Ad Hoc Organ Tracking Committee (OTC) Update

HHS Electronic Tracking and Transport (ETT) Innovations

OPTN BOD Presentation
Project Goals

- Minimize the potential for misdirected or delayed organ transport
- Reduce the chance for incorrect transplantation
- Eliminate manual transcription errors
- Accelerate information transfer about the organs to key stakeholders
- Capture comprehensive organ transport data and logistical information that will prove invaluable to the OPTN for optimizing organ allocation and minimizing geographic variability in organ access for people waiting for a transplant
ETT Project Staff

- HHS Innovation Fellow
  - David Cartier (HRSA)

- UNOS Project Manager
  - John Rosendale

- Committee Liaison
  - Kimberly Taylor

- UNOS Consultant
  - Clive Hohberger, PhD

- HRSA
  - Chris McLaughlin
OTC Membership

- David Marshman – OPO, Chair
- Charlie Alexander – OPO, At Large
- Scott Brubaker – AATB, At Large
- Kevin Carney – TXC Thoracic Coordinator, At Large
- Theresa Daly – TXC Operations, At Large
- Jean Davis – OPO Administration, At Large
- Moshe Feldman, PhD – Human Factors, At Large
- Dean Henderson – TXC Peds, At Large
- Gwen McNatt – TXC Administration, At Large
- Linette Boysen Meyer – OPO Recovery Services, At Large
- Jachin Misko – EBAA, At Large
- Kevin Myer – OPO, At Large
- Tim Pruett, MD – TXC Surgeon, At Large
- Meg Rogers – OPO Administration, At Large
- Gigi Spicer – TXC KPD, At Large
- Michael Strong, PhD – AABB, At Large
- Sean Van Slyke – OPO, At Large
- Robert Teaster – TXC Administration, At Large
### Understanding Variation in Process

#### Site Visits

<table>
<thead>
<tr>
<th>OPOS</th>
<th>Transplant Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>California Transplant Donor Network</td>
<td>University of California-San Francisco</td>
</tr>
<tr>
<td>Living Legacy Foundation (MD)</td>
<td>Johns Hopkins &amp; University of Maryland</td>
</tr>
<tr>
<td>LifeSource (MN)</td>
<td>University of Minnesota</td>
</tr>
<tr>
<td>Gift of Hope (IL)</td>
<td>Northwestern Memorial (IL)</td>
</tr>
<tr>
<td>LifeLink (GA)</td>
<td>Piedmont Hospital (GA)</td>
</tr>
<tr>
<td>LifeNet Health (VA)</td>
<td>VCU Medical Center (VA)</td>
</tr>
</tbody>
</table>

FMEA
Committee Focus

- FMEA of Packaging / Labeling Process
- Development of “Proof of Concept” system
- Evaluation of “other” transportation providers
- Evaluation of tracking methodologies
Process begins with management

30 – 70 Labels by Hand

30 – 70 Manual Validations
The Labeling Solution

Donor Management
- Workflow
- Enhanced Validation
- Print on Demand

Operating Room Process
- Back Table Workflow
- Labels Applied on Demand

Post Recovery
- Package – Shipping Labels & Barcode
- Ship – Scan When Ready to Ship
- Receipt – Scan & Match to Recipient

OPTN Policy Changes
- Modify Required Paperwork
- Modify Labeling Requirements
- Modify Validation Requirements
Project Vision

1st Ad Hoc Committee Meeting
FMEA
Chicago

NWU Sim 1

Parallel In-Field Testing

AOPO & OPTN BOD

Field Test 3-5 OPOs

System Changes - DonorNet Functionality

OPTN Board of Director Review

10/12
12/12
1-3/13
04/13
05/13
06/13
07/13
08/13
09/13
10/13
11/13

Discovery

Development

NWU Sim 2

VCU Sim 3

Innovation Meeting UNOS

Ad Hoc Committee Formation

AOPO & OPTN

BOD

Completion of Initial Pilot & Report to HRSA

Final Recommendations & Requirements by the HHS Entrepreneur

OPTN
Simulation Videos

Case Workflow Video
United Network For Organ Sharing

Ad Hoc Organ Tracking Committee

Recommendations to the Board of Directors
The Committee Recommends (1):

- that the OPTN move forward with field testing at a limited number of OPOs, with preference given to those OPOs that have participated in the pilot study using the prototype of the app that was developed.

- that the OPTN move forward with exploring the development of a validated, deployable app based on the prototype with feedback from the field testing sites.

- that the OPTN begin exploring the long term solution that allows integration between the mobile solution and DonorNet that will allow the matching of the organ with the recipient.
The Committee Recommends (2):

- that the wealth of information provided by the FMEA and risk chart analyses be passed on to the Operations and Safety Committee for further analysis.

- that any labeling system implemented will be able to quickly adapt to the use of a universal donor identification system should one become available.

- that the OPTN and HRSA begin discussions with the leadership of ICCBBA to determine if the ISBT system of coding and nomenclature could be used in the United States organ system with the long term goal of having traceability for all products of human origin.
The Committee Recommends (3):

- that the OPTN continue to evaluate GPS tracking, however it recognizes that other technologies may facilitate this type of monitoring.
As a result of the analysis of the current system and in an attempt to minimize the complexity of the process which can contribute to errors, the following issues were identified, and recommendations made to maximize patient safety.
The Committee Recommends (4):

- that the Operations and Safety Committee along with the OPO Committee review the package documentation requirement in policy 5.5.1 and determine if the majority of this documentation could be uploaded to DonorNet and limit the documentation included with the organ to only those items that are mission critical and need to be physically in the box.
The Committee Recommends (5):

- that the OPTN support the efforts of the OPO Committee in their work to limit the data submission requirement for the DDR be limited to only actual donors. This would take away the disincentive for delaying the generation of the Donor ID and it would be available to be used on all labels. It was noted that we should not overlook the importance of learning more about those referrals that do not go on to donation and consider other options for collecting those data.
The Committee Recommends (6):

- that existing practices be examined and a national standard be recommended to universally mark one of the kidney lateralities for system consistency.
The Committee Recommends (7):

- that the Operations and Safety committee pursue that the requirement for an internal vessel label be removed.