between 2022 and 2024 Q1, 312 complaints (24% of total) were referred to MPSC for further investigation and 169 (13% of total) are pending referral to MPSC. Complaints received in 2022 Q3 had the highest MPSC referral rate at 41%. MPSC referral rate was difficult to trend quarter-over-quarter due to the large volume of pending MPSC referrals in 2023. Open cases often have a "pending" status while the Patient Safety Team conducts their investigation. Given investigations can take upwards of one year, it is not surprising to see a high proportion of pending cases beginning in 2023 Q2.



MPSC Referral Rate	33%	24%	**41%**	32%	29%	20%	13%	16%	6%

Source: Master Case List, 1/1/22 – 3/30/24

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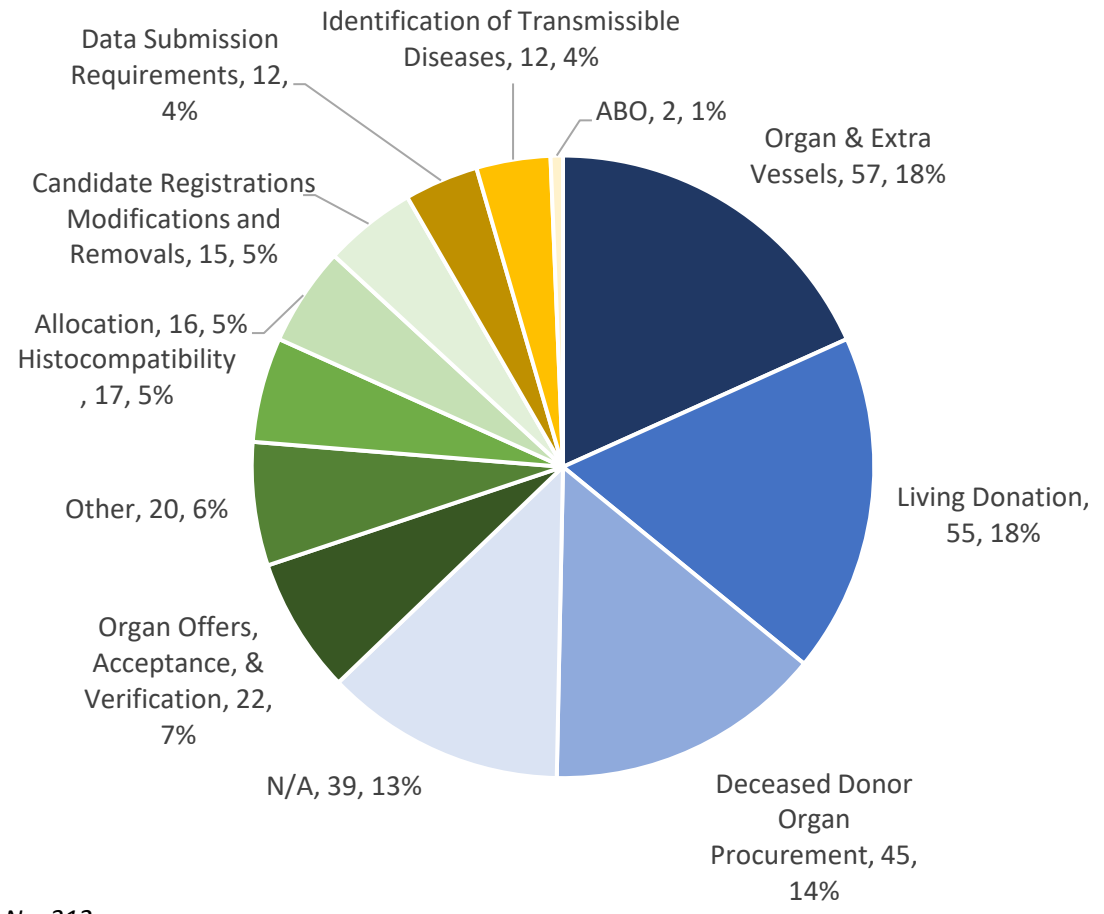
Patient Safety Referrals to MPSC by Primary Classification



312 of the 1,324 complaints (24%) were referred to MPSC for further review. **Almost half of these referrals pertained to organ and extra vessels; living donation; and deceased donor organ procurement.** Living donation complaints have the highest MPSC referral rate, with 63% of complaints being referred for further investigation. Additionally, 94% of complaints referred to MPSC are substantiated.

Primary Classification	Referred to MPSC	Not Referred to MPSC	Pending Referral to MPSC	N/A & Blank	Grand Total	MPSC Referral Rate by Category
ABO	2	4	5	0	11	18%
Allocation	16	63	13	4	96	17%
Candidate Registrations Modifications and Removals	15	58	4	1	78	19%
Data Submission Requirements	12	12	9	0	33	36%
Deceased Donor Organ Procurement	45	100	23	5	173	26%
Histocompatibility	17	15	7	1	40	43%
Identification of Transmissible Diseases	12	132	16	2	162	7%
Living Donation	55	15	17	1	88	**63%**
N/A	39	150		4	193	20%
Organ & Extra Vessels	57	77	41	5	180	32%
Organ Offers, Acceptance, & Verification	22	55	8	2	87	25%
Other	20	134	26	3	183	11%
Grand Total	**312**	**815**	**169**	**28**	**1324**	**24%**
% Substantiated	*94%*	*32%*	*36%*	*11%*	*46%*	-

Source: Master Case List, 1/1/22 – 3/30/24

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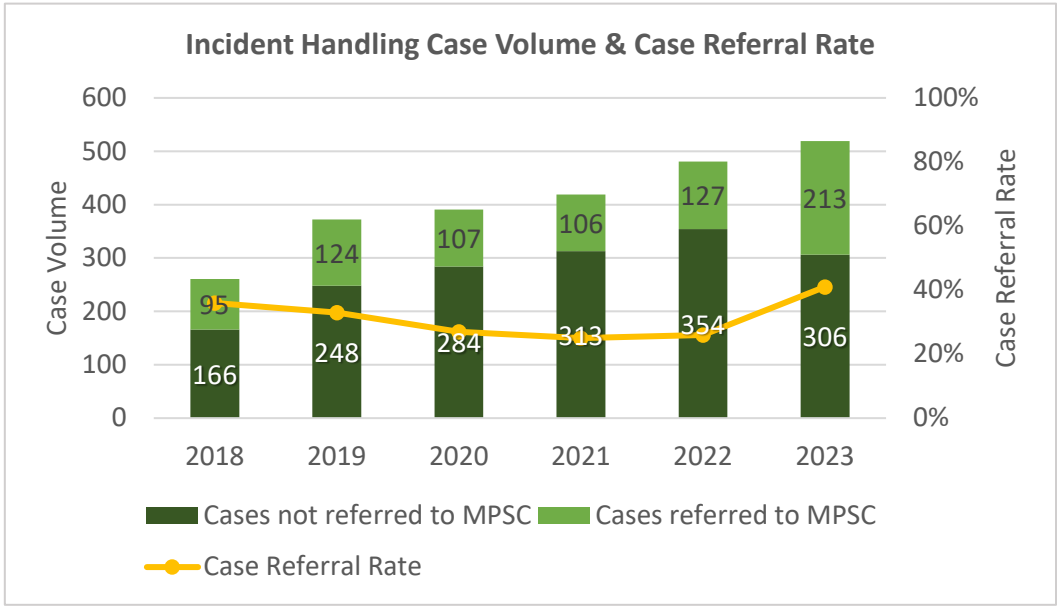
MPSC Performance, Compliance, and Case Activity 2018 - 2023

MPSC performance monitoring is intended to evaluate and review member performance throughout all phases of transplant and identify patient safety issues. Compliance reviews monitor member compliance with OPTN bylaws and policies and provides a framework for MPSC review of potential violations. Both performance and compliance monitoring can identify patient safety issues. It appears 3,706 MPSC compliance and performance reviews occurred from FY 2018 – 2023, while there were 772 incidents reviewed by MPSC. Incidents are reviewed for policy or bylaw violations and risks to patient safety. Per UNOS, "not referred to the MPSC are not violations of OPTN Policies or OPTN Bylaws, and do not include a risk to patient health or public safety."

	Total Reviews	Total Resulting in MPSC Action*	Total Resulting in an Adverse Action Recommendation
2018 FY Total	**859**	**106**	**0**
Performance	294	12	0
Compliance	565	94	0
2019 FY Total	**903**	**127**	**0**
Performance	332	18	0
Compliance	571	109	0
2020 FY Total	**485**	**94**	**0**
Performance	199	13	0
Compliance	286	81	0
2021 FY Total	**489**	**61**	**0**
Performance	281	7	0
Compliance	208	54	0
2022 FY Total	**480**	**83**	**1**
Performance	227	3	0
Compliance	253	80	1
2023 FY Total	**490**	**109**	**0**
Performance	231	8	0
Compliance	259	101	0
Grand Total	**3,706** Performance: 1,564 Compliance: 2,142	**580** Performance: 61 Compliance: 519	**1** Performance: 0 Compliance: 1

**"MPSC Action" includes informal discussions, peer visits, requests to inactivate, Notices of Noncompliance, and Letters of Warning. "Adverse Action Recommendation" includes recommending Probation or Member Not in Good Standing to the Board of Directors.*



Incident Handling Cases Reported by Fiscal Year

	2018	2019	2020	2021	2022	2023	Total
Cases not referred to MPSC	166	248	284	313	354	306	**1,671**
Cases referred to MPSC	95	124	107	106	127	213	**772**
Total Cases	261	372	391	419	481	519	**2,443**
Case referral rate	**36%**	**33%**	**27%**	**25%**	**26%**	**41%**	**32%**

Source: Item 144 Task 3.6.3 OPTN Monitoring Activity Report, FY 2018 – 2023 (10/1/2017 – 9/30/23)

State Data

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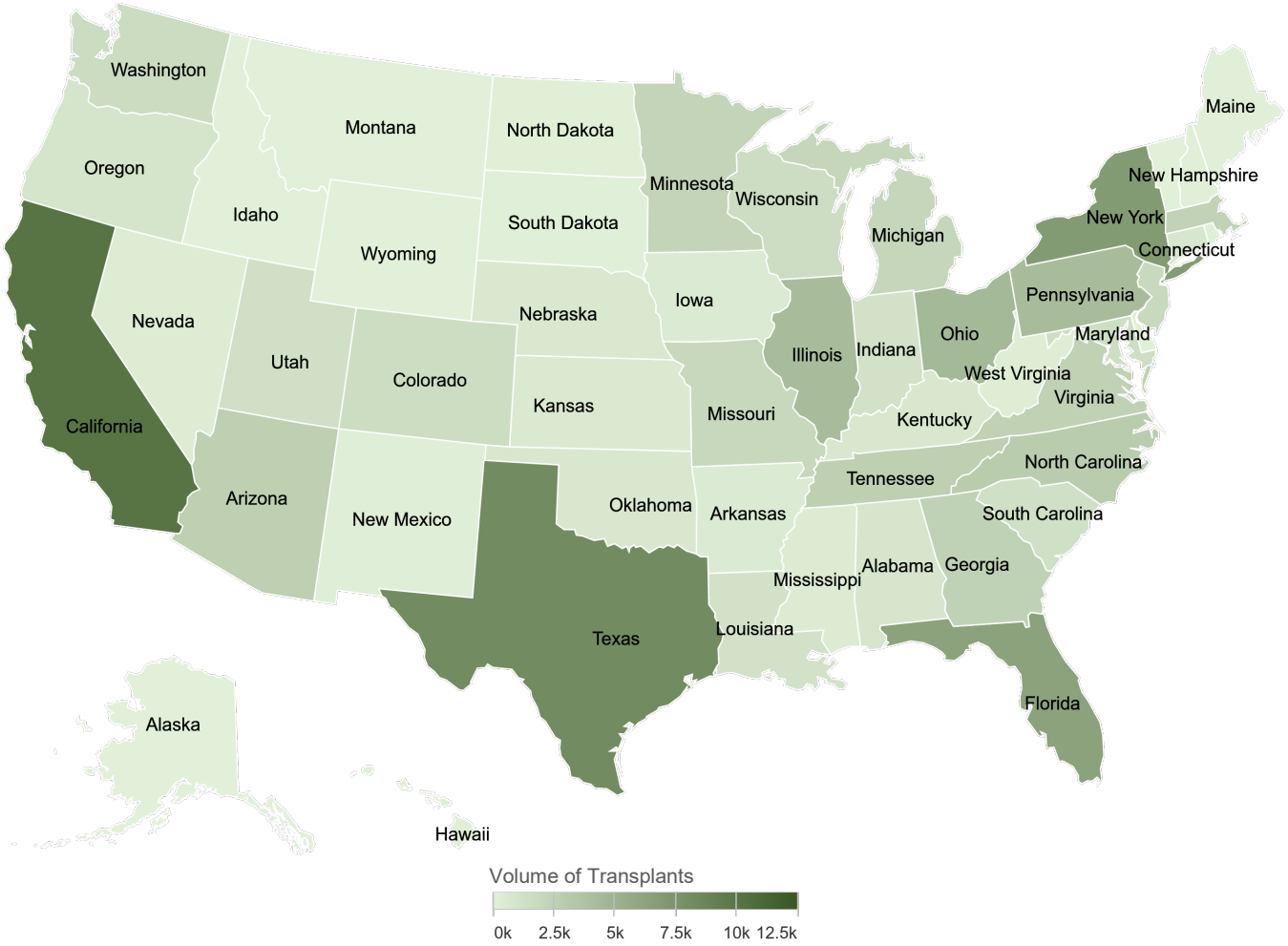
Volume of Transplants Across the United States 2022 - 2023

Between 2022 and 2023, there were **89,519 transplants performed across the United States**. The five states performing the highest volume of transplants include: California (11% of total), Texas (9%), New York (8%), Florida (7%), and Ohio (5%). These **five states cumulatively account for 40% of transplants** performed in the US.



State	Transplants	State	Transplants
AL	894	NE	679
AZ	2,662	NV	317
AR	480	NH	50
CA	10,156	NJ	1,854
CO	1,561	NM	201
CT	781	NY	6,976
DE	94	NC	2,943
DC	1,157	ND	109
FL	6,366	OH	4,524
GA	2,491	OK	762
HI	141	OR	930
IL	4,279	PA	4,234
IN	1,198	PR	219
IA	497	RI	113
KS	539	SC	1,299
KY	749	SD	114
LA	1,188	TN	2,656
ME	86	TX	8,225
MD	1,462	UT	1,353
MA	2,423	VT	22
MI	2,156	VA	2,531
MN	2,256	WA	1,661
MS	400	WV	247
MO	1,963	WI	1,521
Total Transplants in US: 89,519			

Source: OPTN; 2022 – 2023; All Transplants, All Organs; "Transplants by State;" National data - OPTN (hrsa.gov), sourced 6/6/24

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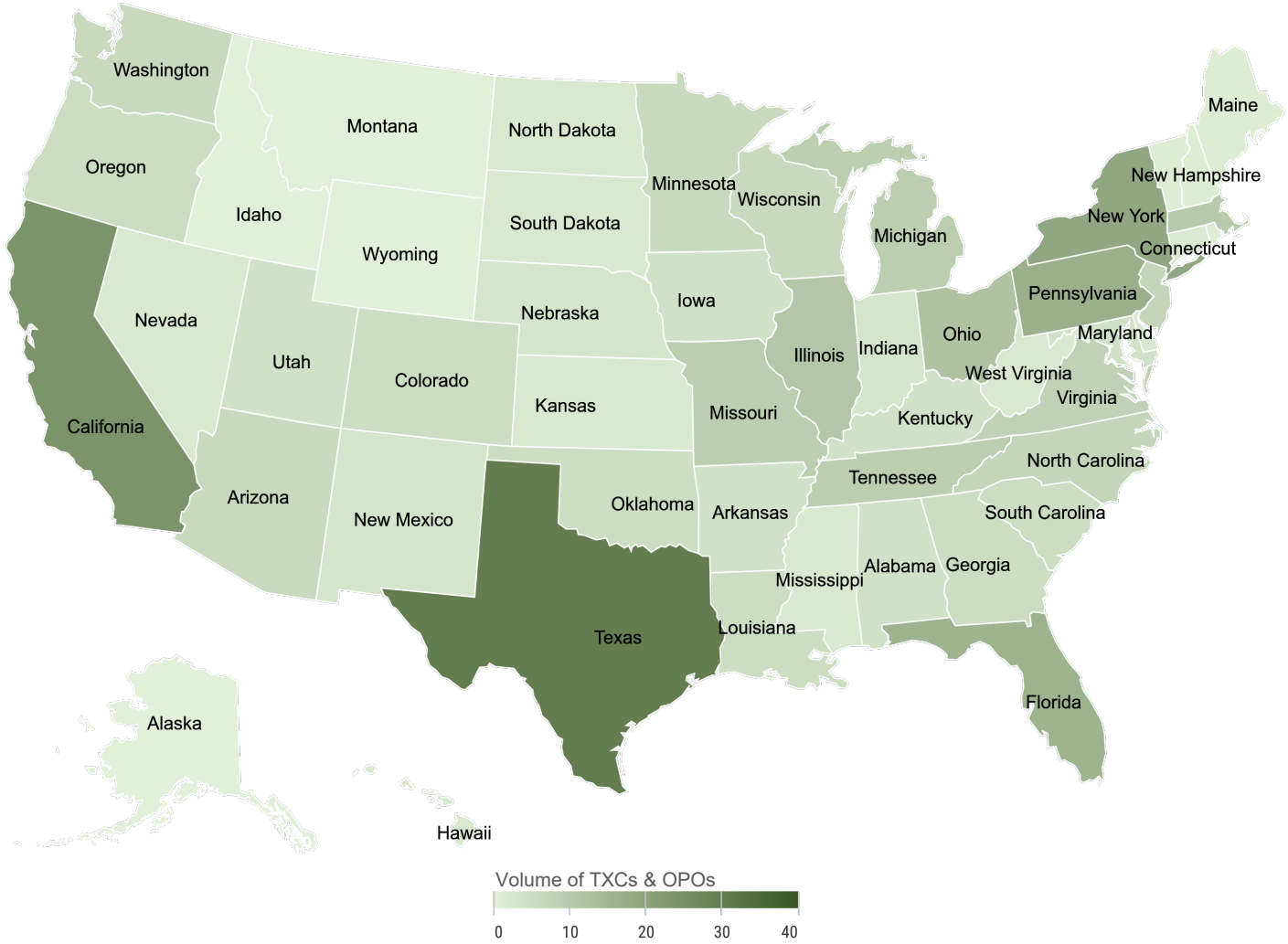
Volume of Transplant Centers & OPOs by State

As of April 4, 2024, there are **304 Transplant Centers and OPOs in the United States**. Five states account for 35% of all OPOs and Transplant Centers in the United States: Texas (10%), California (8%), New York (6%), Pennsylvania (6%), and Florida (5%).



State	TXCs & OPOs	State	TXCs & OPOs
AL	4	NC	7
AR	4	ND	2
AZ	6	NE	3
CA	24	NH	1
CO	5	NJ	7
CT	2	NM	3
DC	4	NV	2
DE	2	NY	19
FL	16	OH	12
GA	5	OK	5
HI	2	OR	5
IA	4	PA	17
IL	11	PR	3
IN	3	RI	1
KS	2	SC	5
KY	4	SD	2
LA	5	TN	9
MA	10	TX	30
MD	4	UT	4
ME	1	VA	8
MI	9	VT	1
MN	6	WA	6
MO	9	WI	6
MS	2	WV	2
Total TXCs & OPOs in US: 304			

Source: OPTN Membership data, 4/4/24

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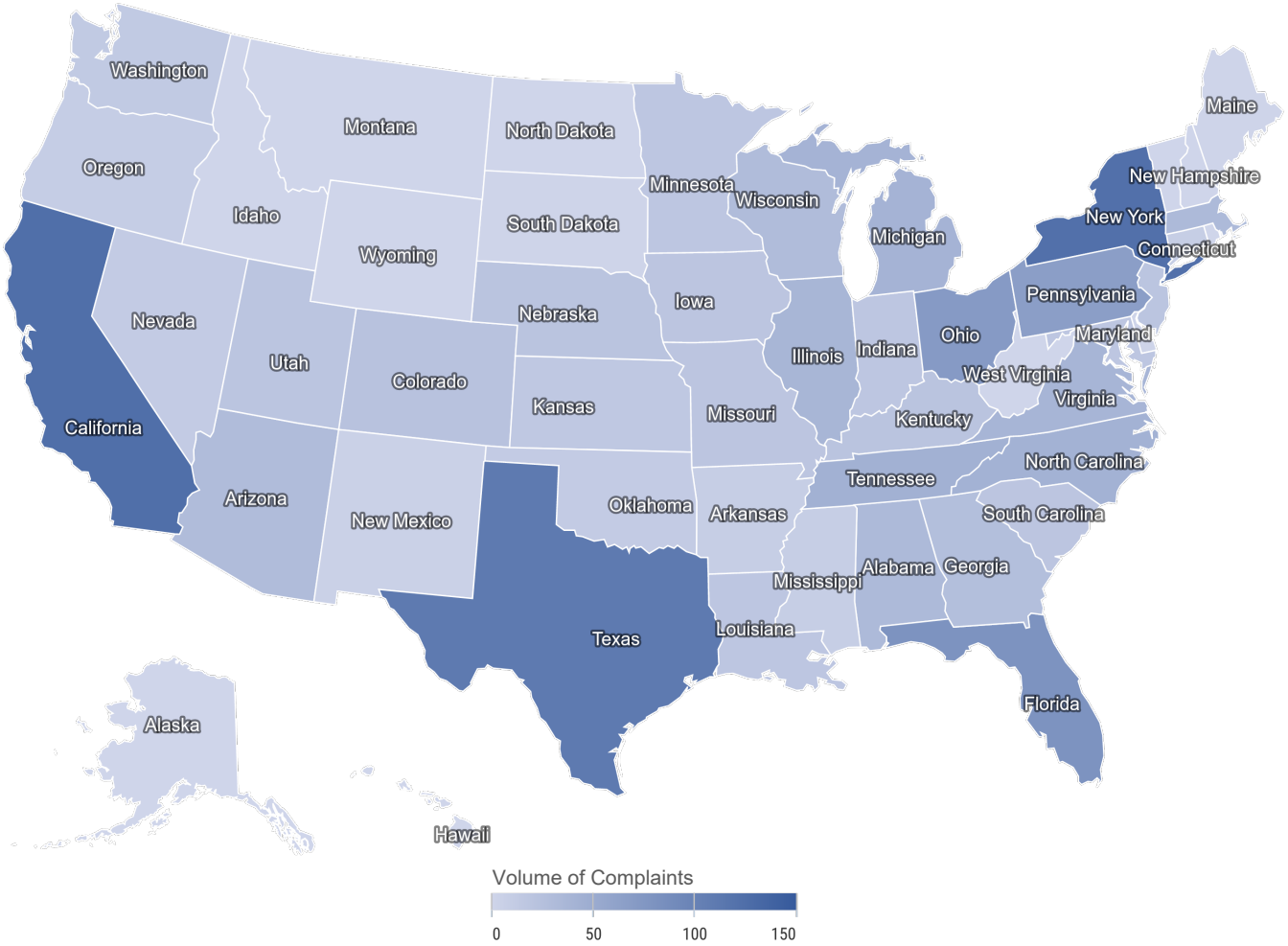
Volume of Complaints by Subject Member State

The top five states whose members had the highest volume of complaints are California (125), New York (123), Texas (111), Florida (80), and Ohio (72). **These five states account for approximately 40% of total complaints in the United States from 1/1/22 – 3/30 2024.** While this is unsurprising given these five states also account for 40% of total transplants, it presents an opportunity to focus resources and provide targeted education relevant to these communities. **A high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting.**



State	Complaints	State	Complaints
AL	33	MO	19
AR	9	MS	9
AZ	30	NC	43
CA	125	NE	21
CO	23	NJ	20
CT	9	NM	5
DC	15	NV	12
DE	1	NY	123
FL	80	OH	72
GA	27	OK	12
IA	19	OR	10
IL	38	PA	67
IN	18	PR	3
KS	16	SC	19
KY	21	SD	1
LA	18	TN	44
MA	33	TX	111
MD	18	UT	20
ME	1	VA	39
MI	41	WA	14
MN	18	WI	30
Total Complaints: 1,287*			

Source: Master Case List, 1/1/22 – 3/30/24

**Excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*

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Complaint Rate by State

To account for volume of transplants by state, a complaint rate was calculated by dividing the state complaint volume by the state transplant volume. **The national complaint rate is 1.3%.** Six states had a complaint rate greater than 2.5%: Alabama (3.4%), Iowa (3%), Kansas (2.8%), Nevada (2.8%), Kentucky (2.7%), and Nebraska (2.7%).

State	Complaints* (2022 – 2023)	State Transplants (2022 – 2023)	Complaint Rate (Complaints/ Transplant Volume)	State	Complaints* (2022 – 2023)	State Transplants (2022 – 2023)	Complaint Rate (Complaints/ Transplant Volume)
AL	30	894	3.4%	NC	34	2,943	1.2%
AR	8	480	1.7%	ND	0	109	0.0%
AZ	28	2,662	1.1%	NE	18	679	2.7%
CA	113	10,156	1.1%	NH	0	50	0.0%
CO	22	1,561	1.4%	NJ	19	1,854	1.0%
CT	9	781	1.2%	NM	4	201	2.0%
DC	15	1,157	1.3%	NV	9	317	2.8%
DE	1	94	1.1%	NY	107	6,976	1.5%
FL	73	6,366	1.1%	OH	59	4,524	1.3%
GA	20	2,491	0.8%	OK	11	762	1.4%
HI	0	141	0.0%	OR	9	930	1.0%
IA	15	497	3.0%	PA	64	4,234	1.5%
IL	36	4,279	0.8%	PR	3	219	1.4%
IN	18	1,198	1.5%	RI	0	113	0.0%
KS	15	539	2.8%	SC	15	1,299	1.2%
KY	20	749	2.7%	SD	1	114	0.9%
LA	15	1,188	1.3%	TN	37	2,656	1.4%
MA	28	2,423	1.2%	TX	101	8,225	1.2%
MD	16	1,462	1.1%	UT	17	1,353	1.3%
ME	1	86	1.2%	VA	36	2,531	1.4%
MI	34	2,156	1.6%	VT	0	22	0.0%
MN	13	2,256	0.6%	WA	14	1,661	0.8%
MO	16	1,963	0.8%	WI	26	1,521	1.7%
MS	8	400	2.0%	WV	0	247	0.0%
				Total	**1,138**	**89,519**	**1.3%**

**Excludes 10 complaints pertaining to multiple states and 20 records where the subject member did not have an associated state*

Source: Master Case List, 1/1/22 – 3/30/24

OPTN; 2022 – 2023; All Transplants, All Organs; "Transplants by State;" National data - OPTN (hrsa.gov), sourced 6/6/24

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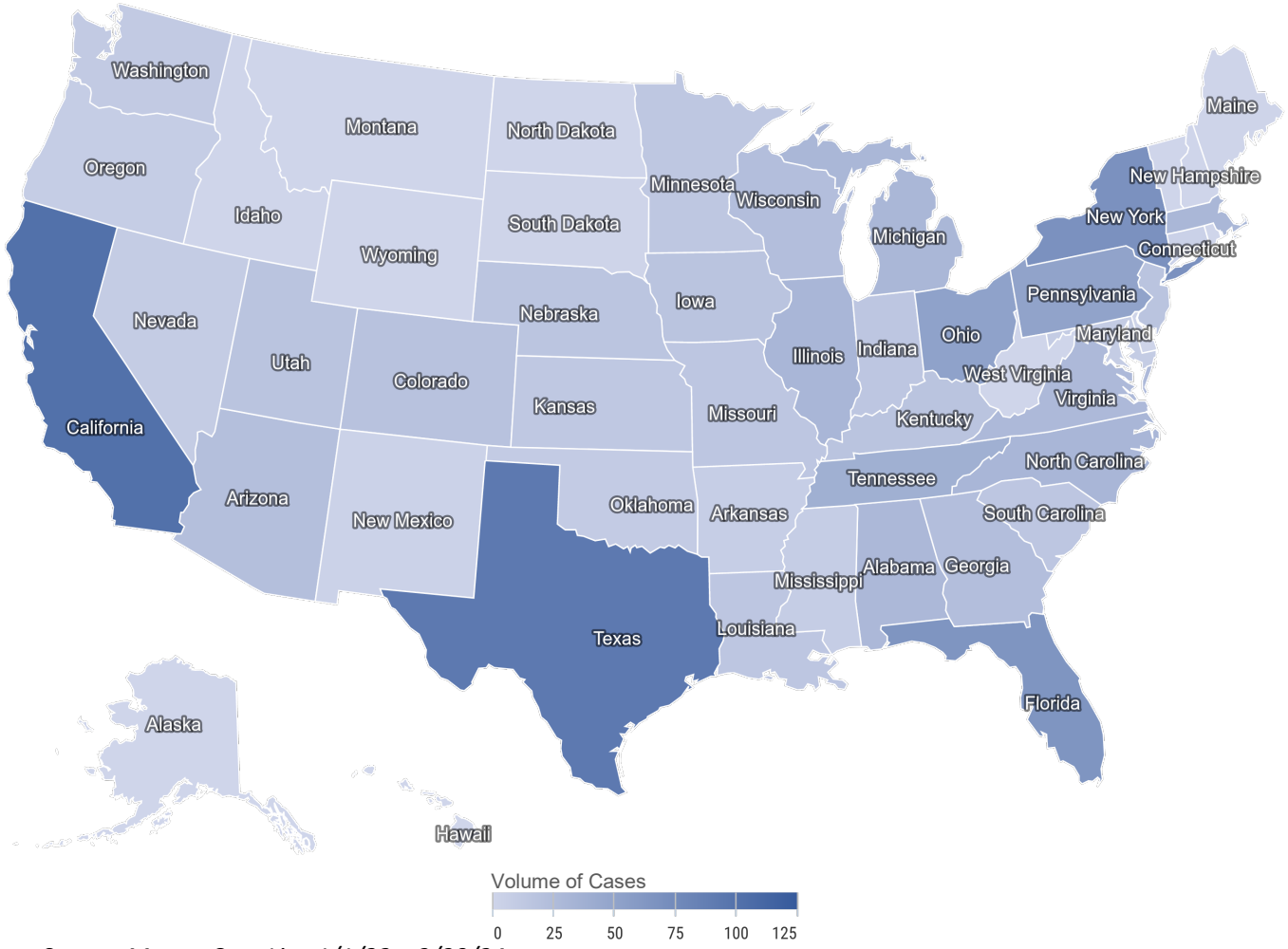
Volume of Cases by Subject Member State

California (102), Texas (93), New York (69), Florida (65), and Ohio (52) are also the top five states with the highest number of patient safety cases. **These five states account for 38% of total cases across the United States & Puerto Rico** from 1/1/22 – 3/30/24.



State	Cases	State	Cases
AL	29	MO	15
AR	7	MS	8
AZ	22	NC	31
CA	102	NE	16
CO	19	NJ	17
CT	4	NM	3
DC	12	NV	9
DE	1	NY	69
FL	65	OH	52
GA	23	OK	10
IA	17	OR	8
IL	31	PA	51
IN	15	PR	3
KS	13	SC	15
KY	17	SD	1
LA	15	TN	38
MA	30	TX	93
MD	9	UT	17
ME	1	VA	28
MI	30	WA	11
MN	14	WI	23
Total Cases: 994*			

Source: Master Case List, 1/1/22 – 3/30/24

**Excludes 8 cases pertaining to multiple states and 5 records where the subject member did not have an associated state*

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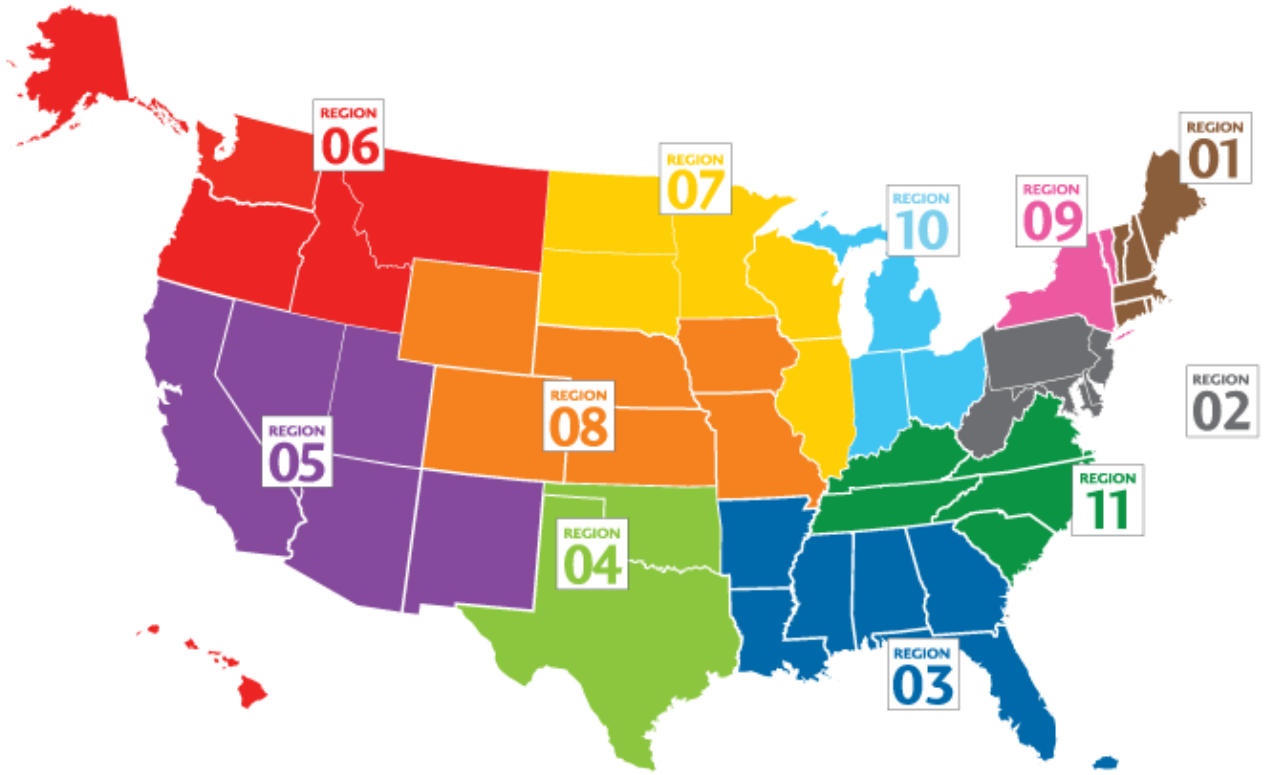
Volume by Region

When consolidating state-level data into UNOS-defined regions, Region 5 had the highest volume of transplants between 2022 and 2023. This region also had one of the largest number of transplant centers and OPOs. **Region 8 reported the highest complaint rate at 1.6%** (calculated by dividing the total number of complaints from members in the region by the total regional transplant volume). The state of Virginia spans two regions (2 and 11), but due to limitations in the national transplant dataset, its data could not be separated by region. Consequently, Virginia's transplant volume was attributed to Region 11, where the majority of its transplant centers and OPOs are located.



Region	Transplant Volume (22-23)	Transplant Centers & OPOs	Complaints by Region Subject Member (22-23)	Complaint Rate (Complaints/ Transplant Volume)
1	3,453	15	38	1.1%
2*	9,048	37	115	1.3%
3	12,038	**39**	157	1.3%
4	8,987	35	112	1.2%
5	**14,689**	**39**	**171**	1.2%
6	2,732	13	23	0.8%
7	8,279	27	76	0.9%
8	5,239	23	86	**1.6%**
9	6,998	20	107	1.5%
10	7,878	24	111	1.4%
11*	10,178	32	142	1.4%
Grand Total	**89,519**	**304**	**1,138**	**1.3%**

**Virginia transplants attributed to region 11 due to the structure of the national transplant data file*

Source: UNOS, Regions: UNOS Regions | Organ Transplant Regional Resources, 6/17/24; Master Case List, 1/1/22 – 3/30/24; OPTN; 2022 – 2023; All Transplants, All Organs; "Transplants by State;" National data - OPTN (hrsa.gov), sourced 6/6/24

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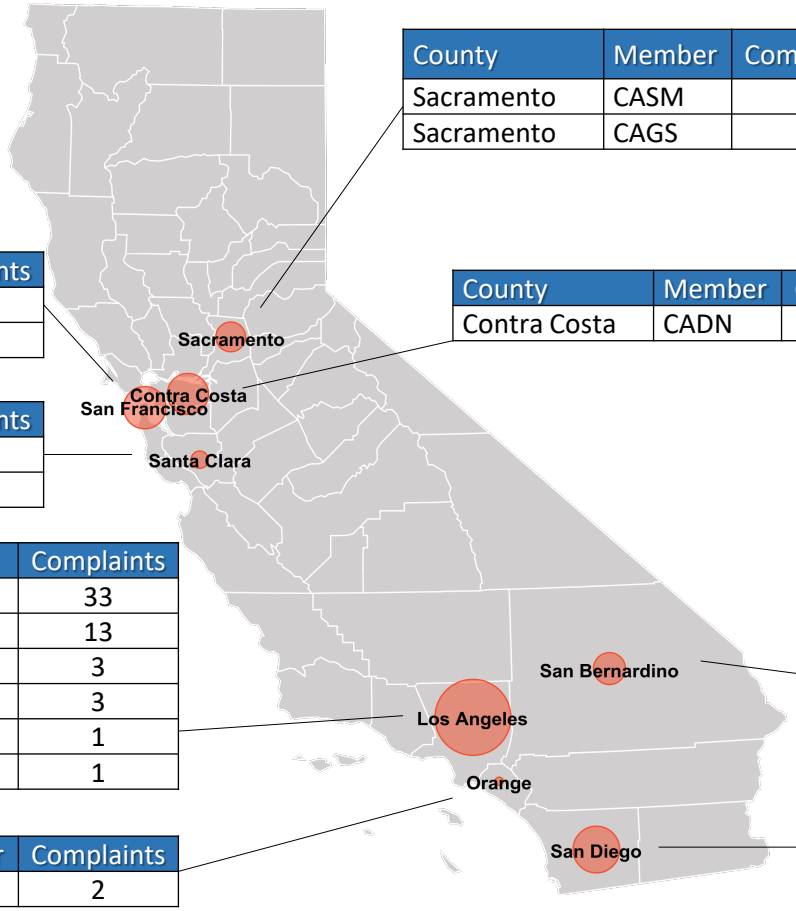
Complaints by Subject Member (OPO/TXC/Lab) - California

Of the 1,287* complaints received from 2022 - 2024 Q1, 10% (125) pertained to OPTN members in the state of California. Approximately half of these complaints related to deceased donor organ procurement (22%), identification of transmissible diseases (14%), and candidate registrations, modifications, and removals (11%). The OPO OneLegacy (CAOP) had the highest volume of complaints of all California members (26%). Approximately half of CAOP's complaints pertained to deceased donor organ procurement. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Sacramento	CASM	2
Sacramento	CAGS	5

County	Member	Complaints
San Francisco	CASF	13
San Francisco	CAPM	2

County	Member	Complaints
Contra Costa	CADN	14

County	Member	Complaints
Santa Clara	CASU	2
Santa Clara	CAPC	1

County	Member	Complaints
Los Angeles	CAOP	33
Los Angeles	CAUC	13
Los Angeles	CAUH	3
Los Angeles	CACS	3
Los Angeles	CANI	1
Los Angeles	CATL	1

County	Member	Complaints
San Bernadino	CALL	8

County	Member	Complaints
Orange	CAIM	2

County	Member	Complaints
San Diego	CASD	14
San Diego	CASH	4
San Diego	CACH	1

Primary Complaint Classification	TXC	OPO	N/A	Grand Total
Deceased Donor Organ Procurement	10	17	0	**27**
Identification of Transmissible Diseases	14	3	1	**18**
Candidate Registrations, Modifications, and Removals	13	1	0	**14**
Organ & Extra Vessels	3	9	1	**13**
Allocation	2	6	2	**11**
N/A	1	2	8	**11**
Other	8	3	0	**11**
Organ Offers, Acceptance, & Verification	5	5	0	**10**
Living Donation	4	1	2	**7**
Histocompatibility	0	2	0	**2**
ABO	1	0	0	**1**
Grand Total	**61**	**49**	**14**	**125**

Map excludes two multi-county CA records and one CA record where the subject member code is not valid
**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

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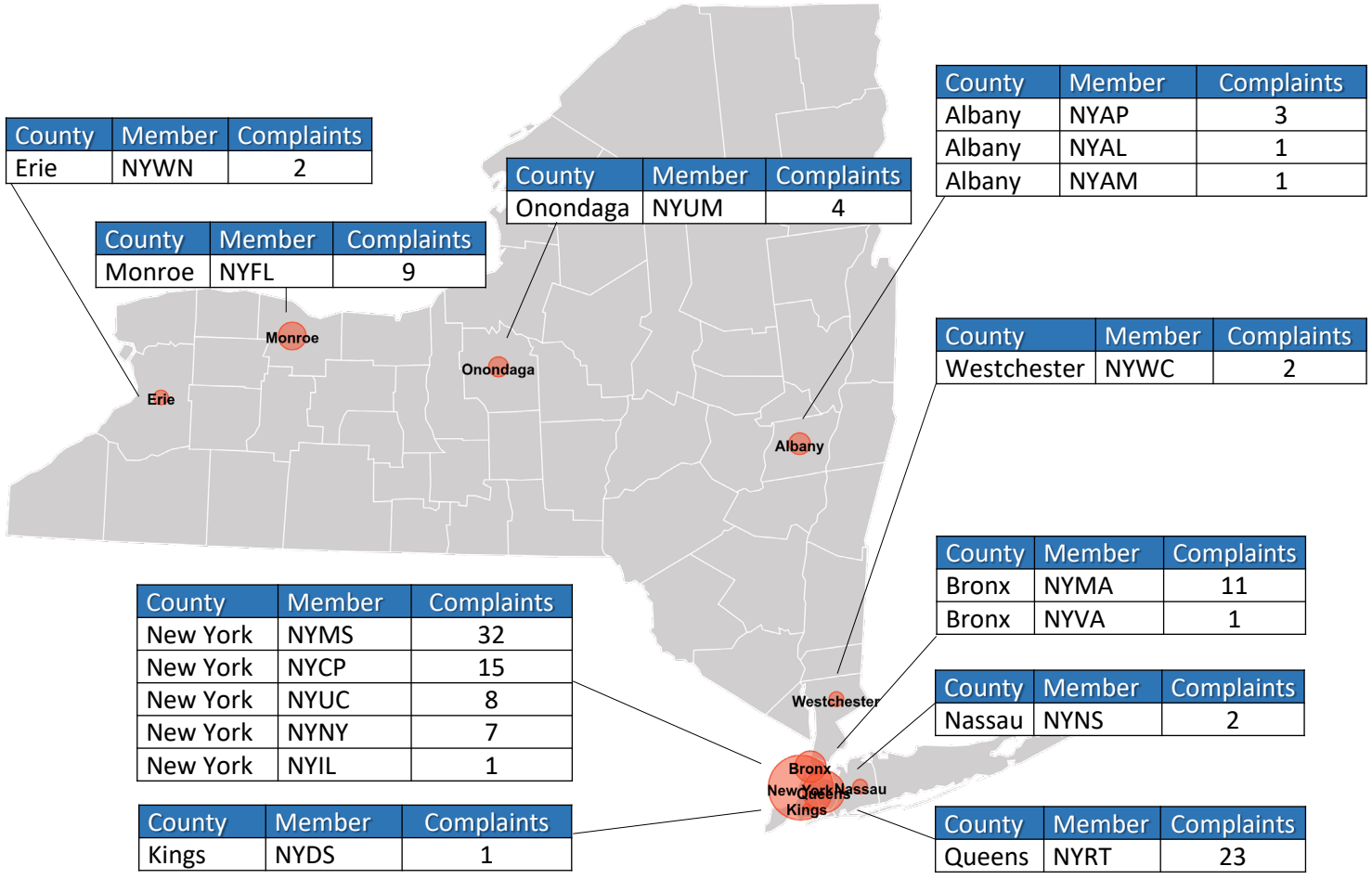
Complaints by Subject Member (OPO/TXC/Lab) – New York

Of the 1,287* complaints received from 2022 - 2024 Q1, 10% (123) pertained to OPTN members in the state of New York. Approximately two-thirds of complaints pertain to identification of transmissible diseases (32%), "other" (14%), and deceased donor organ procurement (11%). Mount Sinai Medical Center (NYMS) had the highest volume of complaints of all New York members (26%), with 70% of NYMS' complaints pertaining to the identification of transmissible diseases. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Erie	NYWN	2

County	Member	Complaints
Monroe	NYFL	9

County	Member	Complaints
Onondaga	NYUM	4

County	Member	Complaints
Albany	NYAP	3
Albany	NYAL	1
Albany	NYAM	1

County	Member	Complaints
Westchester	NYWC	2

County	Member	Complaints
New York	NYMS	32
New York	NYCP	15
New York	NYUC	8
New York	NYNY	7
New York	NYIL	1

County	Member	Complaints
Bronx	NYMA	11
Bronx	NYVA	1

County	Member	Complaints
Nassau	NYNS	2

County	Member	Complaints
Kings	NYDS	1

County	Member	Complaints
Queens	NYRT	23

Primary Complaint Classification	TXC	OPO	Lab	N/A	Grand Total
Identification of Transmissible Diseases	39	0	0	0	**39**
Other	9	7	1	0	**17**
Deceased Donor Organ Procurement	7	6	0	0	**13**
N/A	0	0	1	11	**12**
Living Donation	4	0	0	4	**8**
Allocation	1	6	0	1	**8**
Candidate Registrations Modifications and Removals	6	1	0	0	**7**
Organ & Extra Vessels	6	0	0	0	**6**
Histocompatibility	1	3	1	0	**5**
Data Submission Requirements	3	0	0	0	**3**
Organ Offers, Acceptance, & Verification	2	1	0	0	**3**
DTAC	1	0	0	1	**2**
Grand Total	**79**	**24**	**3**	**17**	**123**

**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

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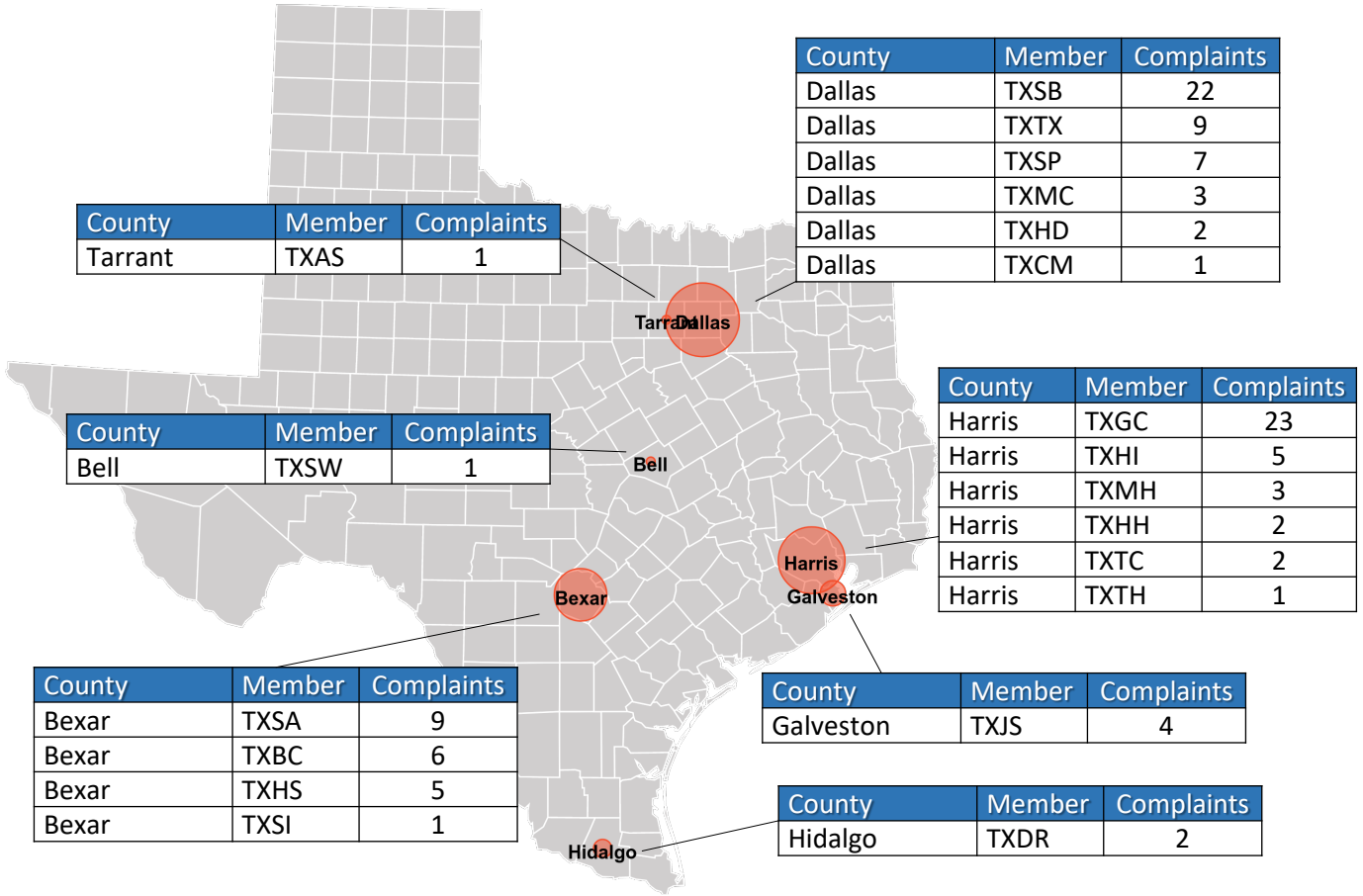
Complaints by Subject Member (OPO/TXC/Lab) - Texas

Of the 1,287* complaints received from 2022 - 2024 Q1, 9% (111) pertained to OPTN members in the state of Texas. Approximately half of complaints were classified as "other" (19%), "N/A" (17%), and Organ & Extra Vessels (16%). Complaints classified as "other" are commonly member-specific and generally do not fall into pre-defined categories. Four of the 21 "other" complaints pertained to member or staffing culture. The OPO LifeGift Organ Donation Center (TXGC) had the highest volume of complaints (21%). Approximately half of TXGC's complaints pertained to organ and extra vessels and organ offers, acceptance, and verification. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Tarrant	TXAS	1

County	Member	Complaints
Dallas	TXSB	22
Dallas	TXTX	9
Dallas	TXSP	7
Dallas	TXMC	3
Dallas	TXHD	2
Dallas	TXCM	1

County	Member	Complaints
Bell	TXSW	1

County	Member	Complaints
Harris	TXGC	23
Harris	TXHI	5
Harris	TXMH	3
Harris	TXHH	2
Harris	TXTC	2
Harris	TXTH	1

County	Member	Complaints
Bexar	TXSA	9
Bexar	TXBC	6
Bexar	TXHS	5
Bexar	TXSI	1

County	Member	Complaints
Galveston	TXJS	4

County	Member	Complaints
Hidalgo	TXDR	2

Primary Complaint Classification	TXC	OPO	Lab	Non-Member	N/A	Grand Total
Other	6	11	2	2		**21**
N/A	1		0	0	18	**19**
Organ & Extra Vessels	7	9	0	0	2	**18**
Identification of Transmissible Diseases	11	4	0	0	0	**15**
Organ Offers, Acceptance, & Verification	3	6	0	0	0	**9**
Deceased Donor Organ Procurement	2	7	0	0	0	**9**
Allocation	2	3	0	0	1	**6**
Living Donation	4		0	0	1	**5**
Candidate Registrations Modifications and Removals	4	1	0	0	0	**5**
Histocompatibility	1	1	0	0	0	**2**
Data Submission Requirements		1	0	0	0	**1**
DTAC	1	0	0	0	0	**1**
Grand Total	**42**	**43**	**2**	**2**	**22**	**111**

Map excludes one multi-county record and one TX record where the subject member code is not listed in the OPTN member directory
**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

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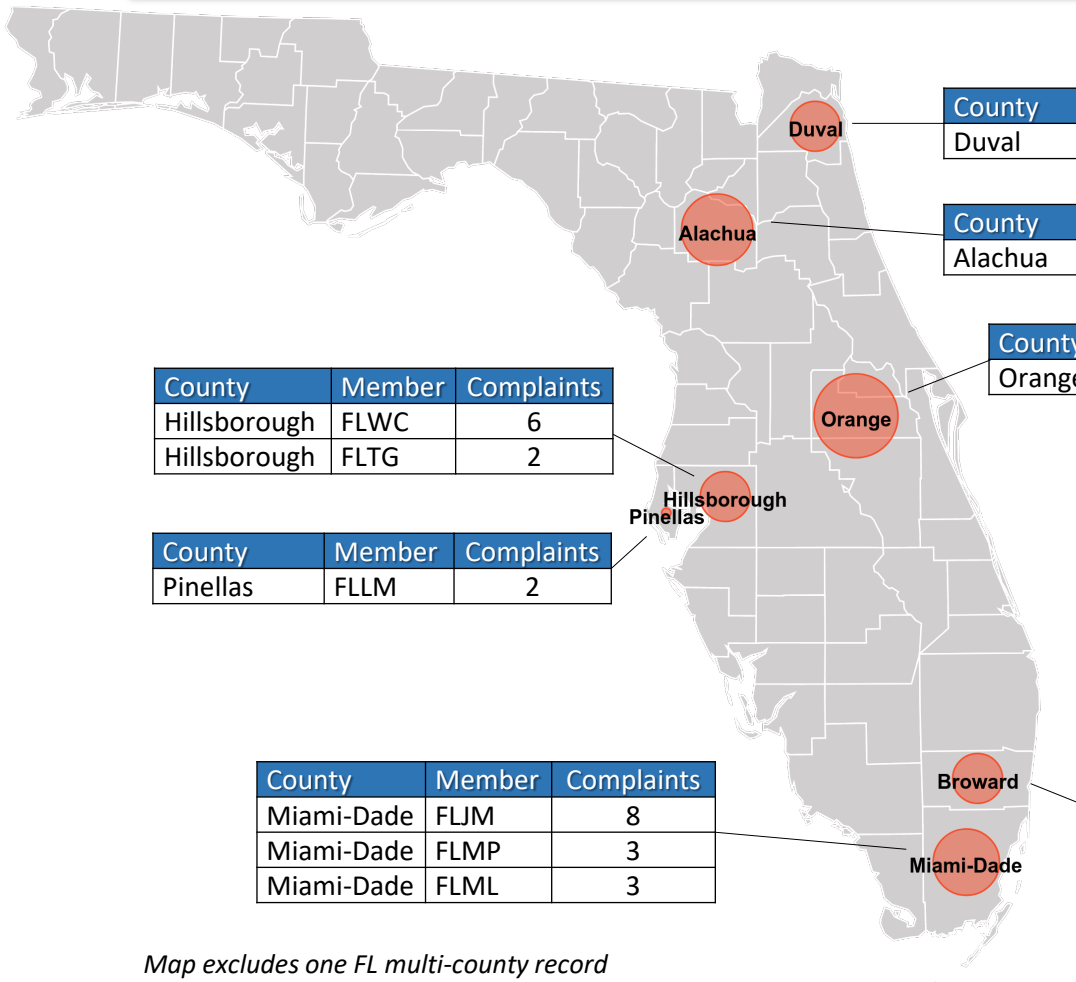
Complaints by Subject Member (OPO/TXC/Lab) - Florida

Of the 1,287* complaints received from 2022 - 2024 Q1, 6% (80) pertained to OPTN members in the state of Florida. Half of complaints were classified as "other" (19%), organ & extra vessels (18%), and deceased donor organ procurement (14%). Member FLFH had the highest volume of complaints in Florida (29%); FLFH operates as a transplant center (AdventHealth Orlando), an OPO (OurLegacy), and a histocompatibility lab (Tissue Typing Lab at Florida Hospital). Ten of the 23 FLFH complaints pertained to deceased donor organ procurement and organ and extra vessels. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Duval	FLSL	8

County	Member	Complaints
Alachua	FLUF	16

County	Member	Complaints
Orange	FLFH	23

County	Member	Complaints
Hillsborough	FLWC	6
Hillsborough	FLTG	2

County	Member	Complaints
Pinellas	FLLM	2

County	Member	Complaints
Miami-Dade	FLJM	8
Miami-Dade	FLMP	3
Miami-Dade	FLML	3

County	Member	Complaints
Broward	FLCC	4
Broward	FLMR	3
Broward	FLBC	1

Primary Complaint Classification	TXC	OPO	Lab	N/A	Grand Total
Other	9	6	0	0	**15**
Organ & Extra Vessels	4	8	0	2	**14**
Deceased Donor Organ Procurement	2	9	0	0	**11**
N/A	0	0	0	10	**10**
Identification of Transmissible Diseases	3	4	0	0	**7**
Candidate Registrations Modifications and Removals	5	1	0	0	**6**
Organ Offers, Acceptance, & Verification	2	2	0	0	**4**
Living Donation	3	0	0	1	**4**
Histocompatibility	0	0	3	0	**3**
Allocation	0	3	0	0	**3**
Data Submission Requirements	1	2	0	0	**3**
Grand Total	**29**	**35**	**3**	**13**	**80**

Map excludes one FL multi-county record
**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

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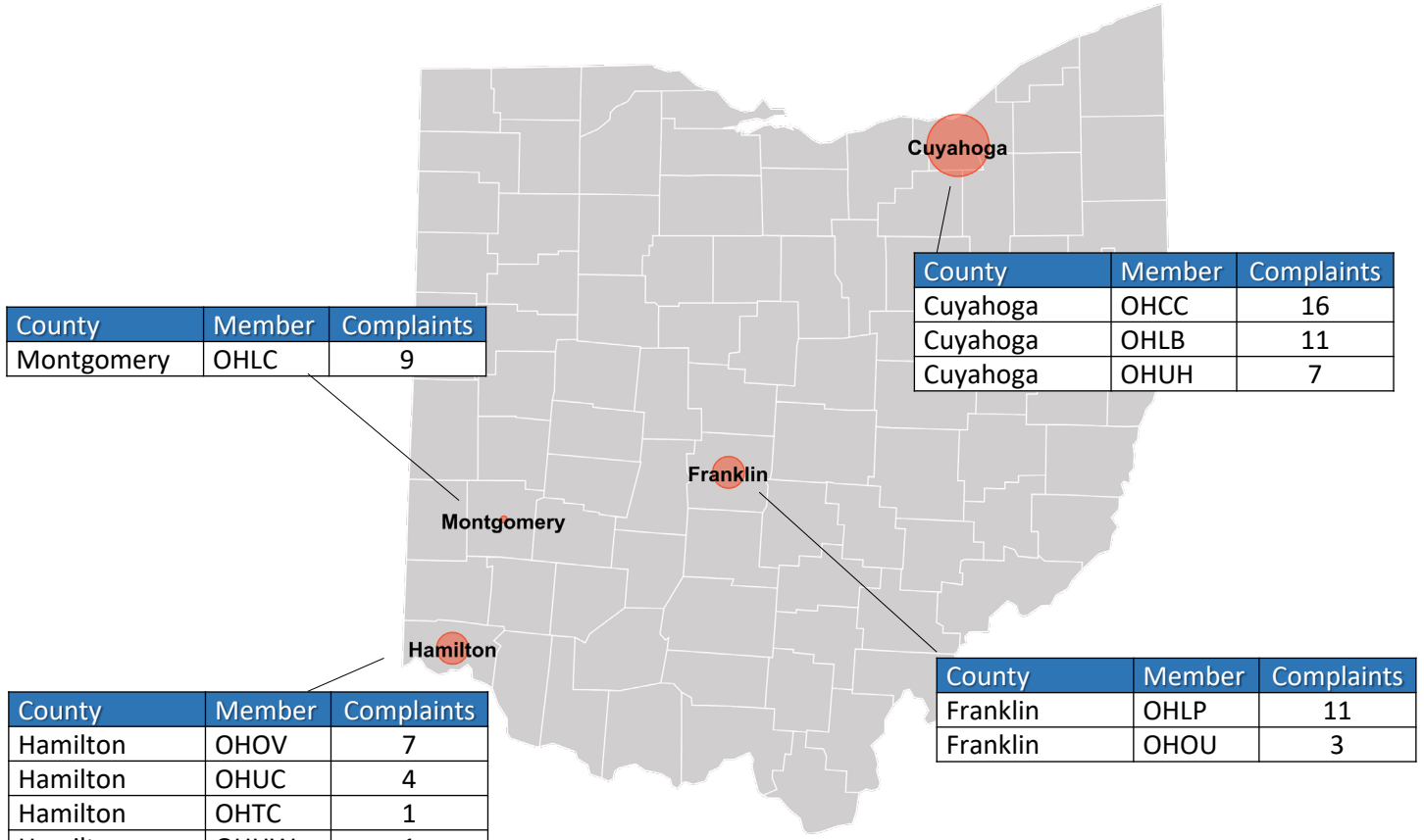
Complaints by Subject Member (OPO/TXC/Lab) - Ohio

Of the 1,287* complaints received from 2022 - 2024 Q1, 6% (72) pertained to OPTN members in the state of Ohio. Approximately half of complaints were classified as identification of transmissible diseases (15%), "N/A" (14%), deceased donor organ procurement (14%), and allocation (11%). The Cleveland Clinic (OHCC) had the highest volume of complaints in Ohio (22%). 70% of OHCC's complaints pertained to identification of transmissible diseases and candidate registrations, modifications, and removals. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Cuyahoga	OHCC	16
Cuyahoga	OHLB	11
Cuyahoga	OHUH	7

County	Member	Complaints
Montgomery	OHLC	9

County	Member	Complaints
Franklin	OHLP	11
Franklin	OHOU	3

County	Member	Complaints
Hamilton	OHOV	7
Hamilton	OHUC	4
Hamilton	OHTC	1
Hamilton	OHHW	1
Hamilton	OHCM	1

Primary Complaint Classification	TXC	OPO	Lab	N/A	Grand Total
Identification of Transmissible Diseases	8	2	0	1	**11**
N/A	0	1	0	9	**10**
Deceased Donor Organ Procurement	2	8	0	0	**10**
Allocation	2	6	0	0	**8**
Organ & Extra Vessels	4	3	0	0	**7**
Candidate Registrations Modifications and Removals	5	1	0	0	**6**
Organ Offers, Acceptance, & Verification	2	4	0	0	**6**
Other	2	3	0	0	**5**
Living Donation	3	0	0	1	**4**
Data Submission Requirements	2	0	0	0	**2**
ABO	1	1	0	0	**2**
Histocompatibility	0	0	1	0	**1**
Grand Total	**31**	**29**	**1**	**11**	**72**

Map excludes on multi-county record
**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

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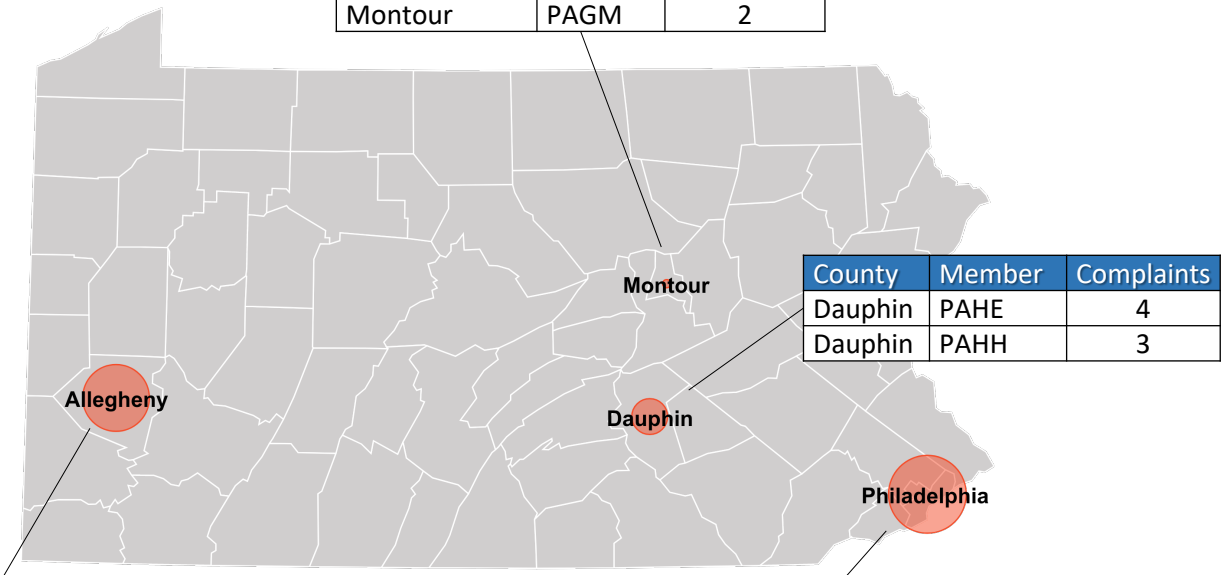
Complaints by Subject Member (OPO/TXC/Lab) - Pennsylvania

Of the 1,287* complaints received from 2022 - 2024 Q1, 5% (67) pertained to OPTN members in the state of Pennsylvania. Over half of complaints were categorized as allocation (15%), deceased donor organ procurement (13%), organ and extra vessels (13%), and "N/A" (13%). The OPO Gift of Life Donor Program (PADV) accounted for 1/3 of complaints in Pennsylvania. 68% of PADV's complaints pertained to allocation; organ offers, acceptance, and verification; and deceased donor organ procurement. However, a high volume of patient safety complaints is not necessarily a negative indicator; it can indicate a member fosters a culture of transparency and safety reporting or a member manages a higher proportion of the population.



County	Member	Complaints
Montour	PAGM	2

County	Member	Complaints
Dauphin	PAHE	4
Dauphin	PAHH	3

County	Member	Complaints
Allegheny	PATF	14
Allegheny	PAAG	5
Allegheny	PAPT	5

County	Member	Complaints
Philadelphia	PADV	22
Philadelphia	PAUP	4
Philadelphia	PATU	3
Philadelphia	PATJ	2
Philadelphia	PALN	2
Philadelphia	PACP	1

Primary Complaint Classification	TXC	OPO	Lab	N/A	Grand Total
Allocation	1	9	0	0	10
Deceased Donor Organ Procurement	2	7	0	0	9
Organ & Extra Vessels	1	6	0	2	9
N/A	1	2	0	6	9
Organ Offers, Acceptance, & Verification	0	7	0	0	7
Other	6	0	0	1	7
Identification of Transmissible Diseases	4	3	0	0	7
Histocompatibility	0	1	4	0	5
Living Donation	2	0	0	0	2
Candidate Registrations Modifications and Removals	1	0	0	0	1
Data Submission Requirements	0	0	1	0	1
Grand Total	**18**	**35**	**5**	**9**	**67**

**Total volume excludes 10 complaints pertaining to multiple states and 27 records where the subject member did not have an associated state*
Source: Master Case List, 1/1/22 – 3/30/24

Next Steps

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Next Steps

01

Perform analyses on additional three-year data request (2019 - 2021) in subsequent Task Order work

02

Identify desired data transparency and data needs from contractor(s)

03

Determine cadence of future, routine data updates

04

Identify HRSA and contractor resources to own data initiatives

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Master Case List Validation Methodology

Step	Pertains to Open/ Closed Complaint File(s)	Validation Step Process	Validation Findings
1	Closed complaints	Validate fields are the same between: • Original 2022 – 2024 closed complaint MCL • Updated 2022 – 2024 closed complaint MCL • 2023 – 2024 open case files	• Fields are the same, with the addition of a "Data Notes" field added to the updated version (field is last column; does not disrupt order of columns) • Verified updated 2022 version fields match updated 2023-current version fields
2	Closed complaints	Combine records from 2022 and updated 2023-current files, resulting in one updated comprehensive "closed" complaint file	• Consolidated into one file titled "Revised Closed Consolidated"; incorporates all updated closed complaints from 2022 to current
3	Closed complaints	• Compare volume of 2022 complaints from the original 2022 closed complaint MCL file and the updated 2022 closed complaint MCL file. Evaluate new/removed records • Compare volume of 2023 – 2024 records from the original 2023 – current closed complaint MCL file and the updated 2023 – current closed complaint MCL file; evaluate new/removed records	• Identified one additional record added to the updated 2022 closed complaint MCL (#491); this record was not included in the original 2022 MCL • Identified two additional records added to the updated 2023 closed complaint MCL (#599, #658); these records were not included in the original 2023-current file
4	Closed complaints	Spot check records from original and updated files to ensure records align (e.g., #200 in the original file matches #200 in the updated file). Performed for 2022 – 2024 records.	• Sampling of 22 randomly selected records all matched between original and updated versions of 2022 and 2023-current files
5	Open & closed complaints	Compare records from the 2023 and 2024 open case files to the missing index values from the original MCL	• All missing records accounted for in the open case files provided 5/3
6	Open & closed complaints	Compare file fields between open and closed case files; map appropriate fields to a single template to allow for file consolidation	• Fields were the same between the 2022 and 2023-current MCL (closed complaints) • Fields varied between the closed complaint MCLs, 2023 open case files, and 2024 open case files • Each files' fields mapped to a single template
7	Open & closed complaints	Merge all files into a single file to provide one comprehensive list of all open and closed complaints from 2022-2024	• 1,324 open and closed records consolidated into one file • Index #1,170 appears to be missing values; UNOS provided record 1170 on 5/24/24
8	Open & closed complaints	Perform final validation to ensure all index values are accounted for	• 247/249 missing index values accounted for; per UNOS on 5/3/24, index #471 was accidentally skipped in the MCL and was never an event or case • Index #1,261 was listed twice (duplicate record); deleted the duplicate from 2023 and kept the record from the 2024 open case file

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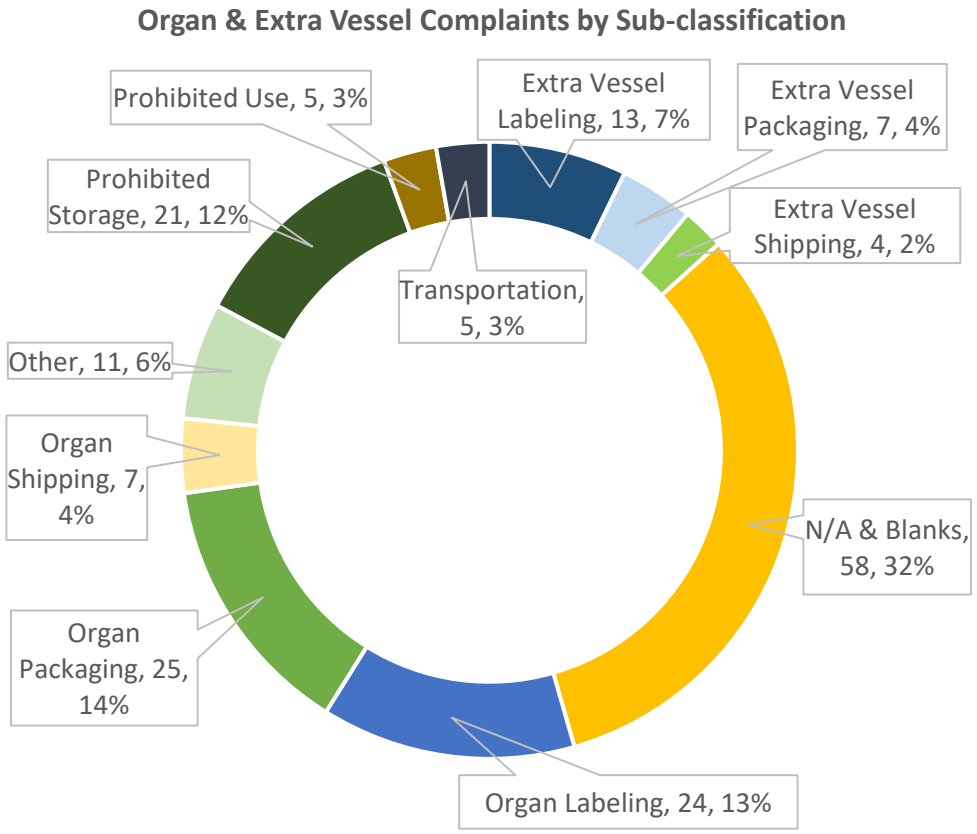
Organ & Extra Vessel Complaints

Organ and extra vessels accounted for the largest portion of complaints across all classifications (14%). Organ packaging and labeling accounted for 27% of organ & extra vessel complaints, 12% related to prohibited storage, and 11% to extra vessel labeling and packaging. Many of these complaints could correlate to OPTN policy violations, as OPTN policy defines parameters for vessel storage and appropriate packaging, labeling, and shipping of organs and vessels.



Primary Classification	Sub-Classifications	Classification Description
Organ and Extra Vessels	• Organ Packaging • Organ Labeling • Organ Shipping • Extra Vessel Packaging • Extra Vessel Labeling • Extra Vessel Shipping • Prohibited Storage • Prohibited Use • Transportation	• Events related to recovered deceased donor organs or vessels • Includes events related to packaging, labeling, and transportation of deceased donor organs and extra vessels and events related to extra vessel storage by the recipient hospital

	Subject Member Type			
Organ & Extra Vessel Sub-classifications	**OPO**	**TXC**	**N/A & Blanks**	**Grand Total**
N/A & Blanks	21	19	18	**58**
Organ Packaging	23	2	0	**25**
Organ Labeling	22	2	0	**24**
Prohibited Storage	0	21	0	**21**
Extra Vessel Labeling	12	1	0	**13**
Organ Shipping	6	1	0	**7**
Extra Vessel Packaging	4	2	1	**7**
Transportation	3	2	0	**5**
Prohibited Use	0	5	0	**5**
Extra Vessel Shipping	2	2	0	**4**
Other	4	7	0	**11**
Grand Total	**97**	**64**	**19**	**180**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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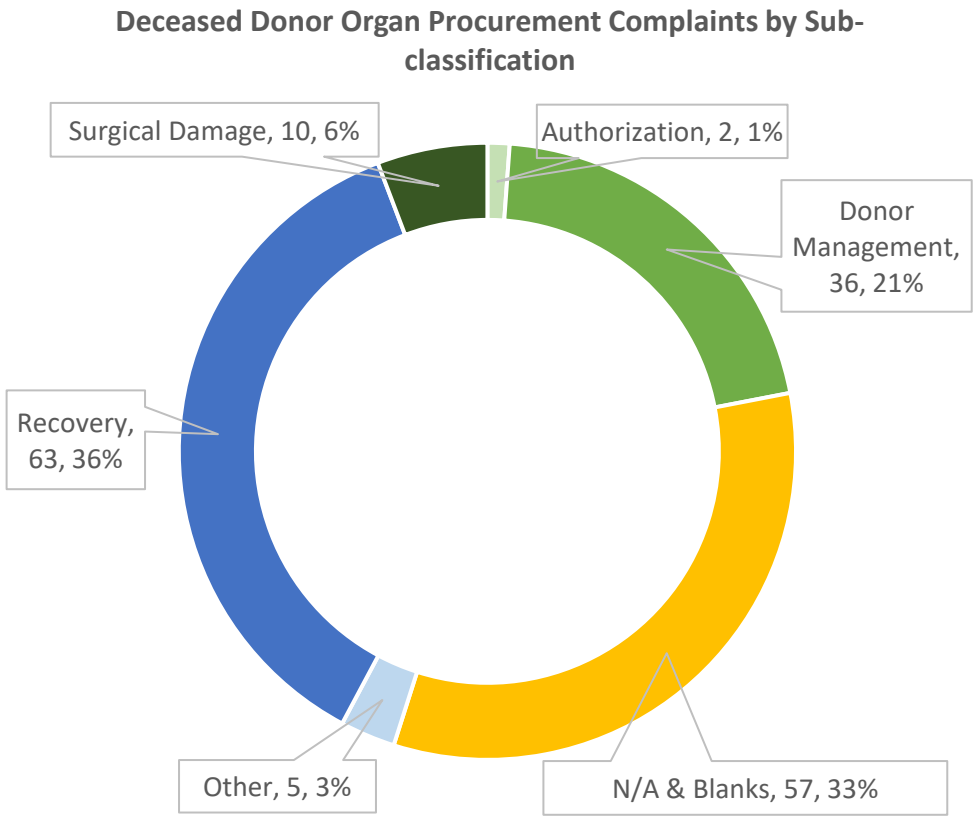
Deceased Donor Organ Procurement Complaints

Deceased donor organ procurement complaints accounted for 13% of the 1,324 complaints received. **Approximately 1/3 of complaints did not have a sub-classification provided. Recovery accounted for 36% of deceased donor organ complaints, followed by donor management (21%)**. Without access to qualitative, case-specific data, it could not be determined whether recovery and surgical damage complaints are synonymous.



Primary Classification	Sub-Classifications	Classification Description
Deceased Donor Organ Procurement	• Authorization • Donor Management • Recovery • Surgical Damage	• Events related to the deceased donor organ donation process prior to and in the donor recovery operating room • Events can be related to donor workup, completion of required donor testing, events that occur during the recovery (including surgical damage), communication between recovery teams, and other issues that arise leading up to and during the deceased donor organ recovery process • Most events in this category occurred prior to the organ being packaged/labeled, and/or leaving the donor OR

	Subject Member Type		
Deceased Donor Organ Procurement Sub-classifications	**OPO**	**TXC**	**Grand Total**
Recovery	49	14	**63**
N/A & Blanks	36	21	**57**
Donor Management	26	10	**36**
Surgical Damage	7	3	**10**
Authorization	2	0	**2**
Other: Media	1	0	**1**
Other: Yes	1	0	**1**
Other: Positive biopsy leading to non-utilization	1	0	**1**
Other: Recovery (No)	0	1	**1**
Other: No	0	1	**1**
Grand Total	**123**	**50**	**173**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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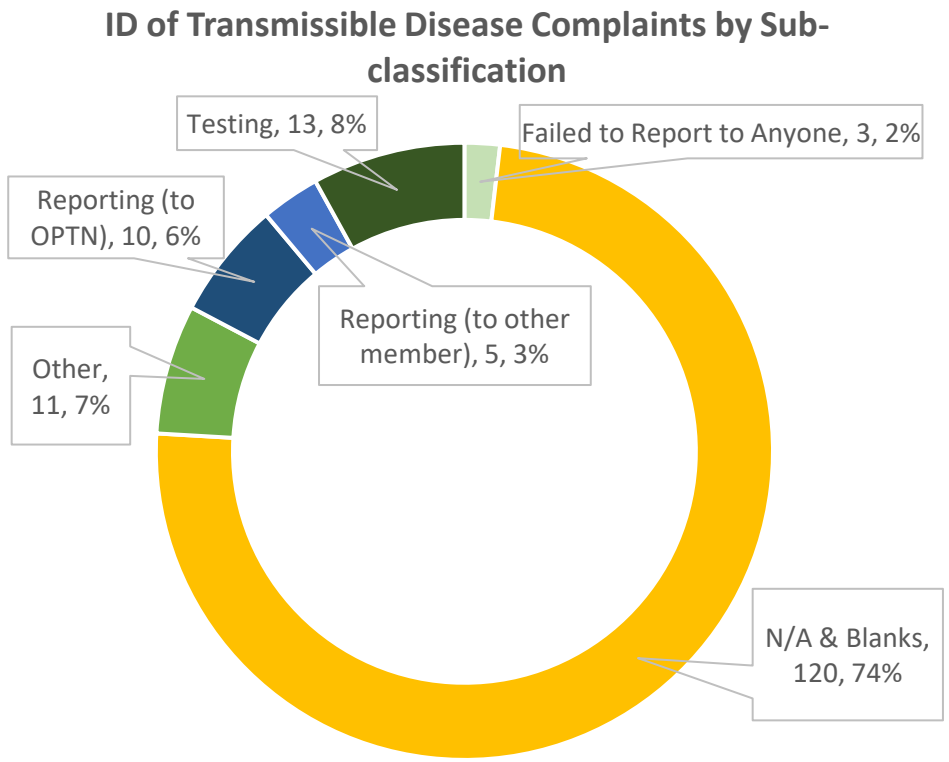
Identification of Transmissible Disease Complaints

Identification of transmissible disease complaints accounted for 12% of total complaints submitted between 2022 and 2024 Q1. Three-quarters of these lacked additional sub-classification information. **Of the remaining 26% of transmissible disease complaints, 8% were related to testing, 9% to reporting to OPTN or other members, 2% to failure to report, and 7% were categorized as "other."** Over half of identification of transmissible disease complaints were identified through automated report (52%). Approximately half of transmissible disease complaints submitted by OPOs, Transplant Centers, and labs were self reports (18/37; 49%), suggesting members are proactively identifying and reporting potential issues with protocol adherence or disease transmissions.



Primary Classification	Sub-Classifications	Classification Description
Identification of Transmissible Diseases	• Testing • Reporting (to OPTN) • Reporting (to other member) • Failed to Report to Anyone	• Events involving the testing, identification, and reporting of infectious disease results • May include events where required infectious disease testing was not completed, not completed according to requirements, or that positive results were not reported to the appropriate entity

	Subject Member Type			
ID of Transmissible Disease Sub-classifications	**TXC**	**OPO**	**N/A & Blanks**	**Grand Total**
N/A & Blanks	96	22	2	**120**
Testing	6	7	0	**13**
Reporting (to OPTN)	8	2	0	**10**
Other: (No)	7	0	0	**7**
Reporting (to other member)	1	4	0	**5**
Failed to Report to Anyone	2	0	1	**3**
Other: Transplant	1	0	0	**1**
Other: Prohibited Storage	0	1	0	**1**
Other: Candidate Work-up; Evaluation	0	1	0	**1**
Other: Data Entry Error	0	1	0	**1**
Grand Total	**121**	**38**	**3**	**162**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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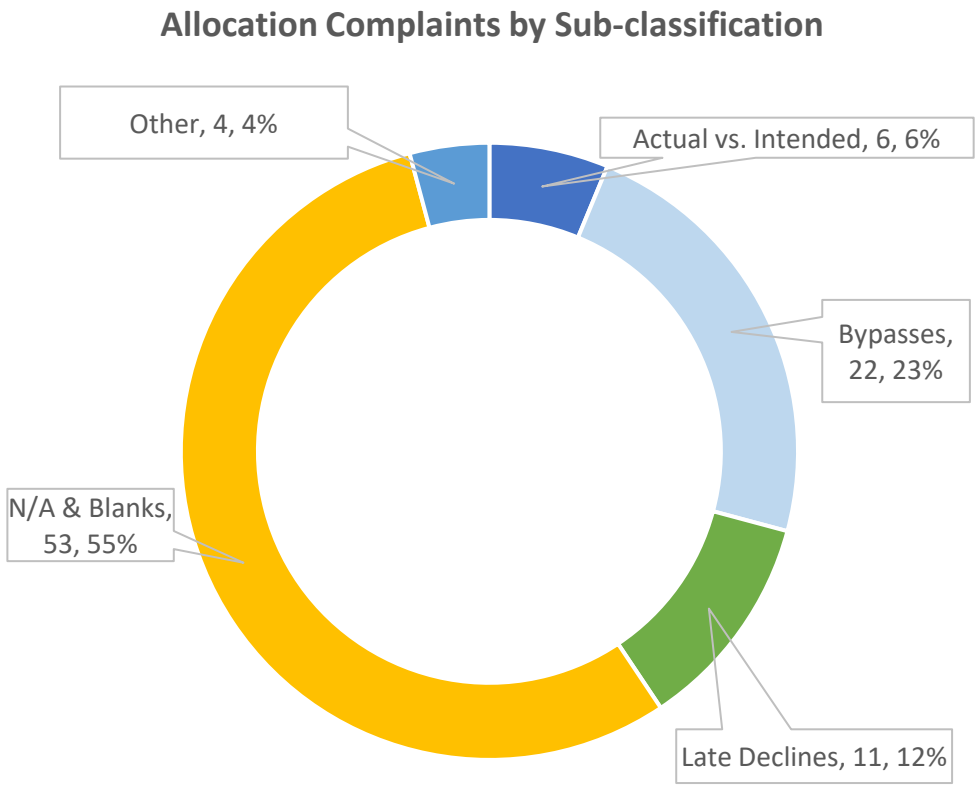
Allocation Complaints

Allocation complaints account for 7% of the 1,324 complains received between 2022 and 2024 Q1. Unfortunately, **55% of the allocation complaints did not contain sub-classification information. Potential bypass issues accounted for 23% of the allocation complaints, while 11% pertained to late declines**. Bypass issues are predominantly submitted by transplant centers pertaining to OPOs (19/22 bypass complaints) and most likely reflect situations whereby a transplant center may have been bypassed within or outside of the match run. Late declines most likely occur once an organ is accepted, and then later declined.



Primary Classification	Sub-Classifications	Classification Description
Allocation	• Bypasses • Late Declines • Actual vs. Intended	• Captures events related to the proper allocation of organs

	Subject Member Type			
Allocation Sub-classifications	**OPO**	**TXC**	**N/A & Blanks**	**Grand Total**
N/A & Blanks	34	10	9	**53**
Bypasses	20	1	1	**22**
Late Declines	0	11	0	**11**
Actual vs. Intended	3	3	0	**6**
Other: Transplant	2	0	0	**2**
Other: Communication	1	0	0	**1**
Other: Offer Issues	1	0	0	**1**
Grand Total	**61**	**25**	**10**	**96**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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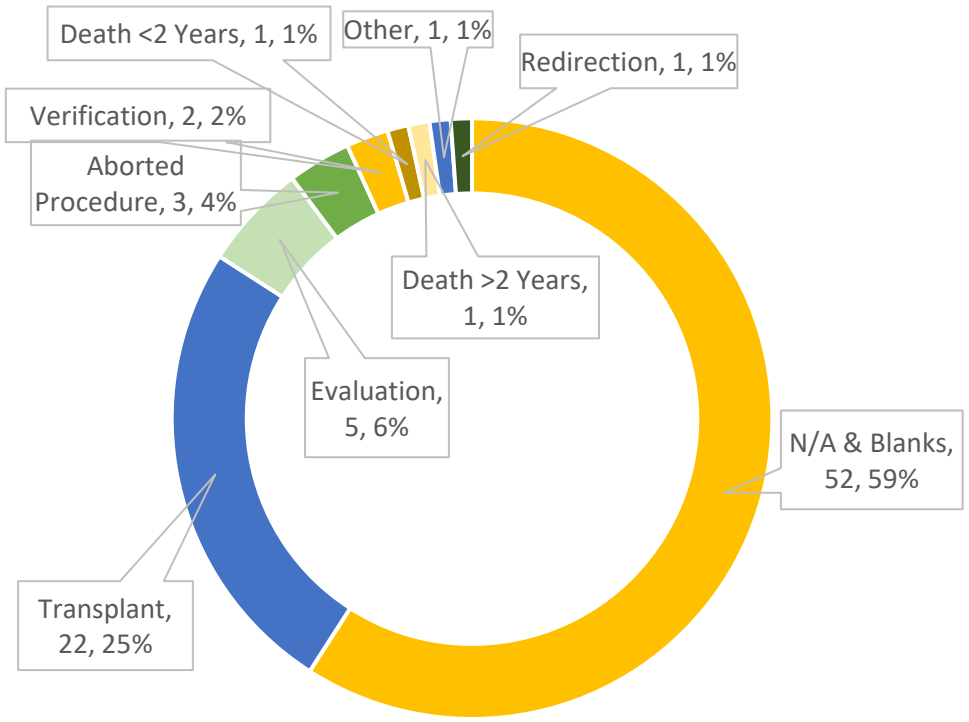
Living Donation Complaints

Living donation complaints accounted for 7% of patient safety complaints. While the majority of living donation complaints lacked sub-classification information (59%), **25% related to transplant, 6% to evaluation, 4% to aborted procedures, 2% to verification, 2% to death within two years, and 2% to redirection and "other."** Evaluation could indicate any event related to the living donor workup process. The transplant sub-classification could pertain to surgical damage to the donor or recipient, medical errors that occur any time during or immediately post-transplant, or living donor issues resulting in non-utilization.

Living Donation Complaints by Sub-classification



Primary Classification	Sub-Classifications	Classification Description
Living Donation	• Evaluation • Transplant • Verification • Aborted Procedure • Death >2 Years • Death <2 Years • Native Organ Failure • Redirection • Reporting, Living Donor Events	• Includes all living donor events, as defined in OPTN policy • May also be issues related to living donor workup and evaluation, concerns reported by pending living donors or prior living donors, and communication issues (usually between the transplant program and the living donor)

	Subject Member Type			
Living Donation Sub-classifications	**TXC**	**N/A & Blanks**	**OPO**	**Grand Total**
N/A & Blanks	31	21	0	**52**
Transplant	20	1	1	**22**
Evaluation	5	0	0	**5**
Aborted Procedure	3	0	0	**3**
Verification	1	0	1	**2**
Death <2 Years	1	0	0	**1**
Death >2 Years	1	0	0	**1**
Other: Candidate Work-up; Evaluation	1	0	0	**1**
Redirection	0	1	0	**1**
Grand Total	**63**	**23**	**2**	**88**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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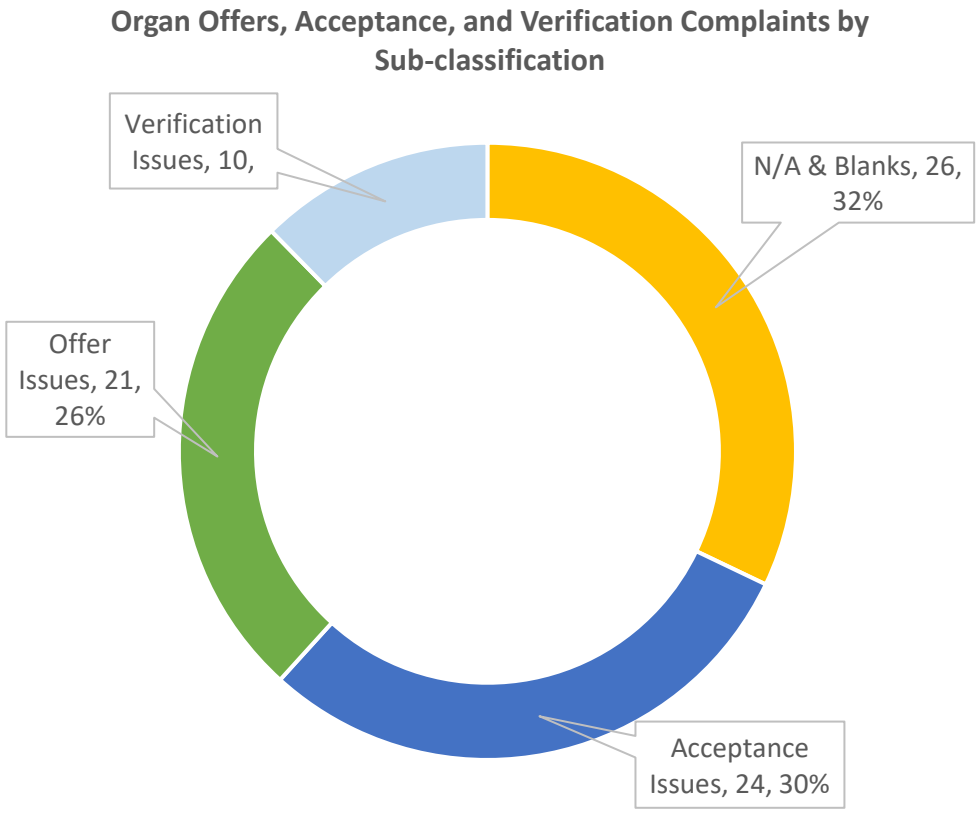
Organ Offers, Acceptance, and Verification Complaints

Complaints about organ offers, acceptance, and verifications accounted for 7% of the 1,324 complaints. Approximately half of these complaints pertained to acceptance and offer issues (28% and 24% respectively). Acceptance issues are distinct and different from complaints concerning the adherence to organ allocation policy. Acceptance and offer issues may involve instances where essential information is not provided, delaying or preventing a transplant center from determining whether to accept or reject the organ.



Primary Classification	Sub-Classifications	Classification Description
Organ Offers, Acceptance, and Verification	• Offer Issues • Acceptance Issues • Verification Issues	• Events related to the actual offering, acceptance, or timeliness of organ acceptances or declines • Includes events related to proper review and verification of donor information prior to acceptance • Does not include whether organs were allocated according to policy (these events fall under the "allocation" classification)

	Subject Member Type		
Organ Offers, Acceptance, & Verification Sub-classifications	**OPO**	**TXC**	**Grand Total**
N/A & Blanks	10	16	**26**
Acceptance Issues	8	16	**24**
Offer Issues	21	0	**21**
Verification Issues	6	4	**10**
Other: Donor Management	2	0	**2**
Other: Organ Labeling	1	0	**1**
Other: Organ Packaging	1	0	**1**
Other: (No)	1	0	**1**
Other: Damage leading to non-utilization	0	1	**1**
Grand Total	**50**	**37**	**87**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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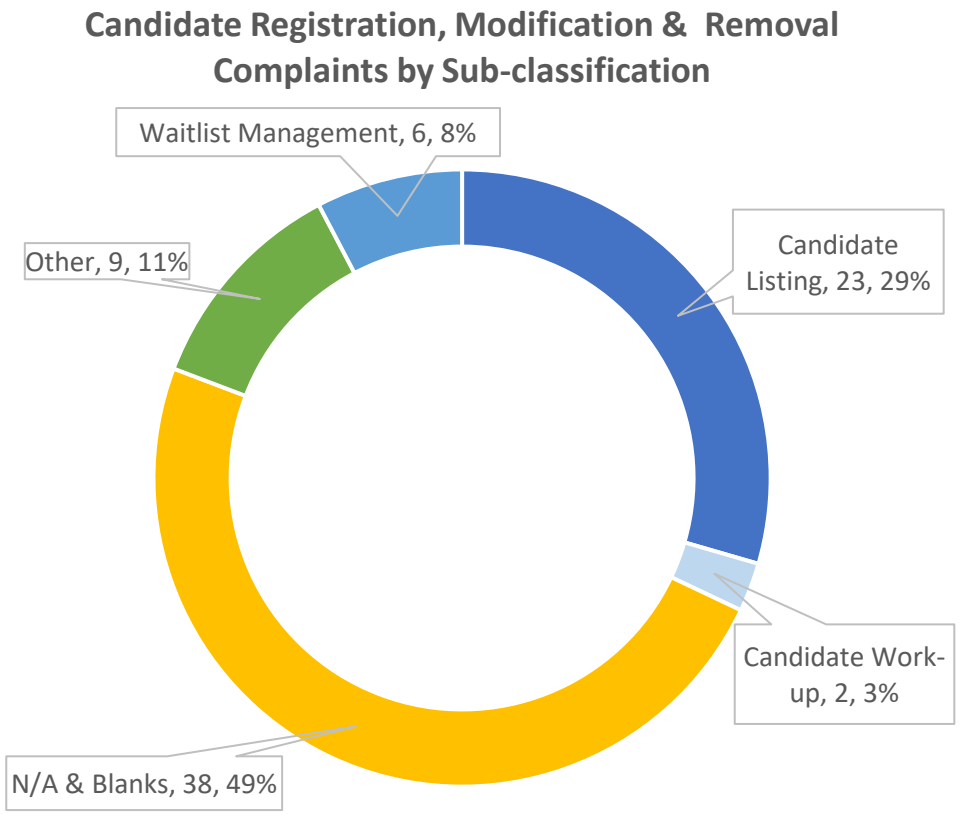
Candidate Registration, Modification, and Removal Complaints

Candidate Registration, Modification, and Removals accounted for 6% (78) of the 1,324 complaints. While approximately half of the candidate registration, modification, and removal complaints did not have sub-classification information, **29% of the complaints pertained to candidate listing**. Five of the nine "other" complaints pertained to authorization. Of note, some of the sub-classifications did not pertain to the candidate registration, modification, and removal primary classification (e.g., donor management is a sub-classification of the deceased donor organ procurement primary classification). Additionally, 52% of candidate registration, modification, and removal complaints were identified via UNOS automated report, indicating automated processes are in place to assist in identifying potential patient safety issues.



Primary Classification	Sub-Classifications	Classification Description
Candidate Registrations, Modifications, and Removals	• Candidate Referral • Candidate Work-up • Candidate Listing • Waitlist Management	• Typically involves pre-transplant patients or events that occurred prior to or just after transplant • Many cases involve the process of listing a candidate on the waitlist, required information and/or updates to the candidate's waitlist record, and required timelines and information for removing a patient from the waitlist • Incorrect discrepant candidate ABO issues should not be classified in this category

	Subject Member Type				
Candidate Registration, Modification, and Removal Sub-classifications	**TXC**	**OPO**	**N/A & Blanks**	**Lab**	**Grand Total**
N/A & Blanks	31	2	4	1	**38**
Candidate Listing	20	2	1	0	**23**
Waitlist Management	5	1	0	0	**6**
Other: Authorization	4	1	0	0	**5**
Candidate Work-up	2	0	0	0	**2**
Other: Donor Management	2	0	0	0	**2**
Other: Data Entry Error	0	0	0	1	**1**
Other: Recovery	1	0	0	0	**1**
Grand Total	**65**	**6**	**5**	**2**	**78**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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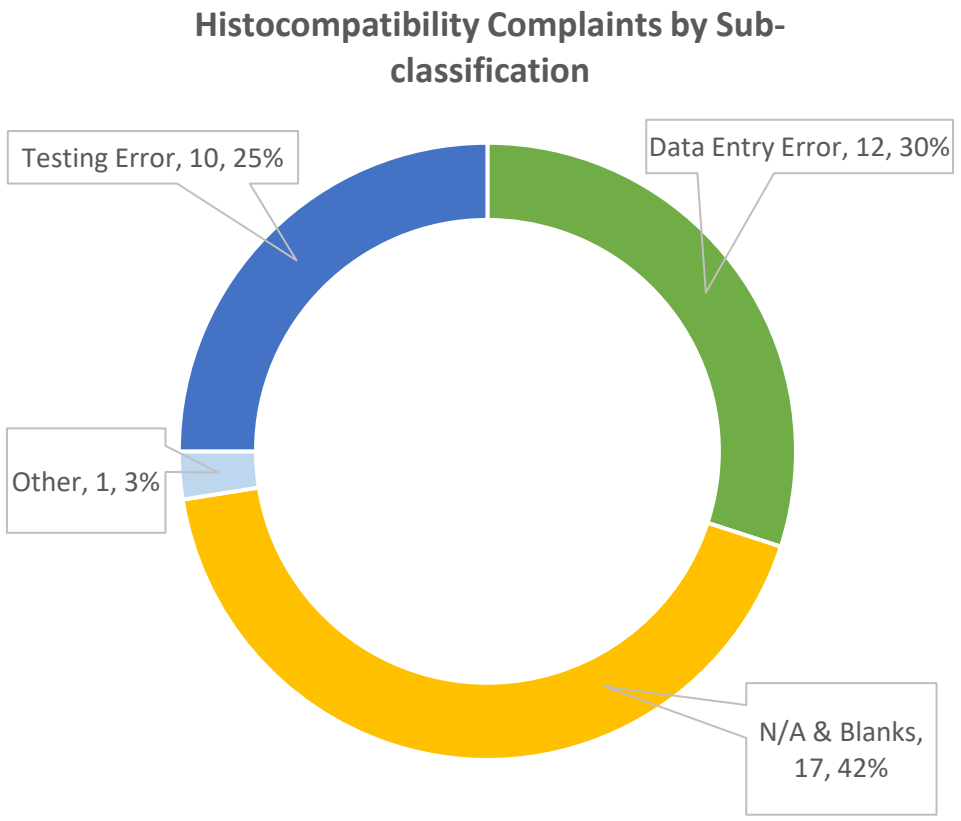
Histocompatibility Complaints

Of the 1,324 complaints submitted between 2022 and 2024 Q1, 3% related to histocompatibility. While 42% of histocompatibility complaints did not have a sub-classification specified, 30% were classified as data entry errors, 25% pertained to testing errors, and 3% were marked as "other." Testing errors could arise from factors such as the inherent margin of error in the tests or from deviations from established testing protocols.



Primary Classification	Sub-Classifications	Classification Description
Histocompatibility	• Data Entry Error • Testing Error	• Events related to inaccurate typing and reporting of HLA

	Subject Member Type				
Histocompatibility Sub-classifications	**Lab**	**OPO**	**TXC**	**N/A & Blanks**	**Grand Total**
N/A & Blanks	6	7	3	1	**17**
Data Entry Error	8	4	0	0	**12**
Testing Error	5	5	0	0	**10**
Other: (Yes)	1	0	0	0	**1**
Grand Total	**20**	**16**	**3**	**1**	**40**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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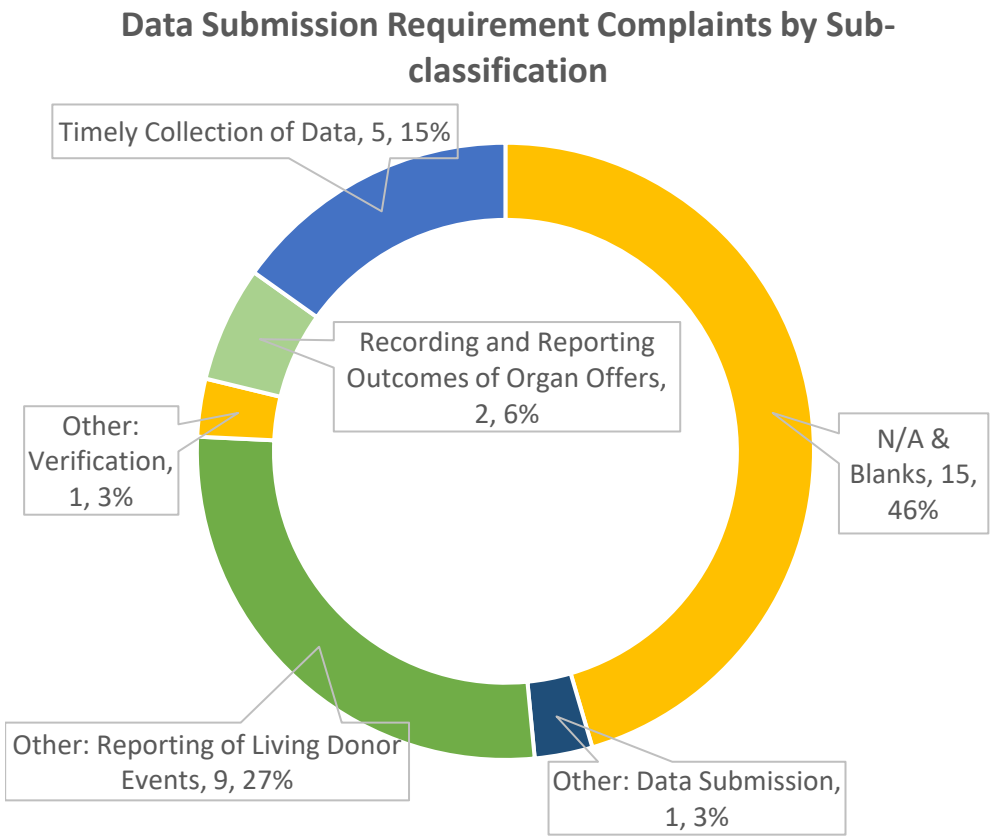
Data Submission Requirement Complaints

Complaints about data submission requirements were uncommon, accounting for 2% of the 1,324 complaints received between 2022 and 2024 Q1. **Approximately half of data submission requirement complaints did not have a sub-classification provided and 21% of data submission requirement complaints fell into pre-defined sub-categories**. An additional 27% of complaints were classified as "other: reporting of living donor events." Due to a lack of complaint-specific qualitative data, it is unclear if these complaints would have been more appropriate if categorized under the "living donor" primary classification.



Primary Classification	Sub-Classifications	Classification Description
Data Submission Requirements	• Timely Collection of Data • Recording and Reporting Outcomes of Organ Offers • Living Donor Data Submission Requirements	• Events involving timely collection and reporting of required OPTN data, including outcomes of organ offers and required living donor data submission into the OPTN system

	Subject Member Type			
Data Submission Requirements Sub-classifications	**TXC**	**OPO**	**Lab**	**Grand Total**
N/A & Blanks	4	11	0	**15**
Other: Reporting of Living Donor Events	9	0	0	**9**
Timely Collection of Data	2	3	0	**5**
Recording and Reporting Outcomes of Organ Offers	1	1	0	**2**
Other: Data Submission	0	0	1	**1**
Other: Verification	0	1	0	**1**
Grand Total	**16**	**16**	**1**	**33**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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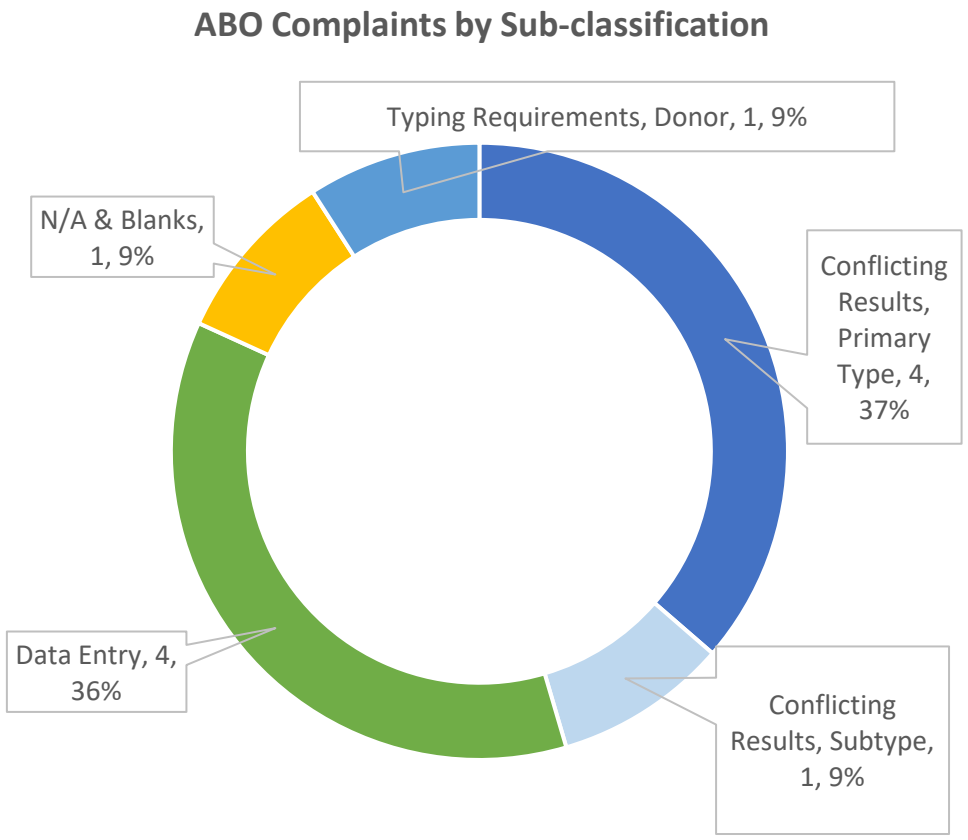
ABO Complaints

ABO complaints were uncommon, accounting for less than 1% (11) of the 1,324 complaints between 2022 and 2024 Q1. **Of these 11 complaints, 45% pertained to conflicting primary and subtype ABO results, and 36% pertained to data entry issues.** According to OPTN policy, members must conduct two independent blood type verifications before recording the information in UNET. If the result documentation from these two verifications conflict, it may indicate a potential quality issue in the blood type verification process and present a risk to patient safety.



Primary Classification	Sub-Classifications	Classification Description
ABO	• Conflicting Results, Primary Type • Conflicting Results, Subtype • Data Entry • Incompatible Recipient • Rare Subtype • Typing Requirements, Donor • Typing Requirements, Recipient	• Events related to the testing, determination of, and reporting of donor, candidate, or recipient ABO • Includes issues related to accurate determination of donor, candidate, or recipient subtyping

	Subject Member Type		
ABO Sub-classifications	**OPO**	**TXC**	**Grand Total**
Conflicting Results, Primary Type	0	4	**4**
Data Entry	2	2	**4**
Conflicting Results, Subtype	1	0	**1**
Typing Requirements, Donor	1	0	**1**
N/A & Blanks	0	1	**1**
Grand Total	**4**	**7**	**11**

Source: Master Case List, 1/1/22 – 3/30/24; UNOS, "Primary and sub classifications_MCL_with Definitions," 6/11/24

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MPSC Actions

Action	Request informal discussion	Request interview	Close with No Action	Issue a Notice of Non-compliance	Issue a Letter of Warning	Recommend Probation	Recommend Member Not in Good Standing
Purpose	Smaller, informal interaction to gather more information.	More formal discussion with member.	Nothing further is required of the member, either because policy violation did not occur or because member took appropriate action.	MPSC expects member to update corrective action, conduct ongoing monitoring, etc. to reduce likelihood of recurrence, but member does not need to report to the MPSC	MPSC wishes to convey concerns about appropriate-ness or effectiveness of issue and the member's response	Adverse actions that are made public; appropriate when member fails to take appropriate steps to mitigate risk to patient health/safety or the integrity of the OPTN, or fails to make sufficient progress after multiple interactions with the MPSC	
Outcome	Smaller group reports back to full MPSC for decision.	MPSC decides next steps immediately after interview.	Final Action	Final Action	Final Action	Right to Interview, Hearing and Board appearance	

Source: MPSC Reference Cards

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Data Documentation Changes

The following fields appear to have changes in documentation practices over time. Documentation changes appear to be a change in documentation consistency or the addition of a new field.

Field	Documentation Change Date	Documentation Change
Primary Classification	August 2022	Not consistently documented until August 2022
Sub-classification	August 2022	Not consistently documented until August 2022
Organ	January 2024	Appears to be a new field effective January 2024; no documentation prior to January 2024
Non-utilization	August 2022	Field appears to have been created July 2022 and not consistently documented until August 2022; however, there continues to be a high volume of “N/A” used throughout the entire data set
Subject Member Type	August 2022	Not consistently documented until August 2022
Reporter Center Code	August 2022	Not consistently documented until August 2022
Reporter Type	August 2022	Not consistently documented until August 2022

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TXC Members

Code	Member Name
ALCH	Children's of Alabama
ALUA	University of Alabama Hospital
ALVA	Birmingham VA Medical Center
ARBH	Baptist Medical Center
ARCH	Arkansas Children's Hospital
ARUA	UAMS Medical Center
AZCH	Phoenix Children's Hospital
AZGS	Banner - University Medical Center Phoenix
AZMC	Mayo Clinic Hospital Arizona
AZSJ	St. Joseph's Hospital and Medical Center
AZUA	Banner University Medical Center -Tucson
CACH	Rady Children's Hospital and Health Center
CACL	Children's Hospital Los Angeles
CACS	Cedars-Sinai Medical Center
CAGH	Scripps Green Hospital
CAHP	City of Hope National Medical Center
CAIM	University of California Irvine Medical Center
CALA	Harbor UCLA Medical Center
CALL	Loma Linda University Medical Center
CAMB	UCSF Medical Center at Mission Bay
CAPC	Lucile Salter Packard Children's Hospital at Stanford
CAPM	California Pacific Medical Center - Van Ness Campus
CASD	University of California San Diego Medical Center
CASF	University of California San Francisco Medical Center
CASG	Sutter Medical Center Sacramento
CASH	Sharp Memorial Hospital
CASJ	Saint Joseph Hospital
CASM	University of California Davis Medical Center
CASU	Stanford Health Care
CAUC	University of California at Los Angeles Medical Center
CAUH	Keck Hospital of USC

Code	Member Name
COCH	Children's Hospital Colorado
COPM	AdventHealth Porter
COSL	Presbyterian/St Luke's Medical Center
COUC	University of Colorado Hospital/Health Science Center
CTHH	Hartford Hospital
CTYN	Yale New Haven Hospital
DCCH	Children's National Medical Center
DCGU	Medstar Georgetown Transplant Institute
DCGW	George Washington University Hospital
DCWH	Washington Hospital Center
DCWR	Walter Reed National Military Medical Center at Bethesda
DEAI	Nemours Children's Hospital Delaware
DECC	Christiana Care Health Services
FLAC	Johns Hopkins All Children's Hospital
FLCC	Cleveland Clinic Florida Weston
FLFH	AdventHealth Orlando
FLHM	Halifax Health
FLJD	Memorial Regional Hospital/Joe DiMaggio Children's Hospital
FLJM	Jackson Memorial Hospital Uni of Miami School of Medicine
FLLM	Largo Medical Center
FLMR	Memorial Regional Hospital
FLSH	Ascension Sacred Heart Pensacola
FLSL	Mayo Clinic Hospital Florida
FLTG	Tampa General Hospital
FLUF	UF Health Shands Hospital
GAEH	Children's Healthcare of Atlanta at Egleston
GAEM	Emory University Hospital
GAMC	Wellstar MCG Health, affiliated w/ Medical College of Georgia
GAPH	Piedmont Hospital
HIQM	The Queen's Medical Center
IAIM	Iowa Methodist Medical Center

Source: OPTN Membership data, 4/4/24

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TXC Members, cont.

Code	Member Name
IAIV	University of Iowa Hospitals and Clinics Transplant Programs
IAVA	The Iowa City VA Health Care System
ILCH	Advocate Christ Medical Center
ILCM	Ann & Robert H. Lurie Children's Hospital of Chicago
ILLU	Loyola University Medical Center
ILMM	Springfield Memorial Hospital
ILNM	Northwestern Memorial Hospital
ILPL	Rush University Medical Center
ILSF	OSF Saint Francis Medical Center
ILUC	University of Chicago Medical Center
ILUI	University of Illinois Medical Center
ILVA	Edward Hines Jr. Veterans Administration Medical Center
INIM	Indiana University Health
INSV	Ascension St. Vincent Hospital
KSUK	University of Kansas Hospital
KYJH	Jewish Hospital
KYKC	Norton Children's Hospital
KYUK	University of Kentucky Medical Center
LACH	Children's Hospital
LAOF	Ochsner Foundation Hospital
LATU	Tulane Medical Center
LAWK	Willis - Knighton Medical Center
MABI	Beth Israel Deaconess Medical Center
MABS	Baystate Medical Center
MABU	Boston Medical Center
MACH	Boston Children's Hospital
MALC	Lahey Clinic Medical Center
MAMG	Massachusetts General Hospital
MANM	Tufts Medical Center
MAPB	Brigham and Women's Hospital
MAUM	UMass Memorial Medical Center

Code	Member Name
MDJH	Johns Hopkins Hospital
MDUM	University of Maryland Medical System
MEMC	Maine Medical Center
MIBH	William Beaumont Hospital
MICH	Children's Hospital of Michigan
MIDV	Helen DeVos Children's Hospital
MIHF	Henry Ford Hospital
MISH	Spectrum Health
MISJ	Ascension St. John Hospital
MISM	Mercy Health Saint Mary's
MIUM	University of Michigan Medical Center
MNAN	Abbott Northwestern Hospital
MNCM	Children's Minnesota
MNHC	Hennepin County Medical Center
MNMC	Mayo Clinic Hospital Minnesota
MNUM	University of Minnesota Medical Center, Fairview
MOBH	Barnes - Jewish Hospital
MOCG	Cardinal Glennon Children's Hospital
MOCH	St. Louis Children's Hospital at Washington University Medical Center
MOCM	Children's Mercy Hospital
MOLH	St Luke's Hospital of Kansas City
MORH	Research Medical Center
MOSL	SSM Health Saint Louis University Hospital
MOUM	University of Missouri Hospital and Clinics
MSUM	University of Mississippi Medical Center
NCBG	Wake Forest Baptist Medical Center
NCCM	Carolinas Medical Center
NCDU	Duke University Hospital
NCEC	ECU Health Medical Center
NCMH	University of North Carolina Hospitals
NDMC	Sanford Bismarck Medical Center

Source: OPTN Membership data, 4/4/24

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TXC Members, cont.

Code	Member Name
NDSL	Sanford Medical Center Fargo
NECH	Children's Nebraska
NEUN	The Nebraska Medical Center
NHDH	Mary Hitchcock Memorial Hospital
NJBI	Newark Beth Israel Medical Center
NJHK	Hackensack University Medical Center
NJLL	Virtua Our Lady of Lourdes Hospital
NJRW	Robert Wood Johnson University Hospital
NJSB	Saint Barnabas Medical Center
NJUH	University Hospital
NMAQ	University Hospital, University of New Mexico Health Sciences Center
NMPH	Presbyterian Hospital
NVUM	University Medical Center of Southern Nevada
NYAM	Albany Medical Center Hospital
NYCC	Long Island Jewish Medical Center - Cohen Children's Medical Center
NYCP	NY Presbyterian Hospital/Columbia Univ. Medical Center
NYDS	State University of New York, Downstate Medical Center
NYEC	Erie County Medical Center
NYFL	Strong Memorial Hospital, University of Rochester Medical Center
NYMA	Montefiore Medical Center
NYMS	Mount Sinai Medical Center
NYNS	North Shore University Hospital/Northwell Health
NYNY	New York - Presbyterian Hospital/Weill Cornell Medical Center
NYSB	University Hospital of State University of New York at Stony Brook
NYUC	NYU Langone Health
NYUM	State University of New York Upstate Medical University
NYVA	James J. Peters VA Medical Center
NYWC	Westchester Medical Center
OHCC	The Cleveland Clinic Foundation
OHCH	Nationwide Children's Hospital
OHCM	Children's Hospital Medical Center

Code	Member Name
OHCO	University of Toledo Medical Center
OHOU	Ohio State University Medical Center
OHTC	The Christ Hospital
OHUC	University of Cincinnati Medical Center
OHUH	University Hospitals of Cleveland
OKBC	Integris Baptist Medical Center
OKCM	Children's Hospital of Oklahoma
OKMD	OU Medical Center
OKSJ	St John Medical Center
ORGS	Legacy Good Samaritan Hospital and Medical Center
ORSV	Providence St. Vincent Medical Center
ORUO	Oregon Health and Science University
ORVA	VA Portland Health Care System
PAAE	Albert Einstein Medical Center
PAAG	Allegheny General Hospital
PACH	UPMC Children's Hospital of Pittsburgh
PACP	Children's Hospital of Philadelphia
PAGM	Geisinger Medical Center
PAHE	Penn State Milton S Hershey Medical Center
PAHH	Pinnacle Health System at Harrisburg Hospital
PALV	Lehigh Valley Hospital
PAPH	UPMC Hamot
PAPT	University of Pittsburgh Medical Center
PASC	St. Christopher's Hospital for Children
PATJ	Thomas Jefferson University Hospital
PATU	Temple University Hospital
PAUP	Hospital of the University of Pennsylvania
PAVA	VA Pittsburgh Healthcare System
PRCC	Cardiovascular Center of Puerto Rico and the Caribbean
PRSJ	Auxilio Mutuo Hospital
RIRH	Rhode Island Hospital

Source: OPTN Membership data, 4/4/24

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TXC Members, cont.

Code	Member Name
SCCH	MUSC Children's Hospital
SCLA	MUSC Lancaster
SCMU	Medical University of South Carolina
SCPG	Prisma Health Greenville Memorial Hospital
SDMK	Avera McKennan Hospital
SDSV	Sanford Health/USD Medical Center
TNBM	Baptist Memorial Hospital
TNEM	Erlanger Medical Center
TNLB	Le Bonheur Children's Medical Center
TNMH	Methodist University Hospital
TNST	Saint Thomas Hospital
TNUK	University of Tennessee Medical Center at Knoxville
TNVU	Vanderbilt University Medical Center
TXAS	Baylor Scott and White All Saints Medical Center - Fort Worth
TXBC	University Hospital, University of Texas Health Science Center
TXCF	Cook Children's Medical Center
TXCM	Children's Medical Center of Dallas
TXCT	Seton Medical Center Austin
TXDC	Driscoll Children's Hospital
TXDL	Dell Children's Medical Center
TXDM	North Austin Medical Center
TXDR	Doctor's Hospital at Renaissance
TXDS	Dell Seton Medical Center at The University of Texas at Austin
TXFW	Texas Health Harris Methodist Fort Worth Hospital
TXHD	Medical City Dallas Hospital
TXHH	Memorial Hermann Hospital, University of Texas at Houston
TXHI	CHI St. Luke's Health Baylor College of Medicine Medical Center
TXHS	Methodist Specialty and Transplant Hospital
TXJS	University of Texas Medical Branch at Galveston
TXLP	Las Palmas Medical Center
TXMC	Methodist Dallas Medical Center

Code	Member Name
TXMH	Houston Methodist Hospital
TXPL	Medical City Fort Worth
TXPM	Parkland Health and Hospital System
TXSP	UT Southwestern Medical Center/William P. Clements Jr. University Hospital
TXSW	Scott and White Memorial Hospital
TXTC	Texas Children's Hospital
TXTX	Baylor University Medical Center
TXUC	University Children's Health
TXVA	Michael E. DeBakey VA Medical Center
UTLD	Intermountain Medical Center
UTMC	University of Utah Medical Center
UTPC	Primary Children's Hospital
VACH	Children's Hospital of the King's Daughters
VAFH	Inova Fairfax Hospital
VAHD	Henrico Doctors' Hospital
VAMC	VCU Health System Authority, VCUMC
VAMV	Hunter Holmes McGuire Veterans Administration Medical Center(inactive)
VANG	Sentara Norfolk General Hospital
VAUV	University of Virginia Health Sciences Center
VTMC	The University of Vermont Medical Center
WACH	Seattle Children's Hospital
WASH	Providence Sacred Heart Medical Center & Children's Hospital
WASM	Swedish Medical Center
WAUW	University of Washington Medical Center
WAVM	Virginia Mason Medical Center
WICH	Children's Hospital of Wisconsin
WISE	Froedtert Memorial Lutheran Hospital
WISL	Aurora St. Luke's Medical Center
WIUW	University of Wisconsin Hospital and Clinics
WVCA	Charleston Area Medical Center
WVWU	West Virginia University Hospitals Inc.

Source: OPTN Membership data, 4/4/24

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OPO Members

Code	Member Name
ALOB	Legacy of Hope
AROR	Arkansas Regional Organ Recovery Agency
AZOB	Donor Network of Arizona
CADN	Donor Network West
CAGS	Sierra Donor Services
CAOP	OneLegacy
CASD	Lifesharing - A Donate Life Organization
CORS	Donor Alliance
FLFH	OurLegacy
FLMP	Life Alliance Organ Recovery Agency
FLUF	LifeQuest Organ Recovery Services
FLWC	LifeLink of Florida
GALL	LifeLink of Georgia
HIOP	Legacy of Life Hawaii
IAOP	Iowa Donor Network
ILIP	Gift of Hope Organ & Tissue Donor Network
INOP	Indiana Donor Network
KYDA	Kentucky Organ Donor Affiliates
LAOP	Louisiana Organ Procurement Agency
MAOB	New England Organ Bank
MDPC	Infinite Legacy
MIOP	Gift of Life Michigan
MNOP	LifeSource Upper Midwest Organ Procurement Organization
MOMA	Mid-America Transplant Services
MSOP	Mississippi Organ Recovery Agency
MWOB	Midwest Transplant Network
NCCM	LifeShare Carolinas
NCNC	HonorBridge
NEOR	Live On Nebraska
NJTO	New Jersey Organ and Tissue Sharing Network OPO
NMOP	New Mexico Donor Services

Code	Member Name
NVLV	Nevada Donor Network
NYAP	Center for Donation and Transplant
NYFL	Finger Lakes Donor Recovery Network
NYRT	LiveOnNY
NYWN	Upstate New York Transplant Services Inc
OHLB	Lifebanc
OHLC	Life Connection of Ohio
OHLP	Lifeline of Ohio
OHOV	LifeCenter Organ Donor Network
OKOP	LifeShare Transplant Donor Services of Oklahoma
ORUO	Cascade Life Alliance
PADV	Gift of Life Donor Program
PATF	Center for Organ Recovery and Education
PRLL	LifeLink of Puerto Rico
SCOP	We Are Sharing Hope SC
TNDS	Tennessee Donor Services
TNMS	Mid-South Transplant Foundation
TXGC	LifeGift Organ Donation Center
TXSA	Texas Organ Sharing Alliance
TXSB	Southwest Transplant Alliance
UTOP	DonorConnect
VATB	LifeNet Health
WALC	LifeCenter Northwest
WIDN	Versiti Wisconsin, Inc
WIUW	UW Health Organ and Tissue Donation

Source: OPTN Membership data, 4/4/24

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Histocompatibility Lab Members

Code	Member Name
ALUA	Histocompatibility and Immunogenetics Laboratory CTI at UAB
ARUA	Tissue Typing Laboratory at UAMS Medical Center
AZGC	Donor Network of Arizona Immunogenetics Laboratory
AZMC	Mayo Clinic in Arizona Histocompatibility Laboratory
AZTL	Vitalant
AZUA	Banner University Medical Center - Clinical HLA Laboratory
CACL	HLA Laboratory at Childrens Hospital Los Angeles
CACS	Cedars-Sinai Transplantation and Immunogenetics Laboratory
CAIL	University of California, Irvine HLA Tissue Typing Laboratory
CALL	Histocompatibility and Flow Cytometry Laboratories at Loma Linda University
CAML	METIC Transplantation Laboratory
CAMT	METIC Immunogenetics Consultants, Inc
CANI	Eurofins Donor & Product Testing (California)
CAPM	Tissue Typing Laboratory at California Pacific Med Ctr
CASD	Histocompatibility and Immunogenetics Laboratory at UCSD
CASL	Stanford Blood Center - Histocompatibility & Immunogenetics Lab- Porter
CAST	Vitalant HLA Laboratory, Northern California
CASU	Stanford Blood Center, Histocompatibility Lab-Hillview
CATL	University of California at Los Angeles, Immunogenetics Center
CAUS	UCSF Immunogenetics and Transplantation Laboratory
COHL	ClinImmune Labs
COIA	Eurofins Donor & Product Testing (Colorado)
CTHH	Hartford Hospital Transplant Immunology Laboratory
CTYN	Histocompatibility and Immune Evaluation Laboratory at Yale
DCGU	Histocompatibility Laboratory at Georgetown University
DCWR	Transplant Immunology Lab at Walter Reed National Medical Center-Bethesda
FLFH	Tissue Typing Laboratory at Florida Hospital
FLML	University of Miami Jackson Memorial Hospital Histocompatibility Testing
FLSF	LifeLink Transplantation Immunology Laboratory
FLSL	HLA Laboratory at Mayo Clinic Florida
FLUF	Immunology Transplantation Laboratory/ Shands Hospital

Code	Member Name
GAEM	HLA Laboratory at Emory University
GAMC	Histocompatibility Immunology Laboratory at the Medical College of Georgia
GAPH	Piedmont Hospital Histocompatibility & Immunogenetics Laboratory
HITL	Eurofins Donor & Product Testing (Hawaii)
IAIM	Histocompatibility Laboratory at Iowa Methodist Medical Center
IAIV	Iowa Regional Histo & Immunogenetics Laboratory at the V.A. Medical Center
IAVA	Iowa Regional Histocompatibility and Immunogenetics Laboratory
ILLU	Clinical Histocompatibility Laboratory at Loyola University Medical Center
ILMM	Histocompatibility Laboratory at Memorial Medical Center
ILNM	Transplant Immunology Laboratory at Northwestern Memorial Hospital
ILPL	Rush Medical Laboratories Histocompatibility Laboratory
ILRL	Gift of Hope Organ & Tissue Donor Network Laboratory
ILUC	Transplant Immunology & Immunogenetics Laboratory
ILUI	Tissue Typing Laboratory at University of Illinois
INCI	Central Indiana Reg. Blood Center Transplant and Immunology Laboratory
INIM	Histocompatibility Laboratory at Methodist Hospital of Indiana
KYJH	Histocompatibility Laboratory at Jewish Hospital
KYUK	Immuno Molecular Pathology Laboratory at the University of Kentucky
LATL	Ochsner Histocompatibility and Immunogenetics Laboratory
LATM	Histocompatibility and Immunogenetics Lab / Tulane Univ School of Medicine
LAWK	Willis Knighton Medical Center Laboratory
MABI	Tissue Typing Laboratory at Beth Israel Deaconess Medical Center
MAMG	Histocompatibility Laboratory at Massachusetts General Hospital
MANM	Tufts Medical Center Laboratory
MAPB	Brigham & Women's Hospital Tissue Typing Lab
MAUM	Histocompatibility Laboratory at UMASS Medical Center
MDAI	Applied Immunogenetics Laboratory
MDTL	Immunogenetics Laboratories at the Johns Hopkins University
MDUM	Immunogenetics Laboratory
METL	Nordx Immunogenetics Laboratory
MIBH	Histocompatibility Laboratory at William Beaumont Hospital

Source: OPTN Membership data, 4/4/24

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Histocompatibility Lab Members, cont.

Code	Member Name
MICH	DMC University Laboratories - Histo & Immunogenetics Laboratory
MIHF	Cellular Immunology & Histocompatibility at Henry Ford Hospital
MIRI	Immunohematology and Serology Laboratory at Michigan State University
MITS	Gift of Life Michigan - Histocompatibility Laboratory
MIUM	HLA Laboratory at the University of Michigan
MNMC	Tissue Typing Laboratory at Mayo Clinic
MNUM	Clinical Histocompatibility Laboratory at University of Minnesota Med Ctr
MOHL	HLA Laboratory at Barnes Jewish Hospital
MOLB	Mid-America Transplant Services Laboratory
MOSL	St. Louis University HLA Laboratory
MSUM	Tissue Typing Laboratory of the University of Mississippi
MWKC	Midwest Transplant Network Histocompatibility Laboratory Westwood
NCBG	HLA/Immunogenetics Lab
NCCM	Immunology Laboratory at Carolinas Medical Center
NCDU	Clinical Transplantation Immunology Laboratory at Duke University Med. Ctr.
NCEC	Histocompatibility Laboratory at Vidant Medical Center
NCMH	Histocompatibility Laboratory at UNC Hospitals
NDTL	Sanford Histocompatibility Laboratory
NDTS	Sanford Clinic - Fargo Histocompatibility Laboratory
NEUN	Molecular Diagnostics Laboratory at The Nebraska Medical Center
NJTL	New Jersey Organ and Tissue Sharing Network Transplant Laboratory
NMTL	Tricore, Inc.
NVGL	Nevada Donor Network, Immunogenetics Laboratory in Nevada
NYAL	Transplantation Immunology Laboratory of the Albany Medical College
NYCP	Immunogenetics Laboratory at Columbia Presbyterian Medical Center
NYDS	Transplantation Immunology Laboratory at Brooklyn
NYFL	Tissue Typing Laboratory at Strong Memorial Hospital
NYIL	Immunogenetics Lab / The Rogosin Institute
NYKS	KSL Diagnostics Transplant Immunology Laboratory
NYMA	Transplant Immunology Laboratory at Montefiore Medical Center
NYSB	Histocompatibility and Immunogenetics Laboratory at Stony Brook
NYSP	SUNY Health Science Center at Syracuse Histocompatibility Laboratory
NYWC	Clinical Laboratory Grasslands Reservation at Westchester Medical Ctr.
OHAL	Allogen Laboratories, The Cleveland Clinic Foundation
OHCO	Tissue Typing Laboratory at University of Toledo Medical Center
OHHW	Hoxworth Blood Center Transplantation Immunology Laboratory
OHOU	Clinical Histocompatibility Lab at Ohio State University Medical Center
OHUH	Histocompatibility Laboratory at University Hospitals of Cleveland
OKDL	Diagnostic Laboratory of Oklahoma
OKMD	HLA Laboratory at OU Medical Center
ORUO	Laboratory of Immunogenetics and Transplantation at OHSU
PAAG	Histocompatibility Laboratory at Allegheny General Hospital
PACP	Children's Hosp. of Philadelphia Immunogenetics Lab
PAHE	Histocompatibility and Clinical Immunology Lab at Hershey Medical Center
PAHH	UPMC Pinnacle HLA Laboratory
PALN	Eurofins Donor & Product Testing (Pennsylvania)
PALV	HLA Lab at Lehigh Valley Hospital
PAPT	University of Pittsburgh Medical Center, Histocompatibility Laboratory, Pre
PATJ	Immunogenetics and Tissue Typing Lab at Thomas Jefferson Univ. Hospital
PATU	Temple University Hospital Immunogenetics Laboratory
PAUP	Immunology Laboratory at the University of Pennsylvania
PRSJ	Immunogenetics Laboratory at Auxilo Mutuo Hospital
SCMU	Tissue Typing Laboratory at the Medical University of South Carolina
SDMK	Avera McKennan Laboratory
TNDL	DCI Laboratory - Nashville
TNML	Mid-South Transplant Foundation Histocompatibility Laboratory
TXBL	Immune Evaluation Lab-Baylor College of Medicine
TXJS	Tissue Antigen Laboratory at UT Galveston
TXLP	Histo & Immunogenetics Lab at Las Palmas Medical Center
TXMC	Transplant Immunology Laboratory at Methodist Dallas Medical Center
TXMH	Histocompatibility and Immunology Lab at Methodist Hospital
TXMS	Texas Medical Specialty

Source: OPTN Membership data, 4/4/24

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Histocompatibility Lab Members, cont.

Code	Member Name
TXSB	Southwest Transplant Alliance Lab
TXSI	Southwest Immunodiagnostics
TXSP	UT Southwestern Histocompatibility Laboratory
TXSR	Histocompatibility and Immunogenetics Lab/University Health System
TXSW	Histocompatibility Laboratory at Scott and White Memorial Hospital
TXTH	Memorial Hermann-Texas Medical Center
TXTX	Transplant Immunology Laboratory at Baylor University Medical Center
UTMC	Histocompatibility and Immunogenetics Laboratory at the University of Utah
VAMC	VCU Medical Center Histocompatibility and Immunogenetics Laboratory
VANG	HLA Immunology Laboratory at Sentara Norfolk General Hospital
VAUV	Tissue Typing Laboratory at The University of Virginia HSC
WABC	Bloodworks Northwest Immunogenetics Laboratory
WAST	Vitalant-Spokane
WIBC	Versiti, Blood Center of Wisconsin
WISL	HLA Laboratory at Aurora St. Luke's Medical Center
WIUW	Histocompatibility Laboratory at the University of Wisconsin

Source: OPTN Membership data, 4/4/24