OPTN Executive Update

David Mulligan, MD
President, OPTN Board of Directors
Region 4
January 28, 2021
2020 | Most lives ever saved by deceased donors

6% 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.
COVID-19 Update
COVID-19 impact on transplantation

Number of transplants by week

Transplants performed


728
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

<table>
<thead>
<tr>
<th>Action</th>
<th>Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Updates to Candidate Data During 2020 COVID-19 Emergency</td>
<td>March 17, 2020</td>
</tr>
<tr>
<td>2. Relax Data Submission Requirements for Follow-Up Forms</td>
<td>April 3, 2020</td>
</tr>
</tbody>
</table>
# State of COVID-19 Testing

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

- 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 hours before procurement
- Upgrade TransNet\textsuperscript{SM} 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

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**Economic Stability**
- Poverty
- Employment
- Food Insecurity
- Housing Instability

**Education**
- High School Graduation
- Enrollment in Higher Education
- Language and Literacy
- Early Childhood Education and Development

**Health and Health Care**
- Access to Health Care
- Access to Primary Care
- Health Literacy
- Insurance Status

**Neighborhood & Built Environment**
- Access to Healthy food
- Quality of Housing
- Crime and Violence
- Environmental Conditions

**Social & Community Context**
- Social Cohesion
- Civic Participation
- Discrimination
- Incarceration

https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health
Data Services Portal
Data Services Portal: What is new?
Data Services Portal: What is new?

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

Send us your ideas! DataPortalFeedback@UNOS.org
Data Services Portal: What is new?

Data Lock Dashboard and Reports

- Released September
- Easily find data discrepancies
- Enhancements starting in February
UNet$^{\text{SM}}$ 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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