

**OPTN/UNOS Operations and Safety Committee  
Report to the Board of Directors  
December 1-2, 2015  
Richmond, VA**

**Theresa Daly, MS, FNP, Chair  
David Marshman, Vice Chair**

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*This report reflects the work of the OPTN/UNOS Operations and Safety Committee from June - November 2015.*

**Action Items**

1. Request for TransNet<sup>SM</sup> Programming in OPTN Information Technology Road Map

Public Comment: Not Applicable

Board Consideration: December 2015

The Health Resources and Services Administration (HRSA) contract modification to the OPTN providing special dedicated funding to support TransNet ended on September 30, 2015. A list of functionality that is planned and can likely be completed with unspent remaining funds has been reviewed with the Committee and the TransNet work group. The OSC agreed that this list as presented will provide functionality for OPO usage as well as basic transplant program usage. The Committee noted that the functionality will be sufficient to support basic mandatory OPO usage.

The Committee discussed additional functionalities that have been identified as desired. Programming on this list will need to be approved and prioritized according to the standard OPTN information technology programming process. The OSC decided that the highest priority should be given to functionality that will eliminate having to have two different processes. This includes three areas: ABO verification prior to organ arrival, living donation, and directed donation. The fourth priority would be to have functionality to track vessels and use the system to perform required reporting. Other items exist on this list but have been given a lower priority. These include mobile device usage and other enhancements to promote usage in the donor management (ICU) phase for OPOs.

The Committee voted unanimously (17-Yes, 0-No, 0-Abstain) to request the OPTN Board of Directors to approve programming for TransNet at the December 2015 meeting. See **Exhibit A**.

Table 1: Requested Functionality

Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
Living donors	This would provide OPO and transplant hospital functionality to label and package living donor organs. It would also provide transplant hospital organ receipt and pre-transplant verification functionality.	High	Do not want two different processes (Manual process for living donors and TransNet functionality for deceased donors)	Very Large	3995
Directed Donation	This would provide transplant hospital functionality allowing printing of recipient ID bands for organs allocated Not on A Match Run (NOMR) as well as receipt and verification of these organs	High	Do not want two different processes (Manual process for NOMR and TransNet process for organs on a match run)	Large	745
Pre-transplant verification when surgery begins before organ arrival	This would provide transplant hospital functionality for completion of the new policy requirement (5.7.A) to be implemented in June 2016 that will require a verification when candidate surgery begins prior to organ arrival. The functionality would include reports that could be generated for documentation of verification	High	Do not want two different processes (Manual process for this verification and TransNet functionality for verification completed upon organ arrival)	Very Small (DR)	56
GPS Tracking	This would provide tracking functionality either through use of a device or through further development of tracking latitude and longitudes that is posted on the TransNet website	Medium	The work group recommends that this functionality using a device be delayed until transplant hospital development and acceptance is further along.		Outside vendor

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Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
iPhone/Android phones	This would provide OPO functionality to use the TransNet application on these devices	Medium	Concerns exist whether the phone screens would be large enough and whether it is wise to use phones for TransNet since they are needed for texting and calling as part of organ offer and information sharing processes.	Large	1645
ICU Enhancements	This would provide OPO enhancements to enable use of application/printing on alternative devices TBD. This will reduce the burden of equipping all staff that conduct donor management prior to recovery with tablets and zebra printers.	Medium	This has been request from multiple OPOs who desire to use TransNet in the ICU/donor management phase but are not able to due to equipment logistics and cost	Large	1645
Vessel disposition functionality including reports, catalog, and feedback to UNet	This would provide transplant hospital functionality to scan vessels upon receipt and record vessels dispositions. This functionality would provide verification functionality for vessels used in secondary recipients. It would generate transplant hospital reports for verifications and disposition. It would upload these data into UNet and satisfy required vessels disposition reporting (policy in effect 10/22/15)	Medium	Transplant hospitals have asked for this functionality. It is not in the high category because it will not solve having two different processes	Small	220
VCA	This would provide OPO functionality to label and package VCA organs.	Low	Currently VCA transplantations are low volume events. The donors and match are not programmed in UNet at this time.	Medium	745
Total Hours					9051

**RESOLVED, that UNOS appropriate 9,000 hours of staff resources over the next two years to implement TransNet functionality as described in Table 1, above.**

## Committee Projects

### 2. Standardize coding system for organ tracking (Electronic Tracking and Transport Project or TransNet<sup>sm</sup>)

*Public Comment:* January 2016 (Estimated)

*Board Consideration:* June 2016 (Estimated)

National voluntary OPO use of TransNet started in March 2015. As of October 2015, 31 OPOs have completed the three-day required training at UNOS headquarters including passing proficiency testing. An additional six OPOs have signed up for future training dates. The Committee developed a survey that was conducted by the Association of Organ Procurement Organizations (AOPO) in September 2015. This survey found that an additional eight OPOs plan to sign up for training. Ten OPOs were uncertain of their future plans. Two OPOs indicated that they did not plan to sign up or use TransNet. The survey also measured reasons for uncertainty of usage to help staff develop targeted strategies to reach all OPOs. The two primary reasons for non-commitment were waiting for product availability in iOS (n = 5) and waiting to hear more feedback from OPO community (n=3). The iOS version of TransNet will be released in December 2015.

The Committee and the TransNet team continue to monitor OPO usage. From September 18, 2014 to November 2, 2015, TransNet was used to package 5,536 organs from 1,641 donors. A study of individual OPO usage showed that a TransNet case was created for 57.3% of all deceased donors recovered by the 31 trained OPOs during September 2015. Fourteen OPOs (46.7%) from this cohort created TransNet cases for every donor recovered. Two OPOs had not used TransNet for any cases and these sites have received individual follow up and technical assistance. Details of this data analysis are available upon request.

TransNet has continued to receive exceptional reviews for training, technical support, and overall process improvement. Community feedback at conferences such as the AOPO Tri-Council has been very positive.

On October 13, 2015, the Operations and Safety Committee voted unanimously (17-Yes, 0-No, 0-Abstain) to send proposed policy out for the January 2016 public comment cycle. The proposal will mandate TransNet use to label deceased donor organs and vessels for those that must be labeled already in current policy (those traveling outside the recovery facility). The proposal will also require transmittal of cases to the OPTN Contractor in real time to enable web-based tracking. The Committee plans proposing an implementation date in 2017 to allow ample time for OPOs to budget, prepare, and train for TransNet.

TransNet project staff are working concurrently on transplant hospital functionality. Fifteen sites were visited during the discovery phase. Five transplant hospitals have started beta testing. A total of 27 transplant hospitals have indicated an interest in beta testing. These sites are in various planning stages with TransNet staff. Getting transplant hospitals live into beta testing has proven to be more timely and involved due to multiple levels of needed approvals at hospitals and equipment issues (e.g. scanners and printers). Another issue facing transplant hospitals is how to integrate the system and process with their own electronic medical records (EMRs). TransNet staff has recognized this issue and has set up preliminary talks with one EMR vendor to assess how these needs might be addressed.

The beta test version for transplant functionality includes an organ check in and pre-transplant verification. The functionality highlights new or positive donor infectious disease testing results. Transplant hospitals use the system to print a recipient ID band that is attached to the candidate prior to surgery. Upon organ arrival, the organ is checked in. In

the operating room, the recipient ID band and the organ label(s) are scanned to ensure right organ/right recipient and ABO compatibility.

The TransNet team met with Centers for Medicaid and Medicare Services (CMS) and other Health Resources and Services Administration (HRSA) staff on July 30, 2015 to provide a demonstration of functionality and discuss future plans. One major goal is to develop a product that will meet both OPTN and CMS requirements in certain policy areas such as ABO verification. Staff will continue to work through HRSA Division of Transplantation staff to collaborate with CMS in reaching this goal where possible to improve safety and OPTN member ability to comply with safety policies.

### 3. Infectious Disease Verification

*Public Comment: January 2016 (Estimated)*

*Board Consideration: June 2016 (Estimated)*

While there is a process for ABO verification to prevent accidental transplant of incompatible blood types, there is no similar process of verification related to infectious disease. Current policy requires verification of all infectious disease results prior to use of deceased donor extra vessels in secondary recipients or living donor recipients as well as for deceased donor organ transplants not on a match run. Policy for these organs specifies that the transplant hospital verify the medical suitability between the deceased donor organ and recipient prior to transplant. Current policy does not require this type of verification in all organ transplants.

There have been cases where positive serology results have been available but inadvertently missed resulting in preventable disease transmission or near misses of preventable disease transmission. In March 2014, the MPSC referred this issue to the Committee and requested development of a policy proposal requiring infectious disease verification at two points during living donor procedures. This safety check will become increasingly important as the HIV Organ Policy Equity (HOPE) Act will allow use of organs from HIV positive donors in HIV positive candidates starting in November 2015 under approved Institutional Research Board (IRB) research protocols with standards set by the Secretary of Health and Human Services. The HOPE Act safety sub group discussed this issue and recommended a process be developed. In June 2014, the full HOPE Act work group also recommended this issue be referred to OSC to develop a proposed process and policy.

A work group with members of the HOPE Act safety sub group and additional representatives from the OPO, Transplant Administrators, and Transplant Coordinators Committees was formed and continues to meet monthly.

Data tabulated in 2014 show there were five proven/probable viral disease transmission advisory cases between 2009 to the present related to this issue. Among these cases, 60% were from deceased donor organs and 40% were from living donor organs. Three cases were related to donor hepatitis C (HCV) infection and two cases were related to donor cytomegalovirus (CMV) infection. Twelve recipients received infected organs and five recipients became infected following the transplantation. In addition, there have been two living donor and one deceased donor cases with similar process issues reported that were not classified as proven/probable transmission.

The work group has developed proposed language that would apply to all infectious diseases that would potentially screen a candidate off a match run (hepatitis B (HBV), HCV,

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HIV, and CMV-intestine candidates only). These were selected following a DTAC recommendation.

The proposal has infectious disease verification checks that would coincide with pre-surgical ABO verifications will go into effect in June 2016. These would occur at deceased donor recovery, living donor recovery, pre-transplant prior to organ arrival, and pre-transplant upon organ receipt. The OSC discussed possible proposal language for the January 2016 public comment cycle at their in-person meeting on October 13, 2015. The Committee identified issues that need further discussion including what will be acceptable sources for verification including when results change post recovery; the ability to conduct the verification in the OR; the concept that if all results are available, negative, and verified prior to organ arrival that this step will not be repeated upon organ receipt; and possible requirements for when infectious disease testing must be completed. The Committee deferred voting at their in-person meeting. Further discussions were held at their October 22, 2015 monthly conference call and at the November 2, 2015 infectious disease verification work group call. The Committee plans to vote on proposed policy language at their November 24, 2015 monthly conference call. A proposal may be sent out for the January 2016 public comment cycle.

### Committee Projects Pending Implementation

#### 4. Clarify requirements for blood type verification

*Public Comment:* [March 14 – June 13, 2014](#)

*Public Comment:* [January 27 -March 27, 2015](#)

*Board Approval:* [June 2015](#)

*Projected Implementation:* *Second quarter 2016 (no sooner than June 1, 2016)*

The Executive Committee approved changing the policy implementation date from February 1, 2016 to effective pending programming and notification to the membership. This request was made because the UNOS Information Technology (IT) department estimated that they could complete programming associated with the proposal in the 2<sup>nd</sup> quarter of 2016. While the programming is not necessary to implement the policy, the programming enhancements will assist members with compliance. A revised policy notice has been provided to members that instructs them to be ready for implementation by June 1, 2016. The IT department has committed to an implementation date of no sooner than June 1, 2016.

An ABO implementation subcommittee has been formed. This subcommittee will guide educational efforts being prepared. The educational plan developed by Instructional Innovations includes two webinars. The first will be held on December 8<sup>th</sup> and already has over 440 registrants. This webinar will review basic policy changes as well as allow for live questions and answers. A second webinar will be scheduled for the spring to address compliance with the policy. The Operations and Safety chair will also present at the UNOS Member Quality staff meeting in December to assist site surveyors with understanding policy changes and implementing the evaluation plan.

An ABO tool kit is being developed for mid-November 2015 release. It will be a resource for members with tools to help prepare and include items such as the approved policy language and a checklist for members to guide their internal planning. The tool kit will be a living resource with additional tools added monthly until implementation. Currently the subcommittee is working on updating the OR templates developed in conjunction with CMS that are currently available for use. Updated templates will be available for use in a paper format. In addition, TransNet<sup>sm</sup> is programming a verification form and the tool kit will contain

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a list of needed fields to assist those programming verifications with EMR vendors. The templates will be prepared to have CMS approval as well to continue the joint effort to enable improved compliance.

### 5. Clarify Data Entry Screens for A2 and A2B in UNet

*Public Comment:* N/A  
*Board Approval:* November 2011  
*Projected Implementation:* January 21, 2016

This programming enhancement will add static text to explain that the A2 and A2B labels throughout UNet are shorthand for blood type A, non-A<sub>1</sub> and blood type AB, non-A<sub>1</sub>B results. This text explanation will help align terminology changes in policy approved by the OPTN/UNOS Board of Directors in November 2014.

## Implemented Committee Projects

### 6. Improvements to Vessel Disposition Reporting

*Public Comment:* March 16 - June 25, 2012  
*Board Approval:* November 2012  
*Implementation Date:* October 22, 2015

The OPTN/UNOS Board of Directors approved a proposal sponsored by the Operations and Safety Committee that would require reporting of vessels disposition within seven days of use or destruction. Although approved in November 2012, the policy implementation date was made dependent on programming the electronic form.

Programming for electronic reporting of vessels disposition in UNet<sup>sm</sup> was released on October 22, 2015. Policy approved in November 2012 by the OPTN/UNOS Board of Directors went into effect requiring transplant hospitals to report extra vessels disposition within seven days of use or destruction. The programming includes an electronic reporting enhancement in Tiedi under a separate tab. The application can be used to report shared vessel situations for both the sending and receiving transplant hospitals. Justifications still need to be reported to Member Quality per current policy. The application also features an expected data report that displays vessels reported as sent by OPOs to transplant hospitals by Donor ID that have not yet had a disposition reported. Members can search, add, and edit vessel disposition reports. In addition, reports developed for Member Quality that identify vessel dispositions not reported within 21 days, late reports, and expired vessels will be also available specific to the transplant hospital. This will enable programs to see the same data that Member Quality will use for policy evaluation.

There were 2,198 vessels dispositions added in Tiedi during the first week post release. The majority of these dispositions were for vessels destroyed (n= 1,821). In addition, there were 1,723 unique vessels application users as of October 29, 2015. These early post production metrics indicate strong utilization of the system.

The OSC will monitor reports of compliance provided by the UNOS Member Quality Department. OSC will request data to assess the number of extra vessels recovered for transplant, those reported as transplanted or disposed, and extra vessels usage reported at the time of waitlist removal. The OSC will inquire DTAC and/or Member Quality to assess whether extra vessel disposition information is being made available to the OPTN as required by policy and whether the information provided is timely and sufficient for



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investigation into cases of potential disease transmissions and for site survey analysis. The OSC will request the above information for review twice per year starting in April 2016.

A training video, released October 8, 2015, is available on the OPTN website and Transplant Pro. In response to member requests, IT security made application program specific permission set up available two weeks prior to release. Other supports to help with vessels policy available on these websites include an updated OPO reporting guide, frequently asked questions, and special instructions for handling vessels in the OR including repackaging.

Targeted efforts were made to notify transplant programs with over 30 expected but missing vessel dispositions prior to release. UNOS Data Quality is continuing to enter paper and fax reports received prior to implementation. New faxes will not be accepted now that the electronic reporting feature is available. The vessels use report previously available in Waitlist has been disabled, as the needed functionality is now available in a more efficient format in the Teidi enhancement.

### 7. Proposal to Allow Collective Patient and Wait Time Transfers

*Public Comment:* [September 29-December 5, 2014](#)

*Board Approval:* [June 2015](#)

*Implementation Date:* [September 1, 2015](#)

The Operations and Safety Committee (OSC) developed this proposal in response to a request from the OPTN/UNOS Board of Directors to allow groups of patients and their wait times to be transferred when a transplant program enters long-term inactivity, closes, or is terminated. Passed by the Board in June 2015, policy now authorizes collective transfers to be done electronically after fulfilling requirements outlined in Appendix K of the Bylaws. Requests for other situations can be made to use the collective transfer function. This is anticipated to reduce potential errors associated with manual data transfer and more efficiently restore opportunities for transplant.

The Committee will track the effectiveness of the changes through review of data regarding the frequency of collective waitlist transfer requests, the number of patients collectively transferred, and the processing time for the collective transfers versus comparable time for individual transfers. While this proposal was implemented on September 1, 2015, the process has not yet been requested for use.

### 8. Proposal to Modify the Sterile Internal Vessels Label

*Public Comment:* [January 27 -March 27, 2015](#)

*Board Approval:* [June 2015](#)

*Implementation Date:* [September 1, 2015](#)

This policy proposal developed by the OSC in response to a recommendation from the Ad Hoc Organ Tracking Committee was approved by the Board in June 2015 and implemented on September 1, 2015.

The new sterile internal vessels label and instruction for completion are available for download at the UNOS store on Transplant Pro. This new label reduces the previously required 15 plus data fields down to six data fields. This new label was designed in coordination with the OPO Committee to preserve the most critical fields (Donor ID, ABO, recovery date, PHS increased risk status, and whether the vessels are from a donor with

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certain positive test results for HIV, HBV, or HCV) while reducing errors observed and reported from hand writing this small label in a sterile field. HBV results were segregated out between core and surface antigen results in response to public comment. This label is not intended to be used for source documentation and the hangtag poly plastic label used on the outermost triple sterile barrier has not been changed.

The proposal will be evaluated by tracking the following:

Indicators	Evaluation Time Points
Number of patient safety situation reports regarding vessel labeling	Post Implementation: <ul style="list-style-type: none"><li>• 6 months</li><li>• 1 year</li><li>• 2 years</li></ul>
Number of proven/probable disease transmission cases involving vessels transplanted into secondary recipients	
Reported extra vessel disposition, including donor serological and increased-risk status	

These cases are also reviewed and followed-up by the OPTN Contractor on a real-time basis.

### Review of Public Comment Proposals

The Committee reviewed four of the public comment proposals released for public comment between August 14-October 14, 2015.

#### 9. Proposal to Increase OPTN/UNOS Committee Terms to Three Years (Policy Oversight Committee (POC))

Committee members expressed general support but identified some specific concerns over the proposal. On the positive side, the three-year term will provide adequate time for new members to learn the processes and workings of committee service. It will allow new members to “find their voice” so that they can meaningfully contribute. A longer term will contribute to the overall efficiency of the group. In a three-year term, a member can accomplish more than a two-year turn. The OSC had voted to support the idea when it was presented earlier this year prior to becoming a formal proposal.

One issue mentioned was the need to have an effective mechanism to deal with members who are unable to participate, do not demonstrate interest, or do not adequately contribute. This can weigh a committee down. It was noted that there is a process to deal with this issue. If a committee has difficult dynamics, then longer terms will just extend dysfunctional dynamics. Another concern voiced was that the longer turnover period would provide challenges in getting new people and ideas into the system and limit overall opportunities.

#### 10. Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation (Living Donor Committee)

It was noted that it might be difficult to identify negative outcomes within the current system and it would be important to track how these recipients fare relative to others. While the therapeutic and domino donor cases may be rare, some members did have some knowledge or experience with the practice. The discussed examples were treated as full living donors and this was challenging or did not seem to fit. It was noted that it might cause someone not to want to donate due to complex requirements and that living donor policy may not make sense in these situations. An organ is going to be removed regardless. If the burden can be safely lowered, then it makes sense to adopt this proposal.

11. Simultaneous Liver Kidney (SLK) Allocation Policy (Kidney Transplantation Committee)

Committee members did not reach consensus on this proposal but all agreed that something needs to be done to address the issue. It was expressed that the kidney community has concerns about these organs being siphoned off without justification while those on the kidney-alone list who have legitimate needs are passed over. One member opined that the kidneys in SLKs are often given to those with adequate kidney function. There was concern that in some sequences the SLK safety net would get any priority over kidney-alone candidates who might have greater needs and actually be on dialysis.

It was noted that there are no current guidelines and that keeping the status quo will continue perpetuating the issue. It seems as though there will be over 600 SLKs this year.

There was discussion over whether the proposal would increase or decrease the number of SLKs. One member indicated it could increase unnecessary SLKs because if someone meets medical criteria they may feel entitled. The diagnosis of chronic kidney failure can vary greatly by transplant nephrologists. On the other hand the proposal will address situations where SLK is done to avoid being counted in SRTR calculated outcomes data or those done without any justification. It will also challenge the liver community, as the evidence reviewed did not support common beliefs. Mortality due to renal insufficiency was not as high as many might believe. Overall, the Committee desires to see a reduction in unnecessary SLKs although some may not agree with all of the points proposed.

12. Proposal to Reduce the Documentation Shipped with Organs (OPO Committee)

The OPO Committee has proposed limiting paper documentation shipped with organs. The documentation would be limited to ABO determination and infectious disease testing results. Current policy requires the entire paper chart to be shipped with all organs. This has been identified as a process that is cumbersome and time-consuming taking away from other pertinent donor management responsibilities.

The Operations and Safety Committee supports the concept behind this proposal. Several committee members did mention issues that must be addressed or else concerns may outweigh the benefits. Members requested that parameters around record permanency, record completion and record deletions/modifications need to be further defined. Members want assurance that the results/notes/records uploaded to DonorNet will serve as a permanent record that can be accessed without concern of time limitations. Transplant program representatives do not want the responsibility to have to go back and download records from DonorNet to meet record retention standards. It was noted that the Final Rule addresses documentation time requirements and that this policy proposal needs to be congruent if applicable. Other questions related to timing of the availability of the complete record and the definition of a complete record were also discussed. The Operations and Safety Committee desires to see these questions answered as the current system is inefficient and does not promote best use of resources.

**Other Committee Work**

13. Trends and Patterns in Patient Safety Situations Reported to the OPTN

The Committee reviewed the last six months of patient safety situation data at their October 13, 2015 in-person meeting. There were 129 patient safety situation reports (79 submitted online through the Improving Patient Safety Portal (IPS)) between January 1 and June 30, 2015. Reporting from transplant hospitals made up 61% of reports during the same time frame which represents an increase of the total proportion of reports originating from this

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source. Nearly one-quarter (23%) of all reports since 2012 involved a communication issue. Seventy of the 230 (30%) of the communication unique safety situation reports involved delayed communications.

Of 811 events reported through both the IPS and other pathways since 2012, organ(s) were not transplanted as a result of the event in at least 91 (11%) cases. Organs were considered not transplanted if either an organ was recovered but discarded due to the event, or an organ was not recovered due to the event. These cases most frequently involved packaging issues, recovery procedure/process issues, and communication issues.

The Committee also reviewed transportation data from the UNOS Organ Center. Between July 2014 and June 2015, the Organ Center facilitated 2,445 shipments. There were a total of 28 shipment failures with 30 of the 36 organs involved being discarded. The primary reasons noted were weather, mechanical failure, or transport cancellation. In addition, there were 109 near misses with delays ranging from 2 to 12 hours. The full report is available upon request.

The Committee and Member Quality are working on ways to improve reporting and use of patient safety data. The Member Quality Director attended and presented at the most recent OSC in-person meeting. Current patient safety data reviewed are considered “front-end” data and are based on the initial report but do not include information resulting from subsequent investigation conducted by the UNOS Patient Safety Incident Handling Team (PSIHT) within Member Quality. Member Quality plans to add a validation step where PSIHT members categorize reports post-investigation. This will account for other factors arising during the discovery process.

In addition, MQ is developing a process where PSIHT will review these data and bring data highlights, trends, and recommendations, including aggregate root cause information, for Patient Safety Advisory Group (PSAG) and OSC consideration as they work on system improvements. The proposed steps would be:

- **Post case categorical analysis/validation**

PSIHT staff will validate data using a standardized classification schema. Part of this effort would include moving towards an existing Healthcare Performance Improvement model, perhaps modified for transplant, to collect more extensive information surrounding individual and system level failure modes. This will allow MQ to both capture factors contributing to error or failure type, but also assess the level of impact or harm.

- **Data mining and trend analysis**

Every 6 months, PSIHT staff will mine the data attempting to identify themes and repeating patterns. They will conduct some casual analysis to identify commonalities across like cases.

- **Data prioritization**

Of potential case types of interest identified, PSIHT will prioritize findings and make recommendations to the OSC based on what would likely have the largest impact and most benefit to the transplant community.

- **Data extraction and dissemination**

PSIHT staff would then manually extract pertinent information from the subset of cases decided upon and disseminate for committee deliberation.

- **Comprehensive analysis by Ops & Safety PSAG**

The OSC could then perform a comprehensive analysis on the data, detect areas of highest concern, as well as elicit learnings regarding failure points and gaps that could jeopardize patient safety or lead to preventable organ discard.

MQ and OSC communications regarding safety data would be based on urgency needs. Pathways already developed would be refined for several types of channels such as the patient safety alert, patient safety trends, and patient safety prevention. Alerts and trends communications will follow an immediate and intermediate time frame and process to communicate urgent matters to the transplant community. Routine events would be presented to Operations and Safety on a quarterly basis. The goal would be to turn lessons learned into actionable knowledge through various patient safety initiatives and educational opportunities. This will help better link findings to improve safety through a systematic approach.

Instructional Innovations has worked with the PSAG and an internal patient safety group to develop two patient safety vignettes that are fictional cases based on trends observed in patient safety reports and referrals for educational topics from the Membership and Professional Standards Committee (MPSC). The first video was released on June 5, 2015. The first video featured two scenarios. One scenario featured a delayed communication of post-transplant results led to recipient death. The other case featured a switched kidney laterality situation where the kidney had to be discarded. As of August 28, 2015, there were 580 views. Video evaluations as well as informal community feedback has been extremely positive. Of the 45 persons completing an evaluation survey, 44 either agreed or strongly agreed that the program addressed timely information needed to perform their job.

A second patient safety video was released on October 29, 2015. This video focuses on how delayed communication and process decisions ultimately led to a liver organ discard. Instructional innovations, PSAG, and internal patient safety experts will continue collaborating on this quarterly series.

#### 14. Brainstorming OPTN/UNOS Strategic Plan Goal 1: Increase the Number of Transplants

The Operations and Safety Committee completed their brainstorming exercise to increase the number of transplants to support the OPTN/UNOS Strategic Plan Goal #1 at their in-person meeting on October 13, 2015. The following list includes all of the ideas presented. The first three listed are the top priorities for OSC to pursue.

- Adjust push/pull outcomes metrics.
  - Outcomes requirements lead to risk aversion plus decreases transplants
  - Fix transplant center metrics and allow flexibility to increase acceptance of marginal organs
  - Increase allowable risk taking
  - Increase use of non-HIV sepsis donors
  - Remove OPO and disincentives to chasing single organ donors and transplant program metrics for using high risk donors based on outcomes
- Reduce non recoveries and discards of transplantable organs
  - Streamline placement of non-perfect or marginal organs through UNet/DonorNet enhancements and provisional testing
  - Put final processes and improvements in place to prevent discard of transplantable organs
  - Develop a better placement process for marginal organs
  - Make DonorNet active, not passive, to allow for increases in donors (dynamic)

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- Back-up offers/provisional yes
- Increase critical care provider education
- Improve transplant center/OPO communications through means such as the previous collaborative
- For intra operative turndowns, mandate a delayed cross clamp unless there is donor instability to increase likelihood of organ placement
- Decrease non-standard donor management that leads to “lost” organs
- Current allocation policy decreases use of hard to place organs. Make appropriate changes. Provisional “yes” leads to delays and later lost organ
- Remove disincentives for living donors
- Improve transplant center list management
- Have more proactive preparation for provisional yes, back-ups
- Develop agreements/extension to cooperate with other countries/territories to increase organ placement from isolated US areas
- Increase the wait time for DCD death
- Reduce knowledge deficit of intensivist/donor hospital staff. Increase education of critical care providers through societies
- Balance out DCD vs. brain death
- Increase DCD awareness. Reduce public awareness deficit by enlisting high profile spokespersons people to push donation message

### 15. Imminent Death Donation Work Group

Operations and Safety is one of several Committees represented on a multi-Committee work group being led by the Ethics Committee regarding Imminent Death Donation (IDD). IDD is a situation where a potential donor has experienced devastating neurological injury and requires a surrogate for decision-making. The intent is to explore this as an organ donation option in cases where a potential donor may not be considered a Donation after Cardiac Death (DCD) candidate because either the potential donor isn't expected to expire within the required DCD time limits; other medical considerations of the donor would make placement of organs after DCD unlikely; or the potential donor's surrogate wants to pursue donation, but declines or objects to the DCD process.

OSC representatives will continue providing feedback on the safety considerations of this issue as well as operations aspects of how this could affect or fit with other donation types.

### 16. Disease Transmission Advisory Committee (DTAC) Request: OSC Feedback on potential project for screening results timing

The Operations and Safety Committee (OSC) considered the DTAC request on whether new policy should be developed that would require infectious disease testing (with certain exclusions such as NAT and EBV) be completed within a defined timeframe. The Committee questioned the number of circumstances under which testing was not being completed prior to transplant. While the number is small and the cases do not appear to be related to “crashing donors”, additional information could not be shared with the Committee as these cases are currently in due process.

Operations and Safety OPO representatives did indicate that the timing suggested “prior to release of the organ by the Host OPO to the transplanting hospital” would seem reasonable. One OPO representative shared that they have recovered organs in “crashing donors” without testing results. Their policy is not to release organs until tests have been resulted. One site does face serious geographic limitations, yet manages to maintain this internal

## OPTN/UNOS Operations and Safety Committee

policy. The OSC while agreeing that the suggested timing is reasonable did not favor policy development at this time. The reasons for this were not having enough information about the cases that spurred the question; concerns over “crashing donor” cases and potential organ wastage; and not desiring to make policy based on outliers that could unintentionally result in organ discard due to results not being available for legitimate reasons.

As the Committee has continued work on its infectious disease verification proposal, members have questioned if this concept needs to be revisited. It is challenging to develop a proposal requiring verification of certain results without requirements for the tests to be completed within a certain period.

### **Meeting Summaries**

The committee held meetings on the following dates:

- July 28, 2015
- August 25, 2015
- September 22, 2015
- October 13, 2015
- October 27, 2015

Meetings summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=60>.

*OPTN/UNOS Operations and Safety Committee*

# Standardize an Organ Coding System for Tracking of Organs: Programming Only Request for TransNet

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# Standardize an Organ Coding System for Tracking of Organs: Programming Only Request for TransNet

## Executive Summary

The Operations and Safety Committee is requesting the OPTN/UNOS Board of Directors (BOD) to authorize hours and placement of the TransNet<sup>sm</sup> project on the OPTN BOD information technology road map. This project was originally approved in November 2011. The project was formed because important information is collected and presented to a center when a donor is identified and organs are allocated. How this information is shared and how recipient and donor variables are analyzed vary from center to center according to local practice. This inconsistency creates issues related to organ transportation, transcription and data entry errors, and miscommunications that can lead to decreased organ utilization.

This proposal requests that the OPTN support continual funding of TransNet programming functionality for transplant hospitals. Dedicated funding from the US Health Resources and Services Administration (HRSA) has ended. We have enough funds to continue work into the second quarter of 2016. Programming through the second quarter will cover functionality needed for nationwide OPO use. Currently, 31 OPOs are using the system nationwide on a voluntary basis. Operations and Safety plans to propose mandatory OPO use in the January 2016 public comment cycle. Some program is in line in anticipation of possible mandatory use. On the transplant hospital side, basic programming will be completed within existing funding. During transplant hospital discovery as well as Operations and Safety Committee discussions, it has become apparent that additional functionality will be needed to provide functionality that works for all donor types and to gain acceptance among transplant hospitals. The Committee is making this request so that work on this important project to provide transplant hospitals full functionality and associated benefits for tracking, verification, and other documentation will continue.

# Standardize an Organ Coding System for Tracking of Organs: Programming Only Request for TransNet

*Affected Policies:* None. This is a programming only request.

*Sponsoring Committee:* Operations and Safety Committee

*Public Comment Period:* No public comment. This proposal does not affect policy and does not require additional data collection.

## What problem will this proposal solve?

Important information is collected and presented to a center when a donor is identified and organs are allocated. There is currently no link or traceability of donor risk to all products allocated. How this information is shared, and how recipient and donor variables are analyzed vary from center to center according to local practice. This creates issues related to organ transportation, transcription and data entry errors, and miscommunications that can lead to decreased organ utilization. Organ labeling and transplant errors continue to occur and represent an emerging patient safety issue (Ison, 2012).

A Failure Modes Effects and Criticality Analysis (FMECA) was conducted by Northwestern University in 2013 to examine the transplantation process from referral through post-recovery phases. Over 40 transplant and hospital professionals worked on the FMECA to identify and rank failure modes. A total of 146 unique vulnerabilities or failures resulting from 60 identified process steps were identified. Of the potential failures, 42 (29%) were estimated to be impacted by the use of the newly developed assistive technology now known as TransNet. Some process failures were deemed to be eliminated (e.g., “label unreadable or illegible”).

While there is a growing body of information through research and proactive assessments such as the FMECA, the true error rates surrounding near miss and adverse events related to wrong organ/wrong person and/or subsequent adverse events such as unintentional ABO incompatibility are not fully known. These situations, however, are likely to be significantly underreported as only 5% to 15% of health care patient safety events are reported through incident reporting systems (Levtzion-Korach, O. et al., 2010 and Vincent, C. et al., 2014). A 2014 UNOS analysis estimated only 13% of actual safety events are reported to the OPTN. The Medical Event Reporting System for (blood) transfusion has documented that near-miss events are 300 times more common than observed adverse events (Kaplan, 2005).

There have been ten reported cases of wrong organ delivered or wrong organ/wrong recipient since 2006. There have been three cases where organs were transplanted into the wrong recipient and in one case graft failure occurred. In two of these situations, more than one organ was expected for delivery on the same day, and the first organ to arrive was transplanted into the wrong recipient. There have been two cases where the wrong kidney was sent (not a laterality issue) and both resulted in organ discard. There have been three cases where the wrong type of organ was sent due to a packaging mix up.

Since 2006, there have been two unintended ABOi kidney transplants both leading to hyperacute graft rejection and three unintended ABOi liver transplants. These involved several different root causes

including lab, documentation, communication, and verification errors. Further discussion and details can be found in the [January 2015 public comment proposal to modify ABO policy](#).

The organ center also tracks transportation failures and near misses for placements that they have facilitated. Between July 2014 and June 2015, the Organ Center facilitated 2,445 shipments. There were 28 shipment failures with 30 of the 36 organs involved being discarded. In addition, there were 109 near misses with delays ranging from 2 to 12 hours. Although the primary reasons noted were weather, mechanical failure, or transport cancellation, roughly a quarter are due to a driver/courier issue and 7-10% are due to a transplant hospital/OPO issue. Since the new Kidney Allocation System has been implemented, the proportion of non-local kidney transplants has significantly increased from approximately 20% to between 30 and 35% (See OPTN site for more info).

## Why should you support this proposal?

The traditional process of packaging and labeling organs has been done in the past entirely by hand. Automating the process will greatly reduce the chances of transcription errors or mistakes due to illegible handwriting. A comprehensive electronic solution would also allow us to ensure that donated organs are matched/ correctly and efficiently with the identified recipient.

TransNet, a service of the OPTN, is a new system that uses barcode scanning technology at the point of organ recovery to help label, package, and track organs and other biologic materials being shipped for transplantation.

TransNet involves using an application developed for an Android tablet and a portable barcode printer that interacts with DonorNet® to supplement the current UNOS labeling system. During the organ recovery process, OPO procurement coordinators can use the system in the operating room to print on-demand labels and scan the information on all organs and materials to be transported. Clinical coordinators also can use it in the ICU, before organs are even recovered, to label blood tubes and other samples. Functionality for iOS will be released later this year.

On the OPO side, functionality exists now for a voluntary mandatory deployment since March 2015. Functionality that would support a planned proposal for mandatory OPO usage will be completed within existing resources. There are some enhancements for OPOs contained in this request that would expand usage during donor management and allow usage on alternative devices.

On the transplant hospital side, basic functionality will be done with existing funds. It has become apparent through transplant hospital discovery and Operations and Safety Committee discussions that significant additions will be needed to allow transplant hospitals to use the system efficiently without needing two processes. Without a “complete” system, the acceptance is likely to continue to be very low and the overall benefits not realized.

TransNet functionality for hospitals will allow transplant hospitals to have a system that can do the following:

- 1.) Scan organs received (organ check in) from OPOs using the TransNet system (This functionality can be programmed with existing resources for deceased donors only)
- 2.) Perform pre-transplant verification as required by both OPTN policy and CMS (This functionality can be programmed with existing resources for deceased donors only)
- 3.) Perform pre-transplant verification when surgery starts prior to organ arrival which will be required by OPTN policy going into effect in 2016
- 4.) Perform organ check in and both pre-transplant verifications on organs from living donors and organs not on a match run
- 5.) Perform verification, tracking, and reporting functions for extra vessels

In addition, TransNet programming hours requested in this proposal will support enhancements for the OPO application currently in use. These enhancements include:

- 1) iPhone/android phone usage
- 2) Ability to use application with alternative devices (e.g. use of their laptop in the ICU during donor management to generate labels to the TransNet printer)
- 3) Labeling and packaging for VCA organs

This proposal has multiple benefits:

- 1.) Full development and ability to use bar code scanning and verification of information directly from UNet<sup>sm</sup> to promote quality practices to assure right organ/right recipient
- 2.) Ability to track organs in route to transplant to facilitate optimal recipient preparation and troubleshoot transportation or location delays
- 3.) Use of bar code scanning to track organ(s) and extra vessels arrival, use, and/or destruction.
- 4.) Simplified and electronic documentation of process points (e.g. time of organ arrival in OR) and capture of electronic signature
- 5.) More timely, seamless, and improved communications between OPOs and transplant hospitals
- 6.) Broader use of information technology by non-transplant staff to perform needed functions without requiring DonorNet access
- 7.) Use of existing mobile devices to perform these functions using the application
- 8.) Provide support for broader tracking and traceability

The use of bar code scanning has been well established in the medical literature to reduce medical errors in medication administration including blood transfusion. The US Food and Drug Administration (FDA) has mandated use of bar code technology since 2004 (69 FR 9120) for labeling biological products. Because organs are regulated by the HRSA, they do not fall under this rule.

If TransNet development and production is slowed now, then critical benefits and a significant evidence-based opportunity to improve process and reduce risk will be delayed further for transplant programs. Acceptability and use by transplant programs will likely be delayed as well.

### How was this proposal developed?

The development of this project is unique from that of other projects. This project started in fall 2012 as a HRSA Innovations project. The project received special dedicated funds through a specific contract modification to the OPTN. The project goals were set forth by HHS in the original HHS Innovations Fellow announcement:

1. Minimize the potential for misdirected or delayed organ transport
2. Reduce the chance for incorrect transplantation
3. Eliminate manual transcription errors
4. Accelerate information transfer about the organs to key stakeholders
5. 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

An Ad Hoc Organ Tracking Committee was formed with representatives from the Operations and Safety, Organ Procurement Organization, Transplant Administrators, and Transplant Coordinators Committees. In addition, subject matter experts in human factors engineering, blood banking, tissue banking, and eye banking were included. The Ad Hoc committee and a HRSA Innovations fellow employed LEAN methodology as they conducted intense discovery visits with over a dozen OPOs and transplant hospitals to observe actual recovery and transplantation with a focus on the labeling, packaging, transport, and receipt processes. This led to a proof of concept prototype to provide electronic labeling, scanning, tracking, and receipt purposes. Three simulations were also conducted to develop further this proof of concept. Using an agile development method, multiple versions were rapidly produced in response to feedback leading to an improved product launched for pilot testing among five OPOs in summer 2013.

Following these pilots and subsequent improvements, beta testing was commenced for eight OPOs. In March 2015, the OPO version was released in a voluntary nationwide deployment. To date, 31 of 58 OPOs are using the system. In addition, 15 OPOs have indicated that they have signed up or will sign up for training by second quarter 2016 in an AOPO survey. As of October 12, 2015 (8:15 am EST), TransNet was used to package 4,043 organs from 1,029 donors. A study of individual OPO usage showed that a TransNet case was created for 40.6% of all deceased donors recovered by the 31 trained OPOs during July 2015.

Getting TransNet to this point has relied on extensive coordination and collaboration with OPOs and transplant hospitals as well as professional organizations such as AOPO. In addition, the TransNet team has met with HRSA and the Centers for Medicaid and Medicare Services (CMS) to open discussions about developing transplant hospital functionality that would meet both OPTN and CMS requirements.

TransNet is developing transplant hospital functionality for organ check-in and pre-transplant verification. Discovery with 15 transplant hospitals to obtain feedback on process and desired use took place early in 2015. Discovery was conducted with hospitals in California, Illinois, New York, and Virginia. Five transplant hospitals are currently signed up for beta testing. Discussions are underway with 27 transplant hospitals who have indicated an interest in beta testing participation. Five transplant hospitals are active in beta testing currently. Bringing transplant hospitals ready to the point of beta testing participation has been challenging due to multiple levels of needed approval and assessment or acquisition of equipment.

### IT Roadmap and Community Requests

The Committee considered having TransNet transplant hospital programming placed into the regular community IT road map. Due to the nature and skill sets required for mobile development, it is estimated that development would be worked on for approximately one-quarter per year. This would delay functionality by an additional 1-2 years. The Committee decided to make this request in order to keep the momentum of the project that has been very well received to date. The Committee feels strongly that stopping development and having only OPO and very limited transplant hospital functionality would be an opportunity missed.

HRSA had established and funded TransNet as a specific innovations (now called entrepreneur) project. The OPTN contract was modified to operate this project with specific dedicated funding. This funding ended on September 30, 2015. HRSA has decided to fund other priorities through contract modifications.

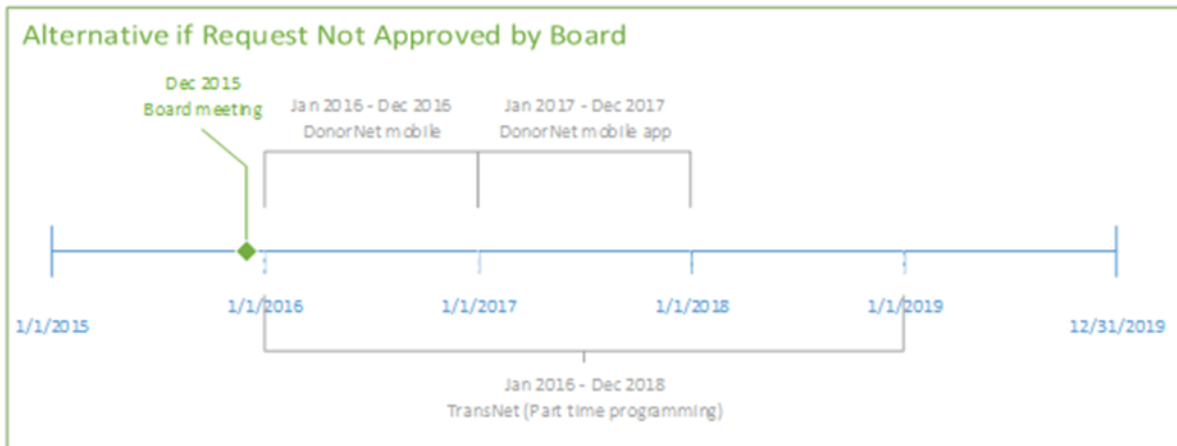
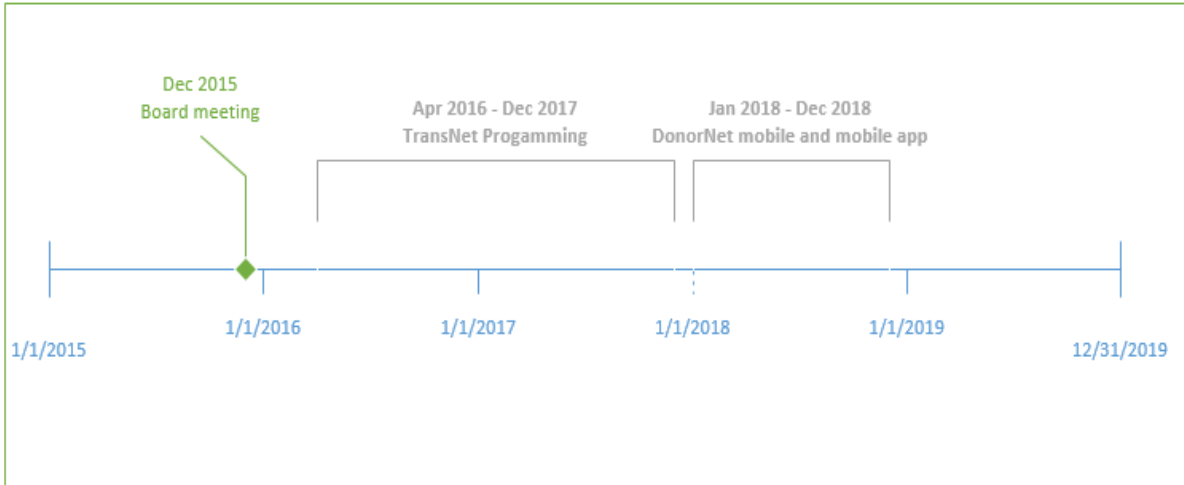
Granting this request for prioritizing TransNet programming will have an impact on development of other non-policy, IT requests from the community (e.g. DonorNet mobile functionality). Historically, UNOS IT has focused most of its IT resources on programming policy related efforts, however over the years, UNOS has received multiple non-policy related enhancement requests from the community. In July 2014, UNOS IT created a new department, Customer Innovations, to focus on prioritization and programming of these enhancement requests. At the same time, the IT team has been working on improving visibility in the transplantation and donation community with a focus on member needs. Through these historical requests as well as recent interactions, there have multiple requests for DonorNet enhancements, which include the ability to utilize DonorNet on mobile devices and a need to create DonorNet companion mobile apps for both OPO and transplant hospital usage. While some of the TransNet functionality requested is web-based, other parts require the skill set of a mobile development team. Currently, there is one development team with the skill set to complete mobile device and application programming.

According to the IT Strategic Plan, UNOS has several efforts underway to improve general UNet services. These include upgrading UNet so that members can access it on the devices of their organizational choice and becoming browser agnostic. UNOS IT is implementing a redesigned UNet Security Administration system to allow site administrators at transplant programs, OPOs, and histocompatibility labs to more easily control access to their portions of the system. Efforts are underway to redesign UNet user interfaces and provide a more consistent look and feel with implementation slated for 2016.

Relevant to this project, UNOS IT is also expanding mobile development capabilities. The IT Strategic Plan includes development of mobile DonorNet functionality. In 2016, UNOS expects to expand mobile accessibility to make UNet available on a variety of mobile devices. In 2017, UNOS IT will develop a DonorNet Mobile App designed to work with smartphones. The mobile applications would be companion

applications for both the OPO and transplant hospital communities. The OPO application would allow users to send offers and view donor information including attachments. The transplant hospital application would allow users to view the donor record, including attachments, and accept/decline offers.

Prioritizing TransNet may delay part of the mobile DonorNet effort. The Operations and Safety Committee believes that TransNet is best suited to receive priority and continue development now given the amount of research and effort into the project.



**How well does this proposal address the problem statement?**

The issues described in the problem statement are well suited for the TransNet solution. Transplant hospitals will scan bar-coded labels against a TransNet generated recipient ID band to assure correct placement and compatibility. The system will also serve as documentation. The scan will take away most risk for human error. The process will also reduce time to complete verifications, prevent transcription errors or misinformation due to direct import of data from UNet, and create other efficiencies.

The risks of error during manual transcription of information are well documented. In the blood transfusion field, cases of incorrect blood components transfused are a major adverse event source. Use of electronic information capture can improve safety by eliminating the risk of manual transcription error, and speeding up the information transfer process (Strong, 2010).



Hemovigilance programs from around the world document that the greatest risk to recipients of blood transfusion is human error, resulting in transfusion of the incorrect blood component. Errors in transfusion care have strong parallels with errors in medication administration. Errors often result from 'lapse' or 'slip' mistakes in which details of patient identification are overlooked. Three areas of transfusion are focal points for improved care: the labelling of the patient's pre-transfusion sample, the decision to transfuse and the final bedside check designed to prevent mistransfusion. Both barcodes and radio-frequency identification technology, each ideally suited to matching alphanumeric identifiers, are being implemented in order to improve labelling and the bedside check. (Dzik, 2006)

Counting and preventing errors has been challenging. The FDA estimates that 414 blood transfusion errors occur annually. In one study, nearly 80% of these were related to bedside or labeling errors. Point-of-care bedside bar-coding applications are being integrated with blood product administration activities to combine patient identification, medication, and product verification. (Dubin, 2010)

Critically ill patients, who are physiologically the most vulnerable to healthcare error, also receive the most intense and complex treatments and Cullen et al (1997) has noted that errors are more common among intensive care patients. (Dzik, 2006)

Solid organ transplant recipients are prescribed a high number of medications, increasing the potential for medication errors. Barcode-assisted medication administration (BCMA) is technology that reduces medication administration errors. The baseline medication administration error rate of 4.8% was reduced by 68% to 1.5% through BCMA use. (Bonkowski, 2014)

When integrated with electronic medication administration records, barcode systems are associated with complete elimination of transcription errors. Furthermore, barcode-assisted dispensing systems are associated with 93% to 96% reductions in dispensing errors, and 85% reductions in potential adverse drug events in dispensing. Most studies have reported large and significant reductions in administration errors by up to 80% after implementation of barcode medication administration systems. (Leung, 2015)

The Health Information and Management Systems Society (HIMSS) has projected that implementation of bedside barcode systems designed for medication and transfusion care cost approximately \$2,000 per bed. Using logic for a 200-bed facility that admits 20 patients a day, it has been estimated that if bedside machine-readable technology prevented half of medication and transfusion errors, then the return on investment (ROI) would be approximately one year. Urgent care areas ROI could be sooner within months (Dzik, 2006)

Coding also will assist with future traceability efforts. It is important to recognize that a coding system does not itself provide traceability, but provides the information infrastructure on which effective traceability can be built. Coding and traceability support each other. (Strong, 2010)

Regulations have been developed based on the benefits of bar-coding utilization. In February 2004, the U.S. Food and Drug Administration (FDA) published a final rule (69 FR 9120) requiring certain human drug and biological products to have on their labels a linear bar code that contains, at a minimum, the drug's NDC number (21 CFR 201.25). The rule also requires the use of machine-readable information on blood and blood component labels (21 CFR 606.121(c) (13)). The FDA anticipated that intended mandatory use would reduce errors in hospitals and health care settings. More information about the FDA bar code ruling is available at:

<http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/AdvertisingLabelingPromotionalMaterials/BarCodeLabelRequirements/>.

FDA is establishing a unique device identification system to identify medical devices. The UDI Rule, establishing the unique device identification system, was published on September 24, 2013 (78 FR139 58786) (the UDI Rule). It requires that the label and each device package of a medical device distributed in the United States bear a unique device identifier (UDI), unless an exception or alternative applies. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human

and machine-readable (bar code) form. The FDA indicates that UDI implementation will improve patient safety, modernize device surveillance, and facilitate medical device innovation. This rule is being phased in over seven years starting in 2014. More information is available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/>.

Developing TransNet to provide full transplant functionality will address issues seen in both transplantation and other areas of health care using an evidence-based method demonstrated to reduce errors in other areas such as medication administration.

## Which populations are impacted by this proposal?

All transplant hospitals would benefit potentially from having this system should they choose to use it once developed. In turn, transplant recipients receiving transplants in a facility using TransNet will be less likely to receive the wrong or an incompatible organ. They will also be less likely to receive an organ compromised due to increased cold ischemic time due to the ability to track and locate organs more efficiently.

OPOs will also benefit. The enhancements requested would allow for expanded use during the donor management (ICU) phase. Currently the need to purchase equipment for numerous staff precludes widespread use in the ICU. This request would expand functionality for adaptation of use on hospital printers and other devices. In addition, functionality would be added for VCA recoveries.

## How does this proposal support the OPTN Strategic Plan?

This proposal supports the OPTN Strategic Plan as follows:

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal
4. *Promote living donor and transplant recipient safety:* The project supports this goal by:
  - Reducing errors related to transcription and readability
  - Providing tracking to optimize timing for transplant and facilitating real time communication about organ status
  - Promoting electronic solution to ensure right organ/right recipient and other verifications
  - Producing electronic verification and documentation
5. *Promote the efficient management of the OPTN:* The project supports this goal by reducing time needed to complete required tasks related to organ management upon arrival to the transplant hospital

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The questions guiding the evaluation of this proposal will be:

- 1.) Is TransNet programming being developed to meet the functionality requested?
- 2.) Are transplant hospitals able to test this functionality?
- 3.) What feedback or improvements would be needed prior to a voluntary national release?



#### Performance Measures:

- 1.) Number of transplant hospitals conducting beta testing of the application
- 2.) Specific functionality gained as described in Table 1: Requested Functionality

#### Timeline for Evaluation:

The Committee will receive monthly updates until the programming is completed to a level acceptable for national voluntary deployment.

## How will the OPTN implement this proposal?

The OPTN will implement this proposal through:

#### Information Technology:

- Continued gathering and refinement of requirements through transplant hospital discovery and Committee input
- Development of requested functionality through agile methods
- Release and refinement of functionality for beta testing by selected transplant hospital participants

#### Policy:

- Coordination of TransNet work group and Operations and Safety Committee review and feedback

This proposal is an enterprise proposal. It will require approximately 9,200 hours to implement. These hours are subject to some change due to the nature of agile software development and previous experience with the OPO development. This project is estimated to take at least two years to develop and be ready for national voluntary deployment. This is in part due to the request to include living donor transplants. This will be a complex part. It will require working with other UNet systems. It will also require special efforts to figure out if and how organs that are not transported can be included to keep the same receipt and pre-transplant verification processes. The Operations and Safety Committee has requested that the functionality be available for all types of transplants including living donors and candidates not on the match run. This is requested so that transplant hospitals will not have to switch back and forth with different processes.

A table of requested functionality is included at the end of this proposal. The estimates provided are at the high end of the typical sizing function.

## How will members implement this proposal?

If this proposal is passed, it will not require members to do anything different. This proposal is for development only. Transplant hospitals that wish to participate in beta testing of TransNet will receive requirements and training needed to volunteer for this phase.

## Will this proposal require members to submit additional data?

This proposal will not require members to submit additional data.

## How will members be evaluated for compliance with this proposal?

Members will not be evaluated for compliance because this request is for programming only for a voluntary system for transplant hospitals.

Table 1: Requested Functionality

Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
Living donors	This would provide OPO and transplant hospital functionality to label and package living donor organs. It would also provide transplant hospital organ receipt and pre-transplant verification functionality.	High	Do not want two different processes (Manual process for living donors and TransNet functionality for deceased donors)	Very Large	3995
Directed Donation	This would provide transplant hospital functionality allowing printing of recipient ID bands for organs allocated Not on A Match Run (NOMR) as well as receipt and verification of these organs	High	Do not want two different processes (Manual process for NOMR and TransNet process for organs on a match run)	Large	745
Pre-transplant verification when surgery begins before organ arrival	This would provide transplant hospital functionality for completion of the new policy requirement (5.7.A) to be implemented in June 2016 that will require a verification when candidate surgery begins prior to organ arrival. The functionality would include reports that could be generated for documentation of verification	High	Do not want two different processes (Manual process for this verification and TransNet functionality for verification completed upon organ arrival)	Very Small (DR)	56
GPS Tracking	This would provide tracking functionality either through use of a device or through further development of tracking latitude and longitudes that is posted on the TransNet website	Medium	The work group recommends that this functionality using a device be delayed until transplant hospital development and acceptance is further along.		Outside vendor
iPhone/Android phones	This would provide OPO functionality to use the TransNet application on these devices	Medium	Concerns exist whether the phone screens would be large enough and whether it is wise to use phones for TransNet since they are needed for texting and calling as part of organ offer and information sharing processes.	Large	1645

Functionality	Short Requirements Description	Operations and Safety Priority	Rationale	IT Estimated Effort	Hours (Upper Limit of Range)
ICU Enhancements	This would provide OPO enhancements to enable use of application/printing on alternative devices TBD. This will reduce the burden of equipping all staff that conduct donor management prior to recovery with tablets and zebra printers.	Medium	This has been request from multiple OPOs who desire to use TransNet in the ICU/donor management phase but are not able to due to equipment logistics and cost	Large	1645
Vessel disposition functionality including reports, catalog, and feedback to UNet	This would provide transplant hospital functionality to scan vessels upon receipt and record vessels dispositions. This functionality would provide verification functionality for vessels used in secondary recipients. It would generate transplant hospital reports for verifications and disposition. It would upload these data into UNet and satisfy required vessels disposition reporting (policy in effect 10/22/15)	Medium	Transplant hospitals have asked for this functionality. It is not in the high category because it will not solve having two different processes	Small	220
VCA	This would provide OPO functionality to label and package VCA organs.	Low	Currently VCA transplantations are low volume events. The donors and match are not programmed in UNet at this time.	Medium	745
Total Hours					9051

## Resolution

**RESOLVED**, that UNOS appropriate 9,000 hours of staff resources over the next two years to implement TransNet functionality as described in Table 1, above.

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