OPTN | UNOS Public Comment Proposal

OPTN/UNOS Organ Procurement Organization Committee

Proposal to Reduce the Documentation Shipped with Organs

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Executive Summary

OPTN/UNOS Policy 16.5.A (Organ Documentation) states that members must send the complete donor record in the container with each transported organ. These requirements originated prior to the availability of electronic medical records and the functionality to upload information into DonorNet®. The OPO Committee discussed strategies to reduce the amount of documentation that is packaged and shipped with each organ, to allow OPO transplant coordinators more time to focus on donor management. The OPO Committee proposes limiting the required documentation to blood type source documentation and infectious disease testing results. OPOs will continue to provide all other pertinent donor information electronically.

Proposal to Reduce the Documentation Shipped with Organs

Affected Policies: Policies 2.2 (OPO Responsibilities) and 16.5.A (Organ Documentation)

Sponsoring Committee: Organ Procurement Organization Committee

Public Comment Period: August 17 – October 14, 2015

What problem will this proposal solve?

OPTN/UNOS Policy 16.5.A (Organ Documentation) states that members must send the complete donor record in the container with each transported organ. These requirements originated prior to the availability of electronic medical records and functionality to upload information into DonorNet®. As a part of the TransNet℠ project, the entire donor process from the intensive care unit to the recovery of organs in the operating room was studied to identify where the process could be made safer and more efficient. After studying multiple donor cases at nine OPOs, the team, as well as the Ad Hoc Organ Tracking Committee, concluded that the amount of time coordinators spent making copies of documents, often at very time-sensitive moments, took the coordinators time and attention away from critical aspects of their job. The practice of including these documents, most of which were already in DonorNet®, in the package with the organ was inefficient and a potential safety hazard. The current requirements can also delay the departure of the transplant teams while donor records are being copied thereby unnecessarily increasing cold ischemic time.

Why should you support this proposal?

This proposal will make the system more efficient without increasing patient safety risks or increasing costs. Providing donor information electronically is a well-established practice in the transplantation community, provides the most updated information, and allows transplant teams to review important information in advance of the arrival of an organ at the transplant hospital. The proposed solution does not affect the current practice of OPOs providing all the necessary donor information to transplant hospitals; it merely reduces redundancies in required documentation and reduces the amount of paper documentation.

How was this proposal developed?

OPOs have expressed the current paper documentation requirements are burdensome. The burden became even more apparent during the development of TransNet℠ while project staff observed donor management and organ procurement practices in six OPOs and seven transplant hospitals. The OPO Committee discussed strategies to reduce the amount of paper documentation that is packaged and shipped with each organ. The Committee agreed there is an inefficient use of OPO staff time to copy voluminous documents and removes the transplant coordinator from focused donor management.

The OPO Committee requested feedback from the Transplant Administrators Committee (TAC) and Transplant Coordinators Committee (TCC) in order to evaluate the potential impact on transplant hospitals with the proposed reduction of paper documentation. Highlights of the feedback include:

Transplant Coordinators Committee

- Utilizing DonorNet® will allow for the communication of current information

- Decreasing the paper documentation packaged with organs decreases the chance of errors and allows coordinators to focus on donor patient care.
- Including UNOS ID, match run, ABO source documentation, and serology results in paper form for verification purposes in case DonorNet® is not accessible.
- Uploading documents in PDF format for easy accessibility
- Verbally notify transplant hospital about important changes, such as updated testing results.
- Uploading all necessary information and additional organ-specific information into DonorNet® by the OPO and, if necessary, printed by the transplant hospital.

Transplant Administrators Committee

- The Committee supported the vision of paperless charts but understands the sequential plan to achieve this goal will require the interim use of paper documentation.
- The Committee noted that paper documentation included with the organs are not the "final chart" because final test results might not be available at the time of organ packaging.
- The Committee expressed concern that DonorNet® is not always accessible in the operating room and some staff are not familiar with how to access the available information.

The OPO Committee discussed this feedback and agreed to retain the requirement to include blood type and infectious disease results source documentation. OPOs will continue to provide all required information and source documentation in DonorNet®.

The Committee discussed adding a requirement to upload all other relevant information, including intraoperative findings, within two hours of completion of organ recovery. However, upon further review of OPTN/UNOS Policy 16.5.A the Committee determined that the additional information such as medical and behavioral information, donor evaluation information, donor authorization, and organ quality information are already required to be provided electronically or verbally prior to organ packaging. Because OPTN/UNOS Policy 16.5 addresses documentation accompanying the organ or vessel, the Committee agreed to remove all the required documentation, except blood type and infectious disease results source documentation, since most of the information is also included in OPTN/UNOS Policy 2.2 (OPO Responsibilities). The Committee is proposing a modification to the title of OPTN/UNOS Policy 16.5.A to make it clear the policy is addressing organ packaging documentation requirements.

OPTN/UNOS Policy 2.2 states that one of the OPO responsibilities is to "report to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type." The policy does not include requirements for when or how OPOs report this information. Additionally, the policy is vague regarding what is considered "donor information" but specific when referencing HLA. Therefore, the Committee is proposing that this vague language be removed from policy, and proposing HLA with the other required documentation addressed in section 2.2 (14). The Committee is also proposing that OPOs be required to submit the information "upon receipt" in order for transplant programs to assess donors and respond to offers in a timely manner. The donor information reporting requirements proposed in this document are not inclusive. OPOs are still required to provide additional information as outlined in OPTN/UNOS Policy 2 (Deceased Donor Organ Procurement).

CMS Regulations

The OPO Committee is aware that changes to OPTN policies will not eliminate the requirements to submit donor documentation with the organs as contained in CMS (Centers for Medicare and Medicaid Services) regulation §486.346(b) and the supporting interpretive guidelines §486.346(b). The OPO Committee will work with Health Resources and Services Administration (HRSA) staff to determine if changes can be made to the CMS interpretive guidelines to allow regulatory compliance to align with the proposed OPTN/UNOS policy changes. If not, the Committee will consider delaying the effective date of the policy change until alignment of regulatory requirements.

How well does this proposal address the problem statement?

Digital technology, including DonorNet®, smart phones, tablets, and web-based devices, has changed the way we communicate and share information. Health care systems have embraced the use of electronic health records (EHR) as a method to provide information and improve patient care. Hospital adoption of EHR systems has increased more than five-fold since 2008.[1] OPOs and transplant hospitals have increased the use of EHR and sending information electronically allows for better communication between OPOs and transplant hospitals. This proposal will reduce the need to copy and ship documentation already provided to the transplant hospitals, which can lead to fatigue, and potential errors and takes away from other donor management tasks including organ labeling and packaging. All OPOs currently attach donor information to DonorNet® in order to provide transplant centers with the necessary information to make informed decisions about donors and to provide access to donor records at any time from any location.

Which populations are impacted by this proposal?

OPOs and transplant hospitals will be impacted by this proposal. The proposed changes will only reduce the documentation shipped with each organ and will not impact the current methods used by OPOs to communicate donor information to the transplant hospitals.

How does this proposal support the OPTN Strategic Plan?

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:* There is no impact to this goal
5. *Promote the efficient management of the OPTN:* This proposal will allow for more efficient and timely communication of donor information to transplant centers by utilizing current technology instead of paper documentation.

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

The Committee will develop a survey to collect information from OPOs and transplant hospitals to assess for efficiencies associated with the policy change. This will include any problems identified during the first six months of implementation that might require additional changes or education.

How will the OPTN implement this proposal?

UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). As this proposal will not require programming in UNet℠, no IT complexity was assigned.

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[1] Charles D, Gabriel M, Furukawa MF. "Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013," ONC Data Brief, no. 16. Washington, DC: Office of the National Coordinator for Health Information Technology. May 2014.

The effective date for this policy change, if approved, might be delayed by the OPTN in order to allow time for alignment with CMS regulations or interpretive guidelines.

The OPO Committee plans to develop a guidance document to identify best practices and establish standard naming conventions for use by OPOs when uploading files. The Committee agreed that the file names should accurately describe the documents contained in the file and OPOs should upload documents individually whenever possible.

How will members implement this proposal?

OPOs must report all required information to the OPTN Contractor upon receipt by uploading the information to DonorNet®. Transplant hospitals will need to be aware that donor information is available in DonorNet® and OPOs will only include the blood type and infectious disease source documentation in the shipping container with each organ. If paper copies of donor information are required, transplant hospitals will need to print the information.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language; however, the proposed language will not change the current routine site surveys of OPTN members. Any data submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested.

Policy Language

Proposed new language is underlined and (example) and language that is proposed for removal is struck through (~~example~~).

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. ~~Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.~~

~~12.~~11. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.

~~13.~~ 12. Ensuring that ~~written~~ documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs: ~~of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.~~

   a. ABO source documentation
   b. ABO subtype source documentation
   c. Infectious disease results source documentation
   d. Death pronouncement source documentation
   e. Authorization for donation source documentation
   f. Human leukocyte antigen (HLA) type
   g. Donor evaluation and management
   h. Donor medical and behavioral history
   i. Organ intraoperative findings

~~14.~~ 13. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

16.5 Documentation Accompanying the Organ or Vessel

16.5.A Organ Packaging Documentation Requirements

Each external deceased and living donor transport container holding an organ must be sent with

~~the complete deceased and living donor record that includes~~ *all* of the following source documentation:

1. Blood type ~~source documentation~~
2. Blood subtype ~~source documentation~~, if used for allocation
3. Infectious disease testing results available at the time of organ packaging
4. ~~Medical and behavioral history information~~
5. ~~Donor evaluation information~~
6. ~~Donor authorization form~~
7. ~~Organ quality information as noted in *Policy 2.12.B: Organ Procurement Procedures*~~

~~Donor~~ The source documentation must be placed in a watertight container in *either* of the following:

- A location specifically designed for documentation
- Between the inner and external transport containers

~~When a deceased or living donor organ is transported, the host OPO or the transplant hospital must include the source documentation with the donor information.~~