

40% Fewer Required Elements on OPTN/UNOS Forms

FOLLOWING AN EXHAUSTIVELY RESEARCHED AND CAREFULLY studied, one-year interdisciplinary process, transplant centers and clinical coordinators will now spend less time completing data fields on required Tiedi® forms. This significant data reduction process, which takes effect on February 7, 2007, will help streamline the OPTN data collection process, reduce the data collection burden on the transplant centers and ultimately allow staff to devote more time to patient care.

How it began—A brief history

The decision to move forward was a direct outgrowth of the Fall 2005 OPTN strategic planning meeting. Responding to the feedback from transplant centers as well as national organizations like the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), the OPTN felt the time had come to address this issue and make data reduction a key element of the OPTN strategic plan.

Deciding What to Keep

The OPTN's newest committee, Policy Oversight (POC), led the charge to push the data reduction effort through. After the ASTS/AST Joint Task Force made its initial recommendations, UNOS staff, and the POC exhaustively reviewed each data element the task force had recommended deleting. A working group of the POC based the decision to keep or remove any item recommended for deletion on the OPTN Principles of data collection.

Essentially they determined whether the data were critical to:

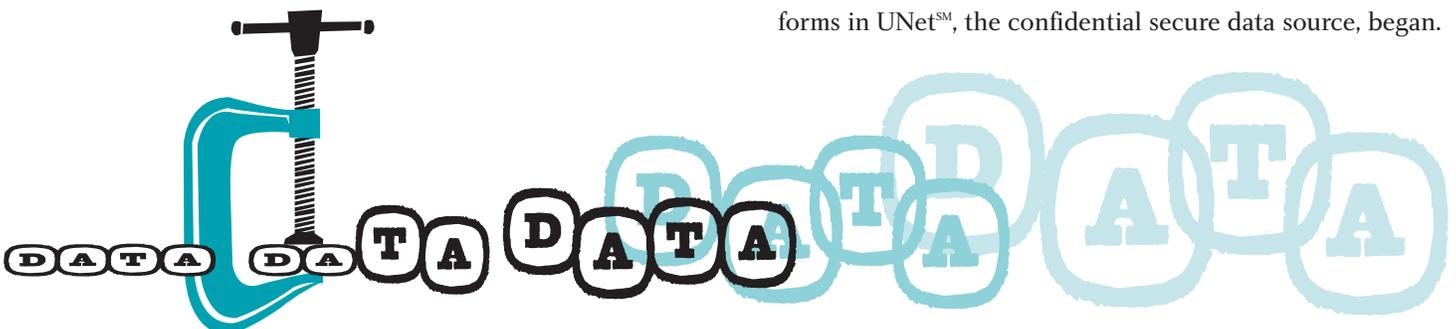
1. OPTN contractual obligations
2. Allocation of organs
3. Policy compliance monitoring
4. Policy development
5. Assessment of Institutional performance
6. Patient care/safety

If a required item did not meet at least one of these data collection goals, the working group recommended that it be deleted. Ultimately every committee had the opportunity to weigh in with their opinion on what should stay and what should go.

Since then, the OPTN/UNOS Board adopted a similar set of resolutions to apply to all future determinations of data collection. See sidebar for a complete listing of current data collection principles.

In May 2006, representatives from the ASTS/AST Task Force, government agencies (HRSA, CMS, USRDS), the Scientific Registry of Transplant Recipients (SRTR) and OPTN/UNOS organ-specific committees as well as several constituent committees (like minority affairs, transplant coordinators, etc.), gathered together with the POC working group to make a final recommendation for public comment.

The POC distributed the final list of recommended data elements for public comment in May/June of 2006 and the Board approved the deletion of those recommended data elements at its June 2006 meeting. The process to ready the forms in UNetSM, the confidential secure data source, began.



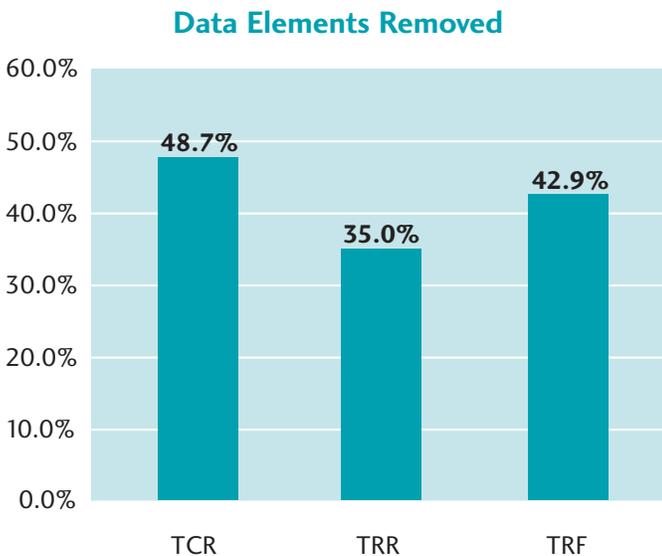
No Change to UNetSM

The online forms that data coordinators use to record required data will not change. The forms will remain the same as will the process to complete them. There will simply be less required information to enter. A note in red at the top of all forms will explain that a significant number of formerly required data fields are now optional. The forms will now validate without these fields being entered. Fields that are still required will be clearly marked with a red asterisk. Additionally, since the fields will be optional, the transplant centers' data import programs will not be affected.

Tiedi[®] Forms Affected by the Project

- Transplant Candidate Registration (TCR)
- Transplant Recipient Follow-up (TRF)
- Transplant Recipient Registration (TRR)
- Post Transplant Malignancy (PTM)

Percentages of Data Elements Removed from each Form



Other information affected:

- Viral Detection Information: specific viruses (HBV, HCV, EBV, HIV, CMV) are retained on the TRR form. Responses remain "Positive," "Negative," "Not Done," and "Unknown/Cannot Disclose". Most details regarding the tests performed have been eliminated. Note: Test specific results were retained for HBV.

- Immunosuppression data will only be collected on the Transplant Registration and on the one year Follow-up.
- For malignancy data, only tumor type, site and date will be collected.

If you have any questions regarding the data reduction project, please contact the UNetSM Help Desk at 800-978-4334.

Guidelines for Future Data Management

Institutional members must provide sufficient data to OPTN to allow it to:

- a) Develop transplant, donation and allocation policies
- b) Determine if Institutional Members are complying with policy
- c) Determine Member-specific performance
- d) Ensure patient safety when no alternative sources of data exist
- e) Fulfill the requirements of the OPTN Final Rule

The OPTN/UNOS Board approved the following operational statements for data collection:

1. The OPTN will only collect data that is contracted by HRSA.
2. Data collected and submitted by Institutional Members to the OPTN may differ in nature and character for specific populations, forming exceptions to Guiding Principles above (e.g. Pediatrics, Living Donors). For these exceptions to the foregoing principles, alternative sources of information must be explored and supported, duplication of existing efforts (e.g. registries) avoided, and sample data collection considered. The need and purpose of any such exceptions must be clearly articulated and subject to Policy Oversight Committee and Board approval, and public comment.
3. All future data requests by OPTN committees must be justified in the context of the above guiding principles and new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN, and be subject to public comment.