Tissue and Organ Donor Epidemiology Study (TODES)

Final Report

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1. INTRODUCTION

Rigorous measures — both mandatory and voluntary — are in place to provide patients with safe, transplantable organs and tissues. These measures include extensive donor screening for medical conditions and possible exposure to infectious diseases, as well as laboratory testing for specific infections, to minimize the risk of transmission by donated organs and tissues. While published reports indicate the incidence of disease transmission in transplant recipients appears to be low, donor-derived infections are of great concern, as they remain a source of morbidity and mortality among recipients.

Efforts to lower the risk of donor-derived infections continue, but gaps in knowledge persist (e.g., infectious disease prevalence in the organ and tissue donor populations, and the effectiveness of various donor screening and testing protocols). A lack of standardization of screening and testing protocols presents a challenge in obtaining quality data to address these questions. The purpose of this study is to create a pathway for further research that will contribute to a better understanding of the infection risks associated with organ and tissue transplantation (as described below), and provide an indication of the value of uniform testing and screening protocols.

The overarching goals of the Tissue and Organ Donor Epidemiology Study (TODES) are to (1) develop a study design or framework to effectively collect and analyze demographic, screening, and infectious disease testing data obtained from deceased organ, tissue, and eye donors, including "referral-only" donors (that is, deceased individuals referred for donation but ultimately deemed ineligible), in a standardized manner; (2) identify challenges to obtaining such data in a consistent and standardized format; and (3) identify limitations and sources of bias from data captured in this exploratory study. The data management methods and tools developed during the study are intended to inform approaches of future studies and serve as a pilot project for those studies.

The need for such data has been expressed by federal and nonfederal stakeholders in multiple forums, including:

1. 2005 Centers for Disease Control and Prevention (CDC) intervention workshop on preventing organ and tissue infection transmission that concluded systems integration is required across the organ and tissue transplant communities, including organ procurement organizations (OPOs), eye and tissue banks, and infectious disease experts to improve recognition and prevention of donor-derived transmission events.[1]

2. 2009 Public Health Service (PHS) white paper on patient safety and donor health, recommending strategies that could be used to address data gaps and improve biovigilance efforts.[2]

3. 2010 Food and Drug Administration (FDA) workshop on emerging infectious diseases, emphasizing the need for data to evaluate the potential for donor-derived disease transmission through organ and tissue transplantation.[3]
4. CDC publication on estimating risk of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) in potential organ donors, identifying the need for more research on the frequency and sources of nucleic acid test (NAT) false-positive results in potential organ donors.[4]
5. 2013 PHS guideline to improve organ recipient outcomes by reducing the risk of HIV, hepatitis B virus (HBV), and HCV transmission through transplantation. Gaps in the literature and quality of evidence affected the ability to reach firm conclusions for or against certain interventions. Further research was recommended in numerous areas, including estimating incidence and prevalence of HIV, HBV, and HCV among deceased donors and developing standardized algorithms for discrimination of initially reactive (positive) organ donor immunoassay and NAT results.[5]

An article by Greenwald et al. in 2012[3] summarized the 2010 FDA workshop on emerging infectious diseases and identified the following challenges when evaluating potential donors for transmissible diseases:

- The unknown sensitivity and specificity of current medical and behavioral history tools to screen donors for risk factors associated with infectious agents;
- The difficulty in distinguishing acute from chronic or persistent infections using standard testing modalities, especially given the prolonged window period of many serological assays and the limited sensitivity and specificity of NAT for some infections especially those acquired within days of donation;
- The limited ability of NAT to identify infections not associated with active blood stream involvement; and
- The variability in performance between different assays, including those used for donor screening and those used for diagnostic reasons, where performance characteristics have not been evaluated in the deceased donor setting; this may limit the ability of transplant personnel to compare and interpret some tests.

Factors Contributing to the Prioritization and Development of the Tissue and Organ Donor Epidemiology Study

- Infectious disease transmission associated with organ and tissue transplants is not fully understood and likely underreported.
- Data on infectious disease prevalence or incidence in potential donors are lacking due to multiple factors including the absence of reliable baseline/denominator data, and existing data are not consistently or centrally collected.
- Standardized donor screening tests are not always used; test sensitivity and specificity are poorly defined for deceased donors.
- Data on the presence of infectious disease corresponding to donor demographics are deficient; this limits the creation of accurate, data-driven donor-risk profiles.

Data on the prevalence of potentially transmissible infectious diseases in organ and tissue donors are of key importance in developing and refining government regulatory policy and informing policies for private sector transplantation services. However, there is a dearth of data on the prevalence and incidence of positive infectious disease markers and their demographic and risk factor correlates in organ and tissue donors. This limits the ability of the Department of Health and Human Services (HHS) to establish optimal donor screening and testing strategies.

1.1 Overview of TODES

TODES was designed to identify, and collect in a standardized manner, information on deceased persons referred for organ, tissue, and eye donation, and to estimate infectious disease prevalence and incidence for HIV, HBV, and HCV (to the extent possible) in this population. The final study design included (1) developing a participation plan including selected OPOs that provide data for organ and tissue donors and potential donors and selected eye banks that provide data for scleral and corneal donors; (2) developing a study protocol/manual of procedures to obtain data from participating organizations; (3) developing a suitable data management system; (4) compiling the data from participating organizations in a database and developing and implementing a quality control plan to validate the data; (5) analyzing the data; and (6) preparing a report containing summary statistics and donor characteristics, a discussion of the limitations of the data including sources of bias, and recommendations to inform the design of future prospective studies. Essentially, this was an exploratory study to collect retrospective data and assess the quality and usefulness of the available data for analysis.

Retrospective data for all deceased donors during a 5-year period, 2009-2013, were obtained from participating OPOs, tissue banks, and eye banks. For this study, non-ocular tissue data were obtained from OPOs that also serve as tissue banks involved in donor screening and tissue recovery. Some data for deceased organ donors were obtained through the Organ

Procurement and Transplantation Network (OPTN). The OPTN is operated under contract with the HHS, Health Resources and Services Administration (HRSA), Division of Transplantation, by the United Network for Organ Sharing (UNOS). The OPTN brings together medical professionals, transplant recipients, and donor families to develop national organ transplantation policy.

Participating OPOs and eye banks provided decedent data on donors (identified as having at least one organ or tissue recovered with the intent to transplant) and referral-only donors (identified as individuals deemed ineligible for transplant after referral). These data helped to characterize donor screening processes including infectious disease testing protocols for donors of organs, tissues, and/or eyes, and provide an assessment of the availability and completeness of collected donor data.

An ideal study would allow for estimating incidence, prevalence, and risk factors for donors. It would also provide inputs for benefit-risk assessment models to support policy evaluation. The current data that is available electronically and stored by a majority of these organizations are not designed for research purposes and cannot support these activities.

There are numerous limitations and inherent biases of the data captured by TODES that preclude the use of the study findings for policy decisions (refer to the Discussion for more details). The most serious limitations are as follows. (1) The 2009-2013 donor data collected by TODES reflect the 1994 PHS guideline recommendations to reduce the risk of HIV transmission by screening donors to capture behaviors and medical history that could place them at increased risk for HIV infection.[6] The current PHS guideline released in 2013,[5] limited to organ donation, additionally recommends donor screening for HBV and HCV. It includes more sensitive testing, revised risk factors, and more robust informed consent discussions about accepting or rejecting organs from donors known to be infected with HBV or HCV. (2) The retrospective data provided by the organizations were collected to support business operations rather than to address the TODES research questions. (3) The various testing protocols that resulted in the infectious disease marker prevalence estimates lack standardization and may include a variety of assay types (e.g., both donor screening and diagnostic assays). (4) Supplemental tests performed to verify indeterminate or positive test results are not consistently performed because there is no regulatory or policy requirement to do so. Limitations 3 and 4 resulted in a dataset containing a mixture of test results: inconclusive or positive with no further testing, positive results with subsequent testing, and negative results with subsequent testing.

1.2 TODES Technical Working Group

Contractual agreements were executed with study partners: UNOS represented by Research Scientist, Jennifer Wainright; the American Association of Tissue Banks (AATB) represented by the Senior Vice President of Policy, Scott Brubaker; and two expert consultants, Drs.

Emily Blumberg and Timothy Pruett representing the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS). HHS cross-agency team with members designated by the Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services, was also convened. Additional stakeholders included the Eye Bank Association of America (EBAA) represented by the Director of Regulations and Standards, Jennifer DeMatteo, and the Association of Organ Procurement Organizations (AOPO) represented by Charlie Alexander, Chief Executive Officer of The Living Legacy Foundation of Maryland OPO. This large group composed of the study partners, the HHS cross-agency team, and the other associations formed the TODES Technical Working Group (WG). The WG provided guidance on: identifying and recruiting donor organizations; data to collect on donors by type (organ, tissue, eye); and data collection processes, including the data quality plan. Following an in-person meeting of the WG in January 2013, the WG met quarterly by conference call until the formation of the Data Analysis Subgroup (DAS) in the later phases of the study. The DAS was established to inform development of the analysis plan, and discussion and presentation of the study results.

TODES Technical Working Group

- HHS Team
- UNOS – Jennifer Wainright
- AATB – Scott Brubaker
- AST - Emily Blumberg
- ASTS - Timothy Pruett
- EBAA – Jennifer DeMatteo

OPOs screen, arrange for donor testing, and coordinate the recovery of donor organs. Human organs include kidneys, liver, heart, lungs, pancreas, stomach, intestines, and vascular composite allografts such as limbs and faces. The OPTN database contains information pertaining to transplant recipients and deceased donors. Data are collected via electronic data collection forms, including the UNOS Deceased Donor Registration (DDR) Form that is completed by OPOs. The OPTN database contains records since October 1, 1987, on all deceased donors in the U.S. In 2015, there were 9,079 deceased donors (based on OPTN data as of 05/26/2016). Many OPOs also provide donor screening and referral services for tissue and eye banks and may provide tissue recovery services.

Tissue Banks screen, test, recover, process, store, and distribute donor tissues. Tissues from deceased donors generally include human bone, tendons, ligaments, skin, heart valves, and vessels. The AATB collects information on relevant tissue banking activities by conducting periodic annual surveys of tissue banks. The most recent survey was conducted for 2007. The survey reported on donor referral, screening, testing, and consent/authorization activities; tissue recovery, processing, storage, and distribution; and adverse outcomes. Based on the AATB survey report, 29,799 tissue donors were recovered in the U.S. in 2007.

Eye Banks screen, test, recover, process, and distribute donor ocular tissues, such as corneas and sclera. EBAA annually collects and publishes donor statistics on all 76 U.S. and ten international member eye banks. These data are collected electronically from the eye banks and include basic donor demographics, infectious disease test results, and cause of death. Their yearly *Eye Banking Statistical Report* provides a nearly complete picture of eye banking activities in the U.S. Since 2011, the eye banks have submitted data online using EBAA Connect, a real-time, web-based reporting and analytics tool. The EBAA reported 66,526 U.S. donors of ocular tissue in 2015 (based on EBAA data as of 05/26/2016).

1.3 Overview of Report

Two primary study tasks, as defined by the contract award, were to develop a (1) participation plan to identify, recruit, and obtain donor data from appropriate facilities and (2) study protocol and accompanying manual of procedures (MOP). Included in this report are the methods and results for each task. Section 1 presents an introduction and overview of the study. Section 2 describes the methods for developing a participation plan and recruiting OPOs, tissue banks, and eye banks (donor organizations), and the characteristics of prospective participants that declined participation. It also describes the methods for developing a study protocol, including regulatory requirements, data submission and data requirements; and data collection and validation. Section 3 presents the study results. Section 4 discusses the implications of missing data, strengths and limitations of the study; and recommendations for future studies. The overall conclusions are reported in Section 5. References are provided in Section 6. Appendices include a roster of the technical WG members and information on the expert consultants and WG organizations (Appendix A); information on the MOP and data flow (text and diagram) (Appendix B); and the study data dictionary (Appendix C).

2. METHODS

2.1 Study Population

2.1.1 Data Sources

The WG partnered with UNOS to acquire comprehensive data for organ donors, and met with AATB and EBAA WG members to determine which of their members had relatively high volumes of relevant donor data for the period 2009-2013. Next, the WG collaborated with them to collect de-identified data. However, to develop reliable prevalence and incidence estimates for HIV, HBV, and HCV, it was determined necessary to augment the deceased donor data provided by UNOS to include data on "referral-only" donors. Ultimately, UNOS provided data on deceased organ donors; participating OPOs provided supplemental information on UNOS donor data, referral-only donor data, and tissue donor data; and participating eye banks provided data on eye donors (ocular tissue).

2.1.2 Participation Plan and Study Invitation

Several meetings were held with UNOS to review the designated OPTN geographic regions and discuss specific data elements included on the DDR Form. OPOs are required to submit data electronically to UNOS, the OPTN contractor, through the DDR Form for each deceased donor. A research plan was developed to request data from UNOS for donor records with donor identification number for years 2009 through 2013. The plan was submitted to, and approved by HRSA in September 2014. In addition, a data release agreement for obtaining the donor identification number, a personal identifier for each donor, was executed with UNOS prior to purchase and receipt of these donor data in an OPTN Standard Analysis and Research (STAR) file.[a]

Preliminary discussions were held from January to August 2013 with 18 of the 58 OPOs, identified by AOPO and the WG, to (1) discuss the study objectives; (2) review and document their geographic catchment area, population size, and actual or estimated annual number of organ and tissue donors; and (3) characterize their donor screening, testing, and data collection and storage processes for both organ and tissue donors. This included eligibility assessment from the time of donor referral to recovery, and availability of data on deceased donors during the time period 2009-2013.

Six of the largest tissue processing banks were identified to discuss collection of donor data. Plans also included contacting several large laboratories that provide tissue donor infectious disease testing services to discuss the best approach for capturing test results. Determining how best to collect tissue donor data, including infectious disease test results, is complex

[a] This study used data from the OPTN. The OPTN data system includes data on all donor, wait-listed candidates, and transplant recipients in the U.S., submitted by the members of the OPTN, and has been described elsewhere. HRSA, HHS provides oversight to the activities of the OPTN contractor.

because tissue recovered from a single donor is commonly sent to more than one tissue processing bank, and each facility generates their own identification number associated with that donor. Following discussions with the tissue processing banks, the WG decided in September 2013 not to obtain data directly from these facilities or testing laboratories due to the likelihood of duplicate reporting of donor data. Instead, it was decided to approach OPOs that are also tissue recovery banks regarding their ability to provide donor information. This approach limited the representativeness of the TODES data of national organ and tissue donor/donation data. OPOs have highly defined catchment areas in which the populations may differ by demographics, levels of behavioral risk and environmental exposures, and prevalence of infectious diseases.

Final Data Sources – Organ Donors

- UNOS
- OPOs

Final Data Sources - Tissue Donors

- Eye banks
- OPOs that also recover tissue

OPOs may function as a tissue recovery service and/or work directly with local tissue processing banks and eye banks by referring potential donors for recovery of tissues within the OPO donor service area (DSA). Additionally, some OPOs recover, preserve, and distribute corneas from donors within their DSA.

Table 2-1. Number of Prospective Participants by OPTN Region

OPTN Region	No. and Type of Prospective Participants
1	1 (one OPO)
2	2 (two OPOs)
3	5 (four OPOs; one eye bank)
4	2 (two OPOs)
5	4 (three OPOs; one eye bank)
6	2 (one OPO; one eye bank)
7	2 (two OPOs)
8	2 (one OPO; one eye bank)
9	1 (one OPO)
10	4 (two OPOs; two eye banks)
11	4 (two OPOs; two eye banks)

In October 2013, OPOs previously invited to participate in the study were contacted about their ability to additionally collect tissue donor data. Most expressed interest although some raised concerns about limited local resources. At this time, it was expected that OPOs would

provide organ donor data versus receiving the data from UNOS, as described above. It was also decided to collect data on eye (ocular tissue) donors directly from eye banks. Following discussions with EBAA on strategies to obtain donor data, eight eye banks identified as having the highest donor volume of cornea donors were selected to participate. Discussions were held with the selected eye banks to discuss the study and collect information on their organization and donor population.

Overall, 21 OPOs were approached to participate in TODES. The list included at least one OPO from each of the 11 OPTN-defined geographic regions. Within a geographic region, consideration was given to the volume of donors screened and the highest numbers of recovered organs and/or tissues recovered for transplant. Selection criteria also included recruiting some OPOs that served a population with a high prevalence of the HIV, HBV, or HCV. Table 2-1 references the number of prospective participants by OPO region.

Beginning November 2013, recruitment conference calls were conducted with the Director (or designee) of identified OPOs and eye banks to reiterate the study objectives and review the draft list of variables for data collection.

2.2 Prospective Participants

2.2.1 Provision of Data

A total of 21 OPOs and eight eye banks (the prospective participants) provided information on their organizations and donor populations. Of the 29, 13 (the participants) provided donor data for analysis.

The catchment areas served by the prospective participants varied greatly in size.

- With information provided by the AOPO for the year 2013, the TODES study found that of the 21 OPOs, four serve catchment areas of less than 5 million people; 9 serve catchment areas between 5 and 10 million inclusive; and eight serve a population of greater than 10 million. The number of organ donors per million served ranged from 17 to 39 with an average of 25 donors per million.
- With information compiled from publicly provided data by the eye bank participants for the year 2013, the TODES study found that of the eight eye banks, two serve catchment areas of less than 5 million people, three serve catchment areas between 5 and 10 million inclusive; and three serve populations of greater than 10 million. The number of ocular tissue donors per million served ranged from 89 to 415 with an average of 213 donors per million.

Prospective participants were also asked to describe the type of data management software used to record and track donor data at their facility. There was a trend by OPOs to migrate the data capture process for organ and tissue donors from paper to electronic systems

beginning in 2005; however, the timing of this migration varied. One prospective participant transitioned to an electronic system in April 2014.

Each prospective participant typically purchased and used off-the-shelf software developed for the organ and/or tissue community and it was frequently modified or customized for internal use. The donor tracking systems most frequently used by OPOs were DonorTrac Plus™, Daedalus, TrueNorth™, and iTransplant™. Some used more than one type of software over the time period of interest, and by donor type, to track and store information. Midwire Systems™, a clinical information system designed specifically for eye banking, was most frequently used by the eye banks.

In early 2016, 20 of the 21 OPOs provided additional information on their donation screening and recovery processes. However, they were not able to provide information on the extent of attrition at each step of the donor screening process.

- Donor Screening. Five OPOs utilized the services of Statline® to provide all initial screening for donor eligibility; three used Statline® for back-up screening. Eleven OPOs conducted donor screening in-house, and one of the 11 OPOs also utilized an answering service through another OPO, as needed.
- Tissue Donors. Nineteen OPOs provided donor screening and recovery services for tissue processing banks, ranging from 1 to 6 (average 3.8) banks per OPO. One OPO that provided tissue recovery services worked with an eye bank that provided the screening services for potential tissue donors.
- Eye Donors. Eighteen OPOs provided donor screening services for eye banks and ten provided recovery services. One OPO that provided screening services for four eye banks reported they recovered ocular tissue only if organ recovery or tissue recovery also occurred.

2.2.2 Characterization of Donor Organizations That Declined Participation

2.2.2.1 Reasons for Declining Participation in Data Collection

Of the OPOs and eye banks that were invited, 16 declined participation — 12 OPOs and four eye banks. The reasons fall mainly into four categories: resource and/or staff constraints (11), simultaneous software upgrades (3), too much effort and past participation in similar studies (1), and lack of interest (1).

At least three attempts were made to solicit participation after the initial decision to decline. These attempts were made using a combination of electronic communication and follow-up telephone calls and messages. Trends by reason for non-participation or by type of organization were not apparent.

2.2.2.2 Time Frame for Declining Participation

The decision not to participate occurred at three different time points in the study, at the solicitation and invitation stage [declined at outset]; subsequent to discussing and reviewing the specifications of the donor data to be provided [declined after recruiting call]; and during the data extraction phase, after executing data use agreements (DUAs) and providing an estimated data delivery data [wanted to provide data but ran out of time].

2.2.2.3 OPOs and Eye Banks That Declined Participation at Outset

Eight prospective participants communicated during the solicitation and invitation stage that they would not participate. Seven of the organizations could not participate due to staff/resource constraints and one was upgrading their donor software.

2.2.2.4 OPOs and Eye Banks That Declined Participation after Recruiting Call

Five prospective participants declined participation after the recruitment call. Two of the organizations could not participate due to current software upgrades, one had participated in similar studies and considered the level of effort too high, and one had resource and/or staff constraints. Four of these prospective participants were OPOs and one was an eye bank.

2.2.2.5 Prospective Participants That Wanted to Provide Data but Ran Out of Time

The three prospective participants in this category reviewed the data specifications, executed DUAs, and provided a target date for data submission. Monthly reminders were sent to submit their data and to offer assistance. In August 2015, reminders were sent via e-mail and telephone more frequently based on receptivity. All three of the organizations had resource and/or staff constraints preventing a timely submission of data. One of these prospective participants was an OPO and two were eye banks.

2.3 Study Protocol and Participants

2.3.1 Regulatory (IRB, OMB, DUA)

The study objectives; data elements selected for inclusion; and processes for data extraction, transmission, and security were submitted to the contractor's Institutional Review Board (IRB) for review and approval. Since the study involved the extraction of existing data from deceased donors in a manner such that donors could not be identified directly or through identifiers linked to the donors, a request for exemption from IRB review was approved. Likewise, a request for review and approval was submitted to the Office of Management and Budget (OMB) in August 2014. Approval was received in April 2015.

A DUA was executed with each participant prior to data submission. The DUA ensured the confidentiality of donor-level and participant-level data, and stipulated that the participant-level datasets would not be shared with the client and/or study stakeholders.

2.3.2 Eligibility Criteria

Study participants – nine OPOs that also provide tissue donor screening/recovery services for tissue processing banks, and four eye banks, of which two screen tissue donors for tissue processing banks – submitted donor data for analysis. To maximize the volume of data to allow for a more accurate calculation of infectious disease marker prevalence, OPOs were also asked to provide data on referral-only donors, as available. Eligibility criteria for organ donors and referral-only donors included two rules: the donor (1) must have had serological tests performed and (2) must have consent or authorization for organ recovery.

The same eligibility criteria were applied for tissue and eye donors. For study purposes, donors were defined as having at least one organ, tissue or ocular tissue recovered with the intent to transplant.

2.3.3 Data Dictionary

A data dictionary was developed that was a compilation of data elements mainly derived from the UNOS DDR Form and discussions with prospective participants and key stakeholders, and parsed by "donor type": organ donor, referrals-only donor, tissue donor, and eye donor. Refer to Table 2-2 or the data dictionary in Appendix C.

Information collected on the UNOS DDR Form Includes:

- Donor demographics
- Cause of death
- Evidence of consent/authorization
- Behavioral risk status for HIV, HBV, HCV
- Infectious disease test results
- Hemodilution status of donor blood sample
- Medical history and clinical management
- Organ(s) recovered or reasons why not recovered

Table 2-2. Compiled Variables List

Variable	Organ Donors: UNOS/OPTN Provided Data	Organ Donors: OPO Supplemental to OPTN/UNOS Provided Data	Organ Donor Referrals: Referral Information for Those Not in OPTN	Tissue Donors	Eye Donors
Local Donor ID	—	X	X	X	X
Organization ID	X	X	X	X	X
Donor ID (UNOS)	X	X	X	X	X
Tissue ID	—	—	X	X	X
Eye ID	—	—	X	X	X
Date of death	X	X	X	X	X
Time of death	X	X	X	X	X
Sex	X	X	X	X	X
Age at death: years	X	X	X	X	X
Age at death: months	X	X	X	X	X

(continued)

Table 2-2. Compiled Variables List (continued)

Variable	Organ Donors: UNOS/OPTN Provided Data	Organ Donors: OPO Supplemental to OPTN/UNOS Provided Data	Organ Donor Referrals: Referral Information for Those Not in OPTN	Tissue Donors	Eye Donors
1st-person donor designation	X	—	X	X	X
Next of kin or other authorization	X	—	X	X	X
One or more tissues recovered with intent to transplant. Y/N	—	X	X	X	X
One or more organs recovered with intent to transplant. Y/N	X[1]	—	—	X	X
One or more ocular tissues recovered with intent to transplant. Y/N	—	X	X	X	X
Primary Cause of Death (COD)	X	—	X	X	X
Date of death/last time known alive: date	—	—	—	X	X
Date of death/last time known alive: time	—	—	—	X	X
Eye disposition code for each ocular tissue recovered	—	—	—	—	X
Cross-clamp date	X	—	—	—	—
Cross-clamp time	X	—	—	—	—
DCD Donor – date of death	X	—	—	—	—
DCD Donor – time of death	X	—	—	—	—
High risk or increased risk. Y/N	X	—	X	—	—
Date of sample collection	—	X[2]	X[2]	X[2]	X[2]
Time of sample collection	—	X[2]	X[2]	X[2]	X[2]
Sample hemodiluted. Y/N	X	X[2]	X[2]	X[2]	X[2]
HBsAg Screening Test	X	X[2]	X[2]	X[2]	X[2]
HBsAg Confirmatory/ Supplemental Test	—	X[2]	X[2]	X[2]	X[2]
Anti-HCV Screening Test	X	X[2]	X[2]	X[2]	X[2]
Anti-HCV Confirmatory/ Supplemental Test	—	X[2]	X[2]	X[2]	X[2]
Anti-HIV1/2 Screening Test	X	X[2]	X[2]	X[2]	X[2]
Anti-HIV1/2 Confirmatory/ Supplemental Test	—	X[2]	X[2]	X[2]	X[2]
HIV Ag/Ab combination assay	—	X[2]	X[2]	X[2]	X[2]
Anti-HBc (total) Screening Test	X	X[2]	X[2]	X[2]	X[2]
Anti-HBc Confirmatory/ Supplemental Test	—	X[2]	X[2]	X[2]	X[2]
NAT (HIV-1) Screening Test	—	X[2]	X[2]	X[2]	X[2]
NAT (HCV) Screening Test	—	X[2]	X[2]	X[2]	X[2]
NAT (HIV-1/HCV) Screening Test	—	X[2]	X[2]	X[2]	X[2]
NAT (HBV) Screening Test	—	X[2]	X[2]	X[2]	X[2]
NAT (HIV-1/HCV/HBV) Screening Test	—	X[2]	X[2]	X[2]	X[2]

[1] Organs were identified with disposition codes/reasons and reason if not transplanted

[2] Up to 3 sets of test results could be submitted

The data dictionary provided for the inclusion of multiple linking variables (e.g., identification numbers [IDs]) across the participants to minimize the possibility that donors were double-counted in the data analysis. Typically a donor of organs, tissue, and ocular tissue has about three different donor IDs that are assigned by the respective OPO, tissue processing bank, and eye bank. Thus, the following IDs were sought in each data request to support the matching of data: Organization ID, Local Donor ID, Donor ID (UNOS), Tissue ID, and Eye ID.

2.4 Data Collection

The study collected retrospective data from 2009 through 2013 for decedent donors. These data included basic demographic information, limited medical history and behavioral risk data, and infectious disease test results, if available. For a list of data elements collected for the study, refer to the data dictionary. The requisite data were received securely and stored in a SAS™ database that was ultimately used for donor characterization and analysis of the risk of infection.

As described in Section 2.1.2, data was obtained from UNOS, including unencrypted UNOS IDs, on all deceased organ donors from years 2009 through 2013. Some of the data elements important to the study (e.g., HIV, HBV, and HCV NAT) were not collected on the UNOS DDR Form during this timeframe. Therefore, participating OPOs were asked to provide supplemental data on organ donors they reported to UNOS. Using the donor's UNOS ID, the supplemental data were merged with the UNOS data to create a unique donor record. Once a match on UNOS ID was established, the following UNOS and OPO data were compared to identify discrepant records: (1) donor age difference of more than two years; (2) different sexes between the two datasets; and (3) dates of death differing by more than two days between the two datasets. OPO records with only a single discrepant value, were included in the analysis of infectious disease testing results.

In addition, all study participants were encouraged to provide as much data as possible on HIV, HBV and HCV serological test results that were performed. This included the provision of supplemental test results and NAT results, as available.

OPOs do not routinely receive the tissue donor test results. Any results received are usually captured on hard copy and not transferred to an electronic data capture system. Therefore, letters were sent to identified tissue processors asking that they work directly with participating OPOs upon their request to provide test results on specific donors and using donor identification numbers that can be matched. This strategy was not pursued due to the potential for duplicate reporting of infectious disease screening test results.

Data were provided by participants on a flow basis over about 13 months. Four participants provided data in more than one data submission (stages or resubmission). A data flow

diagram (Appendix B) characterizes the steps used to extract, transmit, validate, and store the donor data.

2.4.1 TODES Database

The TODES database was developed in SAS™ and consists of (1) raw data tables submitted by each participant in original format, (2) intermediate raw data tables in SAS™ format created in the process of constructing final derived data tables, and (3) derived data tables in SAS™ format. Each derived data table contains variables as specified in the data dictionary. In addition to individual participant datasets, the TODES database also includes a concatenated version of the derived datasets from each participant, which was used for final analyses.

2.4.2 Data Validation

Most participants delivered a single dataset which contained one record per ID number. These datasets were processed to conform to the TODES data dictionary and incorporated into the TODES database. However, three participants delivered data in multiple datasets, (e.g., an organ dataset and a tissue/eye dataset), with many donors common to both datasets. Also, one pair of participants, an OPO and their affiliated eye bank, delivered one dataset each, and both contained information for many of the same donors identified by common ID numbers. When multiple records for an individual donor were evident, an effort was made to harmonize the information into a single record with respect to infectious disease testing results, donor type, consent/authorization, donor medical history, and behavioral risk status.

3. RESULTS

For the purposes of this study, donors were identified as deceased individuals with at least one organ, tissue, or ocular tissue recovered with the intent to transplant. Table 3-1 summarizes all the TODES records received stratified by organization type (Org Type: OPO or eye bank) and participant (Org Code: A-M and E-J). The TODES database contains 291,848 records received from nine OPOs and 42,451 records received from four eye banks. Records with no indication of donor type (organ, tissue, or eye) are assumed to have not resulted in a donation, and are summarized in the "referrals-only records" column. Most of the OPO records received (255,927) do not indicate donor type; of those records, 254,050 are from two participants (B and L). Among the 42,451 records received from eye banks, only 487 records have no indication of donor type. Conversely, there are 35,921 OPO records and 41,964 eye bank records that provide some indication of donor type. In addition, there are 8,141 OPO records representing organ donors that can be linked to donor data received from UNOS[b] and 1,158 UNOS records with IDs in the UNOS data that cannot be linked to OPO data (OPO- UNOS+, Table 3-7).

Of the 291,848 OPO and 42,451 eye bank records received, the number of records with results for at least one infectious disease test is 23,510 and 40,465, respectively. This is stratified by donor type (organ donors with any test results, tissue donors with any test results, eye donors with any test results), or as referrals-only records with any test results. Based on the TODES definition of a donor, the OPOs identified individuals from whom they recovered tissue as donors. However, for tissue donors, an OPO does not typically receive the results for testing performed *after* the tissue recovery, as those are reported to the tissue and/or eye bank. If the individual is determined to be HIV, HBV, or HCV positive, the donated tissues are ineligible for transplantation purposes per FDA regulations.

When only organ donor records are considered, there are 8,149 records from OPOs and 203 records from eye banks with test results. When only tissue donor records are considered, there are 18,105 records from OPOs and 11,665 records from eye banks. When only eye donor records are considered, there are 6,365 records from OPOs and 40,189 from eye banks. Among referrals-only records with any test data, there are 655 records from OPOs and 276 records from eye banks. Given the small number of referrals-only records and the fact that most of the OPO referrals-only with any test data are from just five participants, the remainder of this report excludes data from referrals-only and focuses on data from deceased donors with at least one organ, tissue, or ocular tissue recovered with the intent to transplant.

[b] The data reported here have been supplied by the United Network for Organ Sharing (UNOS) as the contractor for the Organ Procurement and Transplantation Network (OPTN). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy of or interpretation by the OPTN or the U.S. Government.

Table 3-1. Characteristics of Participant Records: Referrals-only, UNOS Matches, and Records with Test Results

Org Type	Org Code	All Records n	Referrals-only Records n	Records Representing Potential Donors n	Records with UNOS Data/OPO Linked Data n	Records with any Test Results n	Organ Donor Records with any Test Results n	Tissue Donor Records with any Test Results n	Eye Donor Records with any Test Results n	Referrals-Only Records with any Test Results n
OPO	A	5,611	1,455	4,156	751	1,158	751	691	491	104
	B	169,760	164,347	5,413	1,381	1,716	1,384	663	2	238
	C	3,967	42	3,925	652	3,949	652	3,621	0	33
	D	1,867	2	1,865	618	1,860	618	1,370	562	2
	F	8,302	0	8,302	1,135	8,299	1,134	7,636	4,196	0
	I	4,234	235	3,999	1,366	4,060	1,371	3,180	345	117
	K	760	82	678	644	644	644	205	199	0
	L	96,386	89,703	6,683	724	870	725	359	252	101
	M	961	61	900	870	954	870	380	318	60
	Total	291,848	255,927	35,921	8,141	23,510	8,149	18,105	6,365	655
Eye Bank	E	23,044	0	23,044	0	22,924	0	9,266	22,924	0
	G	11,083	417	10,666	0	9,873	0	0	9,663	210
	H	2,644	70	2,574	0	2,500	0	0	2,434	66
	J	5,680	0	5,680	0	5,168	203	2,399	5,168	0
	Total	42,451	487	41,964	0	40,465	203	11,665	40,189	276

Based on all records received; includes known duplicates that were removed in subsequent analyses.

The Organ, Tissue, and Eye Donors with any Test Results are not mutually exclusive, so the record totals may add up to a value greater than that reported in the Records with any Test Results column.

OPO B and Eye Bank E were the only participants that submitted records that could be linked. Linkage of the 169,760 records submitted by OPO B and the 23,044 records submitted by Eye Bank E, resulted in 7,534 records in each dataset that were determined to be matching organ and/or tissue/eye donors.

In summary, the TODES database contains 77,885 records representing deceased organ, tissue, and eye donors with at least one organ or tissue recovered with the intent to transplant (Potential Donors), and 63,975 records, including referral-only records, with at least one infectious disease test result. It follows that the TODES database has records for donors without any recorded infectious disease test results; however, it was not possible to calculate the number of unique organ, tissue, and eye donors with missing infectious disease test results. From the OPOs, 22,855 out of 35,921 donor records have infectious disease test results reported for at least one test, and 40,189 out of 41,964 donor records from the eye banks have infectious disease test results reported for at least one test. However, these data do not imply that 36.4% of donors from OPOs have at least one organ or tissue recovered for transplant without infectious disease testing, or that 4.2% of donors from eye banks have at least one ocular tissue recovered for transplant without infectious disease testing. The TODES database is constructed from retrospective data extracted from participants using existing electronic data systems and may not include all donor data for the period of interest. For example, if a participant receives an infectious disease test result on a paper form only, then these data may not be captured in the participant's electronic database and thus are not part of the TODES database.

3.1 Data Characteristics by Time Period

Table 3-2 presents, for all years combined (2009-2013) and each year separately, the number of records received; the percentage of records for males and for females; the percentages for donors with at least one organ recovered for transplant, at least one tissue recovered for transplant, or at least one ocular tissue recovered for transplant; and the percentage of records with documented consent or authorization. The TODES data are not constructed from a mutually exclusive set of organ, tissue, and eye donors. Thus, some records represent multiple donor types, so the three columns for organ, tissue, and eye donors add up to more than 100%. A total of 74,744 donor records were available after known duplicates were removed. Each successive year has more records than the previous year; 2009 has the least number of records (12,871), while 2013 has the greatest number of records (17,876). For all years combined, the percentage of records is 63.3% for male donors, 11.3% for organ donors, 51.5% for tissue donors, and 73.4% for eye donors. The percentage of donors with documented consent or authorization is 93.8%. There is little variation and no consistent patterns of variation in these percentages by study year.

As shown in Figure 3-1, all seven possible donor type combinations are represented in the TODES database. The number of records within each type is fairly consistent across all study years, except for the "Eye Only" donor category, where the count increased markedly in 2012 and again in 2013. Across all years, the "Eye Only" type has the largest number of records followed by the "Tissue and Eye" and "Tissue Only" types. The "Organ and Eye" type consistently has the smallest number of records. The number of records were also

consistently small for the "Organ Only," "Organ & Eye," and "Organ & Tissue & Eye" donor types.

Table 3-3 shows donor age at death summarized by year. Age at death is typically between 40 and 75 years, with a very stable median age across all years, ranging from 58 to 60. The total number of donor records with missing age data was low (0.2%).

Presented in Table 3-4 is the increased-risk indicator, an assessment of risk status for blood-borne disease transmission. This determination, stratified by year, was provided by UNOS for almost all organ donors (99.8%). The organ donors who met one or more criteria considered as behavioral or medical risk factors for recent HIV infection, according to the PHS guideline, were identified in the UNOS dataset as being at increased risk. Between 10.1% and 16.2% of organ donors per year are classified as increased-risk donors, an average of 13.9% for the study period. Only 0.2% or less of donors per year are missing this information. Data are restricted to organ donors; potential tissue (including ocular) donors with risk factors for certain infectious diseases are deemed ineligible for donation per FDA regulations.

Table 3-2. Characteristics of Potential Donors by Year

Year	Records n	Male %	Female %	Organ Donors %	Tissue Donors %	Eye Donors %	Consent/ Authorization Documented %
2009	12,871	62.6	37.4	10.2	51.3	74.0	97.2
2010	13,527	63.3	36.7	10.5	53.1	71.5	97.4
2011	14,198	63.9	36.1	13.3	54.1	71.7	94.1
2012	16,272	63.3	36.7	11.5	49.9	74.0	91.8
2013	17,876	63.2	36.8	11.1	49.7	75.1	90.1
2009–2013	74,744	63.3	36.7	11.3	51.5	73.4	93.8

Based on all records received; excludes known duplicates.

Figure 3-1. Donor Count by Donor Type and Year

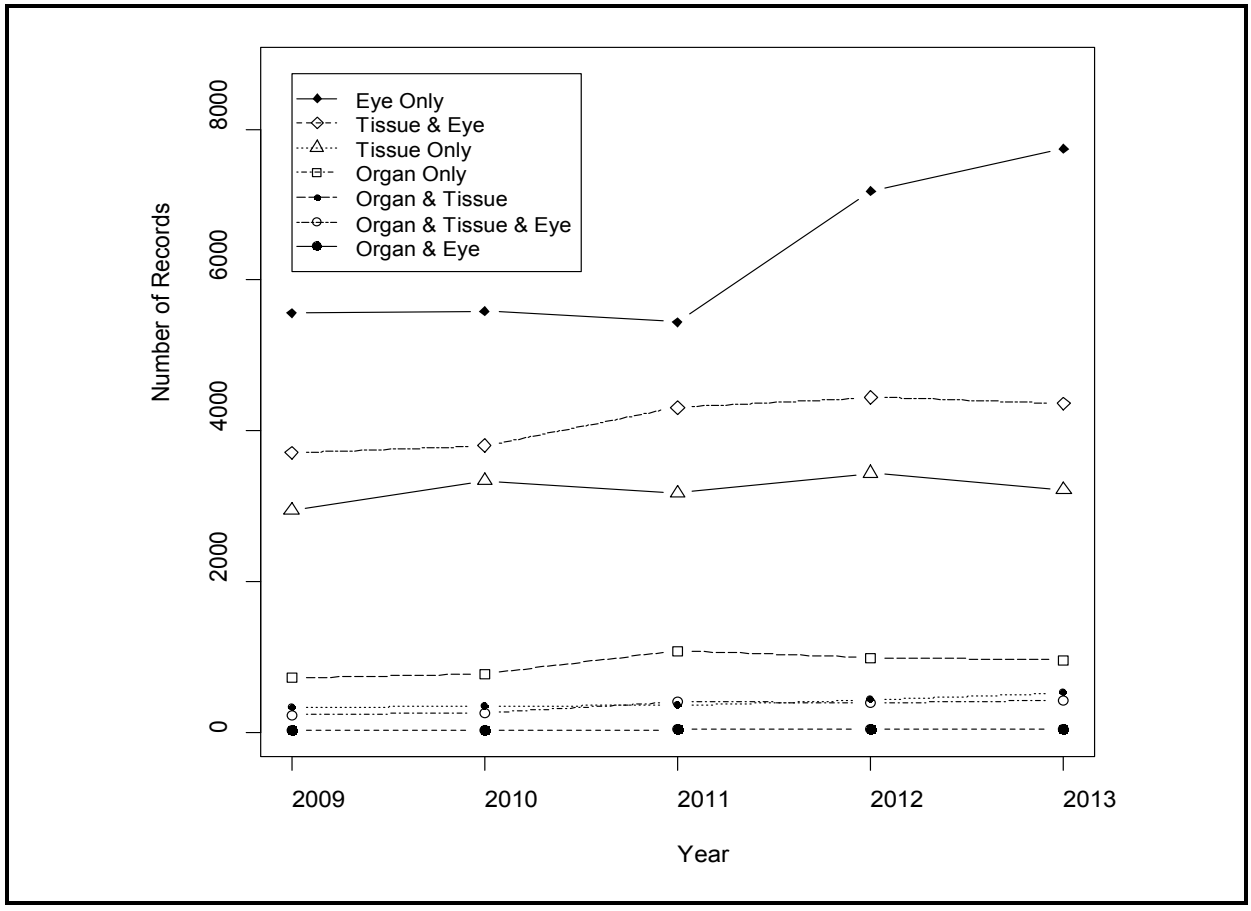


Table 3-3. Donor Age at Death (in years) by Year

Year	Records	<18 n (%)	18–39 n (%)	40–59 n (%)	60-75 n (%)	>75 n (%)	Missing n (%)
2009	12,871	414 (3.2)	1,520 (11.8)	4,394 (34.1)	5,437 (42.2)	1,072 (8.3)	34 (0.3)
2010	13,527	440 (3.3)	1,671 (12.4)	4,638 (34.3)	5,694 (42.1)	1,063 (7.9)	21 (0.2)
2011	14,198	445 (3.1)	1,900 (13.4)	5,065 (35.7)	6,108 (43.0)	664 (4.7)	16 (0.1)
2012	16,272	420 (2.6)	2,081 (12.8)	5,716 (35.1)	7,203 (44.3)	829 (5.1)	23 (0.1)
2013	17,876	483 (2.7)	2,128 (11.9)	6,028 (33.7)	8,181 (45.8)	1,033 (5.8)	23 (0.1)
2009–2013	74,744	2,202 (3.0)	9,300 (12.4)	25,841 (34.6)	32,623 (43.7)	4,661 (6.2)	117 (0.2)

Based on all records received; excludes known duplicates.

Table 3-4. Infectious Disease Risk Status of Organ Donors by Year (data from UNOS)

Year	Records n	Yes n (%)	No n (%)	Not Done n (%)	Missing n (%)
2009	1,266	128 (10.1)	1,132 (89.4)	4 (0.3)	2 (0.2)
2010	1,359	178 (13.1)	1,179 (86.7)	0 (0.0)	2 (0.2)
2011	1,830	250 (13.7)	1,578 (86.2)	0 (0.0)	2 (0.1)
2012	1,809	276 (15.3)	1,532 (84.7)	0 (0.0)	1 (0.1)
2013	1,877	304 (16.2)	1,573 (83.8)	0 (0.0)	0 (0.0)
2009–2013	8,141	1,136 (13.9)	6,994 (85.9)	4 (0.1)	7 (0.1)

Represents donor records from OPOs that can be linked to donor records received from UNOS.

3.2 Data Characteristics by Donor Type

Table 3-5 summarizes for all years combined organ donor only, and tissue or eye donor only records with respect to sex, age at death, primary cause of death (COD), increased-risk indicator, consent/authorization, and records with at least one positive test result. The percentage of males is similar among tissue or eye donors (63.7%) and organ donors (62.1%). The age at death is 18-59 years for most (74.8%) organ donors, whereas the age at death is 40-75 years for 81.2% of tissue or eye donors. As a result, the median age at death among organ donors (41 years) is substantially lower than the median age at death among tissue or eye donors (61 years). Among organ donors, the primary COD is about equally distributed among anoxia, cerebrovascular/stroke, and head trauma. The primary COD reported most frequently for tissue donors is "other;" whereas, anoxia and "other" are about equally distributed among eye donors. With respect to the increased-risk indicator, 24.2% of organ donors are classified as increased-risk donors. Among all donor types, between 93.0% and 100.0% have first-person consent or next-of-kin (NOK) authorization documented in the TODES database. A lack of authorization does not indicate a lack of consent. It may indicate that the information was not available for extraction for the TODES dataset. Finally, among organ donors, 16.6% of records have at least one test result with a positive value. For tissue or eye donors, the percentage of records with at least one positive test result is 4.4%.

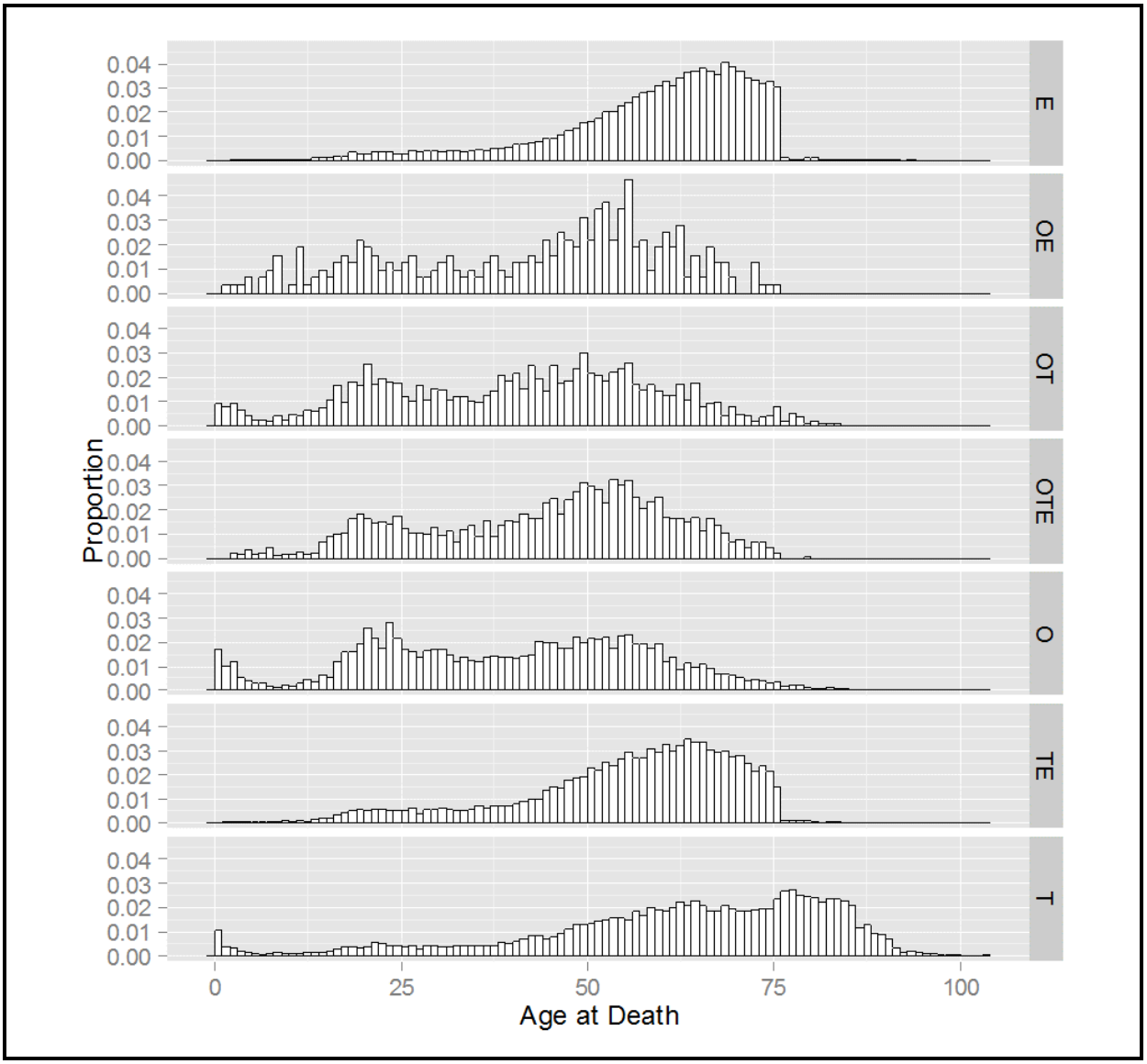
Table 3-5. Categorical Characteristics by Donor Type

Variable	Level	Organ Donor Only n (%)	Tissue or Eye Donor Only n (%)
Sex	Female	1,658 (37.9)	24,067 (36.3)
	Male	2,720 (62.1)	42,209 (63.7)
	Missing	0 (0)	13 (<0.1)
Age at Death	<18 years	487 (11.1)	1,363 (2.1)
	18–39 years	1,604 (36.6)	6,481 (9.8)
	40–59 years	1,669 (38.1)	22,335 (33.7)
	60–75 years	522 (11.9)	31,465 (47.5)
	>75 years	57 (1.3)	4,580 (6.9)
	Missing	39 (0.9)	65 (0.1)
Primary COD	Anoxia	1,426 (32.6)	17,187 (25.9)
	CNS Tumor	11 (0.3)	137 (0.2)
	Cerebrovascular/Stroke	1,151 (26.3)	14,936 (22.5)
	Head Trauma	1,240 (28.3)	2,615 (3.9)
	Other	165 (3.8)	25,220 (38.1)
	Missing	385 (8.8)	6,194 (9.3)
Increased-Risk	Yes	1,059 (24.2)	N/A
	No	3,303 (75.5)	N/A
	Not Done	4 (0.1)	N/A
	Missing	12 (0.3)	N/A
Consent/ Authorization	Yes	4,378 (100.0)	61,626 (93.0)
	No	0 (0)	4,663 (7.0)
	Missing	0 (0)	0 (0)
Positive Test Result	Yes	726 (16.6)	2,891 (4.4)

All variables do not add up to 100% due to rounding error.

Figure 3-2 displays histograms for age at death stratified by donor type. It highlights the following interesting characteristics of the data: (1) there are very few eye donors or organ donors older than age 75; (2) while eye donors in their 70s at time of death are not infrequent, almost all organ donors are younger than age 70; and (3) tissue donors tend to be age 50 and above, with the frequency curve showing a rather long distribution tail to the left.

Figure 3-2. Relative Frequency of Age at Death by Donor Type



Relative Frequency of Age at Death by Donor Type. E – eye only donors, OE – organ and eye donors, OT – organ and tissue donors, OTE – organ, tissue, and eye donors, O – organ only donors, TE – tissue and eye donors, and T – tissue donors

Table 3-6 presents COD by donor type and year. For all organ donors, the percentage with anoxia increases from 26.3% to 33.3% over the 5-year time period whereas the other COD categories remain fairly consistent across all five years of data. Among all tissue and all eye donors, the percentage of records in each primary COD category is relatively consistent across all years although the percentage with missing COD is sharply elevated in years 2012 and 2013. A likely reason for the higher percentage of "other" classifications for eye and tissue donors compared to organ donors is that eye banks and tissue banks use a different

COD classification scheme from the one used by UNOS. For TODES, COD is defined according to the UNOS categories.

Table 3-6. Primary Cause of Death by Year

Donor Type	Year	Anoxia n (%)	CNS Tumor n (%)	Cerebro-vascular/ Stroke n (%)	Head Trauma n (%)	Other n (%)	Missing n (%)
All Organ	2009	346 (26.3)	2 (0.2)	396 (30.1)	390 (29.7)	55 (4.2)	126 (9.6)
	2010	381 (26.9)	4 (0.3)	457 (32.3)	394 (27.8)	65 (4.6)	114 (8.1)
	2011	549 (29.1)	6 (0.3)	588 (31.2)	509 (27.0)	104 (5.5)	130 (6.9)
	2012	560 (30.0)	3 (0.2)	563 (30.2)	503 (27.0)	99 (5.3)	136 (7.3)
	2013	658 (33.3)	9 (0.5)	534 (27.0)	536 (27.1)	109 (5.5)	129 (6.5)
2009–2013		2,494 (29.5)	24 (0.3)	2,538 (30.0)	2,332 (27.6)	432 (5.1)	635 (7.5)
All Tissue	2009	989 (15.0)	3 (0.1)	2,178 (33.0)	477 (7.2)	2,718 (41.2)	238 (3.6)
	2010	1,002 (14.0)	6 (0.1)	2,282 (31.8)	435 (6.1)	3,094 (43.1)	357 (5.0)
	2011	1,026 (13.4)	1 (<0.1)	2,062 (26.8)	515 (6.7)	3,481 (45.3)	600 (7.8)
	2012	1,153 (14.2)	1 (<0.1)	1,688 (20.8)	585 (7.2)	3,159 (38.9)	1,528 (18.8)
	2013	1,228 (13.8)	4 (0.1)	1,970 (22.2)	656 (7.4)	3,142 (35.4)	1,888 (21.2)
2009–2013		5,398 (14.0)	15 (<0.1)	10,180 (26.5)	2,668 (6.9)	15,594 (40.5)	4,611 (12.0)
All Eye	2009	3,264 (34.3)	25 (0.3)	2,470 (25.9)	457 (4.8)	2,889 (30.3)	421 (4.4)
	2010	3,168 (32.8)	33 (0.3)	2,500 (25.9)	408 (4.2)	3,106 (32.1)	458 (4.7)
	2011	2,790 (27.4)	23 (0.2)	2,784 (27.3)	512 (5.0)	3,509 (34.5)	565 (5.6)
	2012	3,416 (28.4)	27 (0.2)	2,772 (23.0)	595 (4.9)	3,961 (32.9)	1,273 (10.6)
	2013	3,776 (28.1)	36 (0.3)	2,957 (22.0)	660 (4.9)	4,140 (30.8)	1,856 (13.8)
2009–2013		16,414 (29.9)	144 (0.3)	13,483 (24.6)	2,632 (4.8)	17,605 (32.1)	4,573 (8.3)

3.3 Merging of OPO and UNOS Records

Table 3-7 presents results by participant (Org Code) produced from merging data records provided by each OPO with records obtained from UNOS. UNOS identification numbers (UNOS IDs) were supplied by each OPO and used to merge individual records between OPO and UNOS datasets. The files from the four eye banks did not contain UNOS IDs, so eye banks are not included in Table 3-7.

For each OPO, three record counts are shown: (1) UNOS IDs present in the OPO data, but not in the UNOS data (OPO+ UNOS-); (2) UNOS IDs present in the UNOS data, but not in the OPO data (OPO- UNOS+); and (3) UNOS IDs present in both OPO and UNOS datasets (OPO+ UNOS+). Most OPOs provided many records with UNOS IDs that are not present in the UNOS dataset. For example, for OPO A, there are 4,860 records in the OPO data that are not in the UNOS data. This is explained by the fact that OPOs typically assign a UNOS ID at the time a patient is identified as a potential donor. However, during the donation

screening process, many potential donors fail to become candidates for donation. On the other hand, most of the records in the UNOS dataset are present in the data from OPOs (range: 60.2% to 100%). For example for OPO D, 618 of 629 (98.3%) records match between the two.

Once a match on UNOS ID was established, three criteria were compared to identify discrepant records: (1) donor age (difference of more than two years); (2) donor sex; and (3) date of death (difference of more than two days). There were no discrepancies based on sex, but discrepancies were identified based on age and date of death from six OPOs. The last column contains a tabulation of the number of records that were discrepant based on one of these criteria. OPO records with only a single discrepant value, were included in the analysis of infectious disease testing results.

Table 3-7. Linkage between Data from UNOS and OPOs

Org Code	Total Records in UNOS Dataset	Record Count: OPO+ UNOS-	Record Count: OPO- UNOS+	Record Count: OPO+ UNOS+	Record Count: Discrepant Data in Variable Fields
A	1,248	4,860	497	751 (60.2)	229
B	1,382	168,379	1	1,381 (99.9)	29
C	654	3,315	2	652 (99.7)	0
D	629	1,249	11	618 (98.3)	57
F	1,135	7,167	0	1,135 (100)	1
I	1,458	2,868	92	1,366 (93.7)	490
K	644	116	0	644 (100)	50
L	724	74,534	0	724 (100)	0
M	1,425	91	555	870 (61.1)	0

3.4 Infectious Disease Testing

Results from infectious disease testing for organ donors present in the UNOS dataset are shown in Table 3-8. These numbers are only descriptive statistics for the TODES dataset. Inferences cannot be made beyond these descriptive statistics because they were not collected in a way to allow for any generalization. The total number of organ donors with test results (positive or negative) in Table 3-8 is 8,138. The small variation in the number of test results among the infectious disease types is due to indeterminate or missing test results. The prevalence of positive tests is calculated for each viral marker by dividing the number of positive tests in the numerator by the total of positive plus negative tests in the denominator, then multiplying by 10,000 to express the result as the number of positives per 10,000 tests. Exact (Clopper-Pearson) 95% confidence intervals for the prevalence of

positive tests are also presented. The prevalence is based primarily on unconfirmed screening test results and may include false positive test results. Furthermore, indeterminate results are not included in the prevalence calculations as they could not be accurately interpreted in the absence of further testing.

Hepatitis B surface antigen (HBsAg) is a serologic marker for acute or chronic HBV infection, both of which can be transmitted to a recipient. This marker has a low prevalence relative to other infectious disease tests in TODES, approximately 10 per 10,000. For example, the prevalence of the hepatitis B core antibody (anti-HBc) serologic marker that indicates current HBV infection or infection that occurred at some time in the past, is substantially higher at 573 per 10,000. The prevalence for hepatitis C antibody (anti-HCV), the sole screening serologic assay for hepatitis C virus, was almost 422 per 10,000. Finally, there were no positive test results reported for the antibody to HIV (anti-HIV) so the prevalence is 0 per 10,000.

In addition to these markers, it was also evident (but not shown in the table) that the nine OPOs performed some testing for hepatitis B surface antibody (anti-HBs) (range: 2 to 651 tests). There were no clear patterns as to when this assay was utilized, although one OPO applied it to approximately 50% of cases screened. The other eight OPOs reported this test as "not done" for the vast majority of cases screened. Prevalence was not calculated.

Table 3-8. Prevalence (expressed as number of positive test results per 10,000 tests) of Positive Infectious Disease Tests (data from UNOS for organ donors)

Infectious Disease Test	Total Test Results n	Positive Test Results n	Prevalence (95% CI)
HBsAg	8,120	8	9.9 (4.3, 19.4)
Anti-HBc	8,133	466	573.0 (523.4, 625.7)
Anti-HCV	8,134	343	421.7 (379, 467.6)
Anti-HIV	8,137	0	0.0 (0.0,4.5)

Indeterminate or missing values were excluded from this analysis.

Table 3-9 presents results for infectious disease testing by donor type (all organ, all tissue, all eye) based on generally unconfirmed screening test results extracted from the participant databases which does not include some of the records contained in the UNOS dataset (OPO- UNOS+, see Table 3-7). Within a donor type, all records representing that donor type are utilized such that overlap among donor types may be present. The prevalence of positive tests is calculated by dividing the number of positive tests in the numerator by the total of positive plus negative tests in the denominator, then multiplying by 10,000 to express the result as the number of positive tests per 10,000 tests.

Exact (Clopper-Pearson) 95% confidence intervals for the prevalence of positive tests are also presented.

When multiple records with the same ID number were identified in the same, or more than one participant's dataset, an effort was made to harmonize the information into a single record with respect to infectious disease test results. This was achieved by prioritizing test results according to the following order: positive, negative, inconclusive, test not performed), null or missing.

Comparing the prevalence values for all organ donors calculated for serological markers from the UNOS data (Table 3-8) to those based on the test results extracted from the databases of the OPOs (Table 3-9), the differences are small. The prevalence for each marker calculated from the different data sources are of the same magnitude, and for all but one pair (anti-HCV), both values and sets of confidence intervals are comparable. Table 3-9 also includes NAT results for HBV, HCV, and HIV which do not appear in Table 3-8 as they were not captured by UNOS at that time.

One notable difference is found between the two tables with regard to HIV. Although there are no anti-HIV positive results in the UNOS data, one positive screening test result appears in the participant data (Table 3-9). A positive HIV NAT result is evident for the same individual, indicating a recent infection. The data for this individual was not transmitted to UNOS because OPTN policy did not permit recovery of organs from individuals known to be HIV positive during the TODES data collection timeframe. There are no other HIV NAT positive results among all organ donors. HIV NAT prevalence is higher (7.1 per 10,000) in all tissue donors than in all eye donors (4.6, per 10,000); however, they are not significantly different because the confidence intervals overlap.

HBV NAT prevalence did not differ among overlapping organ, tissue, and eye donor categories (range: 31.7 to 36.5 per 10,000). However, HCV NAT is highest in all organ donors (276.3 per 10,000), lower in all eye donors (100.6 per 10,000), and lowest in all tissue donors (83.4 per 10,000).

The numbers of tissue and eye donors tested are much higher than for organ donors, reflecting the fact that there are many more potential tissue and eye donors than organ donors. The prevalence for each viral marker when compared for all tissue and all eye donors, while not equal, are consistently of the same magnitude and the corresponding confidence intervals overlap except for anti-HCV.

It is important to emphasize that tissues (including ocular) are not transplanted from these "donors" with positive test results.

Table 3-9. Prevalence (number of positive test results per 10,000 tests) of Positive Infectious Disease Tests Reported by OPOs for All Donors of a Specific Type, Overlap among Donor Types Possible

Donor Type	Infectious Disease Test	Total Test Results n	Positive Test Results n	Prevalence (95% CI)
All Organ	HBsAg	7,624	6	7.9 (2.9, 17.1)
	Anti-HBc	5,705	330	578.4 (519.3, 642.2)
	Anti-HCV	7,665	290	378.3 (336.7, 423.5)
	Anti-HIV	7,660	1	1.3 (0.0, 7.3)
	HBV NAT	5,235	17	32.5 (18.9, 51.9)
	HCV NAT	6,262	173	276.3 (237.1, 319.9)
	HIV NAT	6,259	1	1.6 (0.0, 8.9)
All Tissue	HBsAg	28,713	257	89.5 (78.9, 101.1)
	Anti-HBc	13,368	568	424.9 (391.3, 460.5)
	Anti-HCV	28,730	468	162.9 (148.6, 178.2)
	Anti-HIV	28,707	58	20.2 (15.3, 26.1)
	HBV NAT	10,947	40	36.5 (26.1, 49.7)
	HCV NAT	24,101	201	83.4 (72.3, 95.7)
	HIV NAT	24,065	17	7.1 (4.1, 11.3)
All Eye	HBsAg	46,118	370	80.2 (72.3, 88.8)
	Anti-HBc	23,494	959	408.2 (383.2, 434.3)
	Anti-HCV	46,131	927	200.9 (188.3, 214.2)
	Anti-HIV	46,107	73	15.8 (12.4, 19.9)
	HBV NAT	7,897	25	31.7 (20.5, 46.7)
	HCV NAT	28,042	282	100.6 (89.2, 112.9)
	HIV NAT	28,011	13	4.6 (2.5, 7.9)

Indeterminate values were excluded from this analysis.

When donor type is subset on exclusively organ, tissue, and eye to produce mutually exclusive groupings (Table 3-10), the prevalence of positive infectious disease test results (per 10,000) increases almost two-fold for organ-only donors compared to all organ donors, for non-HIV tests. This is due in part to the approximately 50% drop in the number tested, while the number of positive test results remains relatively unchanged. The results for the number of positive tests for HCV NAT for all organ donors (Table 3-9) is 173 of 6,262 tested organ donors for a prevalence of 276.3 per 10,000 tests; while for organ-only donors (Table 3-10), the corresponding number of positive tests is 167/3,145 for a prevalence of 531.0 per 10,000 tests. The differences are not as extreme for tissue-only and eye-only donors compared to all tissue and all eye donors, respectively, as both the numerators and denominators decrease. For example, among all tissue donors, the number of HBV NAT

positive test results and the prevalence value are 40/10,947 (36.5 per 10,000 results), while among tissue-only donors the corresponding results are 21/4,068 (51.6 per 10,000 results). Other test-related factors that may contribute to the prevalence differences in the mutually exclusive donor type categories are less testing overall and the utilization of different assays with differing sensitivities/specificities.

Table 3-10. Prevalence of Infectious Disease Marker or Nucleic Acid Reported by OPOS for Each Donor Type Separately, Expressed As Number of Positive Tests per 10,000 Tests

Donor Type	Infectious Disease Test	Total Test Results n	Positive Test Results n	Prevalence (95% CI)
Organ Only	HBsAg	3,885	6	15.4 (5.7, 33.6)
	Anti-HBc	2,918	323	1106.9 (995.3, 1226.4)
	Anti-HCV	3,915	280	715.2 (636.4, 800.4)
	Anti-HIV	3,914	0	0.0 (0.0, 9.4)
	HBV NAT	2,647	17	64.2 (37.5, 102.6)
	HCV NAT	3,145	167	531.0 (455.2, 615.2)
	HIV NAT	3,146	0	0.0 (0.0, 11.7)
Tissue Only	HBsAg	9,737	114	117.1 (96.7, 140.5)
	Anti-HBc	4,126	238	576.8 (507.6, 652.4)
	Anti-HCV	9,740	174	178.6 (153.3, 207.0)
	Anti-HIV	9,734	29	29.8 (20.0, 42.8)
	HBV NAT	4,068	21	51.6 (32.0, 78.8)
	HCV NAT	9,400	96	102.1 (82.8, 124.6)
	HIV NAT	9,391	12	12.8 (6.6, 22.3)
Eye Only	HBsAg	28,335	227	80.1 (70.1, 91.2)
	Anti-HBc	14,747	629	426.5 (394.5, 460.4)
	Anti-HCV	28,339	634	223.7 (206.8, 241.6)
	Anti-HIV	28,330	43	15.2 (11.0, 20.4)
	HBV NAT	1,634	6	36.7 (13.5, 79.8)
	HCV NAT	14,191	179	126.1 (108.4, 145.9)
	HIV NAT	14,186	9	6.3 (2.9, 12.0)

Indeterminate values were excluded from this analysis.

Table 3-11 illustrates the seven patterns of results from HBsAG, anti-HBc, and HBV NAT tests in all three donor types (all organ, all tissue, and all eye). For this table, and for 3-12, only donors with NAT and serological screening test results are included, resulting in lower denominators than those found in Tables 3-9 and 3-10. In order to eliminate suspected false-positive screening test results from the HBV prevalence calculations, only those patterns including either an HBV NAT-positive result, or two positive serological tests (HBsAG and anti-HBc), are considered indicative of infection (i.e., Probable Infection=Yes). All single, unconfirmed, positive serologic test results are eliminated from the prevalence calculations. For each donor type, more than 93% are negative on all three tests. The next largest group, ranging from 2.2% to 5.7%, is positive only for anti-HBc, a large proportion of which could be false positive test results, but may indicate HBV infection at some time in

the past. There are 25 (16 plus 9 in table 3-11) total cases in which HBsAg is detected in the absence of HBV NAT which could indicate either an inactive carrier of infection or false positive test results. A single donor in each of the organ and tissue groups (could be the same donor as these groups are not mutually exclusive) is positive for both HBsAg and anti-HBc and is included as a likely true positive. Finally, individuals who are HBV NAT positive, in the presence or absence of HBsAg or anti-HBc, are considered to have active infection which can be transmitted to a recipient. In total, this would include 43 of those tested. HBV prevalence per 10,000 is calculated where probable infection equals yes, and equals: 34.5 for all organ donors, 23.9 for all tissue donors, and 20.0 for all eye donors.

Table 3-11. Prevalence of HBV by Donor Type in a Subset of Donors with Adjustment for Suspected False-positive Test Results

HBsAg Result	Anti-HBc Result	HBV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Organ					
Neg	Neg	Neg	4,630	93.9	No
Neg	Pos	Neg	282	5.7	No
Pos	Pos	Neg	1	<0.1	Yes
Neg	Neg	Pos	4	0.1	Yes
Neg	Pos	Pos	8	0.2	Yes
Pos	Pos	Pos	4	0.1	Yes

Prevalence per 10,000 (95% CI); 17/4,929 = 34.5 (20.1, 55.2)

HBsAg Result	Anti-HBc Result	HBV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Tissue					
Neg	Neg	Neg	6,527	95.8	No
Neg	Pos	Neg	137	3.2	No
Pos	Neg	Neg	16	0.4	No
Pos	Pos	Neg	1	0.1	Yes
Neg	Neg	Pos	1	0.1	Yes
Neg	Pos	Pos	5	0.1	Yes
Pos	Pos	Pos	9	0.3	Yes

Prevalence per 10,000 95% CI); 16/6,696 = 23.9 (13.7, 38.8)

HBsAg Result	Anti-HBc Result	HBV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Eye					
Neg	Neg	Neg	5,856	97.5	No
Neg	Pos	Neg	130	2.2	No
Pos	Neg	Neg	9	0.2	No
Neg	Neg	Pos	2	<0.1	Yes
Neg	Pos	Pos	5	0.1	Yes
Pos	Pos	Pos	5	0.1	Yes

Prevalence per 10,000 (95% CI); 12/6,007 = 20.0 (10.3, 34.9)
Indeterminate values were excluded from this analysis.

Table 3-12 illustrates the four patterns resulting from testing for both HCV antibody (anti-HCV) and HCV NAT in all three donor types. Almost all donors tested, 96.0% or greater,

were negative for both and have no evidence of infection. Donors who were anti-HCV positive and HCV NAT negative, 0.8% to 1.3%, are usually interpreted as false positive or may have cleared a previous infection. Those with anti-HCV negative and HCV NAT positive, 0.1% of each group, are likely to be newly infected and in the window period prior to the development of antibodies. Finally, 580 (0.7% to 2.7%) of those tested (with possible overlap) show evidence of an active infection due to the presence of both anti-HCV and HCV NAT. HCV prevalence per 10,000 is calculated from where probable infection equals yes, and equals: 278.4 for all organ donors; 80.0 for all tissue donors; and 98.9 for all eye donors.

Table 3-12. Prevalence of HCV by Donor Type in a Subset of Donors with Adjustment for Suspected False-positive Test Results

Anti-HCV Result	HCV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Organ				
Neg	Neg	5,930	96.0	No
Pos	Neg	77	1.3	No
Neg	Pos	7	0.1	Yes
Pos	Pos	165	2.7	Yes

Prevalence per 10,000 (95% CI); 172/6,179 = 278.4 (238.8, 322.5)

Anti-HCV Result	HCV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Tissue				
Neg	Neg	23,624	98.4	No
Pos	Neg	193	0.8	No
Neg	Pos	23	0.1	Yes
Pos	Pos	169	0.7	Yes

Prevalence per 10,000 (95% CI); 192/24,009 = 80.0 (69.1, 92.1)

Anti-HCV Result	HCV NAT Result	Number with Pattern	Percent with Pattern	Probable Infection (Yes/No)
All Eye				
Neg	Neg	27,440	98.0	No
Pos	Neg	286	1.0	No
Neg	Pos	31	0.1	Yes
Pos	Pos	246	0.9	Yes

Prevalence per 10,000 (95% CI); 277/28,003 = 98.9 (87.7, 111.2)

Indeterminate values were excluded from this analysis.

3.5 Adoption of Nucleic Acid Testing (NAT)

The adoption of NAT has been a gradual process for the OPOs as illustrated in Table 3-13. From 2009 through 2013, the number of participant records of all donor types that included any NAT test result increased from 10,374 to 15,493, an increase of 49.3%. Of the ten

participants that reported any NAT results for 2009, four of these were eye banks that adopted NAT based on (or prior to) the August 2007 FDA guidance for the tissue industry[7] requiring NAT for HIV and HCV. By 2010, 11 were using NAT (including one additional OPO), and by 2012 that number had increased by one more OPO to 12 of 13 participants.

Table 3-13. Total NAT Tests Reported, and Participants Reporting NAT, by Year

Year	NAT Test Frequency	% Change	Participants Reporting any NAT Results
2009	10,374	-	10
2010	11,571	+11.5	11
2011	12,833	+10.9	11
2012	15,249	+18.8	12
2013	15,493	+1.6	12
Total		+49.3	12

4. DISCUSSION

This retrospective study provides useful information about the practices, procedures, and data availability of OPOs and eye banks pertaining to organ, tissue, and ocular tissue donation. Characterization of the donor populations is the first step in assessing the effectiveness of current donor screening policies. Data on the prevalence of transmissible infectious diseases in deceased persons referred for organ and tissue donation are of key importance to developing and refining government regulatory policies. Infectious disease marker data for referrals-only and actual donors are not uniformly collected nor centrally analyzed, forcing the organ and tissue community to rely largely on the results of studies in blood donors to estimate risk of these infections. However, these populations are not likely to be analogous and thus may provide inaccurate predictive data regarding risk of infectious disease and sensitivity and specificity of screening and confirmatory test results in the organ, tissue, and eye donor populations. The data collection and management methods utilized in TODES, as well as the recognized limitations and potential biases of the data, will inform the design of future prospective studies regarding organ and tissue donation.

The TODES database contains 291,848 records received from OPOs and 42,451 records received from eye banks. Of these records, there were 8,141 OPO records for organ donors that were linkable to donor data received from UNOS. According to the UNOS website (www.unos.org), the national total of deceased organ donors was 40,502 during the period 2009-2013. Therefore, the 8,141 organ donors included in TODES from nine participating OPOs represent 20.1% of the national total during that period. TODES records for eye donors (received from OPOs as well as eye banks) total 54,851 and account for approximately 19.0% of the 289,029 U.S. eye donors reported by the EBAA (www.restoresight.org) for the study period. Given the relatively small number of referrals-only records with test results (655), only descriptive data for these categories are reported.

The number of records stratified by the seven donor-type categories is fairly consistent across all study years with one notable exception. Although each successive year has an increasing number of total records, this was driven largely by the eye donor-only category which achieved a 37.0% increase from 2011-2013. This is consistent with the trend in total national eye donors measured by the EBAA for the period.

During the period of TODES data collection, OPTN policy was based on the 1994 PHS Guidelines for Preventing Transmission of Human Immunodeficiency Virus (HIV) through Transplantation of Human Tissues and Organs[6] for the medical and behavioral history used to assess risk factors for HIV transmission (increased-risk indicator variable). Organ donors who met one or more criteria recognized as risk factors for HIV infection including sexual exposures; vertical transmission; injecting drug use; human-derived clotting factor concentrates; incarceration; and occupational exposures were identified as being at

increased risk. FDA regulations[5] excluded these individuals from tissue (including ocular) donation. The revised PHS guidelines[7] address HIV, HBV, and HCV, but were not incorporated into OPTN policy until the very end of the TODES data collection period (late 2013 or 2014). The major additions to the previous guidelines were:

- Recommendation that donors be screened for both HBV and HCV, in addition to HIV.
- Recommendation for new, more sensitive laboratory testing.
- Inclusion of a revised set of risk factors for HIV, HBV, or HCV infection.
- Emphasis on organ donors. Since 2007, the FDA implemented comprehensive donor screening and testing requirements for tissue donors.
- Recommendation for a robust informed consent discussion between the transplant candidate/decision maker and the clinician.

In the TODES database, 99.8% of UNOS-provided donor records have a determination regarding increased-risk. The percentage of increased risk donors increases gradually over time from 10.1% in 2009 to 16.2% in 2013, with an average for the five-year period of 13.9%. Not surprisingly, the organ donor-only records from the OPOs yields a higher percentage of increased risk donors than the UNOS data, 24.2%, with 99.6% non-missing. Not included in the analysis of increased risk donors are the referrals-only records, for which four OPOs include any risk indicator data (data not shown). Of the 255,927 referrals-only records submitted by OPOs, only 152 include risk indicator data. Of those 152 records, 66 (43.4%) are reported as increased risk, and 54 of those have some infectious disease testing performed. These increased risk referrals have at least one initial positive test result in 72% of cases (39 of 54).

Knowing little about the specific screening assays utilized, and lacking confirmatory test data, it is not possible to interpret indeterminate results. Therefore, they are not included in the prevalence calculations and other analyses. However, the changing testing modalities with the increased use of NAT later in the study period may affect the results, although the specific impact is not known.

Among organ donors only whose data were submitted to UNOS, the prevalence of anti-HIV is 0.0 per 10,000 (95% CI 0.0, 4.5). The lack of positive test results for anti-HIV may be partially attributable to robust screening procedures in place to eliminate any potential donors with a medical history of HIV from the donor pool. Although six participating OPOs had implemented NAT by 2009 and two more by 2012, NAT results were not captured by UNOS at that time, and therefore appear only in the data submitted to TODES by the OPOs. Evident in those data are results for one potential donor who reacted positively on both anti-HIV and HIV NAT, indicating a relatively recent infection. This donor does not appear in the UNOS dataset indicating that the individual was appropriately disqualified from

donation. There are no other HIV positive test results among potential organ donors, therefore, the HIV prevalence per 10,000 in all potential organ donors tested and recorded by the OPOs is 1.6 (95% CI 0.0, 8.9).

The prevalence per 10,000 of hepatitis viral markers in screened organ donors with records submitted to UNOS is 9.9 (95% CI 4.3, 19.4) for HBsAg; 573.0 (95% CI 523.4, 625.7) for anti-HBc; and 421.7 (95% CI 379.0, 467.6) for anti-HCV. When the analysis is subset on donor type (organ, tissue, and eye) to produce mutually exclusive groupings, the prevalence of positive test results per 10,000 increases almost two-fold for organ-only donors compared to all organ donors for HBV and HCV tests. Other test-related factors that may contribute to the prevalence differences in the mutually exclusive categories are less testing overall, more rigorous requirements for the donation of tissues, and the utilization of different assays with variable sensitivities/specificities.

The reported prevalence values for HBV, HCV, and HIV are calculated from largely unconfirmed screening test results and may include false-positive test results. In order to improve the statistical accuracy as much as possible, the patterns of NAT and serological test results are analyzed separately for HBV and HCV and an alternative calculation of prevalence is applied to those patterns most likely to reflect true positives. These include all patterns with a positive NAT result, or those including some additional "supplemental" positive result in addition to a positive screening antibody or antigen assay (e.g., positive HBsAg plus positive anti-HBc with or without a positive NAT result). For HCV, acceptable patterns are anti-HCV plus a positive HCV NAT, or simply a positive HCV NAT alone.

As a result, for HBV, 91-94% of all donors with any positive result are eliminated from the prevalence calculation as a potential false-positive test result. Prevalence values are recalculated for each donor type (Table-3-11). When each prevalence value is compared with the corresponding values calculated separately for each infectious disease test (Table 3-9), these recalculated values are statistically identical to the estimated prevalence resulting from the HBV NAT results alone (Table 3-9). Therefore, a more accurate estimate of the true positive prevalence (per 10,000 tested) of HBV infection is 34.5, 23.9, and 20.0 in all organ, all tissue, and all eye donors, respectively. In total, among the three donor types, there are seven recent infections detected by NAT only that were antibody negative (however, overlap is possible).

Similarly, for HCV, prevalence values are recalculated for each donor type removing potential false positive test results (Table 3-12). When each prevalence value is compared with the corresponding values calculated separately for each infectious disease test (Table 3-9), the recalculated values are statistically identical to the prevalence values resulting from the HCV NAT results alone. In total, among the three donor types, there are 61 recent infections detected by NAT that were antibody negative (however, overlap is possible). A more accurate estimate of the true positive prevalence (per 10,000 tested) of HCV infection

is 278.4, 80.0, and 98.9 in all organ, all tissue, and all eye donors, respectively. For HCV, 31% to 50% of all donors with any positive result are eliminated due to potential false-positive test results.

The adoption of NAT for organ donors was an incomplete process at the time these data were obtained. However, it was already contributing valuable information regarding recent infections in donors of all types.

4.1 Limitations and Potential Biases

There are a number of general limitations of the study data, as well as statistical limitations, due primarily to study design and the quality of the source data for the purposes of this report. The first general limitation is the retrospective data utilized were collected by OPOs and eye banks to support business operations and, for organ donors, donor-recipient matching, rather than to address the TODES research questions. This statement also applies to tissue banks. Furthermore, during the period of interest many of the participating organizations relied at least partially upon manual records which were often not incorporated into the more accessible electronic records retained by a facility.

Another limitation is that the 2009-2013 data collected by TODES reflect the 1994 PHS guidelines for reducing the risk of HIV transmission by screening donors to identify behaviors and medical history that could place them at increased risk for HIV infection.[6] Whereas the current PHS guideline released in 2013[5] additionally recommends organ donor screening for HBV and HCV and includes more sensitive testing, revised risk factors, and more robust informed consent discussions regarding accepting or rejecting organs from donors known to be infected with HBV and HCV.

In addition, some key screening procedures of organ and tissue collection facilities and tissue processing facilities are not well standardized across the industry, resulting in some ambiguity of the data and uncertainty in the conclusions. The various testing protocols that resulted in the infectious disease marker prevalence estimates lack standardization and may include a variety of assay types (e.g., both donor screening and diagnostic assays). Supplemental and confirmatory tests performed to verify indeterminate or positive test results are not consistently performed as there is no regulatory or policy requirement to do so. Flexibility in the order of the donor screening procedures (i.e., whether medical and behavioral history or infectious disease testing is performed first) may have generated a bias in the test results and subsequent calculations.

The lack of a single donation ID which could be used for all donations from a donor (organ, tissue, and eye) limited the ability to link separate records from different facilities and thereby eliminate the potential for duplication in the TODES database. However, when donation records from different organizations could be linked (e.g., an OPO and an eye bank in the same geographic region), anomalies are observed in the test results of some

individual donors. Possible explanations for these inconsistencies include the use of different assays, different testing algorithms, and the lack of confirmatory testing.

For these reasons, and others discussed below, the quality of the retrospective TODES data is not sufficient to adequately address all of the research questions and to accurately estimate infectious disease prevalence.

Another general limitation is the representativeness of the TODES data to the national organ and tissue donor/donation data. OPOs have highly defined catchment areas in which the populations may differ by demographics, levels of behavioral risk and environmental exposures, and infectious disease prevalence. Although TODES includes data from both urban and rural environments and achieves a satisfactory mix of participating sites from most of the geographic regions of the U.S., one notable deficiency is the lack of data from the southeastern U.S. A major objective of TODES is to collect information regarding the results of infectious disease screening assays and to determine estimates of prevalence for HIV, HBV, and HCV. Multiple southeastern states reported HIV infection rates among the highest in the U.S. in 2008 (reference CDC.gov National HIV Surveillance System), and, ideally, should have been included in the sample. However, the voluntary nature of participation in TODES precludes a representative geographical sample. Finally, there are no adjustments made to the data for non-response, and no sampling weights are applied to create a representative sample. For these reasons, the descriptive results in this report should not be used as estimates of disease prevalence in tissue and organ donors.

Eligibility criteria imposed for TODES serves to eliminate many referrals-only records. Inclusion of these records may have allowed for a better characterization of this sub-group and contributed to future decisions regarding screening procedures. The criteria employed for the inclusion of donor records are:

1. First-person consent or third-party authorization for organ recovery, and
2. Record of infectious disease serology or test results.

A serious limitation affecting the prevalence estimates stems from the lack of standardization of infectious disease testing procedures and data records. Confirmatory testing is not required so test results are frequently a mix of screening assay and confirmatory assay results which cannot be differentiated. Positive screening test results may represent false positive or indeterminate test results which could be identified upon confirmatory testing. In the absence of confirmatory testing, these screening results will likely overestimate the prevalence rate.

One of the original objectives of TODES is to estimate HIV, HBV, and HCV incidence, if possible. However, this is not feasible for the following reasons:

1. There is one referral with HIV-positive serology. For tissue and ocular tissue donor candidates, some HIV-positive cases may have been identified early in the screening process based on medical and behavioral history and did not meet the eligibility criteria for inclusion in TODES (refer to section 2.3.2).
2. Standard incidence calculations are performed on data from serial time points, or, at a minimum, two different points in time, but serial data are not typically available for decedents referred for donation.
3. While NAT results may indicate recent infections, this new methodology was being adopted by OPOs during the period of the TODES data collection and was not consistently applied. Furthermore, OPOs do not typically receive the test results for testing performed *after* tissue recovery, as those are reported to the tissue and/or eye bank.

The many limitations and inherent biases of the data captured by TODES preclude the use of the study findings for policy decisions. However, all of the limitations, biases, and data quality issues noted above could be minimized by a prospective study design. A prospective design would allow for use of a standardized protocol for screening procedures including use of confirmatory testing, NAT, records for all referrals (rather than records only for successful cases), a single donation ID, a reconciliation process for questionable variables, and statistical sampling of participating sites.

4.2 Recommendations

4.2.1 Confirmation of Screening Test Results

Confirmatory testing to eliminate false positive test results would potentially increase the availability of organs. It would also allow for improved accuracy of the prevalence of infection and associated donor risk factors.

In 2011, proposed new guidelines from the PHS regarding donor testing for HIV, HCV, and HBV were released for public comment in the *Federal Register* (CDC-2011-0011-0092, regulations.gov). The AST and other advocacy groups raised questions about the interpretation of screening test results and the need for OPOs to develop processes and standardized algorithms for confirming these results. In addition, they felt that confirmation of positive results should take place regardless of whether or not the transplant goes forward to better inform understanding of the utility of the tests and the true prevalence of HIV, HBV, and HCV in donors.

4.2.2 Design of Future Studies

The observations resulting from the retrospective TODES data will undoubtedly inform the design of future studies of organ and tissue donors. Such studies should consider a

prospective design that includes robust specifications for risk factor screening; infectious disease testing, including confirmatory testing and NAT; and demographic variables of interest. A prospective study would require at least some participating organizations to implement donor screening, management, testing, and/or data management procedures that differ from their usual processes, in order to provide data that can address the research questions.

Ensuring the quality of the data will require decisions to be made about the uses of the data to be collected. If the data are to be used to support proposed changes in policy, for instance, only a small amount of missing and non-validated data would be allowed. More detailed test results, including confirmatory testing, and possibly standardized testing algorithms, would also be necessary. In addition, databases at the participating organizations built for business purposes would need some redesign in order to support the scientific objectives of the study, even if the modifications were not permanently built into the system.

Although a statistical sample of participating sites would be optimal, a convenience sample may have to be used. Achieving a broadly representative sample of participating organizations would probably not be feasible due to the tremendous variability in size, geography, demographics, technical services, and referring institutions of these facilities across the U.S.

To eliminate the duplication of records for donors of multiple donation types (organs, tissues, and eye), the utilization of a single donation ID and one donor record across multiple organizations would be optimal for research purposes. Unlike blood donors who receive one ID number for each donation, an organ and tissue donor may receive multiple IDs: unique donor IDs from each organ recovered and each tissue and ocular tissue bank that processes and distributes tissue from that donor. In addition, it will be important to consistently capture the reason for donor ineligibility, as well as demographics, behavioral risk, and test results for "referrals-only" at all participating sites to allow for a thorough analysis of the potential donor pool, and the impact and efficacy of the various steps in the screening process.

The type of organizational flexibility needed for such studies is most likely found in organizations that already possess a research infrastructure. In addition, it may be possible to leverage ongoing research activities in the organ transplant world to inform and facilitate donation research. The developing relationships between organizations engaged in research on different aspects of organ and tissue donation and transplantation may gradually eliminate the data mismatches and missing linkages between separate databases, and build compatibility.

5. CONCLUSIONS

The overarching goals of TODES are to (1) develop a study design or framework to effectively collect and analyze demographic, screening, and infectious disease testing data obtained from deceased organ, tissue, and eye donors, including referral-only donors, in a standardized manner; (2) identify challenges to obtaining such data in a consistent and standardized format; and (3) identify limitations and sources of biases from data captured in this exploratory study.

TODES establishes the feasibility of linking donor files from multiple sources in order to create a complete, or master, donor record including demographics, test results, and risk information for donors of differing donation types. In addition, it provides information for referral-only donors from a limited number of OPOs that will inform the design of future data collection efforts that will require a closer examination of the potential donors eliminated at each step in the screening and qualification process. The data management methods and analytical tools developed during this exploratory study will provide useful information for the design of future studies.

TODES also identifies many of the challenges inherent to the collection of data describing tissue and organ donors, and underscores the need for standardized data collection efforts to provide reliable prevalence and incidence estimates for infectious disease markers and their risk factor correlates. Gaps in current practices in screening and testing of donors for infectious agents, including lack of standardized testing algorithms, variability in assay performance characteristics, inconsistent use of confirmatory/supplemental testing, and failure to identify recent infections, limits the ability to compare and interpret existing test results. Data collected to support business operations and to facilitate donor-recipient matching are too limiting to address the full scope of relevant research questions now and in the near future. Considering the sample size requirements and the volume of data necessary to capture and analyze relatively rare events, comprehensive, accessible electronic data systems are an absolute requirement. Finally, retrospective data may fail to reflect the impact of the most recent guidelines for donor screening and related transplantation practices.

For these reasons, future studies should consider: a prospective design with robust specifications for risk factor screening (e.g., standardized screening process/risk questionnaire and testing of all potential donors regardless of initial screening test results); infectious disease testing (e.g., NAT, serologic assays, and confirmatory/supplemental testing following positive screening test results); and demographic variables of interest. The resulting data will support accurate risk assessments, optimize testing strategies, and inform donor screening policies.

Since 1989, numerous prospective studies related to blood banking and transfusion medicine have been conducted as part of the ongoing Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health. REDS-III has established scientific approaches to assess the risks of contracting transfusion-transmitted infectious agents and has developed several statistical models, including a robust method for estimating incidence of HIV infection in blood donors under various scenarios. Estimates derived from these models are used as part of current transfusion medicine practice to inform potential recipients of blood products of the risks of acquiring known transfusion-transmitted infections. These estimates are also key to cost-effectiveness analyses conducted to evaluate current donor screening strategies (https://reds-iii.rti.org/Accomplishments.aspx).

REDS-III also contributes to mitigating transfusion-transmitted infectious risks through evaluation and implementation of improved donor screening methodologies. For instance, the risks of acquiring HIV or HCV infection through transfusion have decreased from about 1:200,000-300,000 donations to 1:1.5-2.0 million donations over the past 15 years, with much of the decline attributable to the implementation of NAT based on data from REDS-III protocols and analysis of comprehensive donor-donation data captured from participating blood centers.

Consequently, REDS-III has informed regulatory decision-making and public health policies over the last quarter of a century. One recent example is the Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study which demonstrated the feasibility of establishing a centralized, representative, national surveillance effort for known transfusion-transmissible infections (TTI) and their risk factors. The study contributed to the development of a TTI national monitoring system established by the FDA in 2015, which collects data on HIV and Hepatitis B and C for approximately 60% of the Nation’s blood supply.

REDS-III has generated nearly 200 publications and made invaluable contributions to science and public health that continue to impact not only transfusion safety, but transplantation safety as well. Building upon the successful REDS-III model and the information gleaned from TODES, a series of prospective studies for tissues and organs would provide valuable benefits.

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Appendix A:
Tissue and Organ Donor Epidemiology Study (TODES)

Working Group Roster

Charlie Alexander
Chief Executive Officer
The Living Legacy Foundation of Maryland
Baltimore, MD

James Berger, MS, MT(ASCP)SBB
Senior Advisor for Blood and Tissue Policy
Office of HIV/AIDS and Infectious Disease Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Washington, D.C.

Emily A. Blumberg, MD, FAST
Professor of Medicine at the Hospital of the University of Pennsylvania
Hospital of the University of Pennsylvania
Philadelphia, PA

James Bowman, MD
Medical Director
Division of Transplantation
Health Resources and Services Administration
Rockville, MD

Scott A. Brubaker, CTBS
Senior Vice President of Policy
American Association of Tissue Banks
McLean, VA

Jennifer DeMatteo, CIC
Director, Regulations and Standards
Eye Bank Association of America
Washington, DC

Barry Eggleston
Analyst, RTI International
Research Triangle Park, NC

Richard Forshee, PhD
Associate Director for Research
Office of Biostatistics and Evaluation, CBER
Food and Drug Administration
Silver Spring, MD

Melissa A. Greenwald, MD
Acting Director
Division of Transplantation
Health Resources and Services Administration
Rockville, MD

Matthew Kuehnert, MD
Director
Office of Blood, Organ and Other Tissue Safety
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA

Michelle McClure, PhD
Biologist
Division of Human Tissues
Office of Cellular, Tissue and Gene Therapy, CBER
Food and Drug Administration
Silver Spring, MD

Lisa Newman, MSPH
TODES Project Director (for RTI)
Research Epidemiologist
RTI International
Rockville, MD

Elizabeth Phelan
ORISE Fellow
Office of HIV/AIDS and Infectious Disease Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Washington, D.C.

Timothy L Pruett, MD
Chief, Division of Transplantation
University of Minnesota
Minneapolis, MN

Debbie Seem, RN, MPH
TODES Project Director (for HHS)
Office of HIV/AIDS and Infectious Disease Policy
Office of the Assistant Secretary for Health
Department of Health and Human Services
Washington, D.C.

Nathan Sikes, BS
Programmer/Analyst
RTI International
Research Triangle Park, NC

Marian T. Sullivan MS, MPH
Senior Research Epidemiologist
RTI International
Rockville, MD

Jennifer Wainright, PhD
Research Scientist
United Network for Organ Sharing
Richmond, VA

Dan Zaccaro, MS
Analyst
RTI International
Research Triangle Park, NC

Shimian Zou, PhD
Health Scientist Administrator
Transfusion Medicine and Cellular Therapeutics Branch
DBDR, NHLBI, National Institutes of Health
Bethesda, MD

Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS)

The OPTN, established by the U.S. Congress in 1984, is a public-private partnership that links all professionals involved in the U.S. donation and transplantation system. UNOS, a non-profit, scientific and educational organization, has served as the OPTN under contract to the Health Resources and Services Administration (HRSA) since 1986. The OPTN maintains the national waiting list for matching donated organs with transplant candidates. All transplant hospitals and the 58 OPOs are members of the OPTN.

The OPTN database contains information pertaining to deceased and living donors, transplant candidates, and transplant recipients. Data are collected via electronic data collection forms, including the UNOS Deceased Donor Registration Form that is completed by OPOs. The OPTN database contains records since October 1, 1987, on all organ donation and transplantation events in the U.S.

American Association of Tissue Banks (AATB)

The AATB collects information on relevant tissue banking activities by conducting periodic annual surveys of tissue banks. The most recent survey was conducted for 2007. The survey reported on donor referral, screening, testing, and consent/authorization activities; tissue recovery, processing, storage, and distribution; and adverse outcomes.

The AATB, represented by Mr. Scott Brubaker, Senior Vice President of Policy and an expert in tissue donation, provided guidance to TODES on understanding donor data collected by its member organizations and characterizing such data with regard to the TODES objectives. AATB provided contact information for tissue recovery management staff and executive management at the OPOs and communicated with tissue banks that process tissue as well as high-volume infectious disease testing laboratories to develop a viable strategy for collecting data on tissue donors.

At AATB's invitation, the goals and objectives of TODES were presented at the Physicians' Council meeting in Arizona in 2013. The Physicians Council is composed of licensed physicians who provide medical review and approval of proposed standards, policies, and procedures related to tissue banking. The hope was that this group would promote the study in the tissue community and encourage the participation of tissue processing banks in TODES.

American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS)

AST represents approximately 2,200 physicians and health professionals dedicated to improving patient care and advancing the field of transplantation through research, education, and training. ASTS is a membership organization of approximately 1,800 transplant surgeons dedicated to advancing transplant surgery through advocacy, education, and training.

The study expert consultants, Emily Blumberg, M.D., F.A.S.T., and Timothy Pruett, M.D. represented AST and ASTS, respectively. Dr. Blumberg, a Professor of Medicine in the Division of Infectious Diseases at the Perelman School of Medicine at the University of Pennsylvania, is their Director of Transplant Infectious Diseases and the Infectious Diseases Fellowship Program Director. She is former chair of the OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee and has been extensively involved in the development of guidelines for the prevention of donor-derived infections to solid organ transplant recipients. In this role, she participated in several consensus conferences regarding testing (including NAT) and other strategies for prevention of disease transmission (e.g., donor-derived tuberculosis guidelines).She is a member of the HHS Advisory Committee on Blood and Tissue Safety and Availability.

Dr. Pruett is recognized worldwide as an expert in transplantation safety. He is the Professor and Chief of Transplantation at the University of Minnesota. He serves as a member of the Board of Directors of LifeNet Health, Inc, and an Advisor of HemoShear, LLC. His research interests have focused primary on infections in transplant recipients and, in particular, the interactions of the viral hepatides and the transplanted liver. Dr. Pruett is a national leader in raising awareness of organ donation, addressing ethics questions, and maximizing the yield and safety of donated organs. He completed the leadership cycle for the United Network for Organ Sharing, including serving as President. He is a council member of the American Society of Transplant Surgeons and serves on the Transplant Advisory Committee and the American Board of Surgery. Dr. Pruett has over 200 publications, most on transplant-related issues and infections, and has a long-standing interest in access to care in international health settings. Both Dr. Blumberg and Dr. Pruett served as consultants on the project and as members of the Working Group.

HHS Cross-agency Team

The HHS cross-agency team formed the core of the TODES technical WG. Membership was specified by OASH and included OASH staff; and staff from the CDC Division of Healthcare Quality Promotion; NIH Transfusion Medicine and Cellular Therapeutics Branch; FDA Office of Cellular, Tissue and Gene Therapies and Office of Biostatistics and Epidemiology; and HRSA Division of Organ Transplantation.

Eye Bank Association of American (EBAA)

EBAA annually collects and publishes donor statistics on all 76 U.S. and ten international member eye banks. These data are collected electronically from the eye banks and include basic donor demographics, infectious disease test results, and cause of death. Their yearly *Eye Banking Statistical Report* provides a nearly complete picture of eye banking activities in the U.S. Since 2011, the eye banks have submitted data online using EBAA Connect, a real-time, web-based reporting and analytics tool. Strategies for obtaining donor data from eye banks were discussed with Ms. Jennifer DeMatteo, EBAA's Director of Regulations and Standards. Ms. DeMatteo provided a list of Eye Banks by donor volume and contacted executive directors of the eye banks to introduce the project and notify them that they may be contacted for participation in the study.

American Association of Organ Procurement Organizations (AOPO)

AOPO provides support, resources and information to member OPOs to help them save lives through organ and tissue donation. OPOs are responsible for coordinating the organ donation process within their federal-designated service areas (DSAs).

A discussion was held with Mr. Elling Eidbo, Chief Executive Officer, to identify a sample of OPOs to contact to collect characterizing information. This information included organ and tissue donation processes and resulting data, those that perform NAT testing, and those with more of a research focus.

Appendix B:
Study Protocol and Manual of Procedures

Manual of Procedures (MOP)

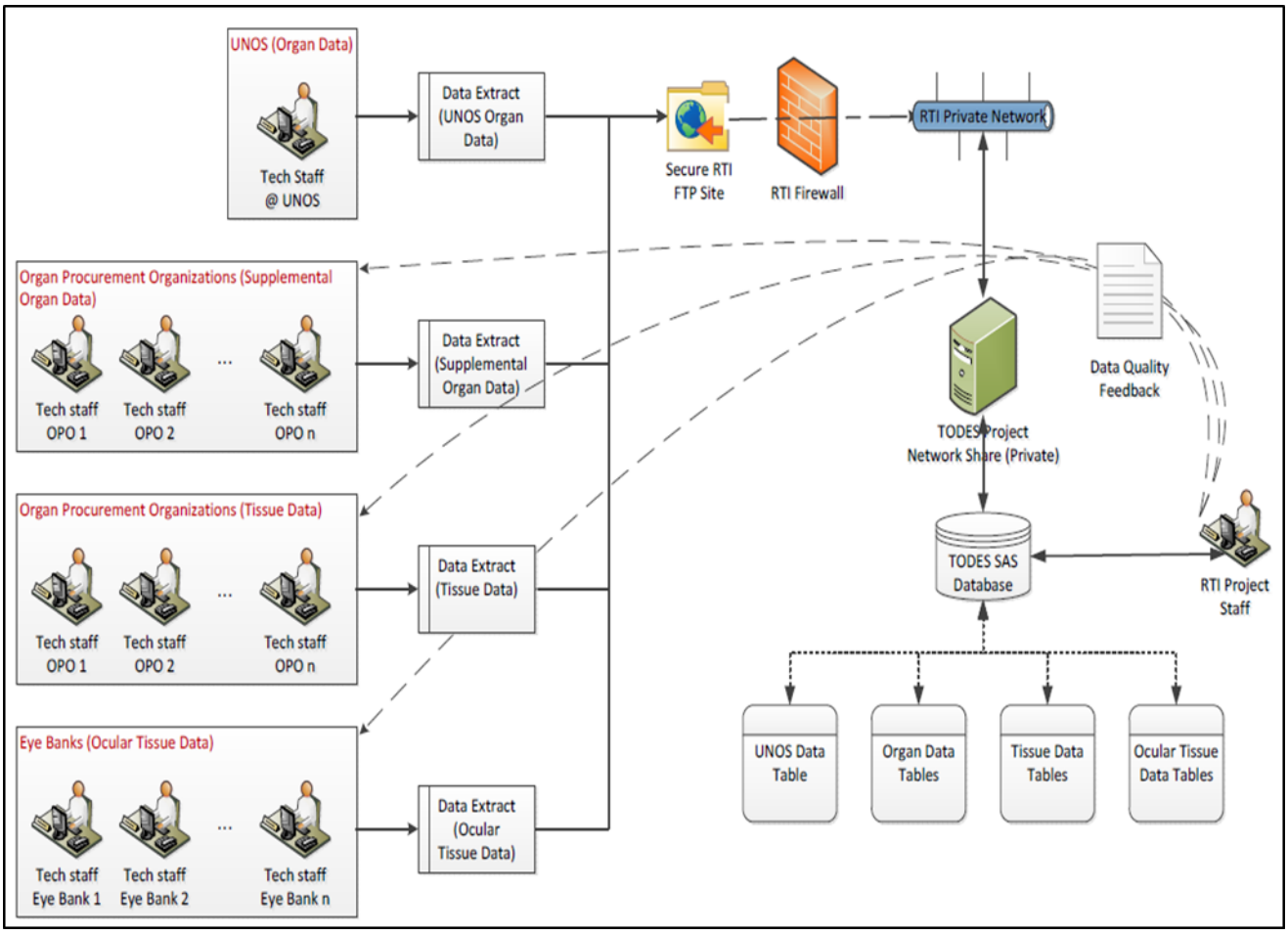
A MOP typically is used by study participants and written prior to study implementation. It serves as a guide that describes the steps of the study, such as eligibility criteria, study flow, and data collection and submission procedures. Because TODES was more of an exploratory study, the MOP was developed and used as an internal guide for revising various processes and quality assurance steps over the course of the study to reflect the final procedures. The contents include the following sections:

- **Regulatory Activities** – Described regulatory approvals including IRB, OMB and DUAs. Section 2.3.1
- **Data Flow** – Characterized the steps to extract, transmit, validate, and store data.
- **Data Dictionary** – Defined the data variables to be collected. Section 2.3.3
- **Data Collection** – Described the donor data to be collected, tracked, managed, and stored. Section 2.4

Data Flow

The data flow diagram in Figure B-1 characterizes the steps used to extract, transmit, validate, and store the donor data. The steps included extraction from the participants' in-house database; uploading to a secure data transfer site; storing the data to temporary SAS™ (Statistical Analysis Software version 9.4, SAS Institute, Inc., Cary, NC) tables for validation checks and resolution; and querying the participant for any required clarification. The final step involved moving the validated data to a master SAS™ database for analysis.

Figure B-1. Data Flow Diagram



Appendix C:
Data Dictionary

1. Introduction — Inclusion Criteria

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to average 85 minutes for OPOs or 55 minutes for Eye Banks per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0990-0427). Do not return the completed form to this address. Expiration date: 04/30/2018.

A. Organ, Tissue, Eye Donors

Inclusion Criteria:

- Must have serology tests performed* (sent for testing by OPO)
- Must have consent or authorization for organs
  - May also have consent or authorization for tissues and/or eyes

Donor fits into one of the following categories:

- Organ donor (Use tab #2, "2. Organ Donor OPO Supplemental," to determine which data variables to provide)
- Organ and tissue** donor (Use tabs #2 and #4 to determine which data variables to provide) organ and eye ** donor (Use tabs #2 and #4 to determine which data variables to provide) organ and tissue** and eye ** (Use tabs #2 and #4 to determine which data variables to provide)
- Also would like NAT results if done and feasible to collect

**At least one (tissue) (eye) recovered with intent to transplant

B. Organ Donor Referral - Tissue, Eye Donors

Inclusion Criteria:

- Must have serology tests performed* (sent for testing by OPO)
- Must have consent or authorization for organs
  - May also have consent or authorization for tissues and/or eyes

Donor fits one of the following categories:

- Organ referral (Use tab #3, "3. Organ Referral Data," to determine which data variables to provide)
- Organ referral and tissue** donor (Use tabs #3 and #4 to determine which data variables to provide)
- Organ referral and eye **donor (Use tabs #3 and #4 to determine which data variables to provide)
- Organ referral, and tissue** and eye ** donor (Use tabs #3 and #4 to determine which data variables to provide)
- Also would like NAT results if done and feasible to collect

**At least one (tissue)(eye) recovered with intent to transplant

C. Tissue, Eye Donors

Inclusion Criteria:

- Must have consent or authorization for tissues and/or eyes
- At least one (tissue)(eye) recovered with intent to transplant
- Must have serology tests performed*

Donor fits one of the following categories:

- Tissue donor (Use tab #4, "4. Tissue-Eye Donor Data ," to determine which data variables to provide)
- Tissue and eye donor (Use tab #4 to determine which data variables to provide) (for the donors the OPO does work up)

2. Organ Donor OPO Supplemental

Data Dictionary of TODES Variables	
Supplemental Organ Donor Information	
Version 1.4, 6/16/2015	**OMB # 0990-0427, Expiration Date 04/30/2018**

The data variables listed below are variable information that is beneficial to the TODES Study. This particular tab lists variables that provide supplemental information about donors that have UNOS information. Each of the variables should be filled in if the organization has the value available.

Extracted Data should capture data from the years 2009, 2010, 2011, 2012, and 2013. Only one record per donor is expected.

There are a number of ID variables listed: UNOS ID, Local ID, Tissue ID, Eye ID. Each of the variables should be filled in if the organization has the value. The TODES study is making a comprehensive effort to link data from UNOS and extracts of OPO organ data, tissue data, and eye data. Each of these *may* come from different organizations yet perhaps not. The TODES Study asks that the ID variables be filled in for help in matching disparate data.

Variable Name	Values	Description	Type	Length	Notes
OrganizationID		**ID of the Reporting Organization**	String	2	Value assigned by RTI
UNOSID		**UNOS ID**	String	25	The UNOS ID of the deceased.
LocalID		**ID Assigned to the Donor by the OPO**	String	25	This could be the referral ID, whatever the local system uses to track the initiating referral and donation.
TissueID		**Donor ID for Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Tissue. This could be a Tissue Bank ID.
EyeID		**Donor ID for Eye Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Eye Tissue. This could be an Eye Bank ID.
DateOfDeath		**Date of Death**	Date	10	Format: MM/DD/YYYY
TimeOfDeath		**Time of Death**	Time	10	Format: hh:mm AM
AgeAtDeath_Years		**Age in Years only**	Numeric	99	

Variable Name	Values	Description	Type	Length	Notes
AgeAtDeath_Months		**Age in Months if not available in years**	Numeric	99	
Sex		**Sex of the Donor**	String	1	
	F	Female			
	M	Male			
	U	Unspecified			
TissueDonor		**Were one or more tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			
EyeDonor		**Were one or more eye tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			
ASSAY RESULTS –List below applies to all donors and qualified referrals. Include all of the following assay results. Include any and all repeat test results for each assay, if available.					
Blood Sample Collection #1					
BloodSampleCollectionDate_1		**Date of Sample Collection #1**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_1		**Time Of Sample Collection #1**	Time	8	Format: hh:mm AM
SampleComments_1		**Comments about Sample Collection #1**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_1		**Sample #1 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			

Variable Name	Values	Description	Type	Length	Notes
HBsAg_Screening_1		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_1		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_1		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_1		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHIV_1_2_Screening_1		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_1		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_Combination Assay_1		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_1		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_ConfSupp_1		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_1		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_1		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_1		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HBV_Test_1		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_1		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
Blood Sample Collection #2					
BloodSampleCollectionDate_2		**Date of Sample Collection #2**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_2		**Time Of Sample Collection #2**	Time	8	Format: hh:mm AM
SampleComments_2		**Comments about Sample Collection #2**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_2		**Sample #2 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			

Variable Name	Values	Description	Type	Length	Notes
HBsAg_Screening_2		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_2		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_2		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_2		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHIV_1_2_Screening_2		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_2		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_Combination Assay_2		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_2		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_ConfSupp_2		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_2		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_2		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_2		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HBV_Test_2		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_2		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
Blood Sample Collection #3					
BloodSampleCollectionDate_3		**Date of Sample Collection #3**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_3		**Time Of Sample Collection #3**	Time	8	Format: hh:mm AM
SampleComments_3		**Comments about Sample Collection #3**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_3		**Sample #3 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			

Variable Name	Values	Description	Type	Length	Notes
HBsAg_Screening_3		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_3		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_3		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_3		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHIV_1_2_Screening_3		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_3		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_Combination Assay_3		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_3		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_ConfSupp_3		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_3		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_3		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_3		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HBV_Test_3		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_3		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

3. Organ Referral Data

Data Dictionary of TODES Variables					
Organ Donor/Referral Information					
Version 1.4, 6/16/2015					**OMB # 0990-0427, Expiration Date 04/30/2018**
The data variables listed below are variable information that is beneficial to the TODES Study. This specific tab lists desired variable information for referrals to the OPO that did not qualify for inclusion into UNOS submitted data. Each of the variables should be filled in if the organization has the value available. **Extracted Data should capture data from the years 2009, 2010, 2011, 2012, and 2013. Only one record per referral is expected.** **There are a number of ID variables listed: UNOS ID, Local ID, Tissue ID, Eye ID. Each of the variables should be filled in if the organization has the value. The TODES study is making a comprehensive effort to link data from UNOS and extracts of OPO organ data, tissue data, and eye data. Each of these *may* come from different organizations yet perhaps not. The TODES Study asks that the ID variables be filled in for help in matching disparate data.**					

Variable Name	Values	Description	Type	Length	Notes
OrganizationID		**ID of the Reporting Organization**	String	2	Value assigned by RTI
LocalID		**ID Assigned to the Donor by the OPO**	String	25	OPO ID
DonorID		**Donor ID, Could be Referral ID**	String	25	This could be the referral ID, whatever the local system uses to track the initiating referral and donation.
TissueID		**Donor ID for Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Tissue. This could be a Tissue Bank ID.
EyeID		**Donor ID for Eye Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Eye Tissue. This could be an Eye Bank ID.
DateOfDeath		**Date of Death - Asystolic**	Date	10	Format: MM/DD/YYYY
TimeOfDeath		**Time Of Death - Asystolic**	Time	8	Format: hh:mm AM

Variable Name	Values	Description	Type	Length	Notes
PrimaryCOD		**Primary Cause of Death**	String	22	
	Anoxia				
	Cerebrovascular /Stroke				
	Head Trauma				
	CNS Tumor				
	Other Specify				
PrimaryCOD_Other Specify		**Other Cause of Death Specified**	String	50	
AgeAtDeath_Years		**Age in Years only**	Numeric	99	
AgeAtDeath_Months		**Age in Months if not available in years**	Numeric	99	
Sex		**Sex of the Donor**	String	1	
	F	Female			
	M	Male			
	U	Unspecified			
FirstPersonDonorDesignation			String	1	
	Y	Yes			
	N	No			
NOK_OrOtherAuthorization		**Organ**	String	1	
	Y	Yes			
	N	No			
TissueDonor		**Were one or more tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			
EyeDonor		**Were one or more eye tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			

Variable Name	Values	Description	Type	Length	Notes
HighOrIncreasedRisk			String	2	
	Y	Yes			
	N	No			
	ND	Not Determined			
ASSAY RESULTS –List below applies to all donors and qualified referrals. Include all of the following assay results. Include any and all repeat test results for each assay, if available.					
Blood Sample Collection #1					
BloodSampleCollectionDate_1		**Date of Sample Collection #1**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_1		**Time Of Sample Collection #1**	Time	8	Format: hh:mm AM
SampleComments_1		**Comments about Sample Collection #1**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_1		**Sample #1 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_1		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_1		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHCV_Test_1		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_1		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_Screening_1		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_1		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_1		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_Screening_1		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_ConfSupp_1		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_1		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_1		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HIV1_HCV_Test_1		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HBV_Test_1		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_1		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
Blood Sample Collection #2					
BloodSampleCollectionDate_2		**Date of Sample Collection #2**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_2		**Time Of Sample Collection #2**	Time	8	Format: hh:mm AM

Variable Name	Values	Description	Type	Length	Notes
SampleComments_2		**Comments about Sample Collection #2**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_2		**Sample #2 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_2		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_2		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_2		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_2		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHIV_1_2_Screening_2		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_2		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_2		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_2		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_ConfSupp_2		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HIV1_Test_2		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_2		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_2		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HBV_Test_2		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HIV1_HCV_HBV_Test_2		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
Blood Sample Collection #3					
BloodSampleCollectionDate_3		**Date of Sample Collection #3**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_3		**Time Of Sample Collection #3**	Time	8	Format: hh:mm AM
SampleComments_3		**Comments about Sample Collection #3**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_3		**Sample #3 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_3		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_3		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHCV_Test_3		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_3		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_Screening_3		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_3		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_3		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_Screening_3		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_ConfSupp_3		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_3		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_3		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HIV1_HCV_Test_3		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HBV_Test_3		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_3		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

4. Tissue-Eye Donor Data

Data Dictionary of TODES Variables	
Tissue Donor Information	
Version 1.4, 6/16/2015	**OMB # 0990-0427, Expiration Date 04/30/2018**

The data variables listed below are variable information that is beneficial to the TODES Study. Tissue Donor data variables are listed below. Please provide the information if your organization keeps these records. Each of the variables should be filled in if the organization has the value available.

Extracted Data should capture data from the years 2009, 2010, 2011, 2012, and 2013. Only one record per donor is expected.

There are a number of ID variables listed: UNOS ID, Local ID, Tissue ID, Eye ID. Each of the variables should be filled in the organization has the value. The TODES study is making a comprehensive effort to link data from UNOS and extracts of OPO organ data, tissue data, and eye data. Each of these *may* come from different organizations yet perhaps not. The TODES Study asks that the ID variables be filled in for help in matching disparate data.

Variable Name	Values	Description	Type	Length	Notes
OrganizationID		**ID of the Reporting Organization**	String	2	Value assigned by RTI
LocalID		**ID Assigned to the Donor by the OPO**	String	25	OPO ID
DonorID		**Donor ID, Could be Organ ID**	String	25	This could be the referral ID, whatever the local system uses to track the initiating referral and donation.
TissueID		**Donor ID for Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Tissue. This could be a Tissue Bank ID.
EyeID		**Donor ID for Eye Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Eye Tissue. This could be an Eye Bank ID.
DateOfDeath		**Date of Death - Asystolic**	Date	10	Format: MM/DD/YYYY
TimeOfDeath		**Time Of Death - Asystolic**	Time	8	Format: hh:mm AM
DateLastTimeSeenAlive		**Date Last Time Seen Alive**	Date	10	Format: MM/DD/YYYY
TimeLastTimeSeenAlive		**Time Last Time Seen Alive**	Time	8	Format: hh:mm AM

Variable Name	Values	Description	Type	Length	Notes
AgeAtDeath_Years		**Age in Years only**	Numeric	99	
AgeAtDeath_Months		**Age in Months if not available in years**	Numeric	99	
PrimaryCOD		**Primary Cause of Death**	String	22	
	Anoxia				
	Cerebrovascular /Stroke				
	Head Trauma				
	CNS Tumor				
	Other Specify				
PrimaryCOD_Other Specify		**Other Cause of Death Specified**	String	50	
Sex		**Sex of the Donor**	String	1	
	F	Female			
	M	Male			
	U	Unspecified			
FirstPersonDonorDesignation			String	1	
	Y	Yes			
	N	No			
NOK_OrOtherAuthorization		**Tissues and/or eyes**	String	1	
	Y	Yes			
	N	No			
TissueDonor		**Were one or more tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			
EyeDonor		**Were one or more eye tissues recovered with the intent to transplant?**	String	1	
	Y	Yes			
	N	No			

Variable Name	Values	Description	Type	Length	Notes
ASSAY RESULTS –List below applies to all donors and qualified referrals. Include all of the following assay results. Include any and all repeat test results for each assay, if available.					
Blood Sample Collection #1					
BloodSampleCollectionDate_1		**Date of Sample Collection #1**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_1		**Time Of Sample Collection #1**	Time	8	Format: hh:mm AM
SampleComments_1		**Comments about Sample Collection #1**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_1		**Sample #1 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_1		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_1		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_1		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHCV_ConfSupp_1		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_Screening_1		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_1		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_1		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_1		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_ConfSupp_1		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_1		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_1		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_1		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HBV_Test_1		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_1		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
Blood Sample Collection #2					
BloodSampleCollectionDate_2		**Date of Sample Collection #2**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_2		**Time Of Sample Collection #2**	Time	8	Format: hh:mm AM
SampleComments_2		**Comments about Sample Collection #2**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_2		**Sample #2 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_2		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
HBsAg_ConfSupp_2		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_2		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_ConfSupp_2		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_Screening_2		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHIV_1_2_ConfSupp_2		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_2		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_2		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_ConfSupp_2		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_2		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HCV_Test_2		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_2		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HBV_Test_2		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_2		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
Blood Sample Collection #3					
BloodSampleCollectionDate_3		**Date of Sample Collection #3**	Date	10	Format: MM/DD/YYYY
BloodSampleCollectionTime_3		**Time Of Sample Collection #3**	Time	8	Format: hh:mm AM
SampleComments_3		**Comments about Sample Collection #3**	String	255	Please do not exceed 255 characters with your comments about the sample.
SampleHemoDiluted_3		**Sample #3 Was Hemodiluted**	String	1	
	Y	Yes			
	N	No			
HBsAg_Screening_3		**HBsAg Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HBsAg_ConfSupp_3		**HBsAg Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHCV_Test_3		**Anti-HCV Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHCV_ConfSupp_3		**Anti-HCV Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_Screening_3		**Anti-HIV1/2 Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHIV_1_2_ConfSupp_3		**Anti-HIV1/2 Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
HIV_Ag_Ab_CombinationAssay_3		**HIV Ag/Ab combination assay**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
AntiHBc_Screening_3		**Anti-HBc (total) Screening Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
AntiHBc_ConfSupp_3		**Anti-HBc Confirmatory/Supplemental Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_Test_3		**NAT (HIV-1) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HCV_Test_3		**NAT (HCV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_Test_3		**NAT (HIV-1/HCV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

Variable Name	Values	Description	Type	Length	Notes
NAT_HBV_Test_3		**NAT (HBV) Test**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			
NAT_HIV1_HCV_HBV_Test_3		**NAT (HIV-1/HCV/HBV) Test**	String	7	
	NEG	Negative			
	POS	Positive - Generic			
	POS HIV	Tested Positive for HIV			
	POS HBV	Tested Positive for HBV			
	POS HCV	Tested Positive for HCV			
	INC	Inconclusive			
	TNP	Test Not Performed			
	NULL or (blank)	No Record Available OR Not Specified			

5. Additional Tests

Data Dictionary of TODES Variables					
Additional Test Information					
Version 1.4, 6/16/2015					**OMB # 0990-0427, Expiration Date 04/30/2018**
The data variables listed below are variable information that is beneficial to the TODES Study. List any tests conducted on the donor/referral that are not listed in the Assay tests in the previous tabs. Each of the variables should be filled in if the organization has the value available. **Extracted Data should capture data from the years 2009, 2010, 2011, 2012, and 2013. Multiple records per donor can occur.** **There are a number of ID variables listed: UNOS ID, Local ID, Tissue ID, Eye ID. Each of the variables should be filled in the organization has the value. The TODES study is making a comprehensive effort to link data from UNOS and extracts of OPO organ data, tissue data, and eye data. Each of these *may* come from different organizations yet perhaps not. The TODES Study asks that the ID variables be filled in for help in matching disparate data.**					

Variable Name	Values	Description	Type	Length	Notes
UNOSID		**UNOS ID**	String	25	The UNOS ID of the deceased if available.
LocalID		**ID Assigned to the Donor by the OPO**	String	25	This could be the referral ID, whatever the local system uses to track the initiating referral and donation.
TissueID		**Donor ID for Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Tissue. This could be a Tissue Bank ID.
EyeID		**Donor ID for Eye Tissue if different from the LocalID**	String	25	The ID associated with the donor if the donor is donating Eye Tissue. This could be an Eye Bank ID.
NameOfTest		**Specific Name of the Test Performed on the Donor/Referral**	String	50	
TestResult		**Result of the Test Performed**	String	4	
	NEG	Negative			
	POS	Positive			
	INC	Inconclusive or Unknown			

Variable Name	Values	Description	Type	Length	Notes
TestComments		**Comments about the test and/or result**	String	255	Please do not exceed 255 characters with your comments about the test.
SampleHemoDiluted		**Test Sample was Hemodiluted**	String	1	
	Y	Yes			
	N	No			

6. Release Notes

Version 1.4 Update

1. Added recent burden disclosure language to inclusion criteria and OMB number including expiration date first page.
2. Modified header of each tab to appear in the printed version of each page of this document.
3. Renamed file as version 1.4 dated 06/16/2015.

Version 1.3 Update

1. Added recent OMB Number to each tab in the workbook.
2. Removed the word "Draft" from specific descriptions at the top of tabs.
3. Removed the words "Pilot" and "Draft" from the workbook title/file name.

Version 1.2 Update

1. Removed the word "Ocular" and converted every reference of "Ocular" to "Eye" across all variables and descriptions.
2. Adjusted description language to say "Were one or more tissues recovered with the intent to transplant?" on tissue donor definition variable.
3. Adjusted description language to say "Were one or more eye tissues recovered with the intent to transplant?" on eye donor definition variable.
4. Inserted the word, "if," into the sentence, "Each of the variables should be filled in if the organization has the value."
5. Inserted the description, "Tissues and/or eyes" into the NOK_OrOtherAuthorization variable.
6. Changed Date of Death description from "Asystolic Date of Death" to "Date of Death - Asystolic".
7. Changed Time of Death description from "Asystolic Time of Death" to "Time of Death - Asystolic".
8. Added Time of Death variable to the Supplemental tab to match UNOS data request.
9. Corrected "Date/Time" data types to be either "Date" or "Time" in different tabs.
10. Corrected Nat Test response of HCV to HBV, line 103 on the Supplemental tab.
11. Updated name of NAT tests to replace the word "Screening" with "Test" since NAT is not a screening test.
12. Added information to the inclusion criteria to cite which tab(s) to use for the different bucket scenarios.
13. Changed the word, "Gender" to "Sex" in variable names.

Version 1.1 Update

1. Combine Eye and Tissue into one tab.
2. Updated Cause of Death with UNOS option values.
3. Provided 3 separate entries for Sample Date Collection Date and Time variables. Added Blood to the name of the Sample Collection.
4. Added Comments for each Sample Collection.
5. Included Hemodilution identification variable with the Sample Collection sets.
6. Embedded Sample Collection Date and Time plus Comments and Hemodilution within the tests. Grouped the variables together at the beginning of each Sample Collection set.
7. Added an introductory tab with inclusion criteria.
8. Specified Date of Death as "Asystolic Death" Included in Comment. Same with Time of Death.

9. Adjusted language to be "Were one or more tissues recovered for transplant" on tissue donor definition variable.
10. Adjusted language to be "Were one or more eye tissues recovered for transplant" on ocular donor definition variable.
11. Adjusted Tissue and Eye Donor descriptions.
12. Deleted Cross Clamp Date and Time.
13. Deleted DCD Date and Time.
14. Corrected lengths of fields and data types where necessary.
15. Grouped all "Death" variables together.
16. Removed comment under DOD Last Time Seen Alive.
17. Responses for NAT duplex and triplex were modified to include "POS HIV", "POS HBC", "POS HCV". Adjusted "POS" comment to say, "Positive - Generic".
18. Deleted Tissues Recovered, Eyes Recovered variables.
19. Deleted "OneOrMoreOrgansRecWIntent" variable.