

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*

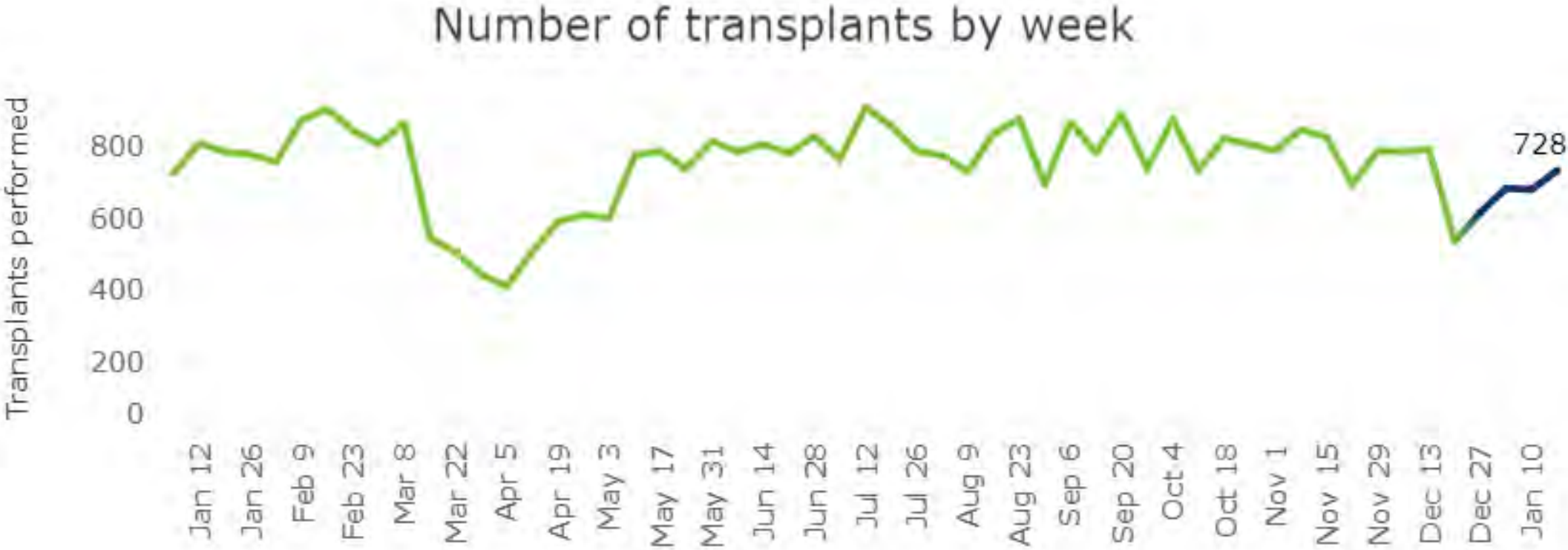


*Graphic updated 1/21/2021. Based on OPTN data as of January 1/11/21. Data subject to change based on future data submission or correction.

OPTN

COVID-19 Update

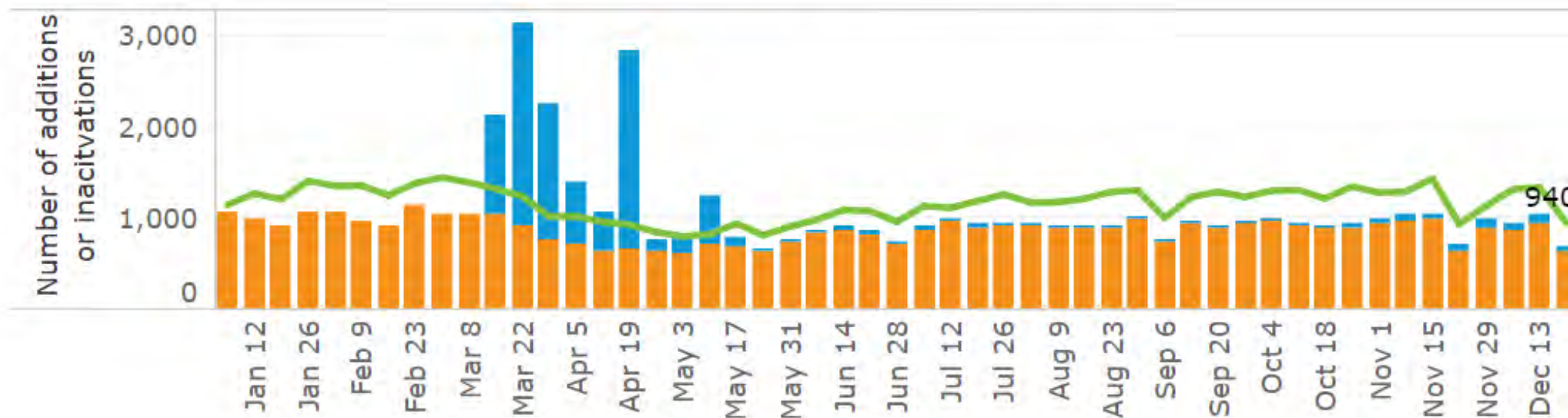
COVID-19 impact on transplantation



Waitlist changes

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

Waitlist additions and inactivations

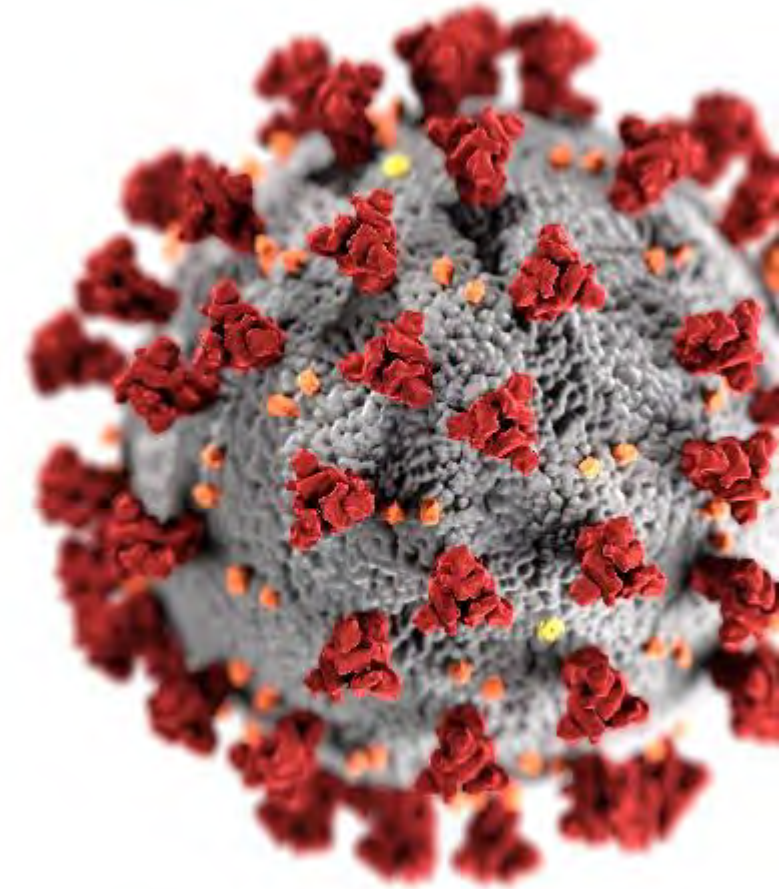


Week of waiting list registration or Most recent period of inactivation

*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

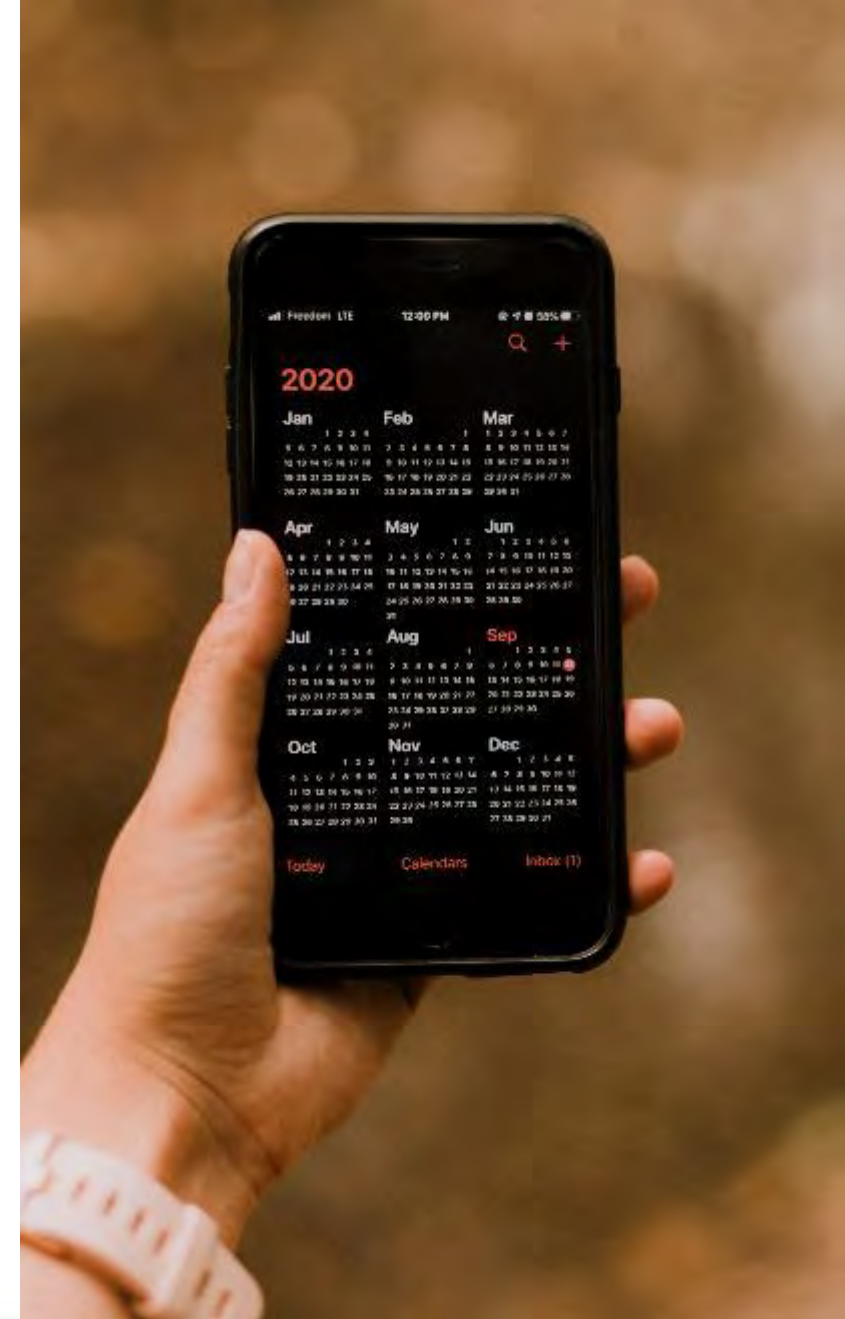
Monitoring updates- site surveys

- 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

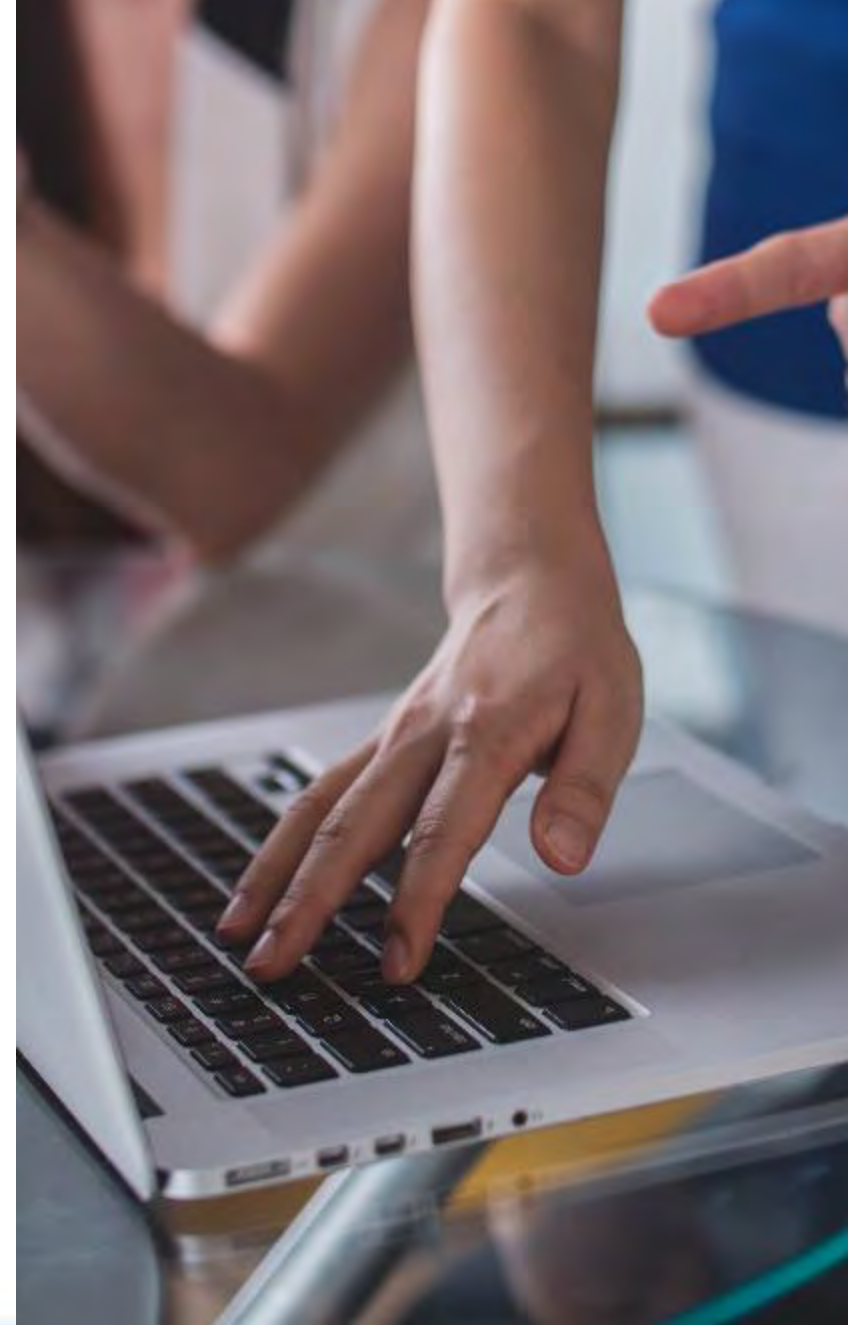
About the review

- 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

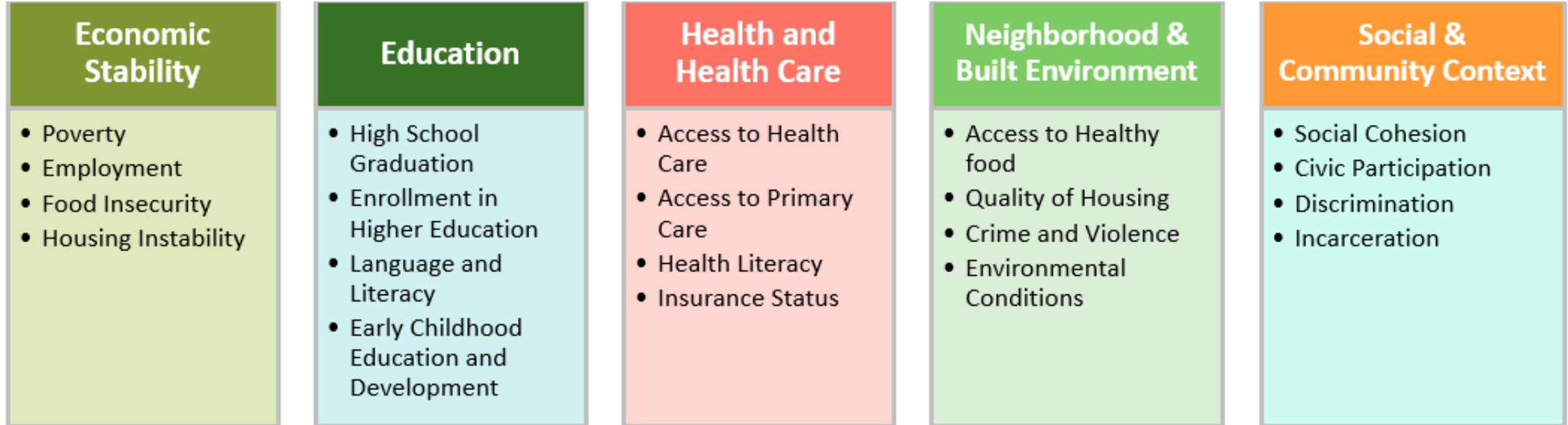
- Educational courses - available *now*
 1. *PHS Guidelines in OPTN Policy*
 - Updating policy, systems, labels - [OPO/Hospital](#)
 2. *Talking About Risk Criteria For Disease Transmission*
 - Guiding the conversation with patients for organs with risk criteria - [Hospital](#)

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 top navigation bar includes the UNOS Data Services logo and a user dropdown menu for 'ALUA-TX1 University of...'. 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 elements: a 'PUBLICATION TITLE' input field with the placeholder 'Enter Publication Title', a 'PUBLICATION DATE' section with radio buttons for 'Greater Than or Equal' and 'Less Than or Equal', a 'CATEGORY OF REPORT' dropdown menu set to 'All Report Categories', an 'ORGAN' dropdown menu set to 'All Organs', and a 'FILES PER PAGE' dropdown menu set to '10'. There are also 'Clear' and 'Apply' buttons at the bottom of the filter section.

New Data Quality Section

New Data Request Section

Search on report title in Data Files section

Data Services Portal: What is new?

UNOS Data Services

Overview

Visual Analytics

Data Files

Data Requests

Data Quality

Documentation

Custom Reports

Custom Report Builder

Have Feedback or questions? dataportalfeedback@unos.org

Custom Report Builder

1 Select Data Source

2 Select Data Points

3 Select Filter Options

Select a data source to begin.

SELECT DATA SOURCE *

Transplants Performed At Center

Data as of: 01/18/2021

Description: Data on all transplants performed at your transplant center since October 1, 1987, includes data elements from time of removal to the waiting list along with HUSC collected on the TCD, TBE, and most recent follow-up. Updated weekly (Mon 9 p.m.) with data as of Friday of the previous week.

NAME OF NEW REPORT *

DESCRIPTION OF REPORT *

File name (description of your new report)

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

Data Lock Dashboard TXC Documentation

Data Lock Dashboard

Potential data quality issues for forms due between 8/1/2019 and 8/14/2020

Center	% Total Issues	% Validation Issues	% Other Issues
National	1.8%	0.0%	1.8%
UNOS-TX1	1.5%	0.0%	1.5%

Validation Issues would prevent a form from validating, such as out-of-range data and data that has not yet been completed. **Other Issues** do not prevent a form's validation, but are outside plausible ranges determined by the SRTR or are marked "missing, not done, etc."

Percentage of kidney TCR fields with issues for the past year

For both graphs below:
View all fields with issues

Top national data quality issues			Top UNOS-TX1 data quality issues		
Form	Field	% Total Issues	Form	Field	% Total Iss..
Kidney TCR	Primary Diagnosis//Specify:	23.0%	Kidney TCR	Highest Education Level:	5.2% (11 forms)
Kidney TCR	Age of Diabetes Onset:	9.7%	Kidney TCR	Primary Diagnosis//Specify:	5.9% (1 forms)
Kidney TCR	Year of Entry to the U.S.:	9.6%	Kidney TCR	Symptomatic Peripheral Vascular..	5.5% (8 forms)
Kidney TCR	Cognitive Development:	8.2%	Kidney TCR	Working for income:	5.5% (8 forms)
Kidney TCR	Academic Activity Level:	8.0%	Kidney TCR	Previous Pancreas Islet Infusion:	4.0% (7 forms)
Kidney TCR	Exhausted Peritoneal Access:	6.6%	Kidney TCR	Age of Diabetes Onset:	2.6% (2 forms)

Form Type: (All) LDR TCR TRR

Month Form Expected: August 2019 - August 2020

Form Organ: (All) Heart Heart-Lung Kidney Kidney-Panc Liver Lung Pancreas

Form Age: All Ages Adult Pediatric

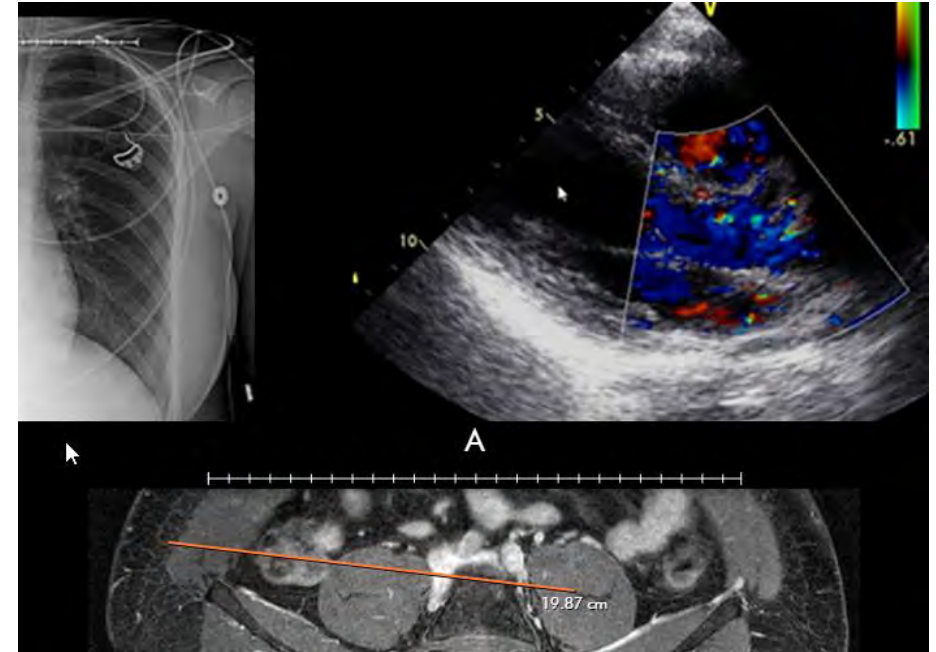
Form Status: (All) Expected Validated

Field: (All)

- 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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