UNOS
UNITED NETWORK FOR ORGAN SHARING
Saving lives together

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Executive Director & CEO

May 18, 2023

The Honorable Ron Wyden
Chairman
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

Senator Charles Grassley
Member
Senate Committee on Finance
135 Hart Senate Office Building
Washington, D.C. 20510

VIA ELECTRONIC MAIL

Dear Chairman Wyden and Senator Grassley,

Thank you for the opportunity to provide additional information following the briefing that took place on April 20 regarding the UNet outage. It is a pleasure to continue collaborating with your offices as we work together to improve the nation's organ donation and transplant system.

I am writing to follow up on several additional questions posed by your staff, in this case focused on the Organ Procurement and Transplantation Network (OPTN) Network Operations Oversight Committee (NOOC), how this committee analyzed, debated and came to operational conclusions regarding system availability and soundness, as well as the work that takes place within and the specific role and function of UNet. Importantly, on May 10, UNOS IT staff identified the root cause of the outage. I will follow-up to provide you with the root cause analysis once it is finalized.

There is additional information for your review in the attached Network Operations Metric and Monitoring Report, released in June of 2022.

NOOC overview

In the attached documentation, you will see that the NOOC discussed system "uptime" on several occasions. The overriding direction of the discussions and ultimate decisions were focused on the needs of the system's users, patients and industry best-practices.

The NOOC is an operating committee of the OPTN, made up of patients, transplant professionals, transplant family members, members of the public with background in IT operations, end users of UNet and Department of Health and Human Services (HHS) representatives. It assists the OPTN Board of Directors in its oversight of OPTN operations, including the matching function; the process of official data collection, including data from potential donors, deceased donors, living donors, transplant candidates, and transplant recipients required for the matching function; and other OPTN activities. The NOOC reviews metrics associated with the OPTN matching function and develops an annual review of network operations and metrics, which is submitted to the HHS Contracting Officer Representative (COR).

UNet overview

UNet is the software used by organ donation and transplant professionals every day. It is a secure network of applications consisting of the following:

- **Waitlist:** Waitlist is the application where transplant hospitals list patients in need of a transplant, manage patient health data, and calculate patient medical urgency and predicted transplant benefit.

- **DonorNet™:** DonorNet is the application that allows OPOs to manage deceased donor data, create match runs, and send electronic organ offers to transplant hospitals. It is this same application that transplant hospitals use to review organ imaging and accept or decline organ offers.

- **Data Services Portal:** The Data Services Portal is where OPOs and transplant programs can go to understand their organ donation and transplantation activities, access interactive tools to assist in evaluating their processes, review insights to identify areas for improvement, utilize reports to support their operations, and build custom reports for specific data needs.

- **Transplant Information Electronic Data Interchange (TIEDI):** TIEDI is the application used to collect data for donor, candidate, and recipient-specific records for pre- and post-transplant.

NOOC's determination of clinically acceptable system availability and up-time

As a part of the committee's ongoing oversight and metrics review**,** the NOOC conducted a detailed review of the clinically acceptable availability of the OPTN matching function (uptime) in June of 2022. Based upon this review, the NOOC recommended that the OPTN maintain a 99.9% OPTN matching function uptime, excluding planned maintenance. Where practical, the NOOC recommended that planned maintenance periods should not exceed 30 minutes. You can review the NOOC's full Clinically Acceptable Availability of the OPTN Matching Function mini-brief from June of 2022.

The 2019 OPTN contract with HRSA required 99.5% availability for the matching function. Matching function availability in the contract was initially measured as the overall UNet system availability and included *both* planned and unplanned downtime. Planned downtime is time when UNet is purposefully taken off-line in order to perform system maintenance or to deploy organ allocation policy changes. The OPTN posts system notices to inform UNet users of planned maintenance. **UNet has met or exceeded 99.5% availability throughout the contract period.**

In January of 2022, a modification to the OPTN contract was made to increase the availability requirement to 99.9% and to *exclude* planned maintenance. February 2023 was the first month since this contract modification that system availability fell below 99.9%. However, we remain on track to far exceed this mark for the year, as we have done every year since 2006. Since the outage in February of 2023, UNet has consistently **met or exceeded 99.9% availability.**

At the NOOC's December 2021 meeting, HRSA requested a clear statement from the NOOC on the clinically acceptable availability for the OPTN matching function. In response to this request, the NOOC Chair with UNOS staff under the direction of the Chair conducted individual interviews with each of the NOOC members and advisors. UNOS staff also contacted Gartner, a leading technology research and consulting firm, to obtain general information about system availability in the health care sphere. The findings from the interviews conducted by the NOOC Chair were presented and reviewed by the committee at the February 2022 NOOC meeting. We have attached the relevant meetings minutes to this letter for your review. We have also included, as previously mentioned, the NOOC's Clinically Acceptable Availability of the OPTN Matching Function mini-brief.

Planned vs. unplanned downtime

NOOC members and advisors recognized the need for planned downtime in order to improve and maintain the system. Due to the nature of organ allocation as described above, the committee determined that planned downtime of 30 minutes was not clinically impactful.

The committee members and advisors discussed appropriate baselines and benchmarks for the matching function and concluded that a service level of 99.999% is not warranted based on the clinical timeframes outlined below. There is more information available in the Clinically Acceptable Availability of the OPTN Matching Function mini-brief.

Feedback from Gartner

As a part of this assessment of appropriate availability baselines and benchmarks, UNOS staff gathered feedback from Gartner.

Gartner noted that when supporting a health care system on a nationwide scale like UNet, it is virtually impossible to achieve 99.999% availability, mainly due to the number and variety of endpoints across the national network. Regional systems may be able to provide that level of availability in the specified location where it is hosted, but guaranteeing 99.999% availability across the entire nation is not feasible based on size, scope and grid accessibility.

These types of systems may be able to provide 99.999% availability in the locations where they are hosted, but it is virtually impossible to guarantee 99.999% availability across the nation.

Gartner also confirmed that major electronic health record system providers (EHRs) generally resist giving an availability service level agreement (SLA) guarantee. Gartner noted that EHRs instead often refer to the SLA of the hosting environment instead of the availability of the application itself. Among the leading EHR providers, Epic historically does not provide an availability guarantee for its application, and Cerner will not provide a standard SLA, but will guarantee a 99.96% SLA for a premium. While UNet is technically not an EHR, Gartner agreed that it is comparable to EHRs for system availability purposes.

Finally, Gartner commented that planned maintenance is not normally included in the availability metrics, but it also noted that systems need to ensure adequate operational contingencies, early communication of planned downtime and infrastructure redundancies to protect against any

unintended downtime during planned maintenance. Direct quotations from Gartner's assessment can be found in the attached mini-brief.

NOOC and the clinical impact of the outage

During our briefing, we mentioned that while the goal is to *always* maintain consistent and reliable system availability, the specific outage that occurred on February 15 was not clinically impactful.

Concerns about the clinical impact of February 15 outage were raised during the NOOC meeting on February 28, 2023. The committee discussed that, while a 45-minute outage is unfortunate, organ allocation before and after the match runs take decidedly longer than that brief window of time. In fact, as previously mentioned, the time between an offer being accepted and a patient entering the operating room is performed over several hours, sometimes even days. It was also discussed, as recorded in the meeting minutes, that transplant coordinators on the ground are in possession of a printed copy of backup recipients on the waitlist, which they take with them into the operating room. The list sometimes also includes backup physicians in case the need suddenly arises to expediate placement of the donor organ.

Finally, it was mentioned during the meeting that when an organ is in the process of being allocated, there are multiple individuals who have already seen that specific offer. During any unexpected outage, those individuals will not necessarily need UNet to further analyze the organ.

Based on this information, as well as the reality that the time between organ offer and acceptance can take multiple days and that a significant portion of the organ donation and transplant process takes place outside of UNet, the NOOC determined that an outage of 44 minutes is not clinically impactful.

We have attached the NOOC meeting minutes from both February 16 and 28, 2023 to this letter for your review.

The role and function of UNet and its use on February 15

Organ allocation is a meticulously designed process, coordinated by organ donation and transplant professionals from organ procurement organizations (OPOs) and transplant hospitals. This is evidenced by the fact that organ offers occur hours or days before the actual organ recovery operation takes place. Additionally, most organ recoveries occur at night when operating rooms are available for organ recovery. Likewise, OPOs add information about donors into UNet well before the organ recovery operation or organ offers occur. In other words, adding a donor in UNet is not the same as, and typically happens before, making organ offers for that donor.

To illustrate, UNOS staff reviewed the duration of time between a donor being added to UNet and final organ acceptance. In calendar year 2021, according to the Clinically Acceptable Availability of the OPTN Matching Function mini-brief, this timeframe averaged between 48 and 84 hours, depending on the organ.

There were around 211 matches that were run on February 15, which aligns with the number of match runs initiated per day on average. Specifically, during the time of the incident, our data shows only two deceased donors being entered into the system to run new matches. These matches were run at 6:29 a.m. and 8:34 a.m., respectively, both of which occurred outside the brief window when UNet was unavailable. Final acceptances for these organs were not completed until a day or two later, in keeping with the above-mentioned data regarding the duration of time between a donor being added into UNet and final acceptance.

To answer a related question offered by committee staff, our data show that 15 patients were removed from the waitlist due to death on February 15. Any death on the waitlist is tragic and our commitment to serving every patient waiting continues to be the driving force behind our community's work. However, the number of waitlist deaths on February 15 was not significantly higher or lower when compared to the week prior, the week the incident took place, and the week after. We have included a graph of the data for your review.

As we have sought to convey, a great deal of work must take place before donor information is ever added into the DonorNet application, and the work continues outside of the application once a recipient has been identified. While UNet's role is critical, its part in the process, from organ recovery to organ transplantation, is only one part of a much larger workflow. We hope these additional data points may help put the impact of the outage into perspective.

Non-time-sensitive work taking place within UNet

While UNet is used for a wide variety of tasks, including time-sensitive work, UNet is also routinely used for a wide variety of non-time sensitive work. For example, a transplant hospital may use the Organ Offers dashboard in the Data Services application to review past organ offers made to candidates at their transplant hospital. This dashboard provides hospitals with a summary of offers, donor acceptance rates and candidate and donor information about each match run. This type of task is performed by transplant professionals within UNet and provides data that can help inform future decisions about organ acceptance, but does not directly affect patients and is not time sensitive.

Additionally, OPOs and transplant hospitals are required by OPTN policy to submit different types of data. Through TIEDI, members receive, complete and submit these records electronically. For example, OPOs are required to complete a deceased donor registration form in TIEDI 60 days after an organ donation takes place. This data collection does not affect patient care, nor is it time critical.

The UNet Waitlist application includes an option for building custom reports and exporting waitlist data. It also contains many pre-built report options for accessing transplant candidate information. Hospitals will use this option within UNet to run any number of reports. For example, staff could use this tool to determine the specific number of candidates with different blood types according to medical urgency status. Running these reports does not directly affect patient care and is not time sensitive.

Policy currently in place

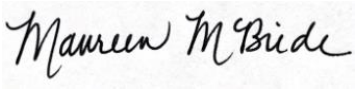
There is a specified OPTN policy in place, established in the event of an incident that makes UNet inaccessible for transplant programs, OPOs or any other user. OPTN Policy 1.4.E states that if: "the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. Must refer to recent matches of similar blood type and body size for ranking transplant candidates.
2. Must use transplant program waiting lists to match the best organ with waiting transplant candidates.
3. Must document and report to the OPTN their process for allocation during the outage."

The goal of this policy is to ensure continuity and ongoing service to patients in the rare occurrence that UNet is unavailable for an extended period. There are other OPTN policies in place, specifically related to the allocation of donor organs during emergencies.

I hope that this fuller context and additional information about the role and decision-making process of the NOOC as well as the role and different services provided within UNet addresses many of the questions posed during the recent briefing. Please let me know if you have any additional questions, and I appreciate your continued interest and partnership in improving the nation's organ donation and transplantation system.

Sincerely,



Maureen McBride, Ph.D.
Chief Executive Officer
United Network for Organ Sharing

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Contract: HHSH250-2019-00001C
Task: 3.2.5.5
Item: A061
Due: June 21, 2022
Submitted: June 13, 2022

Network Operations Metrics and Monitoring Report

NETWORK OPERATIONS METRICS AND MONITORING REPORT

PWS Excerpt:

3.2.5.5 Support an OPTN BOD Network Operations Oversight Committee

The Contractor shall work with the OPTN BOD to establish, support, and maintain a Network Operations Oversight Committee to assist the OPTN BOD in its oversight of the OPTN operations, including the OPTN matching function, the process of official OPTN data collection, including data from potential donors, deceased donors, living donors, transplant candidates, and transplant recipients required for the OPTN matching function and other OPTN activities.

The Contractor shall support the committee in developing objective metrics to:

- monitor the efficiency and effectiveness of the OPTN matching function, including conformance of matching function to OPTN BOD approved policies;
- monitor timeframes for implementing BOD approved policies, based on complexity of work
- monitor the frequency of policy programing revisions occurring post-implementation; and
- monitor progress toward direct electronic data submission from electronic medical record systems of OPTN members to reduce data collection burden

The Contractor shall assist the committee in developing an annual review of network operations metrics and submit the report to the COR prior to the end of the base contract period, and 180 business days from the beginning of optional contract performance periods. The Contractor shall support the committee chair in making annual presentations of the findings of the metrics review to the BOD and EC.

Performance Standards

a) Standard: Annual committee review and report of metrics includes the following:

- Assessment of match run outcomes reflecting OPTN BOD approved policies.
- Timing of policy/programming implementation following approval by the BOD
- Status of improved data linkage to members and resulting improvement in data quality (as identified in the DAC data process report) and reduction in data entry burden on members

SCHEDULE OF DELIVERABLES & MILESTONES

1. Network Operations Metrics and Monitoring Report (Base Year) – September 27, 2019
2. Network Operations Metrics and Monitoring Report (Option Year 1) – June 18, 2020
3. Network Operations Metrics and Monitoring Report (Option Year 2) – June 21, 2021
4. Network Operations Metrics and Monitoring Report (Option Year 3) – June 21, 2022
5. Network Operations Metrics and Monitoring Report (Option Year 4) – June 21, 2023

This report reflects the work of the OPTN Network Operations Oversight Committee from April 2021 – March 2022.

PURPOSE

The Network Operations Metrics and Monitoring report provide objective metrics that the OPTN Network Operations Oversight Committee (NOOC) identified to monitor the implementation of the OPTN matching function and the process of official OPTN data collection. These objective metrics monitor the efficiency and effectiveness of the matching function, monitor timeframes for implementing OPTN Board of Directors (BOD) approved policies, monitor the frequency of policy programming revisions, and monitor progress toward direct electronic data submission from electronic medical records.

The NOOC contract task also includes a performance standard to monitor the status of improvements in data quality (as identified in the Data Advisory Committee data process report) and reduce data entry burden. The NOOC will review recommendations from the OPTN Data Advisory Committee (DAC) for improving data quality, as described in DAC's annual report to the BOD and included in the DAC data process report.

Note that the tools described in this report are those used by the OPTN Contractor. These tools are proprietary systems that deliver required functionality for the OPTN. The following table describes the description of the OPTN tool along with the proprietary name used by the OPTN Contractor. The proprietary names are used throughout this report.

OPTN System Name	**Proprietary System Name used by OPTN Contractor**
OPTN Computer System	UNet℠
OPTN Data System	TIEDI®
OPTN Organ Labeling, Packaging and Tracking System	TransNet
OPTN Donor Data and Matching System	DonorNet®
OPTN Waiting List	Waitlist℠
OPTN Kidney Paired Donation Pilot Project (KPDPP)	KPDPP

BACKGROUND

Some of the metrics included in this report are based upon the BOD Project Delivery Commitment (PDC) for the implementation of BOD projects and the OPTN contract's timeline for customer support resolution of issues.

In 2016, the OPTN BOD established the following PDC for the implementation of BOD projects:

- The implementation of 100% of BOD projects complete within 12 months of their approval date

The BOD may grant exceptions to the PDC. In the past, the BOD has granted exceptions to allow member organizations more time to prepare for the policy implementation, to expedite the implementation of another BOD project, or to accommodate an implementation dependency that is outside of the control of the OPTN (e.g. Office of Management and Budget (OMB) approval of data collection forms).

APPROACH

UNOS staff compile these metrics each quarter and review them internally before sharing them with the Network Operations Oversight Committee at their next scheduled meeting.

UNOS staff also compile a Network Operations and Monitoring report each year and review it with the Network Operations Oversight Committee before submitting it to the COR. Each report includes information compiled over each complete quarter during the reporting period. This report includes metrics for the four complete quarters in this reporting period (April 2021 – March 2022).

The metrics included in this report cover a range of factors and are designed to give the NOOC insight into the overall performance of the OPTN matching function. Indicators included in this report illustrate efficiency, availability, accuracy, and timeliness of the matching function. These measures have been included based on requirements of the OPTN Contract, directives from the OPTN Board of Directors, and requests from members of the NOOC.

Efficiency measures include:
- Distribution of match run times
- Organ offer notification delivery and response time
- Percentage of Official OPTN data elements in Waitlist℠, DonorNet®, and TIEDI® that can be submitted via API
- UNet℠ API projects implemented and planned
- UNet℠ API Adoption

Availability measures include:

- Matching function availability by month
- Occurrences of scheduled matching function downtime
- Matching Function Issues by category by month

Accuracy measures include:
- Policy implementation revisions affecting the matching function

Timeliness measures include:
- Policy Project Implementation Performance (based on Board of Directors Project Delivery Commitment (PDC) for implementation of BOD projects)
- Median policy project implementation time

This report also includes the following additional information:
- UNet℠ Usability Survey Results

We also work with the Network Operations Oversight Committee to identify additional metrics to address the anticipated challenges described at the end of this document.

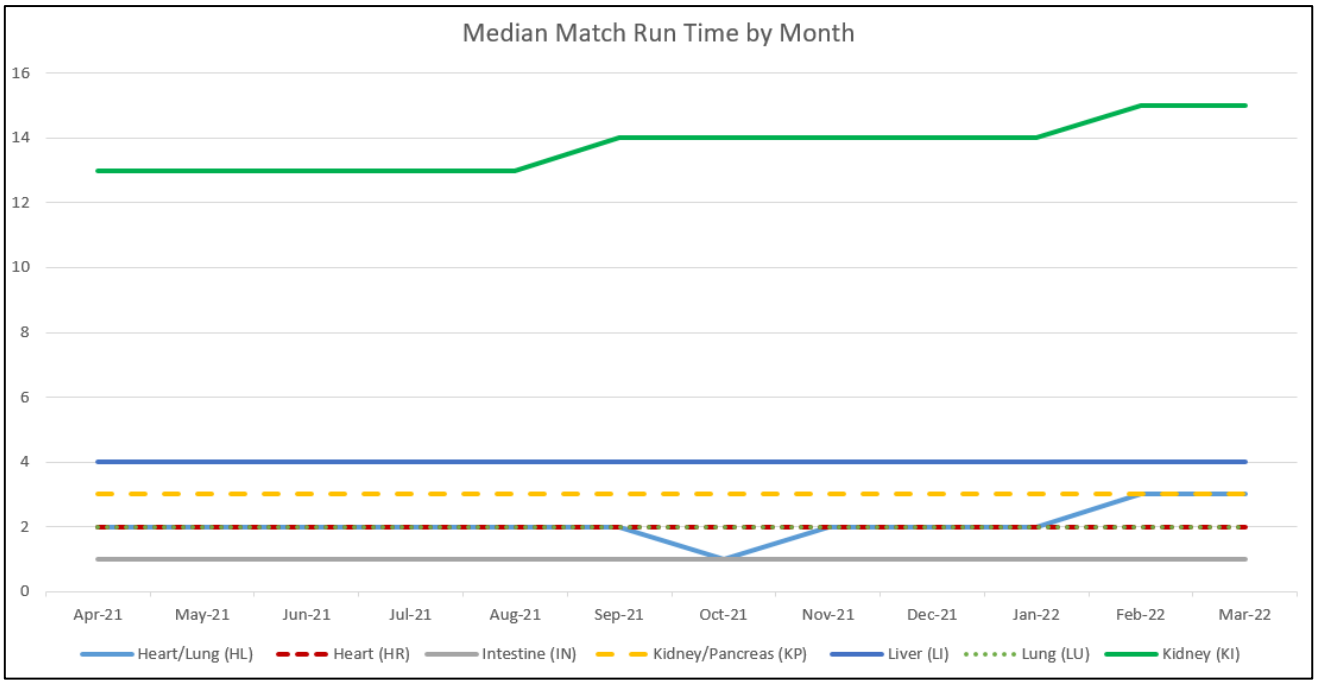
REPORT

Efficiency Measures

Distribution of match run times (in seconds) by organ

Running a match is the first step that OPO users take in the UNet^{SM} system when they are ready to begin organ allocation. When OPO users run a match for an organ, UNet^{SM} checks to see that all of the required donor parameters are available and then run an algorithm that produces an ordered list of potential recipients for the organ according to OPTN policy. The total runtime is the number of seconds it takes for the algorithm to produce the list the potential recipients.

The charts below show that the median match run time for kidney remained under 16 seconds during the reporting period. The median match run time for the other organs is under 5 seconds.



Month	Organ(s)	Min (Sec.)	Median (Sec.)	99th Percentile	Max (Sec.)	Count
Apr-21	Heart/Lung (HL)	1	2	6	9	591
	Heart (HR)	1	2	5	8	487
	Intestine (IN)	1	1	3	5	669
	Kidney (KI)	7	13	20	44	1641
	Kidney/Pancreas (KP)	1	3	8	24	831
	Liver (LI)	2	4	10	35	1656
	Lung (LU)	1	2	5	33	867
May-21	Heart/Lung (HL)	1	2	8	33	611
	Heart (HR)	1	2	5	16	452

Month	Organ(s)	Min (Sec.)	Median (Sec.)	99th Percentile	Max (Sec.)	Count
	Intestine (IN)	1	1	3	17	735
	Kidney (KI)	7	13	22	230	1752
	Kidney/Pancreas (KP)	1	3	8	36	890
	Liver (LI)	1	4	9	45	1721
	Lung (LU)	1	2	6	21	873
Jun-21	Heart/Lung (HL)	1	2	7	43	665
	Heart (HR)	1	2	5	12	428
	Intestine (IN)	1	1	3	43	795
	Kidney (KI)	7	13	23	103	1772
	Kidney/Pancreas (KP)	1	3	8	43	941
	Liver (LI)	2	4	11	93	1753
	Lung (LU)	1	2	7	62	950
Jul-21	Heart/Lung (HL)	1	2	6	12	669
	Heart (HR)	1	2	5	7	487
	Intestine (IN)	1	1	3	4	769
	Kidney (KI)	7	13	23	333	1760
	Kidney/Pancreas (KP)	1	3	6	11	911
	Liver (LI)	2	4	10	64	1773
	Lung (LU)	1	2	4	17	949
Aug-21	Heart/Lung (HL)	1	2	6	13	577
	Heart (HR)	1	2	6	12	437
	Intestine (IN)	1	1	3	25	759
	Kidney (KI)	7	13	26	177	1572
	Kidney/Pancreas (KP)	1	3	8	187	867
	Liver (LI)	2	4	10	230	1657
	Lung (LU)	1	2	5	32	822
Sep-21	Heart/Lung (HL)	1	2	7	21	534
	Heart (HR)	1	2	6	30	458
	Intestine (IN)	1	1	3	15	634
	Kidney (KI)	7	14	26	175	1496
	Kidney/Pancreas (KP)	1	3	7	29	796
	Liver (LI)	2	4	8	89	1564
	Lung (LU)	1	2	7	62	749
Oct-21	Heart/Lung (HL)	1	1	6	27	566
	Heart (HR)	1	2	6	14	436
	Intestine (IN)	1	1	3	34	706
	Kidney (KI)	7	14	25	333	1598
	Kidney/Pancreas (KP)	1	3	6	27	854
	Liver (LI)	2	4	10	86	1649

Month	Organ(s)	Min (Sec.)	Median (Sec.)	99th Percentile	Max (Sec.)	Count
	Lung (LU)	1	2	5	62	829
Nov-21	Heart/Lung (HL)	1	2	7	153	555
	Heart (HR)	1	2	5	8	502
	Intestine (IN)	1	1	3	144	693
	Kidney (KI)	7	14	23	168	1606
	Kidney/Pancreas (KP)	1	3	8	156	849
	Liver (LI)	2	4	10	156	1635
	Lung (LU)	1	2	5	144	794
Dec-21	Heart/Lung (HL)	1	2	6	12	509
	Heart (HR)	1	2	8	45	462
	Intestine (IN)	1	1	3	5	664
	Kidney (KI)	7	14	23	86	1599
	Kidney/Pancreas (KP)	1	3	6	55	796
	Liver (LI)	2	4	9	59	1606
	Lung (LU)	1	2	5	12	732
Jan-22	Heart/Lung (HL)	1	2	8	29	488
	Heart (HR)	1	2	5	12	473
	Intestine (IN)	1	1	3	6	705
	Kidney (KI)	7	14	23	233	1586
	Kidney/Pancreas (KP)	1	3	7	16	781
	Liver (LI)	2	4	10	100	1608
	Lung (LU)	1	2	5	66	706
Feb-22	Heart/Lung (HL)	1	3	7	19	569
	Heart (HR)	1	2	7	23	458
	Intestine (IN)	1	1	3	8	693
	Kidney (KI)	8	15	26	57	1571
	Kidney/Pancreas (KP)	1	3	7	14	827
	Liver (LI)	2	4	9	53	1627
	Lung (LU)	1	2	6	59	786
Mar-22	Heart/Lung (HL)	1	3	6	102	601
	Heart (HR)	1	2	6	27	502
	Intestine (IN)	1	1	3	100	756
	Kidney (KI)	8	15	24	105	1722
	Kidney/Pancreas (KP)	1	3	6	101	889
	Liver (LI)	2	4	9	104	1770
	Lung (LU)	1	2	5	102	869

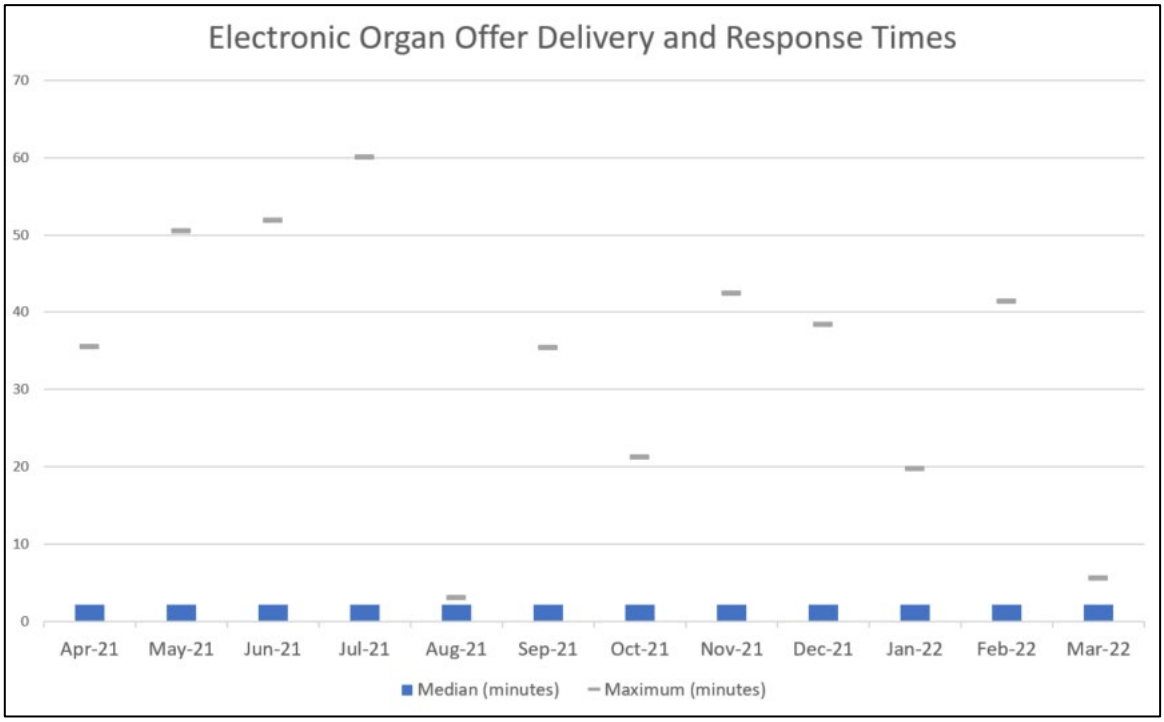
The Kidney matches are approximately 85% of all match runs. The median is within normal ranges. Since the match algorithm must evaluate all candidates listed on the waitlist for a particular organ at the time

of the match run, match run times vary depending upon the size of the waitlist. Since Kidney registrations make up over 80% of all waitlist registrations, the kidney match run times tend to be greater than for other organs. For example, as of 10/20/2021 there were 97,768 kidney waitlist registrations. The organ with the next largest number of waitlist registrations was for liver with 11,921.

Organ offer notification delivery and response time

UNOS uses top tier providers (Twilio and MIR3) to deliver electronic organ offer notifications. The organ offer notification delivery metrics reflect the number of minutes before UNet[SM] receives confirmation that the third-party service has delivered the electronic organ offer.

UNOS adjusted the electronic organ offer configuration when we noticed that one of the two vendors was experiencing delays in sending out electronic organ offers in November and December.



	Number of electronic organ offers		Notification response time in minutes		
Month	**Total**	**Total exceeding 10 minutes**	**Maximum**	**99th Percentile**	**Median**
Apr. 2021	135,211	45	35.52	2.27	2.17
May 2021	145,825	1	50.52	2.27	2.17
Jun. 2021	151,852	9	51.88	2.27	2.17
Jul. 2021	157,058	41	60.03	2.27	2.17
Aug. 2021	146,479	0	3.15	2.27	2.17
Sept. 2021	139,999	6	35.50	2.27	2.17
Oct. 2021	149,748	1	21.33	2.27	2.17
Nov. 2021	154,304	43	42.47	2.27	2.17
Dec. 2021	150,089	75	38.48	2.27	2.17
Jan. 2022	142,926	2	19.78	2.27	2.17
Feb. 2022	142,855	9	41.47	2.27	2.17
Mar. 2022	149,993	0	5.57	2.27	2.17

Percentage of Official OPTN data elements in Waitlist℠, DonorNet®, and TIEDI® that can be submitted via API

Application Programming Interfaces (APIs) allow different computer applications to share data with one another, even when they weren't designed to do that initially. UNet℠ APIs allow software vendors and healthcare IT departments to build seamless and secure interfaces between hospital, OPO and histocompatibility laboratory electronic health records (EHRs) and UNet℠. These interfaces allow users to submit data to UNet℠ directly from their EHR with the aim of reducing data burden, and improving the quality and timeliness of data submission.

The following chart shows the percentage of official OPTN data elements in Waitlist℠, DonorNet®, and TIEDI® that can be submitted via UNet℠ APIs.

	2021									2022		
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Seamless Data Submission to UNet℠	61%	62%	62%	62%	62%	63%	63%	63%	64%	64%	64%	64%
OPO - All Deceased Donor Reporting	91%	91%	91%	91%	91%	91%	91%	91%	91%	91%	91%	91%
Histocompatibility lab – TIEDI® reporting	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Transplant Center - Living Donor Reporting (excludes KPD)	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%
Transplant Center - Candidate Management	24%	28%	28%	28%	28%	28%	29%	29%	32%	32%	32%	32%
Transplant Center - Recipient Reporting	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%	89%

Histocompatibility Labs reporting appear to have only 0% coverage because the data they are responsible for under OPTN policy is limited to just the Recipient and Donor Histocompatibility forms in TIEDI. Their role is supplying and updating data in support of transplant programs and OPOs is larger than that however. The histocompatibility community is directly engaged with HLA and unacceptable antigen reporting throughout UNet, and most major labs information systems have, or plan to, implement the

unacceptable antigen API in Waitlist, which falls under transplant hospital - Waitlist candidate reporting. UNOS IT is currently working with the OPTN histocompatibility committee on revised policies and implementation that will further standardize the HLA collection for patients and donors across the UNet systems (Waitlist, DonorNet, TIEDI and KPD).

UNet℠ API projects implemented and planned

Development work on the Waitlist Registration Lung Allocation Score APIs that began in FY2021 Q3 has now completed. In September, the LAS calculation API and several APIs for data submission and retrieval of lung data were completed and released to production. In December, the remaining APIs were completed, which fully incorporated the recent changes to lung policy released on September 30 (Refine Lung Data Fields)

https://optn.transplant.hrsa.gov/media/4uyjmg30/refine_lung_data_fields_policy_notice_july_2021.pdf and Update Cohort for Calculation of the Lung Allocation Score https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf). A formal demonstration of the new features to integrators was held in January 2022.

Development is ongoing for a series of TransNet APIs designed to support transplant programs in such critical pre-transplant activities including the organ check in and pre-transplant verification processes. The first of these supporting APIs was released in July 2021, and allows for the retrieval of donor ID with organ and laterality for accepted organs. This API supports transplant programs as they prepare patients for surgery following organ acceptance, ensuring the right organ can be associated with the patient in the hospital's EMR, and is documented as the expected organ. Additional design and development work to support organ check-in upon arrival is scheduled for FY2022.

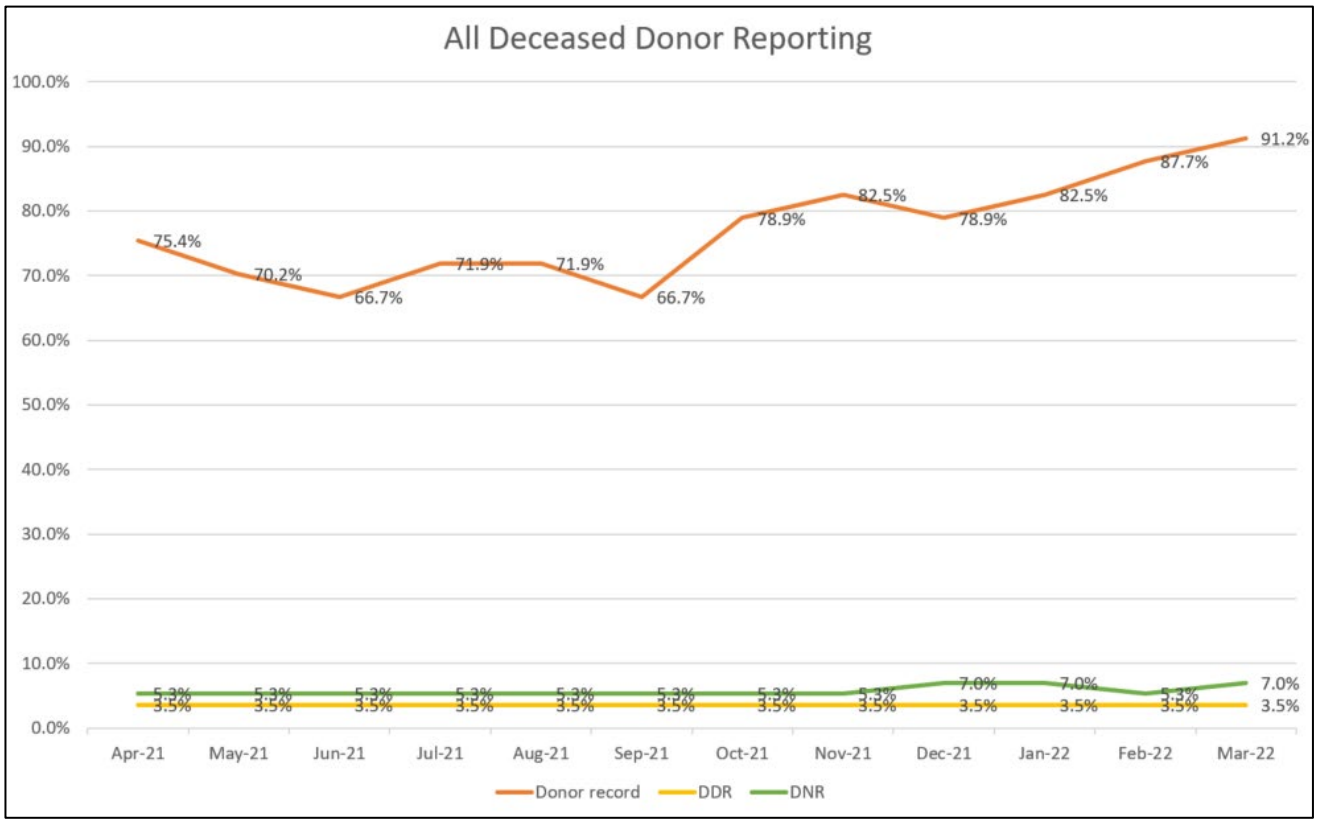
Histocompatibility community needs are a key focus for both API adoption and development looking forward to FY2022. The legacy file-based import to support unacceptable antigen reporting will be deprecated as UNOS supports the community in transitioning to the more secure API-based import that was released in 2019. Reporting of these data represents a significant maintenance burden for waitlist, and is instrumental in safely matching patients to available organs. An API allowing for the retrieval of donor HLA to support real-time virtual crossmatch during the organ offer and evaluation process is scheduled for development and release in Q3 FY2022.

UNet℠ API Adoption

To measure the growing adoption of our API features, UNOS reports the percentage of member institutions utilizing each API feature per month. A few important notes:

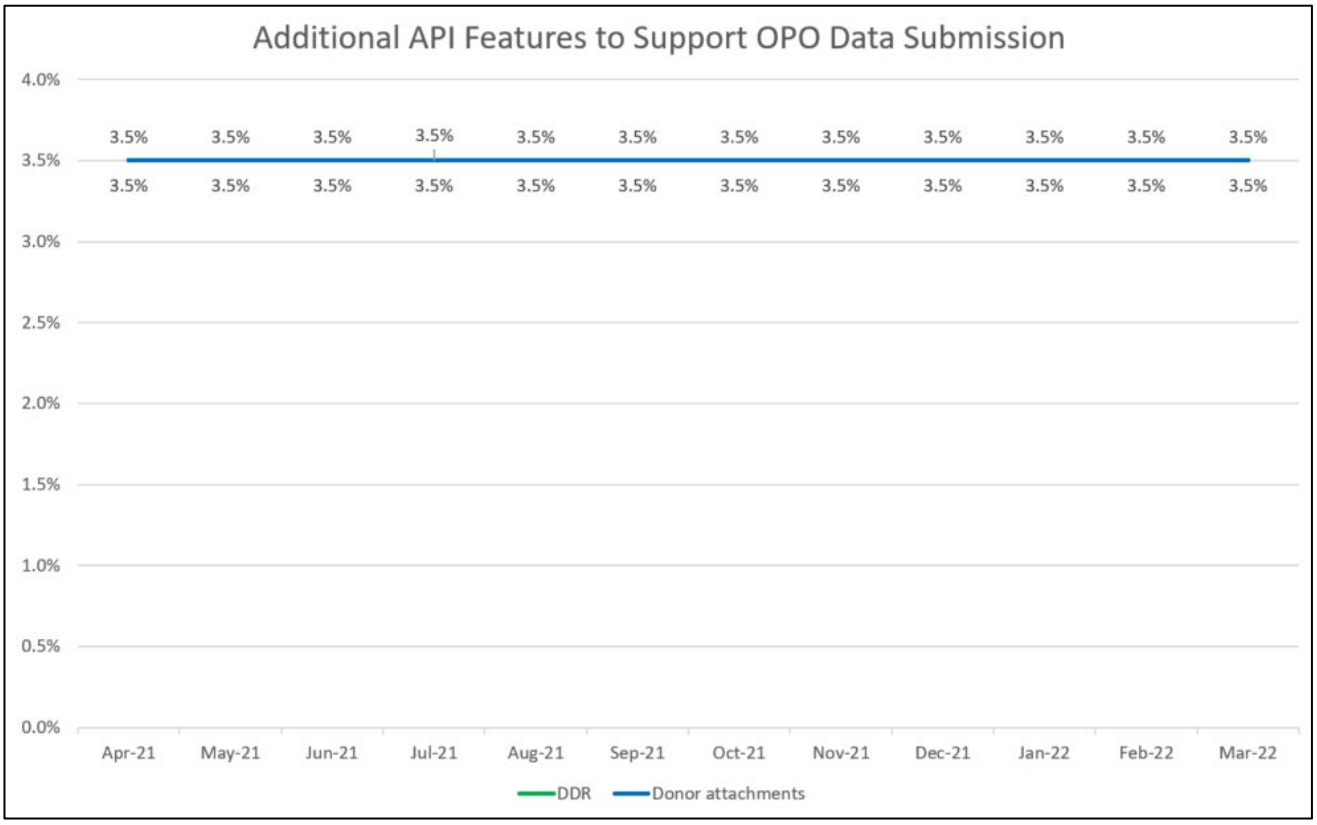
1. Once EHR vendors implement solutions that consume the UNet APIs, member institutions are able to upgrade to those versions of their vendor software, go through a testing and verification process as dictated by their organizations, and then start using them.
2. For some API features, a member institution may not use a feature every month even if they have the capability. For example, if a transplant hospital does not have any expected Transplant Recipient Follow-up (TRF) forms due in particular month, that transplant hospital may not use the TRF Import API feature during that month. Based on this, it is normal to see small variations in adoption percentages per month.
3. For Calculator API features, the adoption metrics are reported based on the total traffic (amount of calls) made per month.

All Deceased Donor Reporting			
API	**API Name**	**Description**	**Data Source**
Donor record	Deceased Donor Record in DonorNet®	This API allows an OPO professional to submit data directly into DonorNet. Donor records are updated regularly during an active case.	The data comes from the Electronic Donor Record (EDR) system.
DDR	Deceased Donor Registration (DDR) in TIEDI® Import	This API allows an OPO professional to submit the required data to the OPTN for DDR and associated DCD forms.	The data comes from the Electronic Donor Record (EDR) system.
DNR	Death Notification Registrations (DNR) - Imminent and Eligible Deaths	This API allows an OPO professional to update one or more DNR records to UNet without leaving their application.	The data provided comes from the Electronic Donor Record (EDR) system.



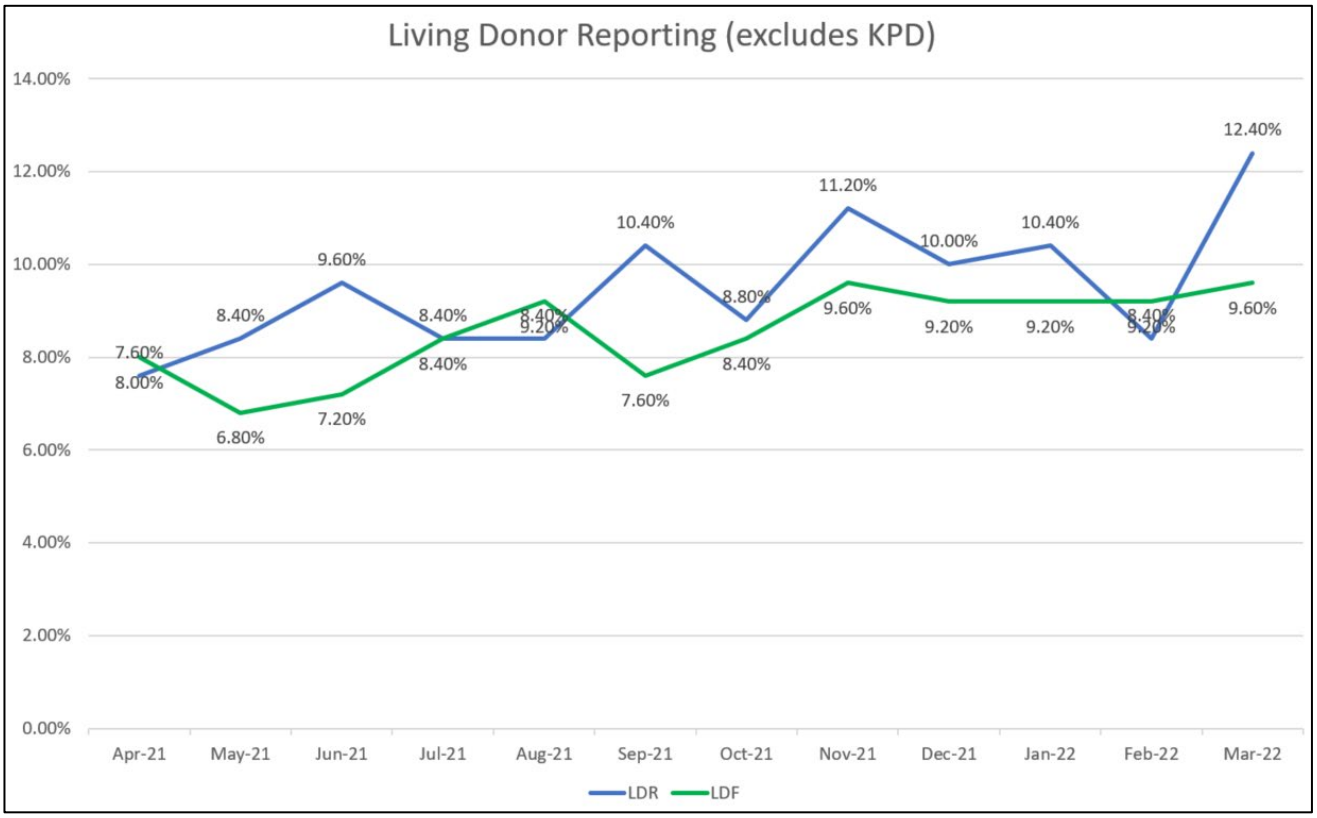
All Deceased Donor Reporting Member Adoption (percentage of OPOs)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
Donor record	**75.4%**	**70.2%**	**66.7%**	**71.9%**	**71.9%**	**66.7%**	**78.9%**	**82.5%**	**78.9%**	**82.5%**	**87.7%**	**91.2%**
DDR	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**
DNR	**5.3%**	**5.3%**	**5.3%**	**5.3%**	**5.3%**	**5.3%**	**5.3%**	**5.3%**	**7.0%**	**7.0%**	**5.3%**	**7.0%**

Additional API Features to Support OPO Data Submission and Other Workflows			
API	**API Name**	**Description**	**Data Source**
DDR	Deceased Donor Registration (DDR) in TIEDI® Export	This API allows an OPO professional to export all expected DDR and associated DCD forms. This API facilitates workflows that promote on-time data submission to the OPTN.	The export data comes from the form in TIEDI.
Donor attachments	Deceased Donor Attachments	This API allows an OPO professional to synchronize donor attachments between DonorNet and other systems.	The donor attachments are added to DonorNet from the Electronic Donor Record (EDR) system, or can be pulled down from DonorNet to complete the record in the EDR.



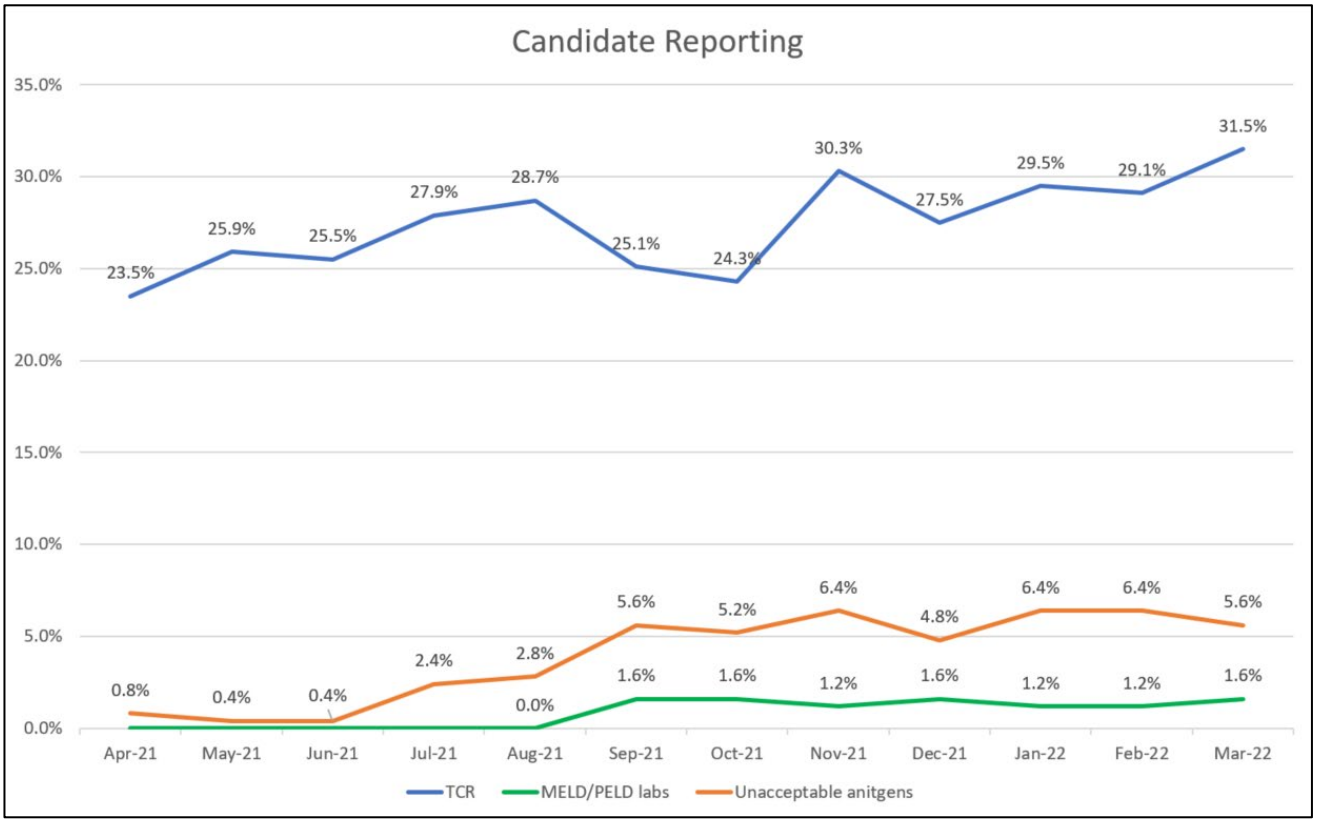
Additional API Features to Support OPO Data Submission and Other Workflows Member Adoption (percentage OPOs)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
DDR	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**
Donor attachments	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**

Living Donor Reporting			
API	**API Name**	**Description**	**Data Source**
LDR	TIEDI® - Living Donor Registration (LDR) Import	This API allows a transplant hospital professional to submit the required data to the OPTN for the TIEDI LDR forms.	The data comes from the Electronic Heath Record (EHR) system.
LDF	TIEDI® - Living Donor Follow-up (LDF) Import	This API allows a transplant hospital professional to submit the required data to the OPTN for the TIEDI LDF forms.	The data comes from the Electronic Heath Record (EHR) system.



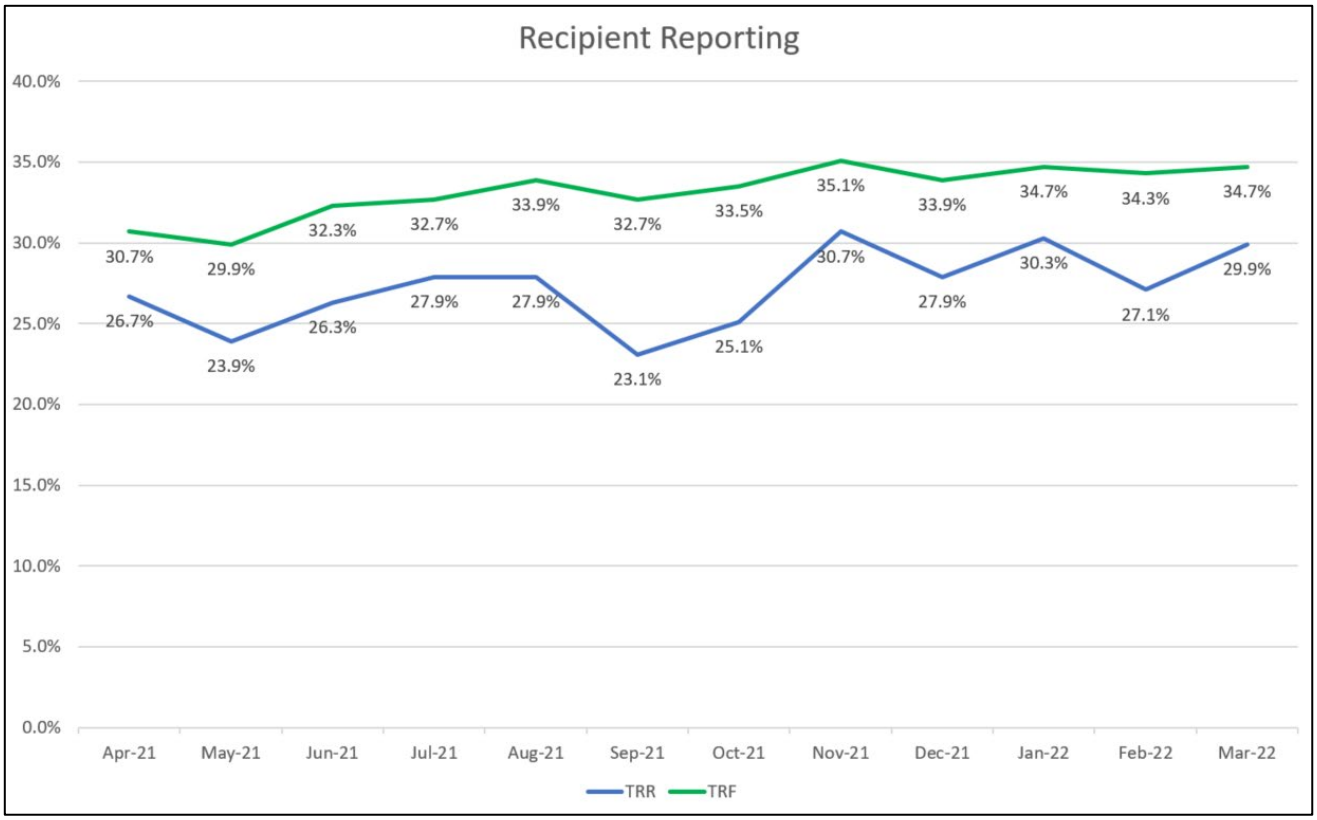
Living Donor Reporting Member Adoption (percentage Transplant Hospitals)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
LDR	**7.6%**	**8.4%**	**9.6%**	**8.4%**	**8.4%**	**10.4%**	**8.8%**	**11.2%**	**10.0%**	**10.4%**	**8.4%**	**12.4%**
LDF	**8.0%**	**6.8%**	**7.2%**	**8.4%**	**9.2%**	**7.6%**	**8.4%**	**9.6%**	**9.2%**	**9.2%**	**9.2%**	**9.6%**

Candidate Reporting			
API	**API Name**	**Description**	**Data Source**
TCR	TIEDI® - Transplant Candidate Registration (TCR) Import	This API allows a transplant hospital professional to submit the required data to the OPTN for the TIEDI TCR forms.	The data comes from the Electronic Heath Record (EHR) system.
MELD/PELD labs	WaitlistSM - Liver Lab data (MELD/PELD)	This API allows a transplant hospital professional to retrieve and submit liver lab data for a liver registration without the need to log into UNet, navigate to Waitlist, and enter the data manually. These data calculate a MELD or PELD score used to rank patients on the match.	The data comes from the Electronic Heath Record (EHR) system.
Unacceptable antigens	WaitlistSM - Unacceptable Antigens	This API allows a transplant hospital or laboratory professional to retrieve and submit unacceptable antigen data without the need to log into UNet, navigate to Waitlist and update or import the data manually.	This data comes from either the Laboratory Information System (LIS) and/or the Electronic Heath Record (EHR) system.



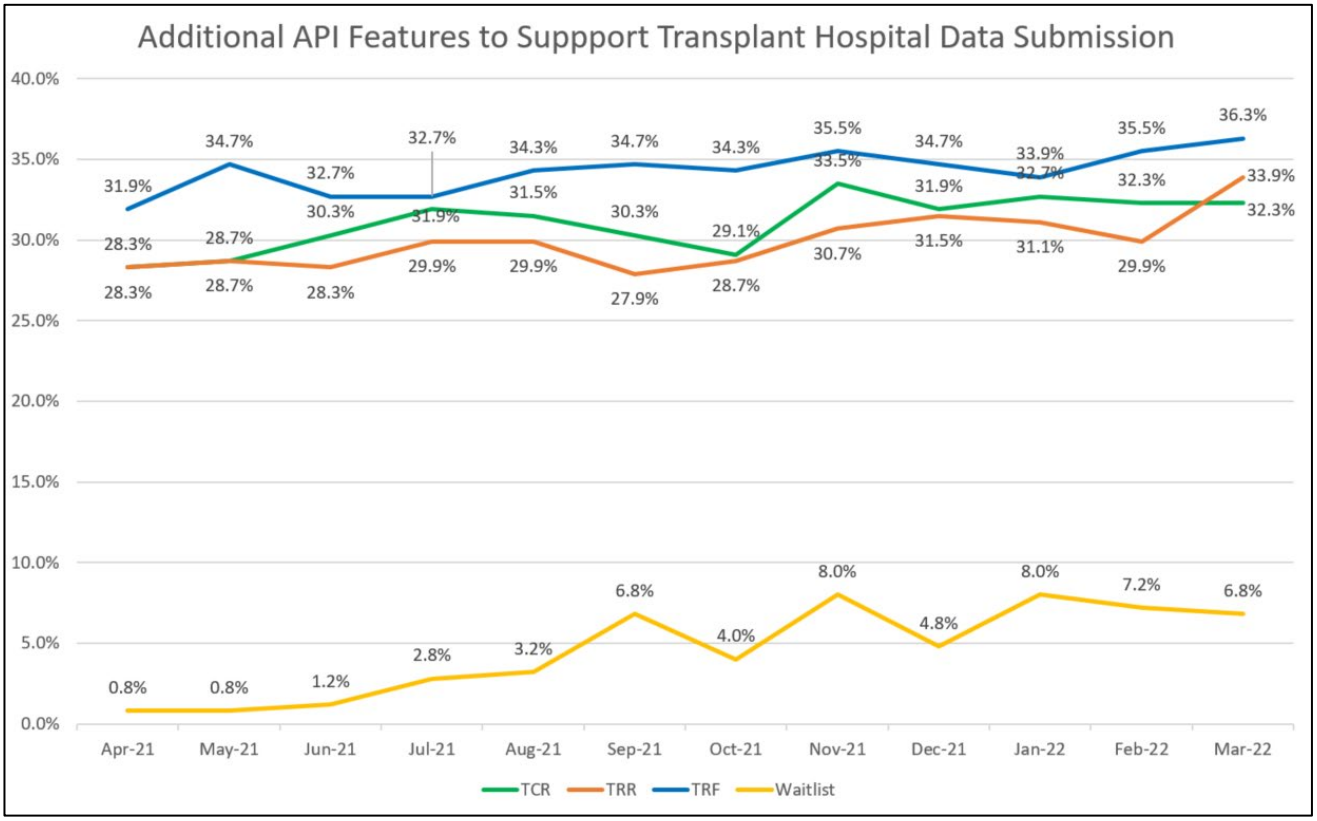
Candidate Reporting Member Adoption (percentage Transplant Hospitals)												
API	2021									2022		
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
TCR	23.5%	25.9%	25.5%	27.9%	28.7%	25.1%	24.3%	30.3%	27.5%	29.5%	29.1%	31.5%
MELD/PELD labs	0.0%	0.0%	0.0%	0.0%	0.0%	1.6%	1.6%	1.2%	1.6%	1.2%	1.2%	1.6%
Unacceptable antigens	0.8%	0.4%	0.4%	2.4%	2.8%	5.6%	5.2%	6.4%	4.8%	6.4%	6.4%	5.6%

Recipient Reporting			
API	**API Name**	**Description**	**Data Source**
TRR	TIEDI® - Transplant Recipient Registration (TRR) Import	This API allows a transplant hospital professional to submit the required data to the OPTN for the TIEDI TRR forms.	The data comes from the Electronic Heath Record (EHR) system.
TRF	TIEDI® - Transplant Recipient Follow-up (TRF) Import	This API allows a transplant hospital professional to submit the required data to the OPTN for the TIEDI TRF forms.	The data comes from the Electronic Heath Record (EHR) system.



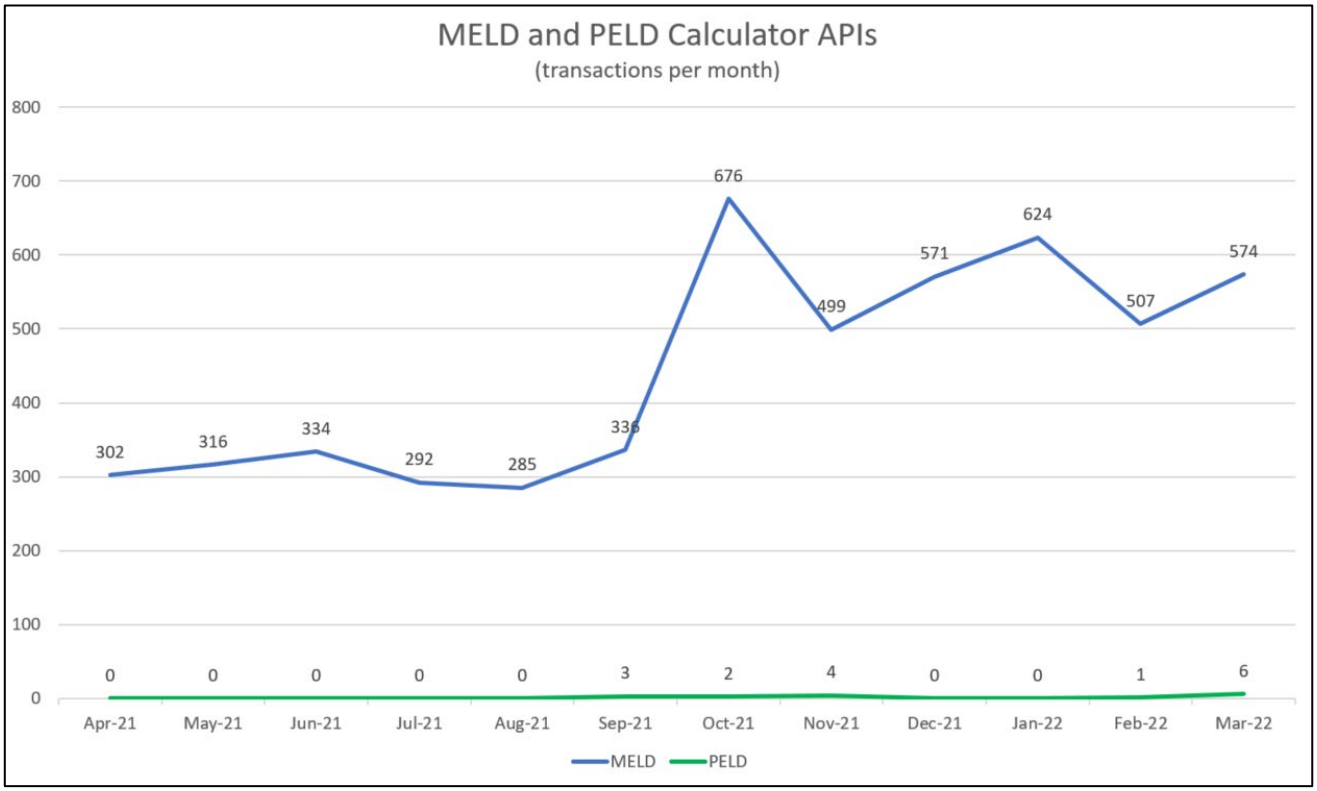
Recipient Reporting Member Adoption (percentage Transplant Hospitals)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
TRR	**26.7%**	**23.9%**	**26.3%**	**27.9%**	**27.9%**	**23.1%**	**25.1%**	**30.7%**	**27.9%**	**30.3%**	**27.1%**	**29.9%**
TRF	**30.7%**	**29.9%**	**32.3%**	**32.7%**	**33.9%**	**32.7%**	**33.5%**	**35.1%**	**33.9%**	**34.7%**	**34.3%**	**34.7%**

Additional API Features to Support Transplant Hospital Data Submission and Other Workflows			
API	**API Name**	**Description**	**Data Source**
TCR	TIEDI® - Transplant Candidate Registration (TCR) Export	This API allows a transplant hospital professional to pull expected TIEDI TCR forms and due dates for newly waitlisted patients. It is designed to facilitate workflows that promote on-time data submission to the OPTN.	The export data comes from the form in TIEDI.
TRR	TIEDI® - Transplant Recipient Registration (TRR) Export	This API allows a transplant hospital professional to pull expected TIEDI TRR forms and due dates for recently transplanted patients. It is designed to facilitate workflows that promote on-time data submission to the OPTN.	The export data comes from the form in TIEDI.
TRF	TIEDI® - Transplant Recipient Follow-up (TRF) Export	This API allows a transplant hospital professional to pull expected TIEDI TRF forms and due dates for transplanted patients. It is designed to facilitate workflows that promote on-time data submission to the OPTN.	The export data comes from the form in TIEDI.
Waitlist	WaitlistSM - Registration Root Retrieval	This API allows a transplant hospital professional to retrieve information about Waitlist registration(s) without the need to log into UNet, navigate to Waitlist, and retrieve the data manually. It is designed to facilitate workflows that promote seamless exchange of registration information between EHRs and the Waitlist.	The data comes from the registration information in Waitlist.



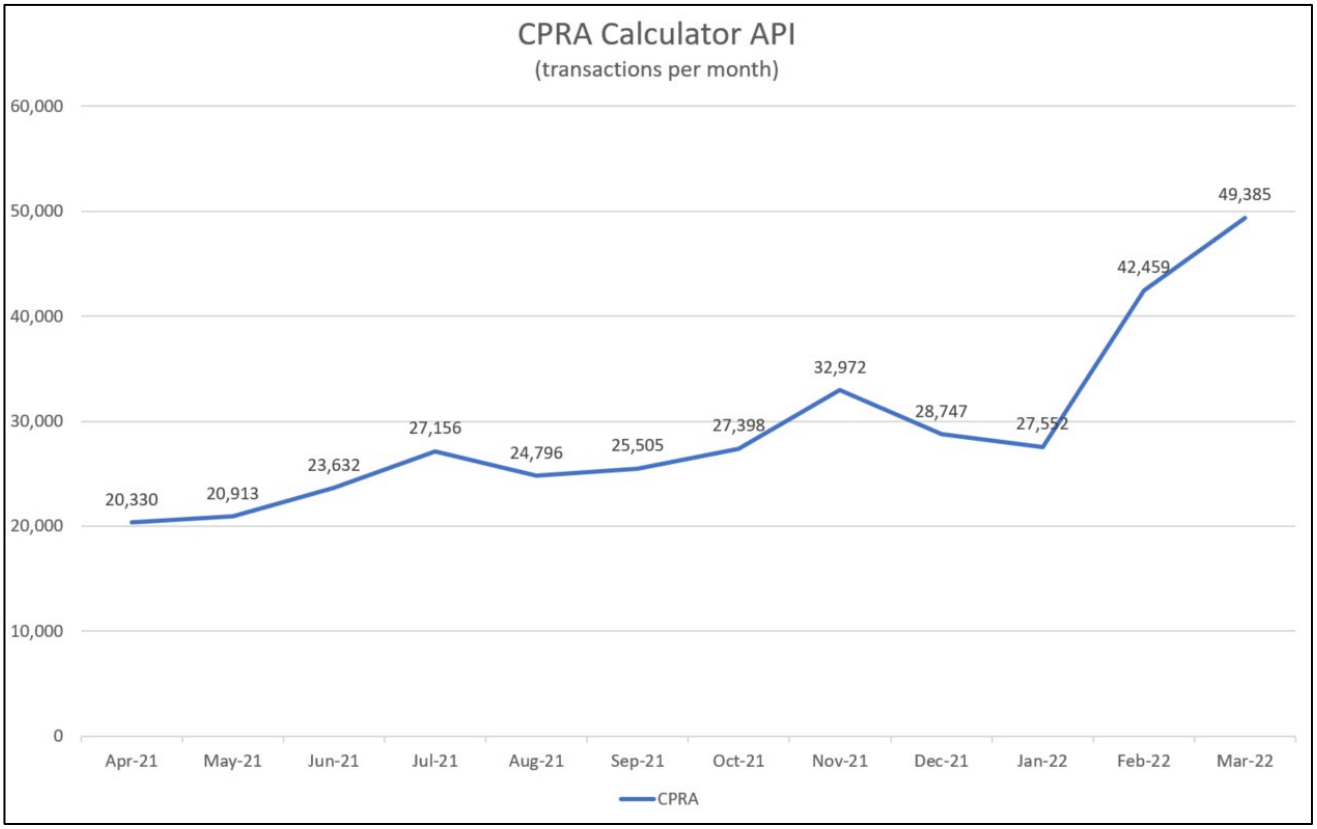
Additional API Features to Support Transplant Hospitals Data Submission and Other Workflows Member Adoption (percentage Transplant Hospitals)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
TCR	**28.3%**	**28.7%**	**30.3%**	**31.9%**	**31.5%**	**30.3%**	**29.1%**	**33.5%**	**31.9%**	**32.7%**	**32.3%**	**32.3%**
TRR	**28.3%**	**28.7%**	**28.3%**	**29.9%**	**29.9%**	**27.9%**	**28.7%**	**30.7%**	**31.5%**	**31.1%**	**29.9%**	**33.9%**
TRF	**31.9%**	**34.7%**	**32.7%**	**32.7%**	**34.3%**	**34.7%**	**34.3%**	**35.5%**	**34.7%**	**33.9%**	**35.5%**	**36.3%**
Waitlist	**0.8%**	**0.8%**	**1.2%**	**2.8%**	**3.2%**	**6.8%**	**4.0%**	**8.0%**	**4.8%**	**8.0%**	**7.2%**	**6.8%**

MELD and PELD Calculators			
API	**API Name**	**Description**	**Data Source**
MELD	MELD Calculator API	This API allows health care providers to calculate the MELD allocation score by providing key clinical lab information. This API enables programs to better manage candidates for transplant both before and after listing in UNet.	Calculator feature
PELD	PELD Calculator API	This API will allow health care providers to calculate the PELD allocation score for pediatric liver patients by providing key clinical lab information. This API enables programs to better manage candidates for transplant both before and after listing in UNet.	Calculator feature



MELD and PELD Calculator APIs (transactions per months)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
MELD	**302**	**316**	**334**	**292**	**285**	**336**	**676**	**499**	**571**	**624**	**507**	**574**
PELD	**0**	**0**	**0**	**0**	**0**	**3**	**2**	**4**	**0**	**0**	**1**	**6**

CPRA Calculator			
API	**API Name**	**Description**	**Data Source**
CPRA	CPRA Calculator API	This API allows health care providers to calculate the CPRA score, which measures a patient's likelihood of positive cross match. This API enables programs to better manage candidates for transplant both before and after listing in UNet, and has also been used for facilitating research or analysis.	Calculator feature

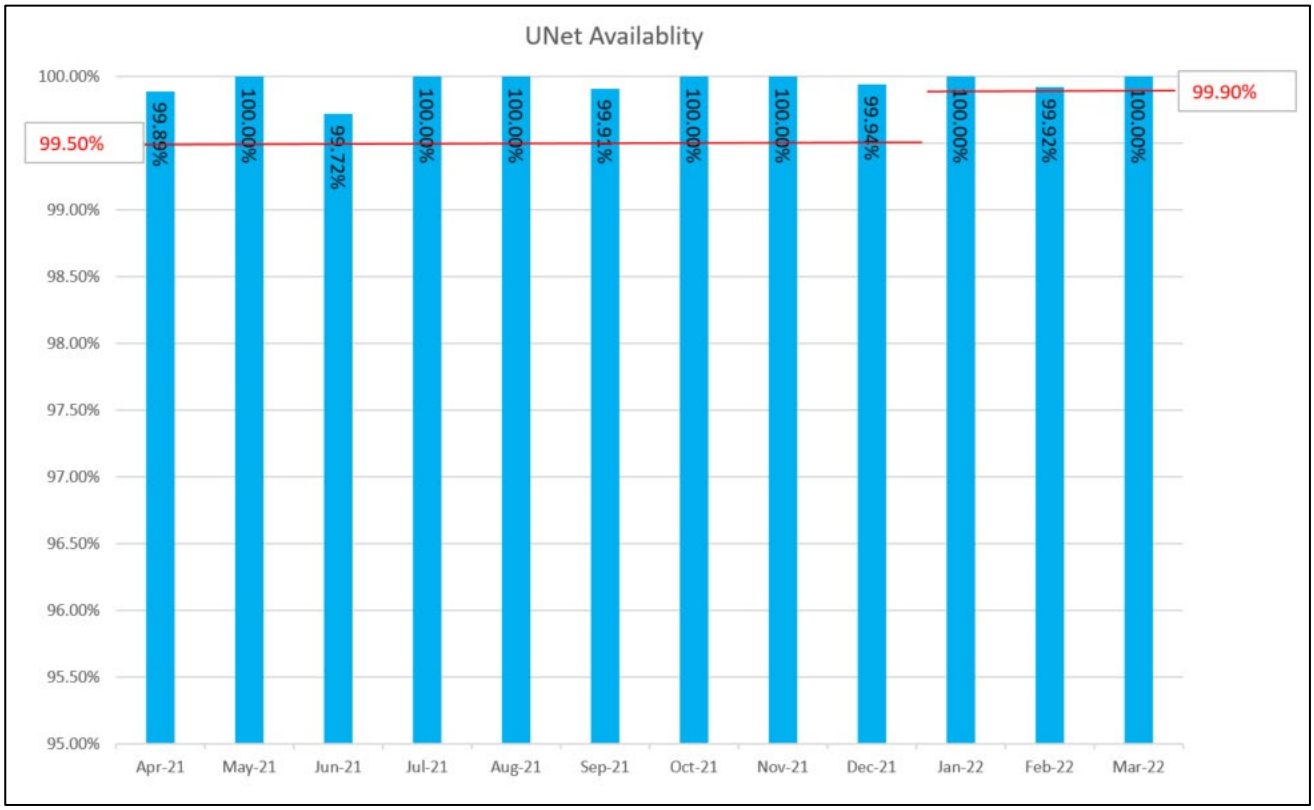


CPRA Calculator API (transactions per months)												
API	**2021**									**2022**		
	Apr	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**
CPRA	**20,330**	**20,913**	**23,632**	**27,156**	**24,796**	**25,505**	**27,398**	**32,972**	**28,747**	**27,552**	**42,459**	**49,385**

Availability Measures

Matching Function Availability by Month

Effective 01/01/2022, Matching Function availability will be reported excluding planned maintenance, with a target service level agreement (SLA) of 99.9%. Prior to 01/01/2022, the matching function SLA had been 99.5% including planned maintenance.



Occurrences of scheduled matching function downtime

SCHEDULED DOWNTIME	
Date:	04/29/2021
Planned Duration:	30 minutes
Actual Duration:	23 minutes
Description:	Planned maintenance as part of the UNet migration to East Region (ER) and West Region (WR) computing environments.
Date:	4/30/2021
Planned Duration:	30 minutes
Actual Duration:	24 minutes
Description:	Planned maintenance as part of the UNet migration to East Region (ER) and West Region (WR) computing environments.
Date:	06/15/2021
Planned Duration:	60 minutes
Actual Duration:	60 minutes
Description:	National Heart Review Board (NHRB) Production Release
Date:	06/17/2021
Planned Duration:	60 minutes
Actual Duration:	60 minutes
Description:	HLA equivalency table update and addition of DPB1 epitopes
Date:	09/30/2021
Planned Duration:	60 minutes
Actual Duration:	40 minutes
Description:	Implementation of the Updated Cohort for Calculation of Lung Allocation Score (LAS) project and the Refine Lung Data Fields proposal
Date:	12/02/2021
Planned Duration:	30 minutes
Actual Duration:	27 minutes
Description:	Implementation of Refusal Codes and DonorNet Kidney Predictive Analytics.
Date:	01/27/2022
Planned Duration:	30 minutes
Actual Duration:	40 minutes
Description:	Kidney Offer Filters National Release
Date:	02/10/2022
Planned Duration:	30 minutes
Actual Duration:	20 minutes
Description:	Implementation of Refusal Codes and DonorNet Kidney Predictive Analytics.

Matching Functions Issues by category by month

OPTN task 3.4.1.1 establishes the following timelines for resolving issues with the OPTN matching function:

Figure 3.4.1-1. Proposed Timelines for Customer Support Resolution of Issues				
Category	Matching Function Availability	Candidate Impact	Examples	Resolved within
1	Unavailable	All	Cannot run a match, system is completely down	1 hour of identification
2	Partially Available	All	Issues with electronic offers, slowness that impacts organ placement activity. Inability to add any candidates to the waitlist list or inability to add a donor	2 hours of identification
3	Partially Available	Some	A portion of the waiting list is impacted (e.g., unable to upgrade a liver candidate's medical urgency, unable to run matches for a specific donor or organ type)	6 hours of identification
4	Available	One	One candidate's data is incorrect, affecting placement on the match	8 hours of identification

			2021									2022		
Category	Matching Function Availability	Candidate Impact	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1	Unavailable	All	0	0	0	0	0	0	0	0	0	0	1	0
2	Partially Available	All	0	0	0	0	0	0	0	0	0	0	0	0
3	Partially Available	Some	1	1	0	0	2	0	1	1	0	0	0	0
4	Available	One	0	0	0	0	1	0	0	0	0	0	0	0

MATCHING FUNCTION UNAVAILABLE (Category 1) ***As per OPTN task 3.4.1.1 requirement - to be resolved within 1 hour of identification***	
Date:	02/26/2022
Duration:	33 minutes
Description:	One node of a high-availability pair of firewall appliances suffered a firmware-level failure, leaving the entire clustered pair in a degraded state and causing a complete interruption of Internet connectivity to UNet[SM]. This degraded state prevented a built-in automated failover of this high availability solution. NOTE: This built-in high-availability solution did work as designed on two previous occasions, on 07/22/2021 and 11/30/2021 without any impact to UNet[SM]. All impacted services were manually transitioned to restore connectivity. Following the incident, the firewall vendor confirmed the hardware failure as a root cause. *Confirmed no impact to matching function or patients.*

MATCHING FUNCTION PARTIALLY AVAILABLE AFFECTIING ALL CANDIDATES (Category 2) *As per OPTN task 3.4.1.1 requirement - to be resolved within 2 hours of identification*
None

MATCHING FUNCTION PARTIALLY AVAILABLE AFFECTING SOME CANDIDATES (Category 3) *As per OPTN task 3.4.1.1 requirement - to be resolved within 6 hours of identification*	
Date:	04/10/2021
Duration:	4 hours 36 minutes
Description:	An upstream network provider outage. Secondary services including Image Sharing, Security Administration, Offer Filters, and TIEDI imports were impacted. The core matching function elements (adding a candidate to the waitlist, inputting donor information, running a match, and sending electronic organ offers) were unaffected. Steps taken to mitigate non-matching functions impact until the provider repaired their issue.
Date:	05/27/2021
Duration:	60 minutes
Description:	10 transplant centers reported inability to open liver matches to view and respond to offers. This was caused by a software release that inadvertently impacted match view functionality for transplant centers. OPOs were not affected by this release. As a workaround, transplant centers were instructed to work directly with their OPOs to input responses for liver offers, until system changes could be made to resolve the issue. The software release was rolled back to restore the capability for transplant centers.
Date:	08/07/2021
Duration:	45 minutes
Description:	A temporary degradation of service occurred delaying two match runs. No other matches or functions were impacted. Troubleshooting was performed by Operations personnel based on Operational Runbook. A misconfigured network setting was identified and corrected. This misconfiguration occurred during a scheduled business continuity/disaster recovery (BC/DR) event that

MATCHING FUNCTION PARTIALLY AVAILABLE AFFECTING SOME CANDIDATES (Category 3) *As per OPTN task 3.4.1.1 requirement - to be resolved within 6 hours of identification*	
	took place shortly prior. The affected matches were re-executed successfully 45 minutes later.
Date:	08/28/2021
Duration:	26 minutes
Description:	Slowness observed when navigating and reviewing or processing match data. Two centers impacted. Database optimization procedures were performed by Operations personnel based on Operational Runbook instructions to remedy the slowness.
Date:	10/12/2021
Duration:	1 hour 24 minutes
Description:	Twenty-four (24) members reported receiving errors when attempting to view donor information. This impacted their ability to respond to organ offers. Investigation found that the root cause was an incorrect network configuration within one of the hosting environments, which was permanently corrected to restore donor summary visibility and offer response capability.
Date:	11/08/2021
Duration:	56 minutes
Description:	Six (6) members reported connectivity issues and inability to access UNet. Investigation found a one-time bulk data transfer in process, which was consuming an excessive amount of network bandwidth and degrading connectivity to UNet. The data transfer stopped, which immediately restored normal connectivity.

MATCHING FUNCTION PARTIALLY AVAILABLE AFFECTING ONE CANDIDATE (Category 4) *As per OPTN task 3.4.1.1 requirement - to be resolved within 8 hours of identification*	
Date:	08/03/2021
Duration:	7 hours 54 minutes
Description:	Automated quality control and monitoring nightly process reported potential errors on the morning of 8/3/2021 on unresolved NLRB forms for one candidate. This is caused when a form should have been either denied or approved based on a NLRB participant's final vote. (NOTE: Monitoring for this scenario was put in place with the release of the NLRB project in 2019) Three forms were affected, two approved and one denied. The forms were corrected the same day upon the completion of investigation of the root cause. Additional Detail. Each time a vote is cast by an NLRB member, "tally" logic is called to see if majority has been met and if so, render a final verdict on the exception case. When a final vote is reached to perform this tally, a transaction of events occurs. The exception form is updated with the proper status based on the tally results (approved/denied), the candidate record may be updated with a new candidate status code (based on the value of the approved exception or denied extension if past the expire date), and an email is sent to the member to notify them of the decision. When one step fails, the entire process fails as intended to ensure accuracy. In this case, a step in the process failed due to a data permissions issue unrelated to this process.

Accuracy Measures

Policy implementation revisions affecting the matching function

The following policy projects were implemented during the reporting period. For six weeks following implementation, the IT team responsible for coding the changes monitors activities associated with the changes to ensure no unexpected or incorrect outcomes.

Implementation Date	Project Name	Number of programming revisions	
		Due to policy adjustment	Due to programming defect
06/15/2021	**National Heart Review Board for Pediatrics** Size: Enterprise https://optn.transplant.hrsa.gov/media/3841/2020-06_thoracic_nhrb_for_pediatrics_policy_notice.pdf	0	2
06/17/2021	**Human Leukocyte Antigen (HLA) Equivalency Tables Update 2020** Size: Enterprise https://optn.transplant.hrsa.gov/media/3839/2020-06_histo_policy_notice.pdf	0	1
9/30/2021	**Refine Lung Data Fields** Size: Small https://optn.transplant.hrsa.gov/media/4uyjmg30/refine_lung_data_fields_policy_notice_july_2021.pdf	0	0
9/30/2021	**Update Cohort for Calculation of the LAS** Size: Enterprise https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf	0	0
10/7/2021	**Further Enhancements to the National Liver Review Board (NLRB)** Size: Large https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/further-enhancements-to-the-national-liver-review-board/	0	0
10/7/2021	**Updating National Liver Review Board Guidance Documents and Policy Clarifications** Size: Very Large https://optn.transplant.hrsa.gov/media/4694/updating_nlrb_guidance_policy_clarification_june_2021_policy_notice.pdf	0	0

Implementation Date	Project Name	Number of programming revisions	
		Due to policy adjustment	Due to programming defect
12/2/2021	**Update to Refusal Codes** Size: Enterprise https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/project-to-update-refusal-codes/	0	1
02/10/2022	**Clarify Multi-Organ Allocation Policy** Size: Very Large https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf	0	0

The following table summarizes the project sizes:

Project Size	Range of Hours
Small	180 – 419
Medium	420 – 749
Large	750 – 1649
Very Large	1650 – 3999
Enterprise	4000+

During the reporting period, UNOS IT implemented 8 projects affecting the matching functions. Three of these projects had revisions since implementation.

National Heart Review Board for Pediatrics

The National Heart Review Board (NHRB) for Pediatrics project created a database field in the waitlist history to indicate the status justification form that supports the status for pediatric heart and heart/lung candidates. This field allows UNOS staff and researchers to quickly determine which status justification form associated with a historical episode of pediatric status 1A or 1B for a candidate. The NLRB project also implemented monitoring to detect if this field is being updated properly.

The day after the NHRB release (06/16/2021) the system monitoring alerted us that the database field was still pointing to the old justification form id after the candidate's status extension took effect. This issue did not affect the candidate's status or have match impact. We released a fix that same day to correct the candidate's data. We also implemented an improvement to the system monitoring to resolve the candidate record and point to the extension form id. We also made an update to the monitoring to eliminate the use of time stamps when comparing the expiration and form begin dates during the processing.

On 06/17/2021, the monitoring alerted us that the pointer field was not being updated with the extension form id due to the timestamp portion of the logic that assigned that value. Candidates were already and remained at the correct status which is what match would have used. The pointer is just a helpful quick reference to show which form is driving the candidate status. On 6/17/2021 we released a fix to correct the candidate's data and to fix the root cause.

HLA Equivalency Tables Update 2020

On 06/17/2021 a systems integrator reported that the active Waitlist export was not exporting the unacceptable antigen data for DQB1. This did not impact organ allocation and a fix was implemented within 1 hour of the issue being reported.

Refusal Code Update

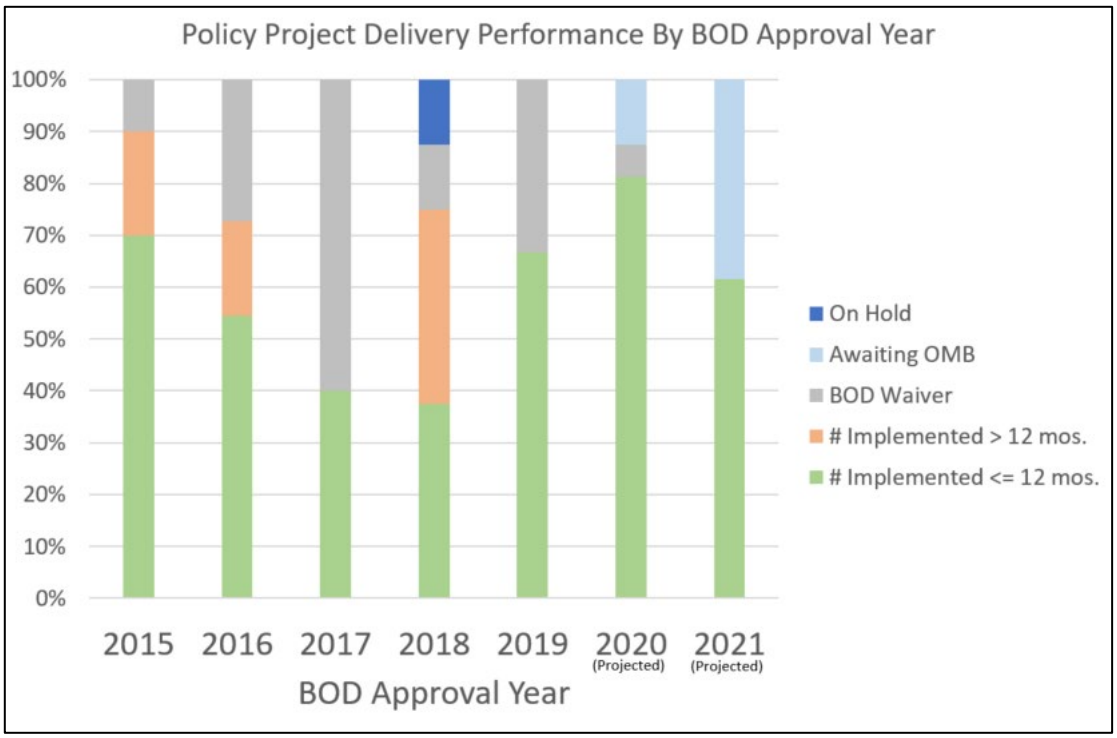
On 12/2/2021 after the implementation of Refusal Code Update project, thirteen institutions reported the inability to add range acceptances in the desktop version of DonorNet. These institutions were advised to use workarounds available to add range acceptances - to either enter acceptances individually or enter range acceptances in DonorNet Mobile. The impacted institutions were able to successfully add range acceptances using the recommended workarounds. The incident was resolved 74 minutes after the issue was identified. A root cause analysis was conducted, as a result, additional testing and validation steps have been added.

Timeliness Measures

Policy Project Implementation Performance by BOD Approval Year

The chart below shows percentage of policy projects by the year of BOD approval year that were implemented with 12 months of BOD approval, were implemented more than 12 months after BOD approval, are awaiting OMB approval before implementation, or were granted a BOD waiver.

All of the policy projects approved in 2019, 2020, and 2021 are projected to be implemented within 12 months of delivery except for those that have a BOD waiver.

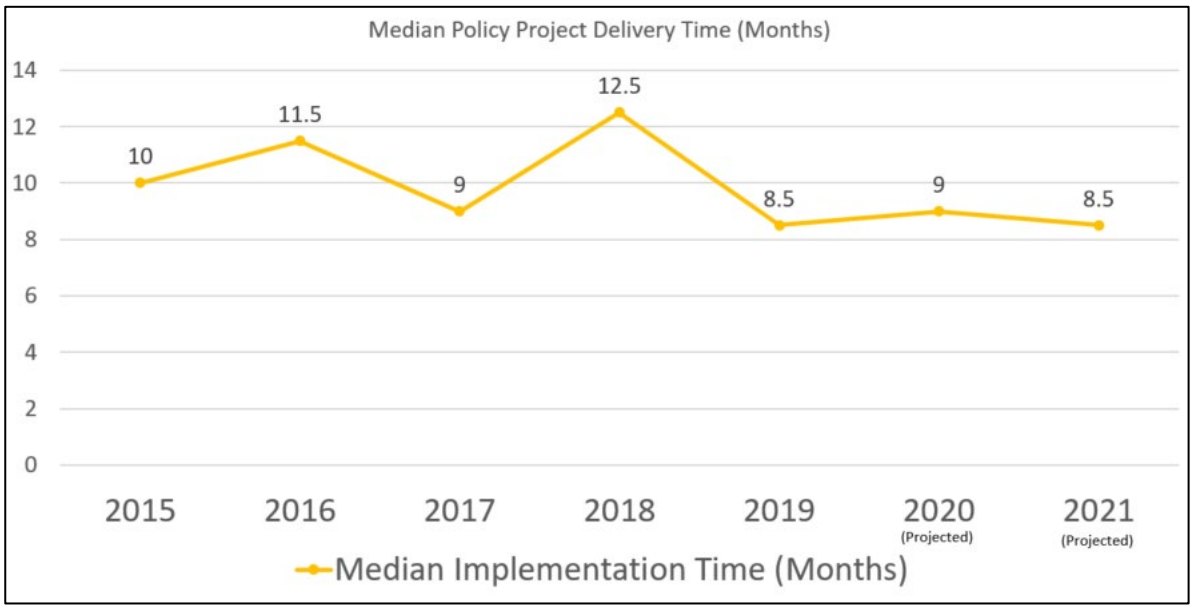


Our project delivery commitment (PDC) performance slowed in 2018 due to delaying several projects to accommodate the multiple changes to liver allocation policy. To recover, we focused in three areas to get the 2018 backlog cleared and 2019 projects back on track. We increased our resource allocation towards policy projects; recalibrated the makeup of Software Engineering teams and temporarily expanded the number to agile teams in early 2020. These efforts temporarily and successfully increased our capacity for policy work resulting in improvements in PDC performance.

Data for BOD approval years 2020 and 2021 are projected because the implementation is in progress for some items or because of items that are on hold or awaiting OMB approval.

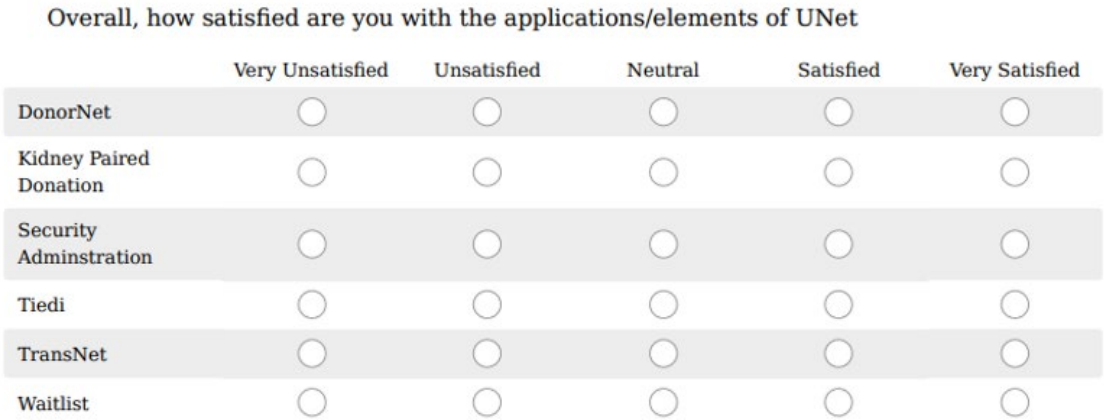
Median Policy Project Delivery Time (Months)

The following chart shows the median policy project delivery time based upon BOD approval year. The median policy project delivery time is calculated using the number of months been BOD approval and policy implementation. For items requiring OMB approval, the median policy project delivery time is calculated using the number of months been OMB approval and policy implementation.

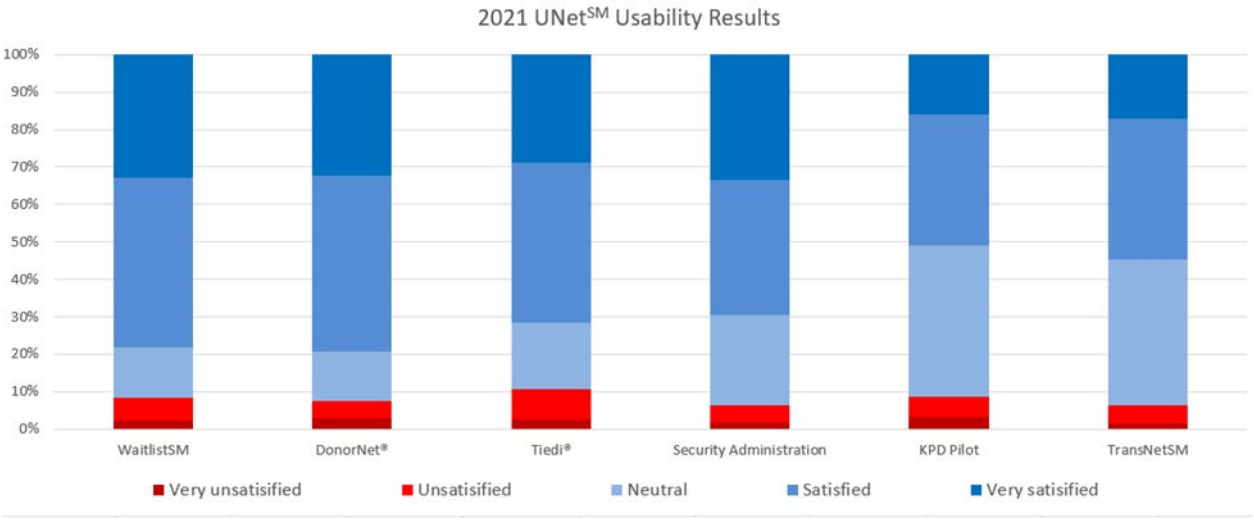


UNet[SM] Usability Survey Results

Each year, we gather feedback from OPTN Members who use UNet[SM] regarding their use of applications via the UNet Usability survey. This survey is sent via Survey Monkey to any individual who has logged into any UNet applications during the last calendar year. Each year we ask "Overall how satisfied are you with the applications/elements of UNet" to determine the ease of use of all of the UNet applications, which include Waitlist[SM], DonorNet®, TIEDI®, KPD[SM], Security Administration and TransNet. The latest survey was conducted from February – March 2021 and the two illustrations below depict the question asked as well as the results. The two illustrations below depict the question asked as well as the results.



For most UNet[SM] components, more than 90% of respondents reported a positive experience. For the KPD pilot, 91% of respondents reported a positive experience.



ANTICIPATED CHALLENGES

The Network Operations Oversight Committee continues to work to identify additional metrics. The metrics included in the original September 2019 report were based on data that are currently available for tracking and measurement. Over time, with additional system enhancements, additional metrics that focus on efficiency and effectiveness from the user's perspective could be added.

Since the September 2019 report, we improved the organ offer notification responsiveness so that it is based upon when user receives the electronic notification rather than when our vendor notifies us the that notification has been sent, added the median policy project implementation times, added UNet^{SM} API projects implemented and planned, and added UNet^{SM} usability survey results.

As a part of the committee's ongoing oversight and metrics review, the NOOC conducted a detailed review of UNet system availability (uptime). Based upon this in-depth review the NOOC recommends that the OPTN maintain the 99.9% UNet uptime excluding planned maintenance. Where practical, planned maintenance periods should not exceed 30 minutes.

UNOS is working with the NOOC to establish baselines for system responsiveness and to develop DonorNet® health metrics for key matching function web pages. Future metrics could monitor efficiency and effectiveness based upon both system availability and responsiveness.

Current metrics also monitor unplanned downtime using database downtime and user reported downtime. Future metrics could monitor downtime and responsiveness closer to a user perspective. However, this would require system changes to collect these data in such a way that the system can be monitored without impairing system performance, corrupting data, or confusing users. In addition, future metrics could include performance details at the sub-function level, i.e., Waitlist^{SM}, DonorNet®, TransNet^{SM}, etc. Accomplishing this would require implementation of advanced monitoring toolsets and processes. UNOS will work with the NOOC to assess the value of more complex metrics versus the implementation effort.

Current metrics that monitor progress toward direct electronic data submission focus on the application programming interfaces (APIs) that are currently implemented and are available for use by electronic medical record system vendors and OPTN members. In April 2021, NOOC began reviewing metrics related to member adoption of APIs. Future metrics could reflect the extent to which vendors and members are using these APIs to reduce data collection burden and improve user workflows. UNOS is working with the NOOC to develop metrics to show the number of institutions or transplant programs who are using APIs to receive or submit data and to show the increased reliance on seamless data exchange as reflected by counts of successful API calls from external systems.

Information Security has begun establishing metrics around vulnerability management as well as SLA's related to alerts and responses as part of incident management. After these metrics have been in place for several months, we will be able to establish trends and provide meaningful and actionable data.

OPTN Network Operations Oversight Committee
Meeting Summary
December 02, 2021
Conference Call

Kimberly A. Rallis, BS, MHA, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Cisco WebEx on 12/02/2021 to discuss the following agenda items:

1. NOOC Metrics Review and Discussion
2. UNet[SM] Product Roadmap
3. Multi-Factor Authentication Update

The following is a summary of the Committee's discussions.

1. NOOC Metrics Review and Discussion

The committee held a discussion on the metrics that reflect the health and reliability of UNet[SM].

UNOS staff plans to preview a draft of the annual report at the April 2022 NOOC meeting. Feedback from HRSA and the committee will be gathered and incorporated into the final report that is provided to the COR and Board of Directors before the June Board of Directors meeting. There was no change to the reporting period for the annual report, which remains April 2021 through March 2022.

UNOS staff provided a copy of the fourth quarter NOOC metrics prior to the meeting. The report covered metrics from July through September 2021.

Committee members requested a UNet[SM] APIs roadmap in conjunction with other OPTN projects roadmap. UNOS staff will review and provide this information at a future NOOC meeting.

HRSA requested a clear statement / recommendation from the committee on what they see as an acceptable percentage of UNet[SM] uptime. Ahead of the next committee meeting, the NOOC Chair along with UNOS staff will meet with the committee members and advisors to solicit further input on this topic. The collected input and other relevant information will be provided to the committee at the next NOOC meeting.

2. UNet[SM] Product Roadmap

Discussion of the UNet[SM] Product Roadmap was postponed to the February 2022 meeting.

3. Multi-Factor Authentication Update

The committee discussed the Multi-Factor Authentication (MFA) progress and viewed a live demonstration. UNet[SM] users will see MFA in March 2022.

Upcoming Meeting(s)

- February, 2022
- April, 2022

Attendance

- **Committee Members and Advisors**
  - Bill Bry
  - Brian Sullivan
  - Clifford Miles
  - Edward Hollinger
  - James Pittman
  - Kimberly Rallis
  - Melissa McQueen
  - Michael Mittelman
- **HRSA Representatives**
  - Adriana Martinez
  - Arjun Naik
  - Christopher McLaughlin
  - Vanessa Arriola
- **UNOS Staff**
  - Alex Tulchinsky
  - Amy Hamner
  - Amy Putnam
  - Bonnie Felice
  - Marty Wilson
  - Michael Ferguson
  - Rob McTier
  - Terri Helfrich
  - Tiwan Nicholson

OPTN

Mini-Brief

Clinically Acceptable Availability of the OPTN Matching Function

OPTN Network Operations Oversight Committee

Prepared by: Kim Rallis, NOOC Chair,
Rob McTier and Alex Tulchinsky,
UNOS Information Technology Department

Contents

Clinically Acceptable Availability of the OPTN Matching Function

Affected Policies: None
Sponsoring Committee: *Network Operations Oversight Committee*
Board of Directors Meeting: *June 26-27, 2022*

Executive Summary

As a part of the committee's on-going oversight and metrics review, the Network Operations Oversight Committee (NOOC) conducted a detailed review of the clinically acceptable availability of the OPTN Matching Function delivered by the UNet[SM] system availability (uptime).

Based upon this review the NOOC recommends that the OPTN maintain the 99.9% OPTN Matching Function uptime excluding planned maintenance. Where practical, planned maintenance periods should not exceed 30 minutes.

Background

The Network Operations Oversight Committee (NOOC) is an operating committee of the OPTN. It assists the Board of Directors in its oversight of the OPTN operations, including the OPTN matching function, the process of official OPTN data collection, including data from potential donors, deceased donors, living donors, transplant candidates, and transplant recipients required for the OPTN matching function and other OPTN activities. To fulfill their charge, the NOOC reviews quarterly metrics associated with the OPTN match function. The NOOC also develops an annual review of network operations and metrics which is submitted to the Contracting Officer Representative (COR).

The percentage of matching function (system) availability by month is one of the metrics that the NOOC regularly reviews. System availability is typically expressed as a Service Level Agreement (SLA), which translates into an amount of allowable downtime per month. The following table shows some typical system availability SLAs:

Availability % (SLA)	Downtime per month
99%	7.31 hours
99.5%	3.65 hours
99.9%	43.83 minutes
99.99%	4.38 minutes
99.999%	26.30 seconds

The 2019 OPTN contact required 99.5% availability for the matching function. Matching function availability is measured as the overall UNet[SM] system availability, and included both planned and unplanned downtime. Planned downtime is time when UNet purposefully taken off-line in order to perform system maintenance or to deploy organ allocation policy changes. The OPTN posts system notices to inform UNet users of the planned maintenance. UNet has met or exceeded 99.5% availability throughout the contract period.

In January of 2022, a modification to the OPTN contract was proposed to require 99.9% availability not including planned maintenance. Since the contract modification, UNet continued to meet or exceed 99.9% availability.

An illustration below shows UNet availability since October 2020.

Month	UNet Availability With Maintenance	Scheduled UNet Maintenance Impact	UNet Availability Without Maintenance
Aug-20	99.95%	0.05%	100.00%
Sep-20	100.00%	0.00%	100.00%
Oct-20	100.00%	0.00%	100.00%
Nov-20	100.00%	0.00%	100.00%
Dec-20	99.83%	0.17%	100.00%
Jan-21	100.00%	0.00%	100.00%
Feb-21	99.72%	0.07%	99.79%
Mar-21	99.77%	0.22%	99.99%
Apr-21	99.89%	0.11%	100.00%
May-21	100.00%	0.00%	100.00%
Jun-21	99.72%	0.28%	100.00%
Jul-21	100.00%	0.00%	100.00%
Aug-21	100.00%	0.00%	100.00%
Sep-21	99.91%	0.09%	100.00%
Oct-21	100.00%	0.00%	100.00%
Nov-21	100.00%	0.00%	100.00%
Dec-21	99.94%	0.06%	100.00%
Jan-22	99.91%	0.09%	100.00%
Feb-22	99.87%	0.05%	99.92%
Mar-22	100.00%	0.00%	100.00%
Rolling Avg 12 Months	**99.94%**	**0.06%**	**99.99%**
Rolling Avg Since Aug 2020	**99.93%**	**0.06%**	**99.99%**

Purpose

At the NOOC's December 2, 2021 meeting, HRSA requested a clear statement/recommendation from the NOOC on a clinically acceptable availability for the OPTN Matching Function.

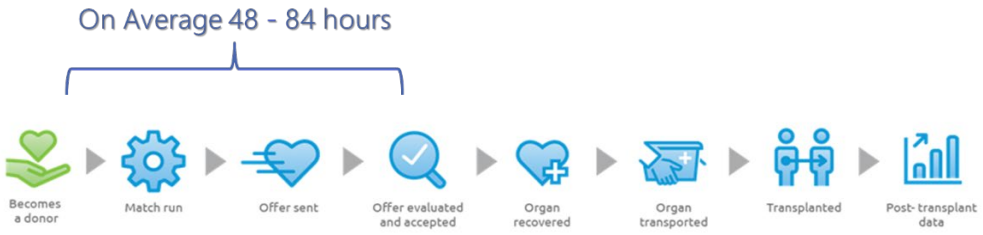
In response to this request, the NOOC Chair (assisted by UNOS staff) conducted individual interviews with each of the NOOC members and advisors.

UNOS staff also contacted Gartner (a leading technology research and consulting firm) to obtain general information about system availability in the healthcare sphere.

The findings from the interviews conducted by the NOOC Chair were presented and reviewed by the committee at the February 2022 NOOC meeting. A summary of the review and input from the committee members and advisors is as follows:

Organ allocation is a critical and multi-faceted workflow

Organ allocation is a critical process and there are many factors and redundancies built into this process. Organ allocation is a planned process as evidenced by the fact that organ offers occur hours or days before the set operating room (OR) time for the transplant and that most organ recoveries occur at night when operating rooms are available for organ recovery. To illustrate the process, UNOS staff looked at the time duration between a donor being added to UNet and organ acceptance. In calendar year 2021, this timeframe averaged between 48 and 84 hours depending on the organ as shown in illustration below.



The table below depicts aforementioned timeframes by organ.

Organ	Average time (in hours) between donor being added to organ acceptance in calendar year 2021
Heart	48
Heart/Lung	49
Lung	51
Liver	52
Intestine	66
Kidney	79
Kidney/Pancreas	84

Committee members noted that there are process dependencies that exist outside of UNet such as organ transportation. The committee chair commented that, "the technology component while a very close partner in marriage to the actual workflows of donor identification all the way through to match

run and then the actual organ allocation process. The technology is not the actual primary driver in this process".

Planned vs. Unplanned downtime

Committee members and advisors often commented that there is a big distinction between planned and unplanned downtime. Members and advisors recognized the need for planned downtime in order to improve and maintain the system. Due to the nature of organ allocation as described above, planned downtime of 30 minutes or less is not clinically impactful.

Members and advisors often stated that unplanned downtime can be more impactful, but an occurrence of 30 minutes or less is clinically tolerable. Committee members and advisors suggested rather than increasing the overall availability it would be best to maintain focus on limiting episodes of unplanned downtime. There could be few episodes of unplanned downtime and any episode of unplanned downtime should be limited to about 30 minutes. OPTN Members should also be periodically reminded of the published best practices and OPTN procedures for situations when technology is delayed or temporarily unavailable.

Value of increasing availability

Committee members and advisors stated that the value of raising system availability to 99.999% (with downtime measured in seconds per month) is unclear. One advisor commented that "Every time you add a 9 the cost increases exponentially".

The committee members and advisors discussed appropriate baseline and benchmarks for the matching function and concluded that a service level of 99.999% is not appropriate because UNet is "not landing airplanes, not a nuclear power plant, or an emergency management system".

Appropriate availability baseline/benchmarks

Although UNet is not an electronic health record (EHR), committee members and advisors agreed that UNet was comparable to an EHR for system availability purposes. It was noted that Epic has not historically, provided a system availability SLA and that Cerner will not provide a standard SLA, but will guarantee 99.96% SLA for a premium. Members and advisors also commented that EHRs have regular planned downtime and that hospitals have procedures for continuing operations during these downtimes.

One NOOC advisor investigated the SLAs for a cloud based computing services. "I investigated what Amazon Web Services and Azure post as availability, which is 99.9%. I looked at the multi-redundancy options and the best guarantee that you can get from Azure is 99.99%. They have consistently paid out some kind of small fee on a regular basis because having 99.99% is really hard. If you look at December alone, Amazon had four outages in that set of services." This advisor also noted that Azure and AWS offer infrastructure availability times. "That is not application availability time. Application availability is far harder to do than [keeping] services and redundant locations up and running at 99.9% or 99.99%." The OPTN matching function availability is an application availability metric.

Another NOOC advisor commented, "As long as the right business continuity and disaster recovery protocols are in place to try to keep as much uptime as possible I think that 99.9% or 99.99% is all that you can ask."

As a part of this assessment of appropriate availability baselines and benchmarks, UNOS staff gathered feedback from Gartner, a leading technology research and consulting firm.

The information provided by Gartner confirmed much of the information from the NOOC interviews. The Gartner consultant stated that when you are trying to support a healthcare supporting system on a nationwide scale like UNet it is virtually impossible to achieve 99.999% availability. Barriers to 99.999% availability are mainly due to the number and variety of endpoints in such systems and national network grid dependencies. These types of systems may be able to provide 99.999% availability in the location where it is hosted but it is virtually impossible to guarantee 99.999% availability across the nation.

Gartner also confirmed that major EHRs resist giving an availability SLA guarantee. EHRs often refer to the SLA of the hosting environment instead of the EHR application availability. Cerner (one of the major EHR vendors) will not guarantee an availability SLA, but will monetize a 99.96% SLA for a premium.

Gartner also commented that planned maintenance is not normally included in the availability metrics, but they also noted that systems need to ensure adequate operational contingencies, early communication of planned downtime, and infrastructure redundancies, in order to protect against any unintended downtime during planned maintenance. Gartner also advised a focus on defining acceptable service levels based clinical risk and impact.

OPTN Network Operations Oversight Committee
Meeting Summary
February 28, 2022
Conference Call

Kimberly A. Rallis, BS, MHA, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Cisco WebEx on 02/28/2022 to discuss the following agenda items:

1. UNet^{SM} Availability
2. OPTN Projects and IT Capacity
3. Multi Factor Authentication (MFA)

The following is a summary of the Committee's discussions.

1. UNet^{SM} Availability

In the December 2022 NOOC meeting, HRSA requested a clear statement/recommendation from the NOOC on what they see as a clinically acceptable percentage of UNet^{SM} uptime. Since the last meeting, the NOOC chair and UNOS staff met with each NOOC member and technical advisor to gather input. The feedback and other relevant information was discussed in today's meeting.

Feedback included four main themes:

- Organ allocation is a critical and multi-faceted workflow
  - Organ recoveries are scheduled at night when there is available OR time
  - There are process dependencies that exist outside of UNet^{SM} such as arranging for transportation
- Planned vs. unplanned downtime
  - 30 minutes of planned downtime is not clinically impactful; 30 minutes of unplanned downtime is clinically tolerable
  - Members recognize the need for planned downtime to improve and maintain the system
  - Focus on fewer and shorter unplanned downtimes
- Value of increasing availability
  - The value must be carefully evaluated. The cost increases exponentially each time a "9" is added.
- Appropriate availability baseline/benchmarks
  - 99.9% (three 9s) is appropriate
  - 99.999% (five 9s) is not appropriate since UNet^{SM} is not an emergency management system
  - Comparable benchmarks are EHR/EMR systems

According to the OPTN contract the UNet^{SM} SLA is 99.5% (two and a half 9s), measured on a monthly basis. This calculates to 3 hours and 65 minutes of both planned and unplanned downtime per month. Looking back at availability since January 2020, UNOS has surpassed 99.5%, inclusive of planned maintenance; the percentage is 99.99% when excluding planned maintenance.

UNOS spoke with Gartner to align the baseline with industry standards on a nationwide scale. Gartner recommend a focus on defining acceptable service levels based on clinical risk impact. Planned maintenance is normally excluded from the availability metrics.

A NOOC mini-brief will be drafted defining the clinically appropriate system availability target. UNOS will incorporate comments from committee members and advisors and will share with HRSA at one of the next COR meetings.

2. OPTN Projects and IT Capacity

Lauren Mauk, Service Owner Manager, reviewed the OPTN Projects Roadmap and the efforts through Q2 2023.

The Policy Oversight Committee (POC), in support of the OPTN staff, looked at the work over the next 5 years and determined that the workload is misaligned to the resource availability to support it. Roger Brown, Director of Policy and Community Relations, explained that the POC is the governance group responsible for managing the OPTN policy portfolio. The POC develops and assesses progress on policy priorities. The POC reviews all new potential OPTN policy projects and determines whether the resources are available to move them forward. The POC also looks at how each project fits into the policy portfolio and how it aligns with OPTN goals.

The committee viewed a diagram of the forecasted roadmap of what this OPTN work may look like. The current budget is about 15,000 hours per Board cycle. For the next few cycles, the budget will be up to 20,000-29,000 hours.

The POC looked at two things:

- What policy work can be done at the current resource level (15,000 hours per Board cycle)
    - Adjust timing/sequencing
    - Reduce scope of forecasted work
    - Reduce amount of forecasted work (either stop work on current projects or not approving future projects)
- What changes need to occur to allow for a larger volume of work?
    - Request additional budget for technical implementation resources

The POC's next step is to better define the project benefit, develop a method to rate project attributes, and measure the potential impact to the community. The POC will request additional resources from the Finance Committee for the next budget cycle.

3. Multi-Factor Authentication (MFA)

UNOS is successfully progressing through the implementation of Multi Factor Authentication (MFA). The next milestone is turning on mandatory enablement for UNet^{SM} Site Security Administrators on March 3. UNet^{SM} Site Security Admins are able to create, remove, and manage UNet^{SM} user accounts and group permissions. It was important to roll out this functionality to the UNet^{SM} Site Security Admins first as they are key to supporting MFA.

Within the last 24 hours, 961 users have logged in with MFA. Ninety-three percent (93%) of users (roughly 1,123) have registered with MFA. Lab users that are unable to access the internet are still able to log into the application without disrupting their workflow. MFA will be activated for all users on March 7.

Since the next time the NOOC meets again is scheduled for late March, the final MFA update will be provided to the committee in writing.

Upcoming Meetings

- April 26, 2022
- June, 2022

Attendance

- **Committee Members and Advisors**
  - Bruno Mastroianni
  - Clifford Miles
  - James Pittman
  - Keith Wille
  - Kimberly Rallis – Committee Chair
  - Melissa McQueen
  - Michael Mittelman
- **HRSA Representatives**
  - Adriana Martinez
  - Arjun Naik
- **UNOS Staff**
  - Alex Tulchinsky
  - Amy Hamner
  - Amy Putnam
  - Bonnie Felice
  - Lauren Mauk
  - Marty Wilson
  - Michael Ghaffari
  - Rob McTier
  - Roger Brown
  - Terri Helfrich
  - Tiwan Nicholson

OPTN Network Operations Oversight Committee
Meeting Summary
February 16, 2023
Webex

Edward Hollinger, MD, PhD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 02/16/2023 to discuss the following agenda items:

1. Welcome
2. OPTN Computer System Outage
3. OPTN Member Security Project Updates: Member Training and Exam
4. Public Facing Dashboards

The following is a summary of the committee's discussions.

1. Welcome

Ed Hollinger, Chair of the Network Operations Oversight Committee (NOOC), welcomed the committee and gave an overview of the meeting agenda.

2. OPTN Computer System Outage

Tiwan Nicholson, UNOS Director of IT Operations, briefed the committee on an OPTN Computer System (also known as UNet) outage that occurred the day prior, February 15. He informed the committee that the OPTN Computer System was inaccessible for forty minutes, no transplants workflows were affected during this time, and no patients were adversely impacted as a result. He shared that the OPTN is working to determine the cause of the outage and is providing regular updates to HRSA and USDS. During troubleshooting, the team found that no OPTN data was lost while the database availability cluster of the OPTN Computer System was in an unhealthy state and rendered the OPTN Computer System inaccessible. Mr. Nicholson confirmed that nothing crashed while the system was inaccessible. Upon restoration of services, the Organ Center followed up promptly with OPTN members that had contacted them and confirmed they were able to resume and complete all their workflows successfully.

Mr. Nicholson provided an overview of the OPTN System's backup technology - Veeam. He shared that incremental backups of the file system, not the database, happen every 90 minutes within the system, and during this time, something in the environment presented itself to Veeam as if it was a new system. Veeam acted appropriately and interpreted this as a new system within the network and therefore triggered a full backup of the system.

The SQL always-on cluster has a self-protect mechanism, and if it detects the system is under a high amount of stress, then to protect the data it will shut the cluster down.

Mr. Nicholson explained that engineers took the action to restart always on cluster restore the service and re-enable the OPTN System availability.

The OPTN is actively working with different vendors, Microsoft, Nutanix, Veeam, etc., to perform a root cause analysis of what caused the system to become inaccessible. Mr. Nicholson assured the committee that the results would be presented to them when available.

Summary of discussion:

A representative from HRSA asked for information about the cluster environment. Mr. Nicholson explained that the environments are connected and the cluster acts as the glue that keeps the environments connected, and during this situation it was as if they became separated. The HRSA representative asked if the backup software is configured to back up from the primary database node and if not, was this a misconfiguration in Veeam. Mr. Nicholson explained that the software is configured to back up the file system, not the database, from a read-only node. Veeam will not backup from the active node so it does not impact the performance or availability of the active node. The node is hosted within Nutanix.

A committee advisor asked about the heartbeat and node configuration of the infrastructure. Mr. Nicholson explained that during this particular situation, the node could not detect the heartbeat. Usually, SQL always-on configuration is able to transfer traffic to another healthy node, but in this case, the cluster management plane interpreted what was happening on the node as worse than regular degradation. This led to the cluster taking self-protection measures to prevent data corruption. Veeam and Microsoft were acting as designed, which is to protect the data.

A representative from HRSA asked if the OPTN should bring back the system hot site or whether there was another precaution that could be in place in the event that something like this were to happen again. Mr. Tulchinsky explained that once the OPTN receives more information about what caused the outage, than they will have a better idea of how to prevent it from happening again. A committee advisor agreed that until the OPTN knows what the root cause of the outage was then making changes won't necessarily increase availability because they won't know whether they're addressing the issue.

A representative from HRSA asked about the geographic balance between the two operating environments, to which Mr. Tulchinsky reminded them that the private cloud consists of one environment in Virginia, and the other is located in Texas, noting that environment diversity is required by the OPTN contract. Mr. Nicholson explained that the OPTN also has a geographic load balancer (GSLB) that they utilize to balance availability across sites. The representative from HRSA asked for more clarification on how the two environments work together. Mr. Nicholson explained that the workload can be taking place in either environment. If an incident occurs, the system can transfer traffic over to the alternate site. The two sites work to simultaneously write data in two places while staying in sync with one another.

A representative from HRSA asked for clarification on how the system backs itself up, what system controls the backup, and how often the backup occurs. Mr. Nicholson explained that Veeam is the backup solution from a file system data backup perspective. In this situation, they are not talking about restoring the data from backup but making sure that healthy nodes at the web and the database layer are keeping the system in sync and are able to direct traffic to a number of active nodes. A committee advisor noted that replication of data and data backup are two different things.

A representative from HRSA asked for clarification on how the OPTN made the determination that no adverse events occurred during the outage. Mr. Nicholson explained that the OPTN followed up with each of its members that called during the outage and directly asked whether the outage had adversely affected them. All members responded positively and none of the calls were connected to match runs, reiterating that there was no known impact to patients.

Next Steps:

The OPTN plans to present the findings from the root cause analysis to the committee when they become available.

3. OPTN Member Security Project Updates: Member Training and Exam

Terri Helfrich, UNOS Director of Information Security, provided an update on the committee's proposal to Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements. She provided an update on the themes from public comment and regional meetings. She briefed the committee on a proposed self-assessment and suggested the creation of a focus group so the committee could obtain a baseline measurement of security frameworks. Ms. Helfrich presented a proposed scoring method for members to use when determining compliance.

Summary of discussion:

A committee member commented that until members have an initial readiness assessment there is not an accurate baseline measurement for members to compare themselves to. The committee won't have a clear idea of what member's IT security may look like without this baseline. They noted there are concerns about the six-month timeframe to implement these changes and members are worried that they could receive a failing grade. An advisor has also heard these concerns and has already seen some members analyzing their security framework to ensure it adheres to the requirements of the policy. A committee member suggested that there should be no pass or fail grade after only six-months; this time should be an opportunity to collaborate with members and not penalize them.

The committee took a deeper look into the proposed scoring and thought it was important to consider how they introduce the scoring. A committee member suggested the NOOC wait to release the proposed scoring or to wait to score members before they determined what an organization's baseline may be. The committee agreed that there is not enough data to determine what the scoring should look like at this time. A committee member suggested reviewing member readiness assessment results before the committee considers scoring. A representative from HRSA suggested the committee consider an internal review process to measure the progress of a member over time and establish parameters on expectations of growth over time.

A committee advisor thought that members may struggle to understand the scoring scale. They noted that although it is an industry standard, they suggested there be a measure of what members should work towards in the future. They suggested setting clear expectations of where members should be and what the indicator of success would be. Another committee member suggested measuring member's growth based on their initial assessment score, every year for three years. They thought it was important to consider members who may have shown substantial improvement in their system but may still be below the standard. They noted that these member's efforts and growth should not go unnoticed. They also thought the inverse was important to consider, that although a member may have a great score, if they haven't shown any effort to better their system, then this is also something the committee should consider. Another committee member suggested that the group could establish a minimum acceptance level for members.

4. Public Facing Dashboards

Tiwan Nicholson, Director of IT Operations, presented on public facing dashboards and asked the committee what public dashboards they thought were important to provide to the public in order to increase transparency and trust in the system across the community. The creation of some public facing dashboards have been mandated within the OPTN Contract modification received late last calendar

year. The committee discussed what is suggested by “public facing” and also explored what metrics they would like to see displayed on these dashboards.

Summary of Discussion:

A committee member suggested the OPTN analyze their system and see what vulnerabilities may lie within the system. They then suggested that the OPTN administer this information to exclusive but appropriate parties to ensure that high risk stakeholders are in the know. A committee member asked if there were any industries or companies comparable to the OPTN that provide these metrics and dashboards so the OPTN can refer to them as guidance. Mr. Nicholson agreed that this could be an interesting starting point and that status dashboards are always a useful place to start if the committee would like to utilize those resources. The information that the OPTN provides to members, to the general public, and to the government adds a unique layer to the capabilities of the OPTN Computer System and the dashboards that can be produced. A representative from HRSA suggested that the OPTN provide information about the status of the OPTN Computer System and not delve in to potential vulnerabilities or otherwise confidential information.

A committee member suggested the team consult the OPTN Patient Affairs Committee (PAC) to receive their perspective on what dashboards and information patients may find most useful. A committee member cautioned the rest of the group to carefully consider the information they want to show on these dashboards as they don’t want members to be overwhelmed by the amount of information, nor do they want information to be lost in the copious amount provided.

A committee advisor suggested the dashboards include uptime of infrastructure to enhance visibility to key applications. This could be important information to exemplify visibility of the system and show that they are running.

A committee member stressed the importance of providing information to the patient community and how these dashboards could be useful to patients and their families. They discussed a tiered approach to have the dashboards display simple patient information and to build out from there so that patients are able to explore the dashboards in more depth if they wish. The OPTN must consider their multiple audiences and provide adequate information to each of these respective groups to maintain trust and visibility of the system. The committee will continue this conversation during a future meeting.

Attendance

- **Committee Members and Advisors**
  - Adam Frank
  - Bruno Mastroianni
  - Clifford Miles
  - Daniel Yip
  - Edward Hollinger
  - Kelley Hitchman
  - Kimberly Rallis
  - Maryjane Farr
  - Melissa McQueen
- **HRSA Representatives**
  - Adriana Martinez
  - Christopher McLaughlin
  - Cliff Myers
  - Manjot Singh
  - Nick Lewis
  - Vinay Vuyyuru
- **UNOS Staff**
  - Alex Tulchinsky
  - Amy Putnam
  - Anna Messmer
  - Bonnie Felice
  - Bridgette Huff
  - Courtney Jett
  - David Klassen
  - Jason Livingston
  - Kristine Althaus
  - Liz Robbins Callahan
  - Marty Crenlon
  - Maureen McBride
  - Michael Ferguson
  - Morgan Jupe
  - Ralph Medina
  - Roger Vacovsky
  - Susie Sprinson
  - Terri Helfrich
  - Tiwan Nicholson
  - Tynisha Smith

OPTN Network Operations Oversight Committee
Meeting Summary
February 28th, 2023
Webex

Edward Hollinger, MD, PhD, Chair

Introduction

The Network Operations Oversight Committee (NOOC) met via Webex on 02/28/2023 to discuss the following agenda items:

1. Welcome
2. OPTN Computer System Outage Update
3. NOOC Goals for Increasing API Adoption

The following is a summary of the committee's discussions.

1. Welcome

Ed Hollinger, Chair of the Network Operations Oversight Committee (NOOC), welcomed committee members and provided an overview of the agenda. Representatives from HRSA introduced a new member of their team to the NOOC, and committee members and advisors introduced themselves in return.

2. OPTN Computer System Outage Update

Tiwan Nicholson, UNOS Director of IT Operations, briefed the committee on the progress of investigation into a system outage that occurred on February 15. Staff have been working to determine a root cause of the outage with support from Microsoft and Nutanix. Mr. Nicholson noted that the investigation continues, it may not be impossible to determine a single root cause of the incident. Since the outage, staff have also been working to amplify incident response processes as well as monitoring and alarming tools based on feedback from Microsoft. Efforts have also been focused to correlate logs for faster visibility so that quicker conclusions and timely actions can be taken within tight timeframes.

These enhancements to incident response processes and tests have been made to create a more robust system and to preclude something similar from happening again, while monitoring and logging tools are utilized during testing to capture system diagnostics on the signals they know occurred during the outage. Nicholson explained that staff continue to explore effective means to maintain cluster availability while protecting the data. During the outage, no data was lost.

After the service was restored, Organ Center Staff reached out to all members they had received calls from during the outage and ensured their systems were back up and operating normally. The members also confirmed that here was no impact to donor or patient workflows, and they were able to successfully complete their allocation and procurement tasks.

Summary of discussion:

A committee member asked how the outage was communicated to the community. Mr. Nicholson informed the NOOC that OPTN members were informed of the outage through the dashboard that is available for anyone that uses the system. A committee member commented that the new proposal to

Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements, requires members to have a site security administrator. The committee member suggested that the site security administrator could also serve as a contact for the OPTN to notify if an outage occurs.

A committee advisor shared feedback they collected from their institution after the February 16 meeting. They asked employees whether the outage adversely affected their work during that time. They said that the outage, although an inconvenience, did not hinder their work. If the outage had lasted multiple hours than that could have been disruptive to the transplant system. The advisor suggested to explore other opportunities to ensure an outage of this sort does not happen again or for longer period of time, which staff is exploring.

A representative from HRSA revisited the notification process to members and asked if there is an alerting mechanism for the status page or an RSS feed. Mr. Nicholson explained that the status page was released in November so there are still opportunities to enhance the page. For example, he noted that a NOOC member asked for a legend to be added to the page and a legend will be added to the page next month. The status page does have subscription capability for a single component of the system, or members may subscribe for all nodes, announcements, and messages for all components. The HRSA representative also asked whether the metrics on the status page updated automatically or if they were updated manually. Mr. Nicholson explained that the messaging is manual, and the calculation is automatic. The representative from HRSA also asked Mr. Nicholson for confirmation that there is a process in place when an incident occurs to update the page, and Mr. Nicholson confirmed this.

A representative from HRSA reminded the NOOC that the NOOC possesses oversight responsibility on dashboards, and if the NOOC thinks there should be different reporting, processes, or granularity then they have the right to make these changes. The HRSA representative stated that the NOOC is the reason the status update requirement was added to the OPTN Contract because HRSA wanted to ensure the dashboard was relevant and useful to members. The representative encouraged the NOOC to bring suggestions about the dashboards to future meetings.

A committee member commented that although a 45-minute outage would be unfortunate, organ allocation before and after the match runs are performed hours, even days before a patient enters the operating room (OR) therefore, a 45-minute outage should not harm the system. Coordinators also have a printed copy of backup recipients they take to the OR with them and sometimes a list of backup physicians as well, in case they need to expediate placement unexpectedly.

A committee advisor suggested the NOOC analyze what procedures OPTN members have in place when an incident like this occurs, so they may have more data on how members react. The advisor also encouraged the NOOC to consider the difference between an inconvenience versus a problem, and what happens during each. The committee advisor also stated that as end users, they are going to know about an issue before the OPTN Contractor does and have the ability to distribute communication to members. The advisor reiterated a prior point, that when an organ is being allocated, there are multiple people who have already seen that offer, so they will not necessarily need the OPTN Computer System to analyze the organ.

A representative from HRSA suggested that it would be beneficial for the NOOC to have a conversation about system availability in general, instead of focusing on this particular outage. They also stated the importance of how a member's downtime procedure falls into incident response for particular outages, and to consider why this happened but also to evaluate the process at which the OPTN Contractor team responded and the adequacy of the response. They suggested that perhaps the next part of enhancing

the incident response process could be to analyze how outages are communicated to committee members and the community at large.

3. NOOC Goals for Increasing API Adoption

Marty Crenlon, Healthcare Integration Program Manager, presented on the committee's goals to increase API adoption. Mr. Crenlon presented OPTN Contract modifications that impact the NOOC's role in API adoption and encourages the OPTN Contractor to enhance API adoption. He shared what the OPTN Contractor's goals are on increasing API adoption, noting that they plan to build out APIs and drive adoption through the community. The OPTN Contract states that the OPTN Contractor is to support the NOOC and their efforts to define goals and tactics, drive wider adoption, and build out requirements for member compliance agreements.

Deliverable A120 is the work that the NOOC has already committed to, and Mr. Crenlon asked the committee for input on whether they should proceed as planned with their API adoption plan, or if there were any items the committee would like to add. Mr. Crenlon also presented the deliverable of A063 that asks what the NOOC would like to enhance in order to further API adoption.

The committee was reminded of the A120 deliverables that were presented in January 2022 for Fiscal Year 2023 for the OPTN's API milestones. These API milestones were to deliver three or more new APIs, increase adoption of the Unacceptable Antigen API to at least 50% of all transplant centers, increase adoption of the Local Deceased Donor Record API to at least 80% of all OPOs in a given month, and to produce a standard API adoption dashboard for quarterly review by HRSA and the NOOC. When it comes to specific activities, there are currently four APIs that are in development, three-member engagement campaigns to gain support on adopting these APIs, and continuous work being done to produce the API adoption dashboard.

Summary of discussion:

A committee advisor asked if the OPTN planned to make API adoption mandatory to increase engagement, or whether they planned to simply encourage members to adopt. They stated that 80% adoption is a lofty goal if adoption was not going to be mandatory. Mr. Crenlon explained that the OPTN has not considered making API adoption mandatory, and that doing so would be an OPTN decision, likely guided by the NOOC.

A representative from HRSA stated that the original goals behind including deliverable A120 in the OPTN Contract was to try and make the system more efficient and reduce the burden of data collection on members. The thought was that this deliverable could aid in facilitating the transmission of data therefore creating more robust policies and improving allocation. Although these were the original goals of the deliverable, it has also helped reduce data entry errors. The representative encouraged the NOOC to consider their role in mandating API adoption and reminded the committee that it is within their scope to make adoption mandatory. They encouraged the NOOC's engagement in decision making around APIs and reiterated the important role APIs serve throughout the transplant community. A committee advisor emphasized the high value impact that these APIs could have and emphasized the importance of creating visibility throughout the community. The advisor offered their assistance in collecting feedback throughout their organization to identify potential gaps APIs could fill.

A committee member asked the NOOC to consider the impact data from APIs could have, which APIs may be more impactful, and how they may impact the system. They encouraged the committee to think about APIs in the context of the security project. They encouraged the committee to consider how APIs fit within the security project and what role they could potentially play.

A committee advisor urged the committee to look to the future, because although there may be APIs within the OPTN, there are still no APIs between donor hospitals and OPOs. What this means is that members are still having to enter this information manually before there is any interaction with the OPTN Computer System. A representative from HRSA said they could bring this concern to the Centers for Medicare & Medicaid Services (CMS). They stated that CMS is working to clarify a donor hospital's role within OPTN API adoption. They confirmed that HRSA is working on addressing this issue and is encouraged to hear this feedback.

Next Steps:

Committee members were tasked to consider what APIs they thought could have the most meaningful impact on their organization and to bring these ideas back to the NOOC.

Attendance

- **Committee Members and Advisors**
  - Adam Frank
  - Bruno Mastroianni
  - Daniel Yip
  - Ed Hollinger
  - James Pittman
  - Kelley Hitchman
  - Kimberly Rallis
  - Maryjane Farr
  - Melissa McQueen
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  - Christopher McLaughlin
  - Cliff Myers
  - Manjot Singh
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  - Vinay Vuyyuru
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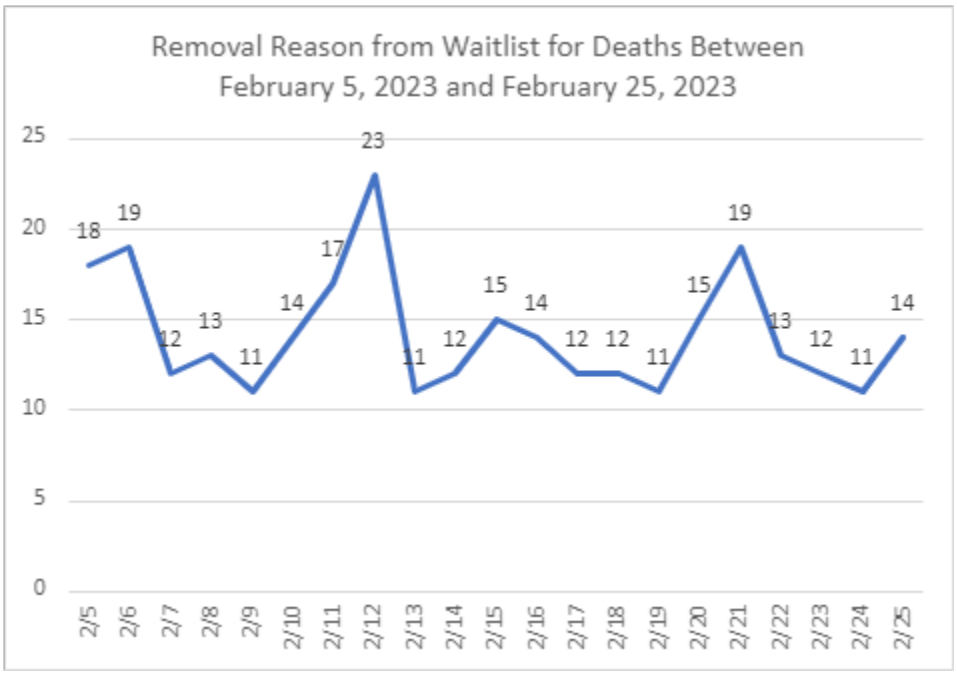
  - Alex Tulchinsky
  - Amy Putnam
  - Anna Messmer
  - Bridgette Huff
  - Courtney Jett
  - Jason Livingston
  - Kristine Althaus
  - Liz Robbins Callahan
  - Marty Crenlon
  - Morgan Jupe
  - Ralph Medina
  - Rob McTier
  - Roger Vacovsky
  - Terri Helfrich
  - Tiwan Nicholson
  - Tony Ponsiglione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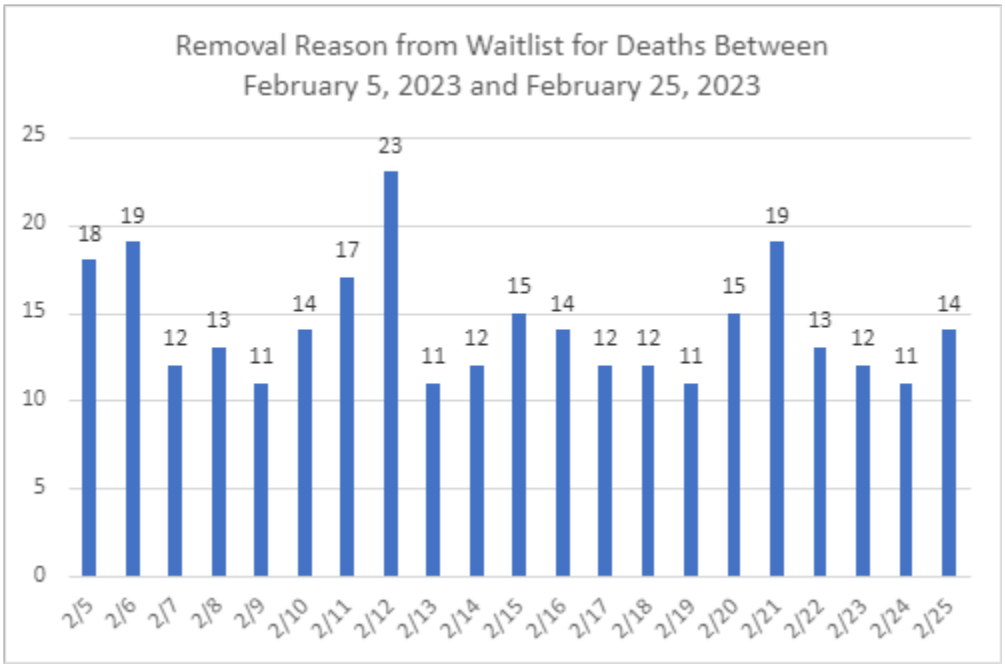
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