

OPTN Executive Update

David Mulligan, MD

President, OPTN Board of Directors

Region 4

January 28, 2021

2020 | Most lives ever saved by deceased donors



increase
in deceased donors
over 2019*

More than
33,000
life-saving transplants
from deceased donors*



10th
record year
in a row for deceased
donation*

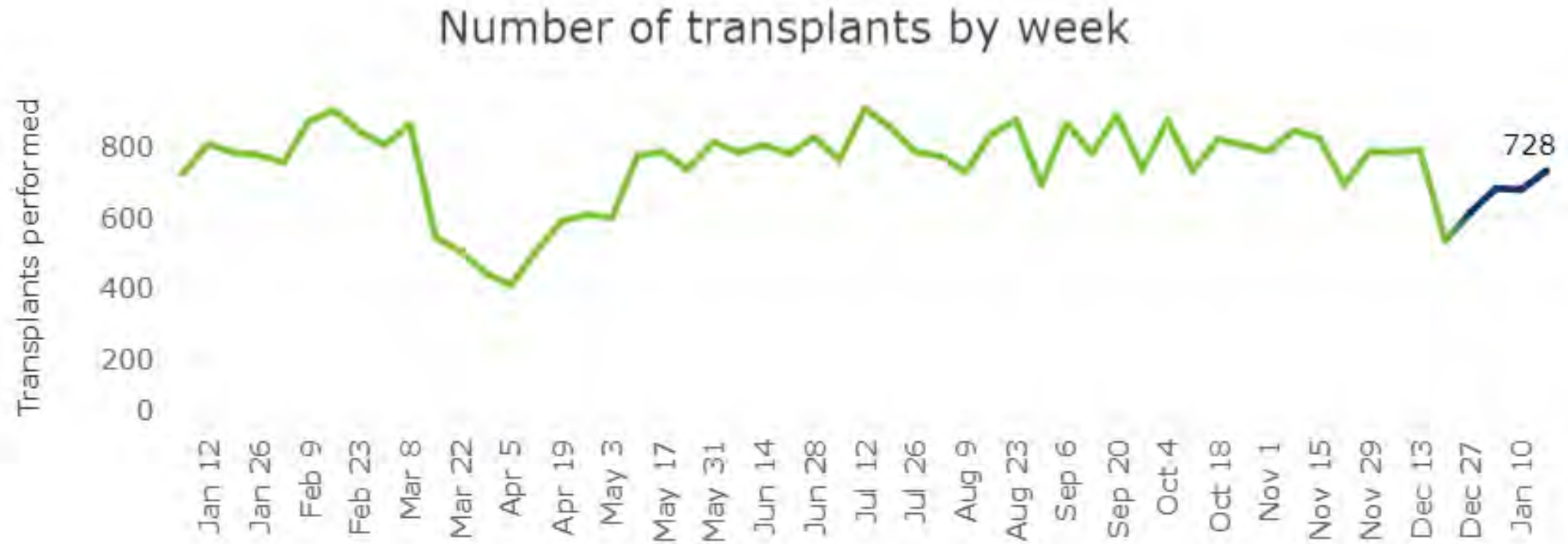


*Graphic updated 1/21/2021. Based on OPTN data as of January 1/11/21. Data subject to change based on future data submission or correction.

OPTN

COVID-19 Update

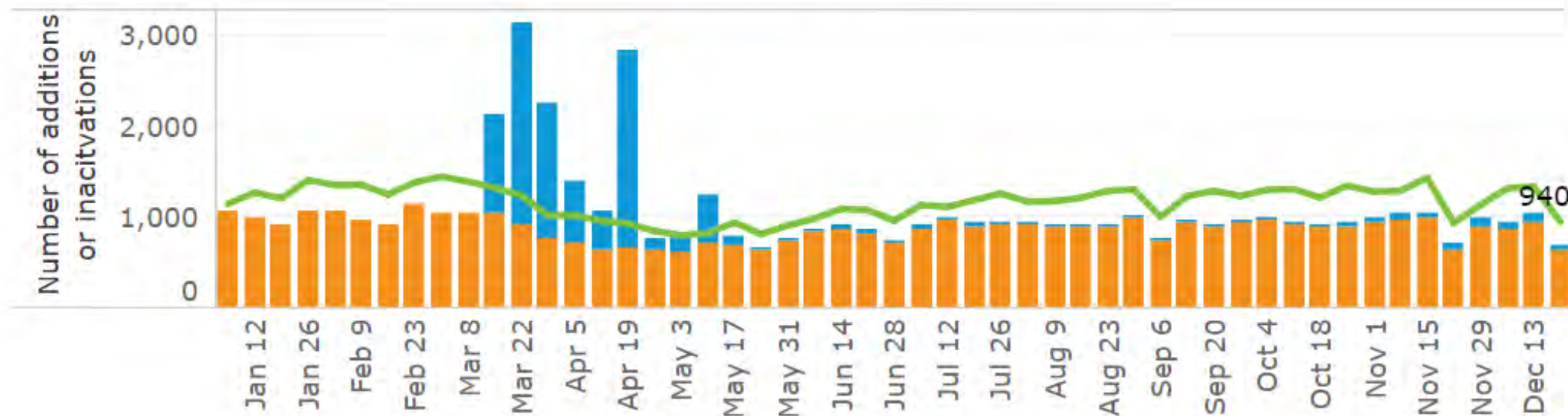
COVID-19 impact on transplantation



Waitlist changes

- New waiting list addition
- Inactivated due to COVID-19 precautions
- Inactivated due to another reason

Waitlist additions and inactivations

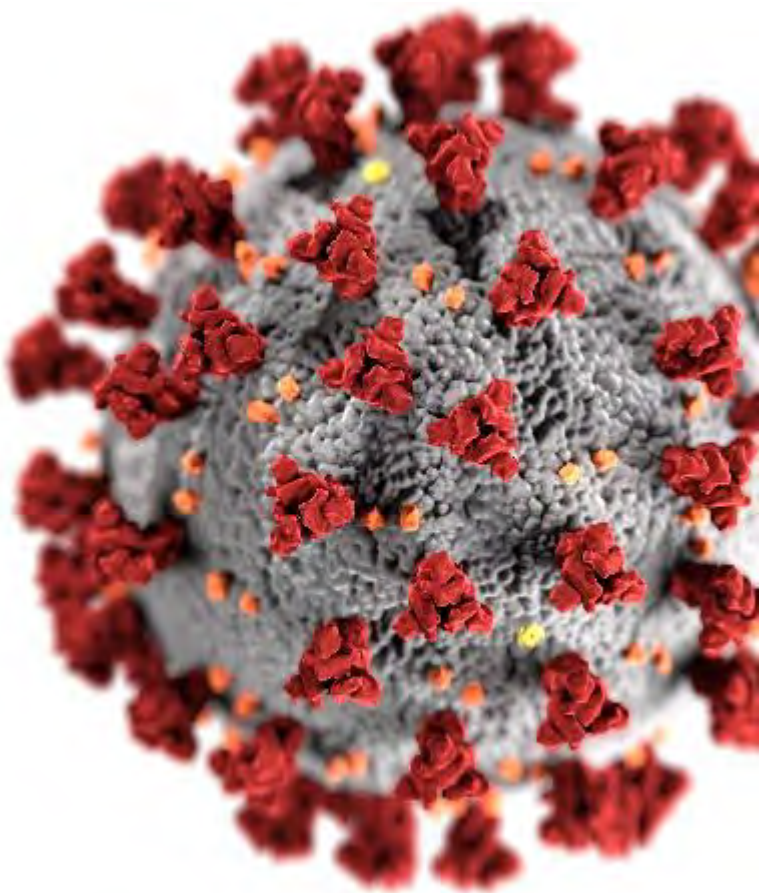


Week of waiting list registration or Most recent period of inactivation

*The COVID-19 Precaution inactive reason became available in UNet the week of Mar 15.

OPTN temporary policy actions

Action	Implemented
1. Updates to Candidate Data During 2020 COVID-19 Emergency	March 17, 2020
2. Relax Data Submission Requirements for Follow-Up Forms	April 3, 2020
3. Modify Wait Time Initiation for Non-Dialysis Kidney Candidates	April 3, 2020



State of COVID-19 Testing

Donor Recovery Dates	Test Type			
	Antibody	Antigen	Nucleic Acid detection	Other/Not reported
4/26-5/23/20	0.9%	0%	94.9%	4.2%
5/24-6/20/20	0.7%	0.9%	94.8%	3.6%
6/21-7/18/20	0.8%	0.8%	93.9%	4.6%
7/19-8/15/20	1.0%	0.9%	94.8%	3.3%
8/16-9/12/20	0.8%	1.5%	96.1%	1.6%
9/13-10/10/20	0.7%	1.1%	96.3%	1.8%
10/11-11/7/20	1.2%	1.3%	95.6%	1.8%
11/8-12/5/20	0.7%	2.2%	95.0%	2.1%
12/6/20-1/2/21	1.0%	2.2%	94.9%	1.9%

- 100% of recovered deceased donors have been tested for COVID-19
- Discrete data elements implemented April 21, 2020
- Some donors have received multiple tests

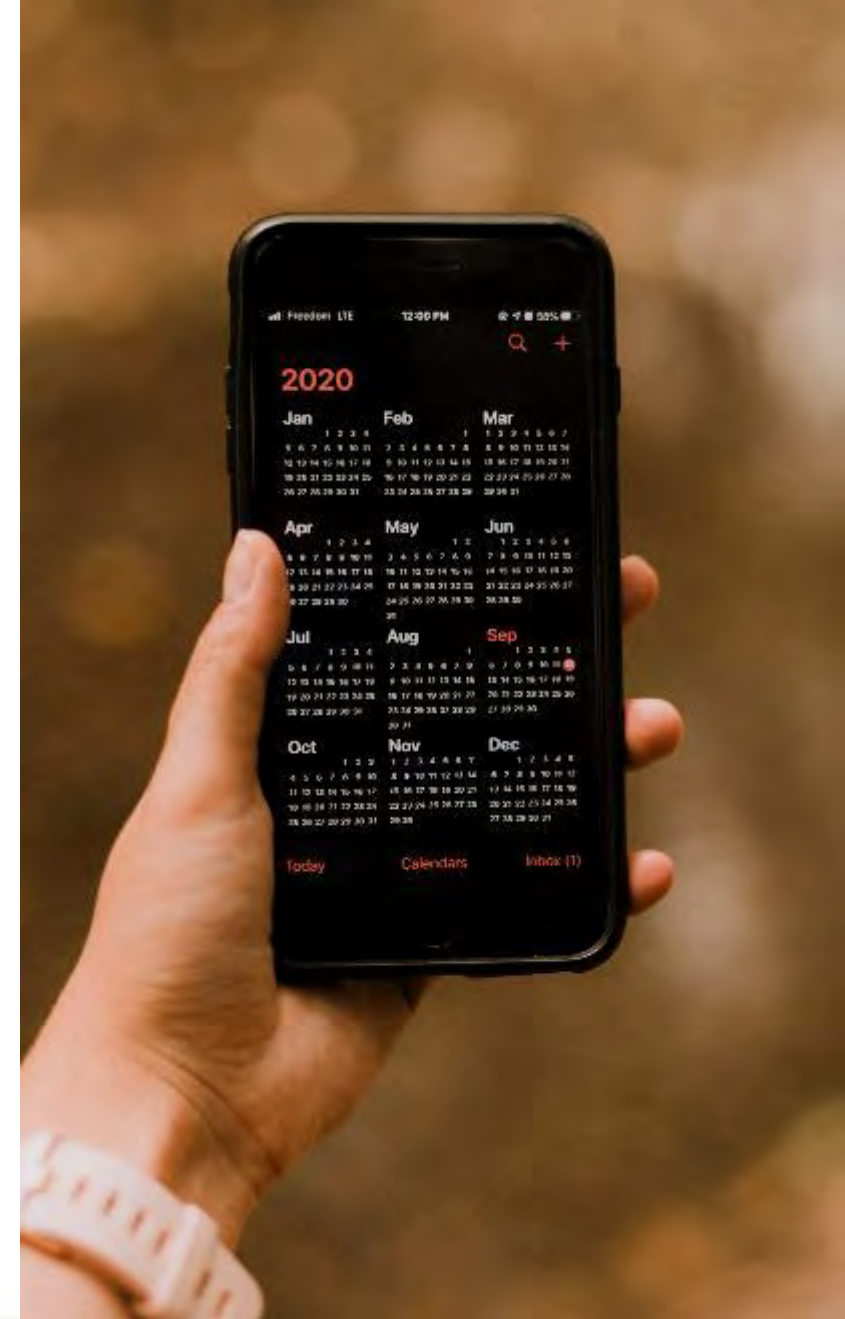
Monitoring updates- site surveys

- In response to the COVID-19 pandemic, UNOS staff ceased traveling to conduct on-site surveys on March 10, 2020
- Recognizing the increased burden COVID-19 has placed on many OPTN members, members may request a postponement of their survey
- Mar. 10 - Jan. 1 UNOS has conducted 81 virtual site surveys
 - Chart reviews still occur utilizing secure file transfer protocols
 - Interviews with video options using virtual meeting platforms.
 - Education on OPTN resources and policies.
- Site Surveys will remain virtual until it is safe for you and for UNOS staff to conduct them in person

Kidney and Pancreas Allocation Policy Implementation Update

Kidney and Pancreas Allocation Policies

- kidney and pancreas allocation policies were scheduled for implementation on December 15
- A critical comment was submitted to HHS Secretary requesting a delay to implement the kidney allocation policy
- A complaint was filed requesting a temporary restraining order
- HRSA directed OPTN to postpone implementation for 60 days to review the critical comments



Delays and their impact

Policy delays

- Eliminate the use of DSA and Region in Kidney and Pancreas allocation policies
- Addressing Medically Urgent Candidates in New Kidney Allocation Policy
- Modifications to Released Kidney and Pancreas Allocation
- Distribution of Kidneys and Pancreata from Alaska

Impact

- Deceased donor organs will **continue to be allocated to patients on the waiting list** using the current DSA and region-based allocation policies
- Current OPTN policy of kidney and pancreata will remain **in effect until at least Feb. 13, 2021**

Making organ matching more efficient

Policy Oversight Committee (POC) workgroups established

- **Match run rules workgroup** sponsored by Operations & Safety Committee
 - “Increase Offer Filters” and “Dynamic Match Run” recommendations
 - Planning for the “Conditional Yes” recommendation
- **Technology tools workgroup** sponsored by Organ Procurement Organization Committee
 - “Communication Enhancements in DonorNet”
 - “Image Sharing” recommendations
- **Biopsy best practices workgroup** sponsored by Kidney Committee
 - “Standardized Pathology Report”
 - “Minimum Set of Donor Kidney Criteria Appropriate for Biopsy” recommendations



Match run rules workgroup

Increase offer filters

- Set adjustable default filters for more tailored screening of organ offers based on center acceptance practices

Develop a dynamic match run

- Screen candidates off the match run in real time as new information is entered regarding serology, anatomy, biopsy, etc.

Create additional acceptance codes to indicate conditional yes

- Provide more information to OPOs about a center's level of interest and desired conditions for accepting an organ offer

Technology tools workgroup

Communications Enhancements in DonorNet®

- Streamlining communication in DonorNet® would allow OPOs the ability to update status of donors and send push notifications before, during and after allocation

Image Sharing

- Develop Guidance to Maximize the Use of Image Sharing Technology across the Entire Network

Biopsy best practices workgroup

Standardized Pathology Report

- Develop a Form that Pathologists Would Complete During Biopsy Readings to Allow for Consistent Analysis across Organ Procurement Organizations (OPOs) and Transplant Programs

Minimum Set of Donor Kidney Criteria Appropriate for Biopsy

- Develop a Minimum Set of Donor Kidney Criteria Appropriate for Biopsy

OPTN Regional Review

Summer 2020 community input results

About the review

- The OPTN, the donation and transplant community, and organ allocation policies have undergone significant change since OPTN Regions were created
- The review will evaluate the structure, processes, performance, and effectiveness of Regions
- Current and future needs of the nation's donation and transplant community will be considered



Community input results

- The first opportunity for input to the study occurred during summer 2020 public comment
- Results will be informational to the selected vendor
- 112 total respondents
- 5 open-ended questions were asked, summarized results identified themes with each question



Comments from members

Members responded that familiarity with nearby transplant centers and OPOs helps to build trust and that ultimately these connections improve donation and transplantation

Members reported that managing interregional relationships should be considered during this project.

Some members responded that there is a history of camaraderie that should to be considered. These members asked the OPTN to support the long-standing collaborative relationships between transplant centers and OPOs.

One member called the OPTN regional structure an “administrative necessity for representation”

Members would design the OPTN regional structure to ensure equal representation by grouping the same number of transplant programs and OPOs in each region

Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Implementation Update

Implementation March 1, 2021

Transplant Hospitals

- Educate staff on changes to risk criteria
- No longer use term “increased risk”
- Revise HIV, HBV, and HCV testing for living donors, candidates, and recipients
- Assess candidates for HBV vaccination need and report status
- Inform intended recipients if risk criteria are present but specific informed consent no longer required
- Arrange for living donor specimen storage and include storage as part of overall living donor consent - implemented June 1, 2021

Implementation March 1, 2021

OPOs

- Modify donor risk criteria screening questions
- No longer use term “increased risk”
- Obtain HIV, HBV, and HCV testing samples within 96 hours before procurement
- Obtain storage specimen within 24 hrs before procurement
- Upgrade TransNetSM application upon release
- Use revised extra vessels labels provided by the OPTN
- June 1: living donor recovery hospitals
 - 10 year storage of living donor blood specimen drawn within 24 hours of procurement
 - Confirm consent to store specimen for 10 years

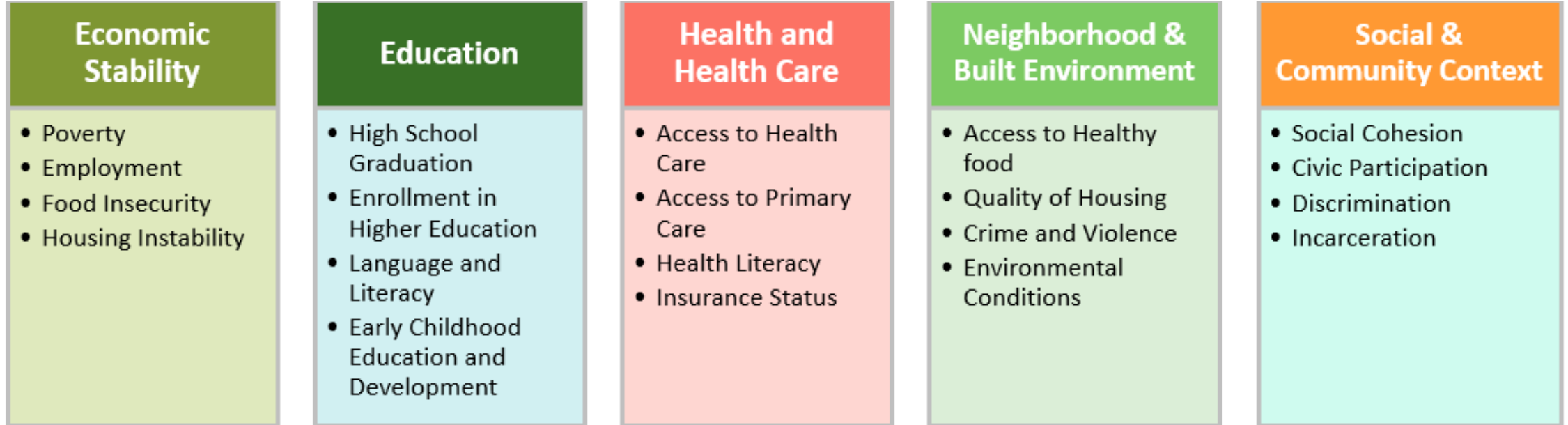
Resources

- Educational courses - available *now*
 1. *PHS Guidelines in OPTN Policy*
 - Updating policy, systems, labels - [OPO/Hospital](#)
 2. *Talking About Risk Criteria For Disease Transmission*
 - Guiding the conversation with patients for organs with risk criteria - [Hospital](#)

Social Determinants of Health (SDoH) Project

What are Social Determinants of Health (SDoH?)

- Conditions in the environments where people live, work, and age that affect a wide range of quality-of-life and health outcomes.
- Domains and elements can differ across SDOH Frameworks ➡ Healthy People 2020



Healthy People 2020. Social Determinants of Health.

<https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>

Data Services Portal

Data Services Portal: What is new?

The screenshot shows the UNOS Data Services portal interface. The left sidebar contains navigation links: Overview, Visual Analytics, Data Files, Data Requests, Data Quality, Documentation, Custom Reports, and Custom Report Builder. The main content area is titled 'Data Files' and includes a sub-header 'Securely view patient-identified and aggregate center and national reports.' Below this is a 'Filter' section with the following fields: PUBLICATION TITLE (with a text input 'Enter Publication Title'), PUBLICATION DATE (with dropdowns for 'Greater Than or Equal' and 'Less Than or Equal'), CATEGORY OF REPORT (with a dropdown 'All Report Categories'), ORGAN (with a dropdown 'All Organs'), and FILES PER PAGE (with a dropdown '10'). There are 'Clear' and 'Apply' buttons at the bottom of the filter section. Three blue callout boxes on the right highlight new features: 'New Data Quality Section', 'New Data Request Section', and 'Search on report title in Data Files section'.

UNOS Data Services

ALUA-TX1 University of

Overview

Visual Analytics

Data Files

Data Requests

Data Quality

Documentation

Custom Reports

Custom Report Builder

Data Files

Securely view patient-identified and aggregate center and national reports.

Filter

PUBLICATION TITLE
Enter Publication Title

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Greater Than or Equal Less Than or Equal

CATEGORY OF REPORT
All Report Categories

ORGAN
All Organs

FILES PER PAGE
10

Clear Apply

New Data
Quality Section

New Data
Request Section

Search on report
title in Data Files
section

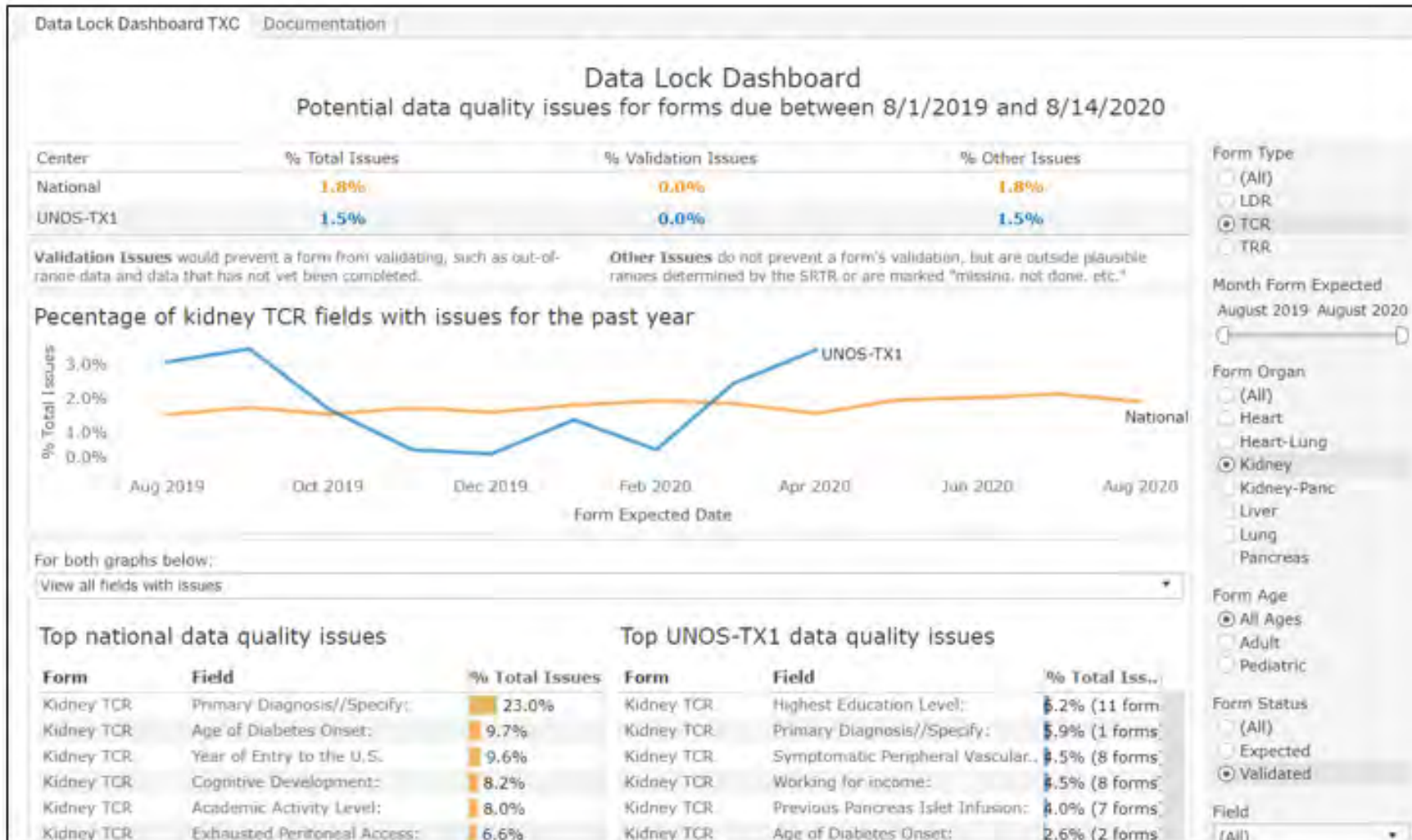
Data Services Portal: What is new?

The screenshot shows the UNOS Data Services Custom Report Builder interface. On the left is a navigation menu with the following items: Overview, Visual Analytics, Data Files, Data Requests, Data Quality, Documentation (highlighted with a blue box), Custom Reports, and Custom Report Builder. The main content area has a blue header with the text 'Custom Report Builder'. Below this is a three-step process bar: 1 Select Data Source (highlighted with a blue box), 2 Select Data Points, and 3 Select Filter Options. The main instruction reads 'Select a data source to begin.' Below this is a dropdown menu labeled 'SELECT DATA SOURCE *' with the selected option 'Transplants Performed At Center'. A blue box highlights the description for this source: 'Data as of: 01/10/2021' and 'Description: Data on all transplants performed at your transplant center since October 1, 1987, includes data elements from time of removal on the waiting list along with Hays collected on the TCR, TBR, and most recent followup. Updated weekly (Mon 9 p.m.) with data as of Friday of the previous week.' Below the dropdown are input fields for 'NAME OF NEW REPORT *' and 'DESCRIPTION OF REPORT *'. At the bottom, a blue box contains the text 'Send us your ideas! DataPortalFeedback@UNOS.org'.

Enhancements to Custom Report Builder

- Data files output in CSV, direct open in Excel
- Descriptions for data sources added, including date of last update
- Documentation with listing of available data elements for each data source

Data Services Portal: What is new?

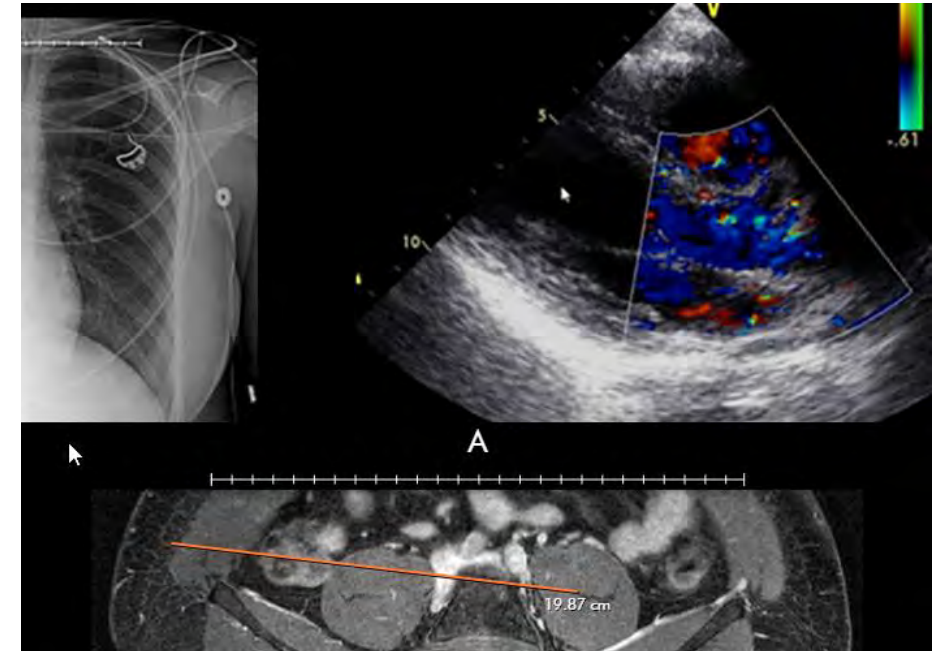


Data Lock Dashboard and Reports

- Released September
- Easily find data discrepancies
- Enhancements starting in February

UNetSM Image Sharing

- 29 OPOs now on board
- Rollout completion target – March
- * *Rollout is voluntary, some OPOs are choosing (at this time) to stay with current Cloud Provider*



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