

**REPORT OF THE OPTN/UNOS
ORGAN PROCUREMENT ORGANIZATION (OPO) COMMITTEE
TO THE BOARD OF DIRECTORS**

**Minneapolis, MN
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The following report represents the OPTN/UNOS OPO Committee's deliberations and recommendations on matters considered by the Committee during its March 31, 2004 meeting.

Organ Availability Issues

1. Proposed Policy Modifications to Policy Section 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Material) and Policies 2.5.7 and 2.5.7.1 regarding documentation to accompany each organ. In June 2003, the Board of Directors accepted a resolution by the Committee that involved a significant amount of revision to Policy Section 5.0. The revision was proposed to the Board, following circulation for public comment, in order to update policy to current accepted medical practice. Subsequent to that date, the Ad Hoc Operations, Histocompatibility and Kidney/Pancreas Transplantation Committees proposed additional revisions for consideration by the Committee. These proposed revisions by the various committees, OPO Committee discussion, and final modification to policy proposal were addressed, including the issue of reuse of disposable organ packaging that was initially introduced by the ABO Joint Subcommittee.

Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials). The Ad Hoc Operations Committee proposed to delete redundant and unnecessary words and to remove the phrase "and pertinent medical data" that is detailed elsewhere in policy. The Committee agreed with the recommendations.

Policy 5.2 (Standard Labeling Specifications) and 5.2.3. The Kidney/Pancreas (KP) Transplantation Committee reported that it is often difficult to read the labels on the transport boxes either because previous labels have not been thoroughly obliterated or removed and felt that the policy should specify that the labels used be a standardized label developed by the OPTN/UNOS. The Ad Hoc Operations Committee, regarding the KP Committee recommendation, noted that not all organs are shipped in boxes. Additionally, the Ad Hoc Operations Committee questioned the last sentence of this policy in light of incoming recovery teams. The last sentence states that "The Host OPO is responsible for ensuring that each tissue or organ container is labeled appropriately." The OPO Committee felt that in the interest of consistency and safety, a standardized external label should be affixed to every organ transport container that is shipped. In addition to the UNOS telephone number currently on the label, a place for the originating OPO telephone number should be added. It was also recommended that the current adhesive to the UNOS label should be made more adherent.

Policy 5.3 (Documentation). The Histocompatibility Committee suggested that the subcommittee delete the wording related to reading sheets, antibody screens and regional crossmatch results from Policy 5.3. The reading sheets from HLA tissue typing tests are extremely detailed involving multiple pages and can be almost impossible to accurately duplicate in another laboratory, particularly the case of typings done using molecular techniques. The reading sheets rarely provide any additional useful information other than that which is included in the HLA typing report. The reference to antibody screens could be interpreted to mean HLA antibody screens done on local patients, and reading sheets and reports are both irrelevant to any other center to which an organ may be transported. Finally, in those regions that use regional crossmatch trays, the results are usually entered directly into UNetsm or transmitted to other centers in that region using electronic means. If a region wishes to share the results of regional crossmatch trays by providing hard copies or faxes, then it is something that could be

included in a region-specific policy. It is rare that any of these sheets are currently being provided, but it was not an absolute requirement in the previous policy. The Ad Hoc Operations Committee proposed to include only the requirements of ABO results in this policy since the other requirements noted are not always available, as indicated by the Histocompatibility Committee comments regarding reading sheets, or are specified as required in other sections of policy. It was noted that the documentation of blood transfusions is included on the donor information form completed by the OPO and included with each organ. With regard to documentation sent with the organ, the OPO Committee noted that it is addressed in Policy 5.5.5 and 2.5.7.1, and that HLA typing is entered into UNetsm making it available to anyone involved. The Committee supported leaving in separate documentation requirement related to ABO to emphasize that copies of the ABO results should be provided in all circumstances.

Policy 5.5 (Standard Organ Packaging Specifications). The ABO Joint Subcommittee opined that the re-use of disposable organ packages should be prohibited and requested that the OPO Committee review policy 5.5 regarding this issue. The Committee conducted a survey of the organ specific and pediatric committees regarding the re-use of transport boxes and the use of coolers and reviewed documentation by the Policy Compliance Department regarding specific packaging and shipping incidences that occurred in the past year. The survey responses were then reviewed, which was followed by a request to the organ-specific and Pediatric committees to respond to the Committee recommendations below.

- The re-use of disposable transport boxes should be prohibited due to the integrity of the box being compromised during the removal of labels.
- Coolers should be allowed for non-commercial transporting when the organ recovery team is taking the organ from the donor hospital to the transplant center. The re-use of coolers should be allowed. All labels from the previous donor organ must be removed before re-using the cooler.
- If the organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the organ should be packaged in a disposable transport box, as outlined in Policy 5.5 (Standard Organ Package Specifications), to comply with OSHA and federal transportation regulations that would require a sealed, leak-proof container.

The Liver/Intestine Transplantation Committee, at its February 5, 2004 meeting, voted unanimously that the recommendations of the OPO Committee would apply to transport of livers. The Pediatric Transplantation Committee, at its January 21, 2004 meeting, reviewed and agreed with the OPO Committee's recommendations.

Policy 5.5.1 refers to the outer container of the organ shipping box. The current policy states that the fiber outer container must be wax impregnated. Most organ shipping boxes currently used are wax coated. The Committee is unaware of any complaints by OPOs or transplant programs about the outer container and supported the language change.

Policy 5.5.2 regarding shipping container specifications to maintain the temperature of the organ. Organs are not packaged with temperature monitors or recorders. The Committee agreed that the policy implies that it can proven the temperature of the organ can be supplied and propose striking that language in the policy.

Policy 5.5.6 regarding the red top tube of blood to accompany organs and tissue typing material for ABO confirmation. The Kidney/Pancreas Transplantation Committee agreed that the provisions should apply to each organ and tissue typing material being transported and should so specify to ensure that adequate tissue typing materials are made available. In addition, staff would not be forced to search the container for the tissue typing material. The Ad Hoc Operations Committee rejected the proposed wording modification of the Kidney/Pancreas Transplantation Committee on the grounds that the modifications did not seem necessary or change the intent of the policy. And the proposed language may be redundant since this is a requirement found elsewhere in policy. The OPO Committee supported the Kidney/Pancreas Transplantation Committee proposal.

The Committee then discussed the Michigan State University School of Packaging report, which outline the thermal insulation properties tests that were conducted using R-factor and heat penetration rate criteria for rating four organ shipping boxes (Exhibit A). The Committee expressed interest in establishing a minimum performance standard for organ shipping boxes to meet that would maintain the temperature of the organ within a specified degree range for an established period of time and will draft a study to be conducted by the School. Once criteria are established, it was agreed that shipping boxes should be required to be tested or certified by an independent body, such as an academic institution, as meeting the minimum accepted standards. The Committee also discussed further pursuing the investigation of commercial carrier or federal transport standards that relate to hazardous materials with regard to box integrity, and the elements that relate to adequate packaging, to ensure minimum required standards are met.

Policies 2.5.7 and 2.5.7.1 regarding documentation to accompanying each organ. The ABO Joint Subcommittee had recommended that the OPO Committee develop a standard form, which would document the informed acceptance by the transplant surgeon at the transplant center of an organ from an OPO. This form would document a verification of all donor information provided and copies would be provided for the OPO and accepting transplant surgeon. Much concern was expressed regarding the logistical complexity in implementing this request with one example being the various models employed by OPOs to import organs. It was also felt that the request was made in context of ABO documentation, and that since that time other procedures have been developed to ensure verification of ABO source documentation. The Committee agreed that the OPO should continue to provide a hard copy of the donor information with each organ as required by Policy 2.5.7.1 and maintain documentation that the information that was provided. In addition, the Committee recommended that ABO, serology and medical/social history form documentation be added to 2.5.7.1 as a current standard of practice.

After lengthy discussion and careful consideration of the various reports and committee recommendations, the OPO Committee voted 14 for, 0 against, 0 abstentions to submit the following proposed policy modifications for public comment.

5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS. The following policies address standardized packaging of transplant organs and tissue typing materials to be transported. When the organ is procured and labeled, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO and ~~pertinent medical data~~ on the container label and within the donor's documentation. Each OPO shall establish and implement an ~~an~~ ~~internal~~ procedure for obtaining verification of donor ABO data and ~~pertinent medical data~~ by an individual other than the person initially performing the labeling and documentation requirements put forth in OPTN/UNOS Policy 5.2 and 5.3. The OPO shall maintain ~~records~~ documentation that such separate verification has taken place and make such documentation available for audit.

5.1 SPECIMEN COLLECTION AND STORAGE. Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or UNOS. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or UNOS. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

5.2 STANDARD LABELING SPECIFICATIONS. The Host OPO shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed OPTN/UNOS standardized external organ container secure label (provided by UNOS), with the OPTN Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The OPO shall label each specimen within the package in accordance with OPTN/UNOS policy. The Host OPO is responsible for ensuring that each tissue or organ container is labeled appropriately.

5.2.1 The Host OPO is responsible for ensuring that the OPTN Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the organ prior to transport.

5.2.2 Each separate specimen container of tissue typing material must have a secure label with the OPTN Donor I.D. Number, donor ABO type, date and time the sample was procured, and the type of tissue. The Host OPO is responsible for labeling the materials appropriately.

5.2.3 The Host OPO is responsible for fixing to the transport container the standardized OPTN/UNOS label completed with the OPTN Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number provided by UNOS.

5.3 DOCUMENTATION. ABO results must be provided by the Host OPO. ~~In all circumstances during which an organ is transported, copies or facsimiles of all reading sheets and reports pertaining to serologies, tissue typing, antibody screens, and regional crossmatch results must be provided after testing and included with any specimen for future testing. Documentation of donor blood product transfusions within the previous 72 hours, due to the fact that transfusions may impact the accuracy of testing, should be made available to the histocompatibility laboratories.~~ Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.

5.4 PACKAGING. In all circumstances during which an organ is transported, the Host OPO is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organs. Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport.

5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS. The re-use of disposable transport boxes is prohibited. If the organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the organ with them from the donor hospital to the transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed before re-using the cooler. The standard package used by OPTN members must have the following properties:

5.5.1 A corrugated, wax ~~impregnated~~ coated fiber outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.

5.5.2 Inside the moisture resistant outer-container, 1-1/2" thick, expanded polystyrene insulated container or its R-factor equivalent must be used ~~to maintain the temperature of the organ.~~ A closed plastic liner must be placed between the outer container and the polystyrene insulated container to encase the ice.

[No changes from 5.5.3 through 5.5.5]

5.5.6 Accompanying ~~the each~~ organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

[No changes from Policy 5.7 through 5.7.3]

2.5.7 ~~Properly packaging ed of all~~ Properly packaged paperwork containing complete donor information ~~shall~~ to accompany each organ to the recipient institution.

2.5.7.1 Written documentation accompanying each organ must include:

- ABO typing source documents
- Serology results
- Medical/Social History form
- Donor evaluation;
- Complete record of donor maintenance;
- Documentation of consent; and
- Documentation of organ quality

2. Proposed Modifications to Policy Section 4.0 Regarding Human Immune Deficiency Virus (HIV), Human Pituitary Derived Growth Hormone (HPDGH), and Human T-Lymphotropic Virus Type 1 (HTLV-1), and Proposed New Policy Regarding Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin. Policy 4.0 involves ongoing discussions by the Committee and consists of three segments related to the potential transmission of donor-related diseases to the recipient. The first segment address potential donors whose screening tests are positive for HIV and individuals who have received human pituitary-derived growth hormone. The second segment addresses potential donors whose screening tests are positive for HTLV I/II. In both of these segments, discussion focuses on whether these organs should be used for transplantation and whose decision should it be to use these organs. The third segment is a separate discussion about the development of a reporting process for potential or actual transmission of diseases or medical conditions thought to be of donor origin by the OPO or transplant center. The proposed new policy contains an inclusive list of reportable diseases and medical conditions, including malignancies, as well as a reporting process.

Policies 4.1 (Screening Potential Donors for HIV) through 4.5 (Human Pituitary Derived Growth Hormone). In the process of reviewing policy related to HTLV at its September 15, 2003, meeting, the Committee concluded that Policies 4.0 through 4.5 should be reviewed and modified to reflect current accepted practice. Subsequently, a joint subcommittee was formed with representatives from the OPO, organ specific and Pediatric committees, utilizing the expertise of Jay Fishman, MD, Infectious Disease Unit, Massachusetts General Hospital. The Joint Subcommittee met by conference call on January 8, 2004 to discuss if HIV-positive donor organs should be considered for transplantation into HIV-positive candidates and if individuals who have received Human Pituitary Derived Growth Hormone (HPDGH) should continue to be excluded as potential donors. Both circumstances allow for exceptions to policy when considering non-renal organs involving extreme medical emergencies. The policy related to HIV includes additional language that allows only those potential donors who have not been tested for HIV to be considered. It was stated that some transplant centers that list HIV-positive candidates would consider accepting organs under certain circumstances from HIV-positive recipients. A search of the OPTN database for cases where HIV-positive organs were transplanted into HIV-positive recipients resulted in none being identified. It was then brought to the subcommittee's attention that the OPTN Final Rule excluded organ recovery from HIV-positive patients.

OPTN Final Rule §121.6 (b) HIV. The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.

With regard to HPDGH, members of the subcommittee questioned whether HPDGH was still available and believed it to be replaced by a synthetic version. It was stated that concerns might be the individual may have received HPDGH many years prior but may not have converted, but that the likelihood of contracting Creutzfeldt-Jacob disease was probably minimal. Cases that were identified related to a few tissue donors that were identified 20 or more years ago. It was noted that the Donor Medical/Social History Form includes a question on HPDGH. The Joint Subcommittee was not wholly supportive of eliminating policy that excludes these individuals due to lack of information, but agreed that more supportive of language stating that acceptance of an organ from a patient that received HPDGH should be at the discretion of the potential recipient and transplant surgeon.

The Joint Subcommittee's report and other pertinent materials were provided to the organ specific and pediatric committees for consideration at the January and February 2004 meetings. Recommendations from these committees were provided to the OPO Committee. Suggested policy modifications by the Kidney/Pancreas Transplantation Committee addressed grammatical changes to HIV policy and language that would allow individuals who received HPDGH to be potential donors, which were accepted by the Committee. The Liver/Intestine Transplantation Committee had approved a motion stating that policy should allow for the possibility of an offer occurring for HIV-positive donors to HIV-positive recipients, but were also aware that Federal Law may prohibit the use if HIV-positive donors. This Committee also supported the Joint Subcommittee's recommendation that the decision to use organs from individuals who received HPDGH should be at the discretion of the potential recipient and transplant surgeon.

In its deliberations, the OPO Committee also considered Federal Law addressing potential donors who test positive for HIV. Although it was noted that certain liver transplant programs may want to consider HIV-positive organs for Status I patients co-infected with HIV and HCV, the Committee determined not to address the issue and suggested that it be pursued by the Liver/Intestine Transplantation Committee if sufficient interest existed.

National Organ Transplant Act, Section 273 (b)(3). An organ procurement organization shall:...(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 274 (b)(2)(E) of this title, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

With regard to HPDGH, it was stated that individuals currently receiving growth hormone are no longer at risk for acquiring Cruetzfeldt-Jacob disease as only recombinant growth hormone is used. The Committee considered a November 2001 report by the Public Health Services Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob disease (Exhibit B). The document stated that in October 2000, the CDC reported 22 deaths from transmission of prion disease, CJD, spongiform encephalopathy, or Mad Cows disease out of 8,000 recipients that received HPDG hormone, of which almost all cases occurred from exposures before 1977, when a new method of purification was introduced. Although noting that the disease can present as late as 20 years, and sometimes up to 30 years after exposure, it was mentioned that in the context of a deceased potential donor in which .3 percent of 8,000 individuals contracted prion disease, the likelihood of one of these individuals becoming an organ donor was extremely remote. As a result, the Committee determined that it should be left to the judgment of the accepting center whether to use these organs.

Policy 4.6 (Screening Potential Organ Donors for HTLV I Antibodies) The Committee, at its September 15, 2003, meeting, considered policy that excludes the recovery of organs from HTLV-positive donors, and opined that the transplant center and candidate should determine the benefits and risks of transplanting an HTLV-positive organ after reviewing OPTN data regarding HTLV-positive donors. The Joint Subcommittee that met on January 8, 2004, reported that OPTN data indicate some centers accept HTLV-positive organs for transplantation, and that the transplant community recognizes that a certain number of donor HTLV-positive test results are actually false positive as confirmed by Western Blot. The Joint Subcommittee also concluded that policy should not absolutely exclude HTLV-positive donors. Subsequently, Liver/Intestine Transplantation Committee concluded that due to the high rate of false positives for HTLV, these organs should not be excluded from donation. The Pediatric Transplantation Committee supported the Joint Subcommittee conclusion to not absolutely excluded HTLV-positive donors.

At the Committee's request, UNOS Research staff conducted further analysis related to HTLV-positive donors and the recipients of those organs (Exhibit C). There were 32 donors between January 1, 1995 and January 31, 2004 that were reported by OPOs as being HTLV positive. These 32 donors were recovered at 20 different OPOs, and resulted in 58 transplants (11 hearts, 22 kidneys, 22 liver, and 3 lung). Nine were further determined to be HTLV negative due to OPO keying error. Of

the remaining 23 donors, 13 had confirmatory tests for HTLV of which 5 returned as HTLV positive, 5 negative, 2 as inconclusive and 1 as indeterminate. Approximately four different types of confirmatory tests were used, as reported by the OPO. For each donor that was confirmed positive by a second test, the transplant center that received the organ was contacted to determine the transplant recipient's HTLV status pre-transplant as UNOS does not collect HTLV results on transplant candidates. No information was available as the centers reported that the test was not documented in the chart, was not performed, or the center did not reply. It was noted that this study did not capture the HTLV-positive screened potential donors where no effort was made to place the organs as that information is not available. One OPO reported having approximately 20 to 25 potential donors over the past 6 years who were HTLV positive, and from whom organs were not recovered.

The Committee agreed that HTLV testing is problematic with many false positives; confirmatory tests are frequently not done; and when done, the test often is not completed on a timetable that allows for organ transplantation. Therefore, the Committee proposes the current policy reflect the recommendation of the subcommittee and various committees that were asked to comment, and supports modifications to the policy that would allow a transplant center to make a decision regarding use of these organs on a case-by-case basis.

New Proposed Policies 4.6-4.8 Regarding Screening Organ Donors for and Post-transplant Reporting of Transmission of Disease or Medical Conditions, including Malignancies. The Committee recognizes the importance of establishing a formal system for reporting cases where transmissible diseases or medical conditions, including malignancies, are detected by an OPO in a donor after organs are procured, or detected by a transplant centers either before or after the organs have been transplanted. The initial draft proposal was developed by UNOS staff and presented to the Executive Committee, which deferred consideration of the proposal pending deliberation by appropriate committees. It was determined that the OPO Committee would take the lead in addressing the proposal.

Initially, concerns were expressed related to discoverability when reporting these cases to UNOS with the impression that as part of the quality improvement process, confidential issues such as these are now discoverable similar to peer review. UNOS legal counsel responded that the likelihood for someone to obtain the data was no greater by reporting it to UNOS. Release of patient specific data would only be pursuant to a subpoena directed to UNOS or directly to the member from whom UNOS received the data. Anyone serving a subpoena on UNOS could serve that same subpoena on a member, and the data would be provided directly from the member unless the member chose to object to the subpoena.

With regard to determining the scope of diseases and medical conditions that OPOs should report in order to meet policy requirements, the Committee concluded that an inclusive list be developed and incorporated into the proposal. With respect to screening donors for known medical conditions or diseases, it is the Committee's understanding that the policy would reflect the standard of practice at the time of reporting. A working group was formed that drafted an inclusive list of diseases and medical conditions for reporting. A Joint Subcommittee representing the OPO, organ-specific and Pediatric committees reviewed the list and agreed that the transplant center should refer to the same "diagnosis list" as the OPO for reporting purposes. Additionally, the Subcommittee supported the inclusion of policy language that would address the necessity to report autopsy finding and culture results that pose potential risk to the recipients. OPO representatives verified that the receipt of pathology reports from donor autopsies is fairly standard and pertinent results should be disseminated to the recipient centers, if warranted. Subsequent to the Joint Subcommittee meeting, Jay Fishman, MD, an infectious disease expert, and the UNOS medical staff reviewed and suggested revisions to the list. The Committee agreed that the revised list be incorporated into policy.

The Committee concurred that disclosure of a potential or actual adverse event should be immediate with the most feasible method being by telephone and the OPO as the central contact to notify effected transplant centers. Whether the adverse event occurred prior to transplant or 6 months post-transplant, the contacting and reporting process by the OPO and transplant center would be the same. The Joint

Subcommittee, noting that some cancers of donor origin may not be detected in the recipient for a number of years post-transplant, thought that the UNOS generated database for reporting all recipient cancers could serve as an avenue for reporting. The Pediatric Transplantation Committee, at its January 21, 2004 meeting, noted and emphasized the importance of timely and complete communication regarding HIV-related results and donor malignancies.

The Committee felt that transplant center or OPO that initiated the process would also notify the OPTN through the Organ Center immediately. If an acute situation, the Organ Center would assist the parties involved in disseminating the information. Contacting the Organ Center would create a back-up notification so that the opportunity to prevent the transplant of that organ is not missed; it would start a process of data collection and verification that the process is taking place; and from a risk management perspective, it would document that the suspicion of an adverse event was voluntarily reported. UNetsm would serve as the eventual consolidated clearinghouse for the information, once developed, for both actual versus suspected transmission of diseases, and would also facilitate the identification of near misses in order to determine the processes that prevent adverse events. It was thought that the UNOS Policy Compliance Department would be ultimately responsible for following up with the various entities involved to ensure that the information was collected and transmitted accurately and expeditiously.

After careful and thorough consideration of the various reports, regulations and committee recommendations, the OPO Committee voted 14 for, 0 against, 0 abstentions to submit the following proposed modifications to Policy 4.0 for public comment.

Policy 4.0 Acquired Immune Deficiency Syndrome (AIDS), and Human Pituitary Derived Growth Hormone (HPDGH), and Human T-Lymphotropic Virus Type (HTLV-1), and Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin.

~~These policies apply to the pretransplant consideration of potential organ donors and/or potential organ recipients with regard to AIDS, HPDGH and HTLV-1.~~

4.1 Screening Potential Organ Donors for ~~Anti-HIV Antibody~~. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for ~~Anti-Human Immune Deficiency Virus (HIV) Antibody (Ab)~~. If the potential donor's pre-transfusion test for HIV the antibody is negative and blood for subsequent transfusions has been tested and found to be negative for ~~HIV-Ab~~, retesting the potential donor for ~~HIV-Ab~~ is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for ~~HIV-Ab~~. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the UNOS Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control. The Host OPO must communicate the donor history to all institutions receiving organs from the donor.

4.1.2 Organ Sharing. UNOS members shall not knowingly participate in the transplantation or sharing of organs from donors who are confirmed ~~reactive for HIV positive-Ab~~ by an FDA licensed screening test unless subsequent confirmation testing unequivocally indicates that the original test's results were falsely positive for HIV-Ab.

- 4.1.3 Exceptions. Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HIV ~~antibody~~. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases.
- 4.1.4 Donor Consent Forms. UNOS member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.
- 4.2 Screening Potential Transplant Recipients for HIV ~~Antibody~~. Testing for HIV ~~Ab~~ shall be a condition of candidacy for organ transplantation, except in cases where such testing would violate applicable state or federal laws or regulations. Patients whose test results are confirmed positive should undergo appropriate counseling.
- 4.2.1 HIV ~~Ab~~ ~~Sero~~ Positive Transplant Candidates. A potential candidate for organ transplantation whose test for HIV ~~Ab~~ is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy.
- 4.2.2 Informing Personnel. Health care personnel caring for patients who test positive for HIV AIDS ~~antibody~~ should be so informed.
- 4.2.3 Patient Treatment. Administering treatment to patients who test positive for the HIV ~~antibody~~ should not be optional or discretionary for health care personnel.
- 4.3 Disclosure of Information About HIV ~~Antibody~~ Status. UNOS member institutions are urged to comply with state and federal statutes and regulations applicable to the disclosure of personalized data on actual or potential organ donors or recipients.
- 4.4 General Recommendations. All UNOS member institutions are requested to adopt an overall health care policy addressing special HIV-related problems with regard to transplant candidates and recipients. It is recommended that each institution's HIV-related health care policies incorporate the specific UNOS policies 4.1, 4.2, and 4.3 set forth above. It is also recommended that member institutions make their policies available upon request to the press and the public.
- 4.5 Human Pituitary Derived Growth Hormone. People who have received Human Pituitary Derived Growth Hormone (HPDGH) from human tissue (not recombinant) shall be evaluated deferred as organ donors with potential organs used at the discretion of the accepting transplant center and with informed consent from the recipient patient. ~~An exception to this policy may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has received HPDG.~~ The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases. The use of recombinant HPDGH carries no additional risk of transmissible disease.
- 4.6 Screening Potential Organ Donors for ~~HTLV-I Antibody-Transmission of Diseases or Medical Conditions, including Malignancies~~. All potential donors are to be ~~tested by a screening test licensed by the FDA for Human T Lymphocyte Virus Type I (HTLV I) Antibody (Ab) screened for transmissible diseases or medical conditions, including malignancies, through the collection of medical/social history information.~~ If the potential donor's pre-transfusion test for the HTLV-I antibody is negative and blood for subsequent transfusions has been tested and found to be negative for HTLV I Ab, retesting the potential donor for HTLV I Ab is not necessary. If no pre-transfusion sample of the donor's blood is available, the Host OPO must provide to each recipient transplant program the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing

indicates that the original tests' results were falsely positive for HTLV I Ab. If additional tests related to HTLV I Ab are performed, the results of all tests must be communicated immediately to the UNOS Organ Center and all recipient institutions. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.6.3 below. Medical conditions that should be screened for by history include the presence of malignancies, treated and untreated, or any other known condition that may be transmitted by the donor organ that may reasonably impact the candidate or recipient. In addition, donors shall be tested for recognized transmissible diseases, as defined in policy 2.2.7.1, using screening tests licensed by the FDA for testing these specific diseases. If additional testing is performed, the results of these tests must be communicated immediately to all recipient institutions. The OPO is responsible for timely follow-up of donor screening tests. Documentation of any suspected or confirmed transmissible disease or medical condition identified prior to or following procurement must be communicated by the Host OPO to all potential recipient centers and the OPTN according to Policy 4.7.

4.6.1 Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control. The Host OPO must communicate the donor history to all recipient institutions.

4.6.2 Organ Sharing. UNOS members shall not knowingly participate in the transplantation or sharing of organs from donors who are confirmed positive for HTLV I Ab by an FDA licensed screening test unless subsequent confirmation testing unequivocally indicates that the original test's results were falsely positive for HTLV I Ab. Reporting. Known conditions that may be transmitted by the donor organ must be communicated to the transplant centers: These may include, but are not limited to, the following:

- Unknown infection of central nervous system (encephalitis, meningitis)
- Herpes simplex encephalitis or other encephalitis
- History of JC virus infection (causes progressive multifocal leukoencephalopathy)
- West Nile virus infection
- Cryptococcal infection of any site
- Rabies
- Creutzfeldt-Jacob disease
- Other fungal or viral encephalitis
- Untreated bacterial meningitis
- Infection with HIV (serologic or molecular)
- Active viremia: herpes, acute EBV (mononucleosis)
- Serologic (with molecular confirmation) evidence of HTLV-I/II
- Active hepatitis A or B
- Infection by: Trypanosoma cruzi, Leishmania, Strongyloides, Toxoplasmosis
- Active Tuberculosis
- SARS
- Untreated pneumonia
- Untreated bacterial or fungal sepsis (e.g. candidemia)
- Untreated syphilis
- Multi-system organ failure due to overwhelming sepsis, such as gangrenous bowel
- Active malignant neoplasms, except primary CNS tumors and skin cancers (basal cell, squamous cell)
- Melanoma, Merkel cell, cutaneous kaposi
- Hodgkins' disease and non-Hodgkin's lymphoma
- Multiple myeloma
- Leukemia
- Aplastic anemia agranulocytosis
- Miscellaneous carcinomas
- Any new conditions identified by the CDC as being a potentially communicable disease

4.6.3 Exceptions. Exceptions to the guidelines set forth above may be made in cases involving non-renal organs, when, in the medical judgment of the staff of the Host OPO and recipient institution, an extreme medical emergency warrants the transplantation of an organ, the donor of which has not been tested for HTLV I Ab. The transplant surgeon is obligated to obtain informed consent from the recipient or next of kin in such cases. Organs from donors with a positive screening test or confirmed medical conditions that may be transmittable, with the exception of HIV, may be transplanted at the discretion of the transplanting program with the informed consent of the recipient.

4.6.4 Donor Consent Forms. OPTN member institutions are encouraged to include in each donor consent form a notice that all potential donors will be screened for medical acceptability for organ donation and that results of such tests may be the basis for not using the organ in transplantation.

4.7 Post Transplant HIV Reporting. When a transplant program director is informed that an organ recipient at that program is confirmed positive by Western Blot for HIV, or has died from HIV related causes, the director program shall notify as soon as practicable, the medical director or executive director of the procuring OPO and the UNOS Organ Center director by telecopying and mailing a completed UNOS Transplant HIV/Hepatitis B Form. The medical director or executive director of the procuring OPO shall be responsible for:

- i. notification of the positive HIV test results as soon as practicable to any tissue bank and the director of any other transplant program that received tissue or an organ from the donor who is the subject of the investigation;
- ii. management of the investigation to determine whether the organ donor was infected with HIV; and
- iii. submission of a final written report to UNOS within 45 days which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including final HIV serology status of the organ recipients who are the subjects of the investigation.

Upon receipt of a completed UNOS Transplant HIV/Hepatitis B Form that reports a confirmed positive Western Blot HIV test result, UNOS shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. UNOS will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the positive HIV test results and will request that any additional HIV test results be submitted to the procuring OPO with a copy to UNOS. UNOS will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.

4.7 Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, including Malignancies. When a transplant program is informed that an organ recipient at that program is confirmed positive for or has died from a transmissible disease or medical condition for which there is substantial concern that it could be from donor origin, the transplant program must notify by phone and provide available documentation, as soon as possible and not to exceed one complete working day, to the procuring OPO. The overall intent is to transfer the knowledge/concern from one transplant center to all other transplant centers who have accepted organs from the same donor as quickly as possible. The transplant center originating the concern of transmissibility should not wait for all medical documentation that will eventually be available, but communicate that center's concerns through the OPO and OPTN to all other centers involved with that same donor as soon as possible so the other centers could use their medical judgment as to which, if any, investigations or actions need to be performed on their patients.

The procuring OPO shall be responsible for:

- i. communication of the test results and diagnosis as soon as practicable to any transplant center and tissue bank that received an organ or tissue from the donor who is the subject of the investigation;
- ii. management of the investigation to determine whether the organ donor was diagnosed with a potentially transmissible disease or condition;
- iii. notification of the event to the OPTN as soon as possible; and
- iv. submission of a final written report to the OPTN within 45 days, which specifies the organizations and individuals who were notified, when the notifications occurred, and results of the investigation including test results of the organ recipients who are the subjects of the investigation.

The OPTN shall assist the procuring OPO in identifying all organ transplant programs and recipients who received an organ from the donor who is the subject of the investigation. The OPTN will monitor the notification process to verify that the procuring OPO and all recipient organ transplant programs have been notified of the disease or medical condition and will request that any additional diagnostic test results be submitted to the procuring OPO with a copy to the OPTN. UNOS will forward a copy of the OPO's final report to the recipient transplant centers and the Division of Organ Transplantation of the Health Resources and Services Administration. Note: The identities of the donor and any organ recipient who are the subjects of the investigation shall remain confidential and all correspondence will refer to the donor and recipients by their donor identification number and recipient social security numbers. Under no circumstances should a transplant program or OPO disclose this information in a manner that is contrary to applicable law.

3. **Roles and Responsibilities of the Coordinating OPO.** The objective of the ABO Joint Subcommittee in requesting that the OPO Committee consider the necessity of defining the role and responsibility of the “coordinating OPO” was to ensure that the patient receiving the organ was on a match run list. It is the Committees understanding that the purpose of any further proposed policy modifications would be to prevent situations where the organ is transplanted into a second patient within a transplant center (when the organ cannot be transplanted into the originally designated patient) without first confirming the second patient is on the match run and, therefore, ensuring the donor and recipient blood types match.

Some of the concerns brought up by the members included: diversity in the process between OPOs regarding who serves as the clearinghouse for organ imports and offers, and this process also varies between OPOs with regard to the organ being offered; the cost and staffing could increase significantly for some OPOs that do not currently take organ offers; and although some members felt adding the additional layer of the OPO was unnecessary from a risk management position when the organ could be offered directly with the transplant center, others felt that the OPO needed to remain involved to maintain public trust in the system.

There are logistical complexities inherent when sharing organs outside the Host OPO donor service area while attempting to ensure the organ is allocated fairly by the match run or that it is not wasted due to extensive cold ischemic time, such as whether to use the Host or Receiving OPO match run list as the back-up list and determining who would be responsible for running the receiving OPO match run.

Although the Committee agreed these issues were important, it was determined that resolving this dilemma could not be accomplished in this policy. Ultimately, the Committee agreed that the current language in Policy 3.2.3 (Match System Access) addresses the concern outlined by the ABO Joint Subcommittee which states that the Host OPO is responsible for allocation of the organ unless it is delegated to the local OPO, and that the organ shall be allocated only to a patient who appears on a match run.

4. **Protocols for When the Match Run List is Exhausted.** The Committee agreed that this issue is currently addressed in Policy 3.2.3 (Match System Access). The intent of the ABO Joint Subcommittee was to guarantee that organ allocation was made from a match run list and that current policy provides a mechanism for updating patient information, such as height or weight parameters, to

ensure patients are on the match run list and organs are not wasted. Policy 3.2.3 states that [in the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a patient who appears on a match run].

5. Reporting of Individual Data for all Eligible Deaths. The SRTR requested the collection of individual data by OPOs for all eligible deaths (Exhibit D). Currently, eligible deaths are collected each month by OPOs and sent to UNOS as an aggregate number for each hospital in its designated service area (DSA). Per the SRTR, the objective is to develop a measure of the organ donation process that is easily quantifiable and reproducible; is based on nationwide data; accounts for patient characteristics, as well as DSA and hospital factors; and facilitates improved understanding of differences in organ donation potential.

The SRTR provides monthly statistics by OPO including donation rates, which is the donation rate per eligible death. From the eligible deaths, crude donation rates are calculated as well as adjusted rates, which take into consideration, for example, what would be expected given the characteristics of the hospital. Collection of individual information on each eligible death would allow for further calculation of the notifiable death rate. Although more than half of the individual information on eligible deaths for this study is on the Deceased Donor Registration form for those patients who did consent and became donors, additional data collection is being requested for the nonconsented deaths who are eligible, which is estimated at 107 forms per DSA per year.

Proposed data elements include:

- Provider Information: OPO center code/name; deceased hospital name/provider number; data and time of brain death; data and time of call/OPO notification; interval between declaration of eligibility and OPO notification; eligible death identified only in retrospective review (Y/N)
- Patient Information: OPTN ID; name, age, gender; city, state, zip code, race/ethnicity, citizenship, cause of death, mechanism of death, circumstances of death, procurement and consent, medical examiner, clinical information

With regard to collection of the interval between declaration of eligibility and OPO notification, it was noted that established triggers for hospitals may vary among OPOs with regard to declaration of eligibility and that some OPOs do not collect information about this type of notification. Therefore, it was agreed that for consistency, the point of eligibility would be the date and time of brain death pronouncement.

After a brief discussion, the Committee voted 14 for, 0 against, 0 abstentions to support the following resolution for consideration by the Board of Directors.

**** RESOLVED, that a pilot project involving a representative number of OPOs be created for the purpose of defining a more acceptable measure of OPO performance and for identifying types of potential donors with high conversion rates through the acquisition of the identified individual data elements on eligible deaths. Implementation of the project shall be executed pending development and programming in the UNOS System and subject to the availability of Personnel and financial resources.**

6. Discussion of DCD Donors Regarding Maximizing Organ Recovery. With increasing recognition and support of organ recovery from DCD donors seen as a best practice within the transplant community, as well as by members of the Secretary of the Department of Health and Human Service's Advisory Committee on Organ Transplantation and participants in the Organ Donation Breakthrough Collaborative Initiative, the Committee agreed that a joint subcommittee on DCD be formed to include representatives from the OPO and organ specific committees to discuss the various issues that impede implementing DCD policies and organ recovery. Some of the concerns expressed related to the lack of experience by transplant programs that do not recover organs from DCD donors and the potential effects on OPOs from pursuing these donors. It was also stated that certain programs appear hesitant

to accept these organs for their patients, and current allocation policies do not allow sufficient flexibility in matching DCD donors with the most appropriate recipients to maximize the recovery and utilization of these organs. In addition to forming the Joint Subcommittee on DCD, the Committee will survey OPO Executive Directors regarding how their respective OPOs are approaching DCD and work with the SRTR to obtain data analysis regarding best outcomes for ECD and DCD donors.

7. **New Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), 3.4.7.2 (Regional/National Communications Disruption), and 3.4.7.3 (OPTN Operational Disruption).** The Health Resources Services Administration (HRSA) requested the OPTN develop policies for maintaining the organ matching and allocation process during times of regional or national emergencies that compromise telecommunication, transportation, or the function of or access to the OPTN wait list or matching system. OPTN staff drafted the policies for consideration by the OPO Committee, which felt the policy was necessary and the process clearly stated. The policy was approved by the Board and became effective December 22, 2003, concurrent with Public Comment. The proposal was distributed for Public Comment on March 15, 2004.

Public Comment Response

As of May 20, 2004, 83 responses have been submitted to UNOS regarding this proposal. Of these, 49 (59.04%) supported the proposal, 0 (0%) opposed the proposal, and 34 (40.96%) had no opinion. The Committee addressed the written comments received and considered the comments made during Regional and Committee meetings (Exhibit E).

Proposed Modifications Based on Public Comment

There was one comment made regarding this proposal related to a grammatical error, which was corrected.

Policy Proposal

The Committee, therefore, offers the following resolution for consideration by the Board of Directors.

****RESOLVED, that Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption), and 3.4.7.3 (OPTN Operational Disruption) shall be approved as set forth below effective June 25, 2004.**

Committee vote: 14 for, 0 against, 0 abstentions.

3.4.7 Allocation of Organs During Regional/National Emergency Situations. In the event of a regional or national emergency situation that compromises telecommunications, transportation, or the function of / access to the OPTN waiting list and organ matching system, a notice and instructions will be distributed, if possible, to all OPTN transplant centers and organ procurement organizations advising them of the impact of the situation on the OPTN system and how members should proceed with organ allocation, distribution and transplantation. OPTN members should reference Policies 3.4.7.1; 3.4.7.2; and 3.4.7.3 in cases of regional/national emergency.

3.4.7.1 Regional/National Transportation Disruption. In these situations, the OPTN and members are able to communicate and the waitlist and matching systems are accessible, but transportation of organs is either not possible or severely impaired. Members are required to contact the OPTN to determine proper operating procedures.

3.4.7.2 Regional/National Communications Disruption. In these situations, the OPTN and members are unable to communicate through one or more of the available communications methods (internet and phones) and the waitlist and matching system are operational.

Internet Outage. Members are required to contact the OPTN and determine the proper operating procedures.

Telecommunications (Land and Mobile Phone) Outage. Internet contact with the OPTN should be made via e-mail to determine operation procedures and to obtain assistance. Members will continue to use the waitlist and matching system for organ allocation and distribution. Organ procurement organizations must document any variations in allocation or distribution due to telecommunications problems for submission to the OPTN Policy Compliance.

Combined Outage. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not accessible. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN Policy Compliance.

3.4.7.3 OPTN Operational Disruption. In these situations, the OPTN and members are unable to communicate through any communications method and the waitlist and matching system are not operational. The organ procurement organizations should reference recent matched of similar ABO and body size for ranking local transplant candidates. If a similar match is available, the local organ procurement organization should use local transplant program waiting lists to best match the donor organ with waiting transplant candidates. Organ procurement organizations must document their process for allocation for submission to the OPTN Policy Compliance.

Other Issues

8. Public Comment Document.

Proposed Modifications to Policies 3.5.5.1 (Kidney/Non-renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements) The Committee supports the modifications in the proposal. Committee vote: 13 for, 0 against, 0 abstentions. It was stated that for many OPOs, this policy change will reduce the number of kidneys being shipped and the amount of cold ischemic time. One Committee member also expressed concern that it was their understanding that the purpose of the modification was to promote a policy that allowed for placement of more organs, specifically a policy that supported the OPO's ability to make more kidney/pancreas offers versus pancreas only offers and that the modifications did not appear to support that purpose.

Proposed Modifications to Policy 6.4 (Exportation and Importation of Organs – Development Status) The Committee supports the modifications in the proposal. Committee vote: 14 for, 0 against, 0 abstentions.

Proposed Modifications to Policy 3.1.4 (Patient Waiting List) The Committee supports the modifications in the proposal. Committee vote: 13 for, 0 against, 0 abstentions

Proposed Modifications to Policy 3.2.3 (Match System Access) The Committee supports the modifications in the proposal. Committee vote: 13 for, 0 against, 0 abstentions

The Committee did not take a position on the remaining proposals in the Public Comment Document.

9. Living Non-directed Organ Donation. The Committee was asked to review and respond to a White Paper by the Ethics Committee on living non-directed donation (Exhibit F). Overall, the Committee

supported the concept of the document, but discussed several issues. First, the observation is that non-related donation is illegal in most European countries, which may to some extent be due to the risk, however small, of death or need of transplantation for someone who has no relationship with the recipient. Second, the document implies that a living non-directed kidney donation should be allocated in the same manner as a deceased donor kidney, which would mean the transplant center that invests the time and cost in recruitment, psychological work-up of the donor, and tissue typing may not be allocated the organ for a patient in that center. If this is correct, then the Committee would not support this allocation method. If the intent of the paragraph is to ensure that a patient within the transplant center appears on the match run, then the text should be revised to accurately convey the message.

OPO COMMITTEE MEETING
March 31, 2004

Committee Members Attending

John M. Holman, Jr, MD, PhD
 Joseph S. Roth
 Paul E. Morrissey, MD
 Joe Guillory, RN
 Tammie S. Peterson, RN, BSN
 Phyllis G. Weber, RN, CPTC
 Monica Johnson Tomanka
 Judy Suchman
 Sidney Anthone, MD
 Ladora A. Dils, RN, CPTC
 Richard Neal Garrison, MD
 Joseph F. Nespral, CPTC
 Kevin A. Myer, MSHA, CPTC
 Mary Ann C. Lunde
 Ginny A. McBride, RN, MPH, CPTC

Chair
 Vice Chair, Region 2 Representative
 Region 1 Representative
 Region 3 Representative
 Region 4 Representative
 Region 5 Representative
 Region 6 Representative
 Region 7 Representative
 Region 9 Representative
 Region 10 Representative
 Region 11 Representative
 At-large Member
 At-large Member
 At-large Member
ex-officio – HRSA

UNOS Staff

Debbie Seem, RN, CPTC
 John Rosendale, MS
 Chris Williams

Committee Liaison
 Committee Biostatistician
 UNOS Staff

SRTR Staff

Robert Wolfe, PhD
 Josh McGowan, MS

URREA
 URREA

Unable to Attend

Patricia D. Brewster, MS
 Edward Y. Zavala, MBA

Region 8 Representative
 At-large Member

March 4, 2004
 Report to Debbie Seem, RN, CPTC
 UNOS

Subject: Thermal Properties of Organ Transport Containers

Objective: To explain the meaning of R factor rating for organ shipping packages. UNOS wants to use this rating in specifying thermal properties of organ transport packages.

Background: A variety of packages are now in use by UNOS members for shipping donor organs. The suppliers of these packages specify the thermal properties by giving an R rating. The ratings seem to differ among the suppliers; their meaning and applicability to the organ containers is not clear. The containers all use a combination of materials, the thicknesses are different, the methods of closing the containers are different and other details of construction are different. UNOS is preparing to specify packaging for organ donor containers. They need a specification of thermal performance.

R-factor determined for four UNOS containers: We tested 4 UNOS containers and calculated three R-factors for each one. **We tested the containers for their thermal insulating properties at 70° F.** The results are in the table below:

Thermal Insulating Properties of Four UNOS Containers at 70°F			
	1	2	3
Container	R-factor per inch of thickness	R-factor for container tested	HPR for container tested
Safe Guard -1.5" thick EPS, 12"x10"x9" I.D.	3.9	6.3	0.296
Polar Tech 2 - 2.0" thick EPS, 12"x12"x11.5" I.D.	3.9	8.3	0.304
New York Hospital - 1.0" thick EPS 13"x10"x8" I.D.	3.9	4.9	0.386
Clarke Pkg Corp - 7/16" thick Urethane, 14"x11.25"x9" I.D.	4.2	2.9	0.464

Discussion of table:

1. Columns 1 and 2 are R-factors like those quoted to UNOS by the suppliers of the containers, except that these are measured on UNOS boxes. The values are very close to suppliers' numbers. Both factors calculate the resistance in terms of

unit area of material and unit degree of temperature difference between inside and outside of container. The suppliers' R-factors do the same thing.

2. Column 1 is the resistance to heat flow of the insulating material, calculated to unit thickness of the material. The units of this R are $(\text{hr-ft}^2\text{-}^\circ\text{F})/(\text{btu-in of wall thickness})$. All three EPS boxes have the same R-value, regardless of wall thickness. Urethane is a very good insulating material, so when the R for the Clarke container is calculated to unit thickness, urethane is higher than EPS.

3. Column 2 is the resistance to heat flow of the box at the wall thickness tested. A box with thin wall will have a smaller R-factor value than a box with a thick wall. The units of this R are $(\text{hr-ft}^2\text{-}^\circ\text{F})/(\text{btu})$. The thickest EPS wall has the highest R-value, and the thinnest wall has the lowest R-value. The urethane in the Clarke box is very thin (only 7/16"), so the R-value for the box as tested is lower than the "as tested" value for the EPS boxes. A 1" thick urethane box would be much better than any of the EPS boxes, provided that the urethane was continuous around the corners. The Clarke box is constructed using flat panels inserted into a six-sided box. This leaves gaps at all of the corners. These gaps allow heat to pass into the box.

4. Column 3 is the Heat Penetration Rate (HPR). It is the rate at which heat (in btu) penetrates the container. It is a direct measure of the performance of the container as constructed and tested. It accounts for size, thickness, construction and closure variations. The units of HPR are $\text{btu}/(\text{hour-}^\circ\text{F})$. We recommend this as the best property to specify for your purpose.

5. The heat flow properties of insulating materials change with temperature. The heat flow rate increases at higher temperatures. All of the materials in the table will have much higher HPR or much lower R at 100° F than at 70° F. The relationship is not linear and it is not the same for all materials. Therefore, we recommend that your specification include an HPR for at least two temperatures.

Thermal properties at another temperature: We measured the Heat Penetration Rate (HPR) for the Polar Tech 2 container and the Clarke container at 102° F. The values were 0.473 for the Polar Tech 2 and 1.38 for the Clarke container. The Polar Tech 2 container HPR increased by 56% from the value at 70° F, while the Clarke container HPR increased by 197%.

Discussion of R rating : The R value provided by suppliers is for the insulating material in flat sheet form. It is a valid rating for the material alone. This value does not account for package shape or construction. It does not account for addition of material such as corrugated paperboard in the form of an outer container. It does not account for the type of closure or for any gaps that may be present as a result of the method of construction. The R-value cited by the supplier usually accounts for thickness, but it may be calculated in at least two different ways. (1) Some suppliers report an R-value per inch of wall thickness.

(2) Others report an R value for each wall thickness that they offer for sale. Neither of these R-values is useful for your purpose; the values cannot be compared to each other nor can they easily be related directly to your need. You already know this.

You can base your specification on a measure of the insulating performance of the containers that you use. You know from your experience which containers work best, so if you measure the thermal performance of those, you can choose the value that represents the performance of the containers you like. We have devised an easy test that will serve your purpose. This test will allow you to specify (1) the number of hours required to melt a certain amount of ice, or (2) the amount of ice that melts in a certain amount of time, or (3) the number of btus (heat) that flow into the package in a certain length of time.

The Test conducted at the School of Packaging:

1. Place a known weight of ice in the container to be tested.
2. Close and seal the container, and store it at a known temperature
3. Measure the length of time the container is stored (about 24 hours)
4. Open the container, remove all of the melted ice (water) and determine the amount of ice that melted. It takes 144 btus to melt 1 pound of ice.
6. Pounds of ice melted /number of hours of storage = melt rate in pounds per hour
7. (melt rate in lbs/hr x 144 btu/lb) = heat penetration rate in btu per hour at the temperature of storage.
8. The temperature of storage may differ a little from one experiment to another. The heat penetration rate is more at higher temperatures than at lower ones. Therefore, we calculate the heat penetration rate per degree of temperature difference between inside and outside of the container. Inside the container is ice, melting at 32⁰ F. Outside the container is the temperature of storage.

**THE SEVENTEENTH
REPORT OF THE PHS INTERAGENCY COORDINATING COMMITTEE ON
HUMAN GROWTH HORMONE AND CREUTZFELDT-JAKOB DISEASE
November 2001**

The Seventeenth Report
of the
**PHS Interagency Coordinating Committee on
Human Growth Hormone and Creutzfeldt-Jakob Disease**

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The Seventeenth Report

of the

PHS Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease

I. INTRODUCTION

This is the Seventeenth Report of the PHS Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease, which was established on May 29, 1985, by the then Acting Assistant Secretary for Health. This Report primarily reflects the deliberations of the Committee at its meetings of November 4, 1999, and November 6, 2000. A list of the agencies and representatives participating in the Committee follows below. Dr. Allen M. Spiegel, Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), presides as Chairman of the Committee.

A. Background

During the period from late February to early April of 1985, officials of the Public Health Service (PHS) were notified of the deaths of three people who had received medical treatment with human growth hormone (hGH), distributed by the National Hormone and Pituitary Program (NHPP). The clinical course of each individual was reported to have been compatible with Creutzfeldt-Jakob Disease (CJD).

Officials of the National Institutes of Health, the Food and Drug Administration, and the Centers for Disease Control immediately responded to these reports by outlining a strategy to address the situation. Within a week of notification of the first case, distribution was halted for pituitary-derived hormones used for purely experimental, non-therapeutic purposes. A week after notification of the second and third cases, a decision was made to halt temporarily the distribution of hGH for all clinical use, except to patients with life threatening hypoglycemia, and to initiate epidemiological studies to assess the full extent of the problem.

To facilitate the scientific review of this issue, the then Acting Assistant Secretary for Health formally established the Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease. The purpose of the Committee is to advise the Assistant Secretary for Health regarding a coordinated PHS response to the scientific questions surrounding hGH distribution in relation to CJD. The Committee originally reported at three-month intervals, and it now reports annually or as significant new information becomes available.

¹Dr. Spiegel replaced Dr. Phillip Gorden, who was reassigned from the NIDDK Directorship, which included his position as Chair of the PHS Interagency committee on hGH-CJD, on Nov. 15, 1999.

The PHS Interagency Coordinating Committee provides updated information to recipients of pituitary-derived human growth hormone supplied through the NHPP to keep them informed of the progress of the study and of new developments with regard to growth hormone administration and CJD.

B. Goals of the Public Health Service Related to hGH-CJD

The PHS is expending maximum efforts to answer the scientific and public health questions raised by the reported deaths. The PHS objective has been and continues to be to protect the public from health risks through the following actions:

- To inform physicians who have administered pituitary hGH and their patients of the current state of knowledge about health risks associated with pituitary hGH;
- To determine which NHPP products may have been contaminated by the CJD infectious agent;
- To ensure the continued availability of NHPP hormones for non-human research purposes; and
- To bring to bear the relevant expertise available on these issues from throughout the scientific community in the most expeditious and well coordinated manner.

Another objective of the PHS when the Coordinating Committee was formed was to assure uninterrupted supplies of growth hormone to children with need. This goal was met when the FDA approved recombinant hGH in 1985.

C. Roster of Committee Members

<u>Agency</u>	<u>Representative</u>
<u>National Institutes of Health</u>	
National Institute of Diabetes and Digestive and Kidney Diseases	Dr. Allen M. Spiegel, Chairman Dr. Judith Fradkin Dr. Saul Malozowski
National Institute of Neurological Disorders and Stroke	Dr. Paul Brown
National Institute of Child Health and Human Development	Dr. James Mills
<u>Centers for Disease Control and Prevention</u>	Dr. Lawrence B. Schonberger Dr. Dixie Snider
<u>Food and Drug Administration</u>	Dr. Diane Wysowski Dr. Elizabeth A. Koller

II. OVERVIEW

A. Creutzfeldt-Jakob Disease (CJD)

Creutzfeldt-Jakob Disease is a rare neurological disease that occurs in the general population at a rate of one in one million per year, affecting predominantly persons over 54 years of age. CJD is caused by an infectious agent with a long interval from the time of infection until symptoms first appear. These symptoms include progressive dementia, involuntary movements (myoclonus), visual and speech abnormalities, and lack of coordination. This rare disease can occasionally be clinically confused with other dementias, particularly Alzheimer's disease. There is no cure or treatment for CJD currently available; the illness progresses invariably to death, usually within three to six months of onset.

B. The National Hormone and Pituitary Program

The National Pituitary Agency (the present National Hormone and Pituitary Program) was established in 1963 by the then National Institute of Arthritis and Metabolic Diseases (the present National Institute of Diabetes and Digestive and Kidney Diseases, NIDDK) with support from the College of American Pathologists. Until 1985, it provided pituitary hormones for both clinical and laboratory research. Since 1985, it has supplied materials for laboratory research only.

The NIDDK's Hormone Distribution Program makes available to the research community human and animal pituitary hormones, antisera against these hormones, and selected other hormonal and biological products. Upon request, these materials are distributed to research scientists who use them in research projects which enhance understanding of endocrine and metabolic processes and diseases. The program is an outgrowth of the research community's perceived need for high quality, standardized research materials. Through this program, scientists have access to hormones and antisera of known composition and potency. Most of the products are unavailable commercially. Currently, approximately 170 research materials are distributed. Approximately 7,000 individual vials of human and animal hormones and antisera are awarded to investigators annually for immunochemical research.

In 1992, after 23 years at the University of Maryland at Baltimore, the contract for distribution of these endocrine reagents was awarded to Ogden Bioservices in Rockville, Maryland. At the expiration of this contract in December, 1997, the distribution of these materials was consolidated with the primary source laboratory, Dr. Albert Parlow at Harbor-UCLA Medical Center in Torrance, California. Through an innovative agreement with Dr. Parlow, the endocrine community has ready access to many additional materials as well as the scientific and technical expertise that Dr. Parlow has accumulated through a career of research on pituitary hormones. Dr. Parlow has already been instrumental in bolstering the inventory of recombinant hormones through contacts with the pharmaceutical industry. Working

with the project officer, Dr. Parlow has added other reagents of value to the research community, such as leptin and recombinant mouse pituitary hormones.

III. UPDATE ON ISSUES

A. Cases of Creutzfeldt-Jakob Disease in Pituitary Hormone Recipients Worldwide

United States

In October 2000, the Committee identified a total of 22 CJD cases among the U.S. recipients of the NHPP hGH hormone.

Seventeen of these 22 cases of CJD occurred in the originally-defined study cohort of 6,272 hormone recipients whose treatment was confirmed based on information from treatment centers. There have been 506 total deaths in this cohort.

--By the beginning of 1980, there was one confirmed CJD case, albeit preclinical, in the first 72 cohort deaths (1.4 percent). This case-patient died from a non-neurologic illness; the patient's CJD brain lesions were diagnosed years later upon re-examination of autopsy tissue.

--During the 1980s, there were five CJD cases among the 215 deaths that occurred among the originally-defined cohort (2.3 percent).

--From 1990 through 1998, there were nine CJD cases among the 219 deaths that occurred in the cohort (4.1 percent).

In 1999, there were two reported CJD deaths in the originally-defined study cohort; the most recent of these occurred in October.

Five additional CJD cases--one in 1991, two in 1993, one in 1998, and one in 1999--occurred in U.S. hGH recipients who were not in the originally-defined study cohort because they were not identified before 1989 as confirmed hGH recipients. The precise number of such U.S. recipients of hGH who were not initially identified for the study cohort is unknown, but is believed to be about 1,400 persons.

In the U.S., all cases of CJD have so far occurred in people who began hGH treatment before 1977, when a new method of purification that included chromatography was introduced.

Foreign Cases

United Kingdom: The United Kingdom has reported 35 cases among 1,900 human growth hormone recipients.

France: No new additional cases have been reported since 1998. France has reported 74 cases among approximately 1,700 hGH recipients.

Australia: No recent hGH-associated CJD cases have been reported in Australia. Australia had previously recorded one death believed due to CJD in an hGH recipient, and four in pituitary-derived gonadotropin recipients.

New Zealand: A total of five CJD cases were previously reported in New Zealand. All five cases occurred among 46 people who received hGH produced in the U.S. by one of the three laboratories that supplied National Hormone and Pituitary Program hGH prior to 1977.

Brazil: One case was previously reported in an hGH hormone recipient who received hormone produced in a U.S. laboratory that also produced hormone for the National Hormone and Pituitary Program.

Holland: In 1998, Holland reported one hGH-associated CJD case. No new cases have been reported since that time.

B. Epidemiology Study

A major goal of the epidemiology study is to provide hGH recipients the best information possible about their risk of contracting CJD.

The surveillance procedure used in the epidemiology study continues to be identification of all deaths in the cohort of 6,272 identified National Hormone and Pituitary Program (NHPP) hGH recipients through the National Death Index (NDI). The match of NHPP hGH recipients with the NDI has been completed for all deaths through 1998. Although there is an inherent delay in the identification of deaths through the NDI, the Committee believes that the awareness of the CJD problem in the medical community, as a result of publications and presentations at major medical meetings, would likely yield more rapid ascertainment of CJD cases, including cases among recipients who may not have been included in the originally identified study cohort. This has proven to be the case. Of the 22 identified U.S. hGH recipients with CJD, including the 17 cases in the originally-defined cohort, all but two were ascertained prior to the NDI searches by direct reports from physicians or family members.

The follow-up study has been successful in obtaining death certificates for nearly all deaths, but has experienced difficulty in obtaining releases to obtain and review medical records of some deceased members of the cohort identified through the NDI. Written requests are sent to verified addresses of family members to obtain releases; when there is no response, follow up phone calls are made to further extend this effort. In some cases, family members decline to sign a release and in others they may agree to do so but fail to return it despite several contacts. In other cases, after considerable search, family members of these patients cannot be located to request consent to obtain and review records. The study also attempts to retrieve all available neuropathology specimens for review by neuropathologists who are consultants to the study.

Mortality, United States

Through 1998, the total number of deaths in the 6,272 hormone recipients that comprise the study cohort is 506. Of these deaths:

--491 were not due to CJD.

--15 (3.0 percent of the deaths in the cohort) were individuals who were known to have been infected with the CJD agent. Two additional cohort members died of CJD in 1999.

There had been 254 non-CJD deaths reported in this cohort in a 1991 publication that included the complete ascertainment of deaths through 1986 (*Journal of the American Medical Association* 1991; 265:880-884). The plurality of deaths were due to brain tumors and other medical problems, which had their onset prior to hGH therapy, and were the cause of the hGH deficiency.

As of 1998, the proportion of deaths in the cohort due to CJD during the 1990s had increased compared to earlier decades. However, since the three additional reported CJD deaths occurred in 1999, including two among the originally-defined cohort, no additional cases of CJD have been identified.

Five additional deaths attributable to hGH administration occurred in U.S. hGH recipients who were not in the originally-defined study cohort because they were not identified before 1989 as confirmed hGH recipients. This cohort is believed to consist of about 1,400 persons.

Thus, 22 deaths due to CJD have occurred in both cohorts, which total approximately 7,700 people.

As of October 1999, the total of 22 CJD deaths constituted 0.3 percent of the estimated total of NHPP hGH recipients in the U.S. Based on the study cohort, however, 0.8 percent of recipients whose treatment began before 1977 developed CJD. These proportions of recipients developing CJD were reported by members of the Committee (Drs. Brown, Fradkin, and Schonberger) and others (*Neurology* 2000; 55:1075-1081).

The separate analysis of recipients who began treatment before 1977 was presented because in that year, the laboratory of Dr. Albert Parlow at Harbor-UCLA Medical Center in Torrance, California, began producing NHPP growth hormone using a new method of production. This method was subsequently shown to substantially reduce CJD contamination in the starting material and no cases have yet occurred among the patients first treated after 1977.

Only 11 percent of patients from the originally defined cohort of 6,272 began treatment with hGH before 1970, yet most of the cases of CJD have occurred in this group. For patients starting treatment before 1970, the proportion developing CJD

is 2 percent. For patients who were known to have been first treated with hGH between 1970 and 1977 inclusively, the comparable proportion is 0.2 percent.

The same three laboratories produced NHPP hGH from the inception of the program in 1963 until 1977. It is not yet known whether the higher rates of CJD among patients treated before 1970 reflect primarily a higher risk of transmission from the earlier preparations or insufficient time for the more recently exposed recipients to develop CJD due to the long CJD incubation time. Some patients who completed treatment in the early 1970s are now approaching 30 years beyond exposure to hGH. It is probable that they are emerging from the incubation period during which they were potentially at greatest risk of developing CJD.

Of the 22 confirmed cases of CJD, six had onset during the last six years of the 1980s, and 15 had onset in the first nine years of the 1990s. (One case diagnosed retrospectively from neuropathologic study of brain tissue died of an unrelated illness in 1979 before she developed clinically apparent CJD.) Thus, the rate of occurrence of new cases of CJD in the U.S. averaged one case per year, 1984-1989; and 1.7 cases per year, 1990-1998.

The average duration of therapy of the confirmed cases was over nine years, while the average duration of therapy for the earlier cohorts (those who began treatment before 1970) was less than four years. Thus, as previously reported, duration of treatment is a major risk factor for development of CJD.

Mortality, International

Mortality of CJD cases internationally is summarized as follows:

- New Zealand, five deaths, representing 10.9 percent frequency for pre-1977 treatment.
- United Kingdom, 35 deaths, representing 1.9 percent frequency.
- France, 74 deaths, representing 4.4 percent frequency, or 5.9 percent of persons treated during the period 1983 to mid-1984.

C. Conclusion of Studies of Animals Injected with Human Growth Hormone

The National Institute of Neurological Diseases and Stroke (NINDS) conducted studies in non-human primates to identify CJD infectivity in samples of 76 lots of growth hormone available from the NHPP. Each lot was inoculated by intracerebral, intravenous, and intramuscular routes into three squirrel monkeys. One of the three squirrel monkeys inoculated with one lot of growth hormone distributed between 1965 and 1968 was found to have clinical signs of progressive neurologic disease, which was verified histologically as CJD as previously reported in the *New England Journal of Medicine*. The remaining two squirrel monkeys inoculated with this lot did not develop disease. Hormone from this lot is not known to have been received by any patient who contracted CJD, although two cases of the 22 cases might have received this preparation. The Committee continues to believe that contamination was probably low level, random, and involved multiple hGH preparations, and that

there is no reason to believe that patients who may have possibly received hGH from the lot that transmitted CJD to the squirrel monkey are at increased risk compared to other hGH recipients treated during this time period.

These inoculated animals were followed for more than ten years. All animals were examined for evidence of CJD upon death. The NINDS reported that all squirrel monkeys injected with hGH have been sacrificed, and the brains of over 200 animals were extracted for analysis of prion protein. Squirrel monkeys, it was noted, are particularly sensitive and susceptible hosts--almost as sensitive as chimpanzees. Moreover, the monkeys were injected intra-cerebrally which greatly increased the risk of transmission. Only one preparation transmitted CJD to one animal. This has previously been reported in a letter to the *New England Journal of Medicine*. A final report on the animal studies is in process.

D. Communication with Growth Hormone Recipients

The most recent letter and Fact Sheet were sent to hGH recipients, parents, and physicians on June 21, 1999. The letter incorporated material developed in response to a number of questions received after the previous mailing, as well as suggestions from the CDC Institutional Review Board (IRB), Dr. Paul Stolley (a distinguished epidemiologist and consultant to the Committee), and members of the Committee. As recommended by the IRB, the PHS established a toll-free telephone number for hGH recipients and families to facilitate contact with PHS staff. This number was provided in the mailing and on an NIDDK website developed specifically to provide updated information to hGH recipients.

The PHS contacted the MAGIC Foundation, a voluntary group for support of people with growth disorders, which has chapters nationwide. This organization agreed to assist hGH recipients make contact with each other and form support groups. In the June 1999 mailing to hGH recipients, the NIH notified all hGH recipients that this opportunity was now available and encouraged those interested in joining such groups to contact the MAGIC Foundation for assistance. The NIDDK website for hGH recipients includes a link to the MAGIC Foundation and information about this opportunity.

E. Advances in Understanding the Biology of Creutzfeldt-Jakob Disease

Some of the world's leading researchers continue to focus their efforts on this disease, but at this point in time there is no effective treatment for CJD. There has been some progress toward developing more sensitive tests for the detection of the diagnostic prion protein, but none have so far been shown to be sufficiently sensitive to detect the protein in human blood or blood components, i.e., to be useful as a diagnostic screening test for preclinical or even clinical disease. Eight research groups have been unsuccessful thus far in identifying the prion as a definitive marker for early disease, but they are progressing in making the prion assay more sensitive.

Progress has also been made in prophylactic therapy against CJD. There is enough known biochemically about the prion protein now to begin to develop drugs to block the transition from prion protein to the development of insoluble amyloid protein, which is present in overt CJD. In fact, drugs have been developed that are effective in tissue culture and in animals.

Thus, vigorous efforts are being mounted and progress is being made. The timeline for useful tests and therapies, however, remains uncertain.

To date, there are three relatively specific diagnostic tests that can be performed on living individuals suspected of having the disease that do not involve a biopsy of tissue. These include examination of spinal fluid, magnetic resonance imaging of the brain, and an electroencephalography. These tests are less useful in the early stages of disease.

TAB A **Minutes of Meeting of the PHS Interagency Coordinating Committee on human Growth Hormone and Creutzfeldt-Jakob Disease, Nov. 4, 1999.**

TAB B **Minutes of Meeting of the PHS Interagency Coordinating Committee on human Growth Hormone and Creutzfeldt-Jakob Disease, Nov. 6, 2000.**

**OPTN/UNOS OPO Committee
Descriptive Data Request**

HTLV Positive Donors

Prepared for:
OPO Committee Meeting
March 31, 2004

By:
John Rosendale and Jessie Maker
Research and Data Management Systems Departments
United Network for Organ Sharing

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Committee Request

1. Identify all positive HTLV donors. Contact the recovering OPO to determine if a confirmatory test was performed. If a confirmatory test was performed, determine if the test was positive. For all donors that were confirmed positive by a confirmatory test, contact the recipient center to find out:
 - a. The HTLV status of the recipient prior to transplant.
 - b. Has the recipient developed a syndrome consistent with the HTLV virus?
 - c. Has anyone in their family had any associated health problems since the transplant?

Background/Purpose

Current OPTN policy does not allow for the transplantation of HTLV positive donor organs, but some transplant centers are accepting them. The issue of HTLV positive donors was discussed at the AOPO Procurement Directors meeting in June 2003. The AOPO Procurement Directors have requested that the OPTN/UNOS OPO Committee discuss this issue at their September 2004 meeting.

At its September 2003 meeting, the OPO Committee reviewed data that listed the following:

- 1 Patient and Graft survival for patients who receive HTLV positive organs
- 2 Rejection frequency for patients who receive HTLV positive organs
- 3 Cause of death for patients who received HTLV positive organs and subsequently died
- 4 The number of transplant centers that transplant HTLV positive organs
- 5 Positive serologies in addition to HTLV

The OPTN currently collects serology data, including HTLV, on all donors via the Deceased Donor Registration form (DDR). The form currently collects both HTLV-I and HTLV-II. Since the test many OPOs use does not distinguish between HTLV-I and HTLV-II a positive reported on either field is considered an HTLV positive donor for the purposes of this analysis. Currently, the reporting of an HTLV positive donor results in a follow up telephone call from the UNOS Data Management Systems (DMS) Department to confirm that this was indeed an HTLV positive donor. Changes are made if needed. The OPTN does not currently collect HTLV data on recipients.

The Committee was concerned that many of the donors that were listed in the OPTN database may have been false positives. While the DMS Department confirms that the reporting OPO meant to list the donor as HTLV positive, they had not asked if a confirmatory test had been conducted. So, the Committee asked that the OPOs be contacted to find out if these were indeed confirmed (by a second test) cases. The Committee requested the data listed above be collected and reported for those donors who were confirmed HTLV positive by a confirmatory test.

Data and Methods

There were 32 "confirmed" donors reported between January 1, 1995 and January 31, 2004. These were donors that the recovering OPO reported as being HTLV positive and when

contacted confirmed that the donor was indeed HTLV positive. These 32 donors were recovered at 20 different OPOs, and resulted in 58 transplants (11 heart, 22 kidney, 22 liver, and 3 lung).

Each of the 20 OPOs were contacted and asked if a confirmatory test was performed to determine if the donor was truly HTLV positive. For each donor that was confirmed by a second test, the transplant center that received the organ was contacted. The centers were asked about the HTLV status of the recipient pretransplant and if the recipient developed any syndrome consistent with the HTLV virus posttransplant. The transplant center was also asked if any of the recipient's family members had any associated health problems since the transplant. The results of these inquiries follow.

Results**Table 1. Donors Reported to be HTLV Positive
January 1, 1995 to January 31, 2004**

Donor	OPO	Organs Transplanted	Confirmatory Test Done	Confirmed HTLV+
1	A	LI	NO	NO
2	B	HR, 2KI, LI	YES	NO
3	C	LI	YES	NO
4	D	LI	YES	NO
5	D	HR, KI, LI	NO	OPO keying error, not HTLV+
6	D	2KI	NO	OPO keying error, not HTLV+
7	E	LI	YES	YES
8	E	2KI, LI	YES	NO
9	F	LI	NO	NO
10	F	LU	NO	NO
11	F	LI	NO	NO
12	G	HR	NO	NO
13	H	LI	NO	NO
14	H	HR, LI	YES	Inconclusive
15	I	LI	YES	NO
16	J	LI	YES	Indeterminate
17	K	HR, LI	YES	YES
18	L	2KI, LI	NO	OPO keying error, not HTLV+
19	M	LI	NO	OPO keying error, not HTLV+
20	N	HR, 2KI, LI	NO	NO
21	O	LI	NO	NO
22	O	LI	YES	YES
23	O	HR, 2KI, LI, LU	NO	OPO keying error, not HTLV+
24	P	HR	NO	OPO keying error, not HTLV+
25	P	2KI, LU	NO	OPO keying error, not HTLV+
26	P	KI	NO	OPO keying error, not HTLV+
27	Q	HR	YES	YES
28	Q	HR, 2KI, LI	NO	OPO keying error, not HTLV+
29	R	HR	NO	NO
30	S	LI	YES	YES
31	S	2KI	NO	NO
32	T	2KI	YES	Inconclusive

**Table 2. Patient and Graft Outcomes for Recipients of Confirmed (by second test) HTLV+ Donor Organs
January 1, 1995 to January 31, 2004**

Year	OPO	TX Center	Donor	Patient Status	Days Posttransplant	Graft Status	Days Posttransplant
Heart							
1998	A	1	AA	Dead	41	Failed	41
2002	B	2	BB	Alive	317	Functioning	317
Liver							
2000	C	3	CC	Dead	922	Failed	922
2002	B	4	BB	Dead	330	Failed	330
2002	D	5	DD	Dead	9	Failed	9
2003	E	6	EE	Alive	182	Functioning	182

**Table 3. Serology Data for Recipients of Confirmed (by second test) HTLV+ Donor Organs
January 1, 1995 to January 31, 2004**

Donor	Donor Serology					Recipient Serology					
	HIV	CMV	HBsAg	HBC	HCV	HIV	CMV	HbsAg	HBC	HCV	Epst Barr
AA	N	N	N	N	ND	N	N	N	N	U	U
BB	N	N	N	N	ND	N	P	N	N	ND	P
CC	N	P	N	N	ND	N	P	N	P	P	P
DD	N	P	N	N	ND	N	P	N	P	U	P
EE	N	P	N	N	ND	N	P	N	N	ND	P

N=Negative, P=Positive, ND=Not Done, U=Unknown, C=Cannot Disclose

**Table 4. Characteristics of Donors Confirmed (by second test) HTLV+
January 1, 1995 to January 31, 2004**

Donor	Age	Ethnicity/Race	Gender	Cause of Death
AA	38	Hispanic	Female	Cerebrovascular/Stroke
BB	57	White	Male	Head Trauma
CC	45	White	Female	Cerebrovascular/Stroke
DD	54	Hispanic	Female	Cerebrovascular/Stroke
EE	53	Black	Female	Cerebrovascular/Stroke

**Table 5. Characteristics of Recipients of Confirmed (by second test) HTLV+ Donor Organs
January 1, 1995 to January 31, 2004**

Recipient	Organ	Age	Gender	Ethnicity/Race	Previous Transplant	On Life Support at TX	Cause of Death
1	HR	61	Male	Hispanic	No	Yes	Multiple Organ Failure
2	HR	55	Male	White	No	Yes	Still Alive
3	LI	67	Female	White	No	No	Graft Failure: Hepatitis
4	LI	49	Male	White	No	No	Unknown
5	LI	62	Male	Hispanic	Yes	No	Brain Dead: Never Recovered From Surgery
6	LI	49	Male	Black	No	No	Still Alive

Table 7. HTLV Status for Recipients and their Families

Recipient	Recipient HTLV Status Pretransplant	Has anyone in their family had any associated health problems since the transplant?
1	Pretransplant HTLV status not documented	Unknown
2	No positive HTLV documented in chart	Unknown
3	Do not test for HTLV pretransplant	Unknown
4	Center did not reply	Center did not reply
5	Nothing about HTLV documented in patient chart	Unknown
6	Center did not reply	Center did not reply

Estimates of Organ Donation Rates for Hospitals and Donation Service Areas (DSAs)

Prepared by the Scientific Registry of Transplant Recipients
for the OPTN OPO Committee
March 31, 2004

SRTR

Objective

To develop a measure of the organ donation process that:

- Is easily quantifiable and reproducible
- Is based on nationwide data
- Accounts for patient characteristics, as well as DSA & hospital factors
- Facilitates improved understanding of differences in organ donation potential

SRTR

ustransplant.org

- DSA / OPO Specific Report
- Table 3 – Donation Rate per Eligible Death
 - Crude donation Rate
 - Adjusted Donation Rate (Hospital Characteristics)
 - Adjusted Donation Rate (Hospital Characteristics, Notifiable Deaths)
- Available on public site since January 2004

SRTR

Eligible Deaths (E)

- Counts are collected by the OPO and provided to the OPTN/SRTR via the UNET reporting system.
 - Age ≤ 70 years
 - In-hospital deaths
 - Brain death
 - Medically Suitable
- 2002 U.S. total ~ 12,700
 - approximately 200 per DSA in 2002

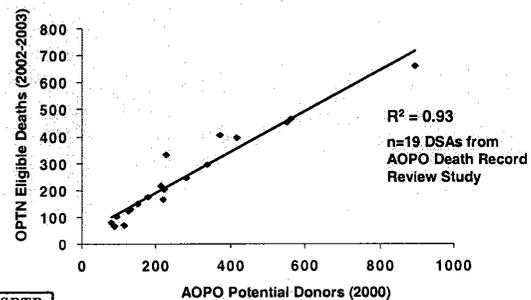
SRTR

Data for Eligible Deaths

- Referral Data report
 - Current: Monthly report submitted at a hospital level as aggregate Eligible Death totals
 - Requested: Individual data for these deaths

SRTR

Validation: Eligible Deaths vs. Potential Donors



SRTR

Current Results

- **Crude Donation Rate is a basic measure**
 - Does not account for determinants of donation
 - Potential variability: reporting of Eligible death
- **Adjusted Donation Rates**
 - Yield interpretable estimates of donation rate
 - Account for Hospital & DSA characteristics, as well as underlying death rate (Notifiable Deaths)
- **Rate per eligible death**
 - Improves upon prior measures including donors per million population

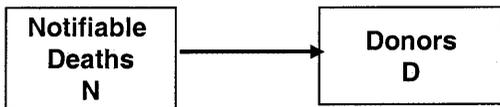
SRTR

Proposed Expansion of Data Collection

- **Adjustment to Crude Donation used to account for differences in:**
 - ✓ Hospital characteristics
 - ✓ OPO characteristics, as appropriate
 - ? Eligible death demographics (race, age-group, cause of death, medical examiner consent)
- **Individual data on each Eligible death would help identify types of potential donors with high conversion rates in order to focus efforts on potential donors that are most likely to donate**

SRTR

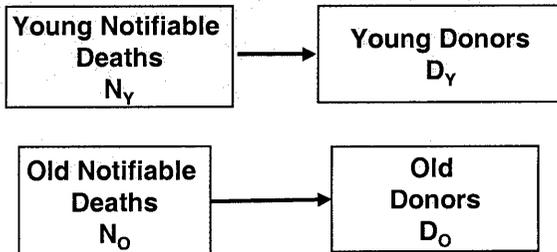
Rate per Notifiable Death (includes non brain-dead), an improvement on rate per population



Crude Rate = D / N

SRTR

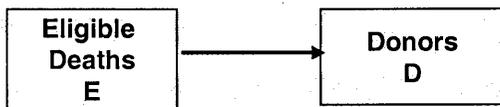
Rates of Donation per Notifiable Death Vary by Demographics



Age-specific rates allow calculation of Expected Donors

SRTR

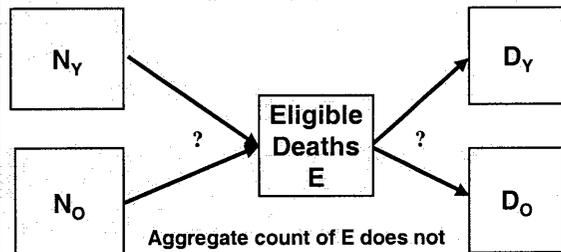
Eligible Deaths and Donors: Adjustment for demographics is not possible with current data



Crude Rate = D / E

SRTR

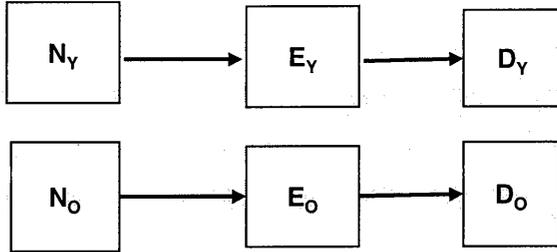
Notifiable Deaths, Eligible Deaths, and Donors



Aggregate count of E does not allow adjustment of donation rate or of rate of identification of E

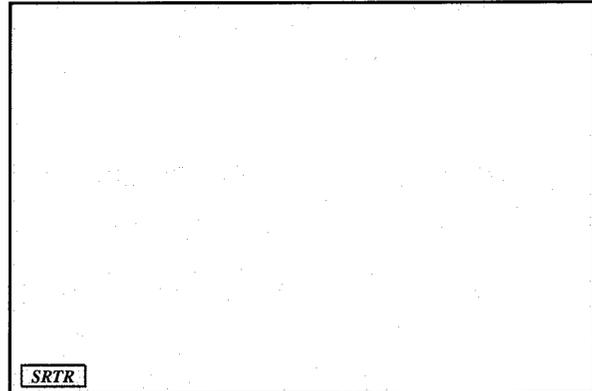
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The Proposed Request for Data: Demographics for Eligible Deaths

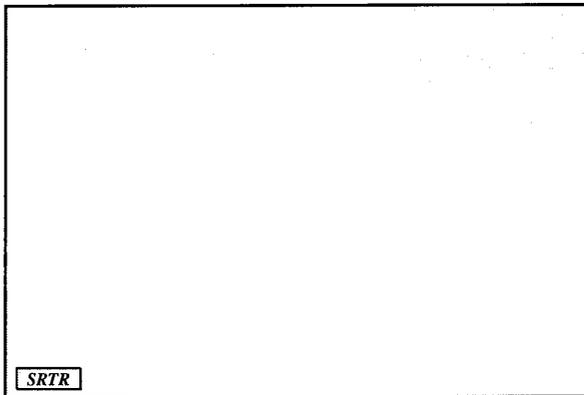


Demographics allow adjustment, evaluation,
and study of rates

SRTR



SRTR



SRTR

Requested Data Already Submitted to OPTN for Most Eligible Deaths

- Deceased Donor Registration form
 - Data collected for all patients in which consent for donation was obtained (including cases where no organs were recovered)
 - DDR form submitted for 51% of total Eligible Deaths
 - Contains a majority of requested data items

SRTR

Data Burden of Eligible Death Form

- Approximately 12,700 total Eligible Deaths in 2002
- Approximately 6,500 consented Eligible Deaths (51% of total)
 - Patient-level data contained in Deceased Donor Registration forms
- Additional data collection sought for Eligible Deaths without consent
 - 6,200 patients in 2002 (49% of total)
 - Average of 107 additional forms per DSA / OPO per year

SRTR

Proposed Data Elements (1)

- Provider Information*
 - OPO center code/name
 - Deceased hospital name/provider number
 - Date and time of brain death
 - Date and time of call/OPO notification
 - Interval between declaration of eligibility and OPO notification
 - Eligible death identified only in retrospective review (Y/N)

* Existing Data Elements; New Data Elements Proposed for Collection

SRTR

Proposed Data Elements (2)

- Patient information*

- OPTN ID
- Name (Last, First)
- Age (Years, Months)
- Gender
- Home city, state, zip code
- Race/Ethnicity
- Citizenship
- Cause of death
- Mechanism of death
- Circumstances of death
- Procurement and consent
- Medical examiner
- Clinical information

* Existing Data Elements

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Conclusions

- Person-specific data are currently collected for consented eligible deaths (51%).
- Deceased Donor Registration form already includes a majority of the proposed data elements.
- Old Donor Referral form included these data
- Additional data collection sought for non-consented eligible deaths
- Individual data on each Eligible death would yield likelihood of donation:
 - Focus efforts on greatest potential
 - Evaluate performance by subgroup

SRTR

Summary of Public Comment

New OPTN/UNOS Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), .3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption) (OPO Committee)

As of 4/29/2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 49 (59.04%) supported the proposal, 0 (0%) opposed the proposal, and 34 (40.96%) had no opinion. Comments on the proposal received to date are as follows:

Comment 1: *Vote: Support*

Approve with correction to one sentence that currently does not make sense (last paragraph) "The organ procurement organizations should reference recent matched (?????) of similar ABO....".

Committee Response: The Committee thanks the commenter for identifying the grammatical error and will correct the policy to change "matched" to "matches".

Comment 2: *Vote: Support*

Hats off to those who think ahead!

Committee Response: The Committee appreciates the response of the commenter.

REGIONAL COMMENT SUMMARY
March 2004

PROPOSAL 23: New OPTN/UNOS Policy 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), .3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption) (OPO Committee)

Sponsoring Committee: OPO Committee

Description: The Health Resources Services Administration (HRSA) has requested the OPTN develop policies for maintaining the organ matching and allocation process during times of regional or national emergencies that compromise telecommunication, transportation, or the function of or access to the OPTN wait list or matching system. OPTN staff drafted the proposed policies for consideration by the OPO Committee. The policy was approved by the Board of Directors and became effective December 22, 2003, concurrent with public comment.

DATE THIS DOCUMENT MODIFIED: 5/3/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04	13 yes, 0 no, 0 no opinion			
2	5/07/04	24 yes, 0 no, 7 no opinion			
3	3/26/04	17 yes, 0 no, 0 no opinion			
4	4/2/04	27 yes, 0 no, 0 no opinion			
5	4/30/04	31 yes, 0 no, 5 no opinion			
6	4/2/04	51 yes, 0 no, 2 no opinion			
7	4/23/04	18 yes, 0 no, 0 no opinion			
8	4/2/04	15 yes, 0 no, 0 no opinion			
9	4/21/04	17 yes, 0 no, 0 no opinion			
10	4/30/04	18 yes, 0 no, 0 no opinion			
11	3/26/04	19 yes, 0 no, 1 no opinion			

COMMENTS:

**OPTN/UNOS Ethics Committee
Living Non-directed Organ Donation - White Paper
August 15, 2003 – Final Version**

The OPTN/UNOS Ethics Committee has endorsed non-directed living donation as morally commendable and ethically acceptable. The Committee has historically expressed concerns regarding the allocation of non-directed donor organs. The purpose of this white paper is to discuss the ethical principles that apply to living non-directed organ donation. This paper will define living non-directed donation and review the concepts of donor motivation, informed consent, risk/benefit analysis, allocation, transplant program considerations and donor follow-up.

Categories and Definitions:

There are three types of non-directed donation: 1) deceased-donor donation, 2) live donor/deceased-donor exchange protocol under an OPTN/UNOS allowed variance, and 3) non-directed donation. With deceased-donor donation, the current OPTN/UNOS policy allows the next of kin the option to direct the donation to a specific individual or transplant center. There is generally no pre-existing relationship between the donor and the recipient and, while typically an anonymous process; anonymity may be waived by mutual agreement of both the recipient and the donor family. With the live donor/deceased donor exchange protocol, the donation is conditioned on a “payback in-kind” to a specified individual. This approach falls under a specific allocation variance, which has been adopted according to OPTN/UNOS policy. In its final form, non-directed donation is the only form of donation operationally designed to be truly altruistic and non-directed at the same time. Under a non-directed donation model, the organ is donated as a gift and placed for distribution through the established allocation system. There are no expectations of return for the gift and no connections between the donor and recipient.

Informed consent:

Potential living donors are healthy individuals who rarely receive medical gain and who would not otherwise be considered “patients.” However, as potential donors they assume a special classification based on undergoing the donation evaluation process.¹ The informed consent process should seek to protect these individuals by insuring that they have appropriate decision-making capacity, accurate and complete information, and freedom from coercion.

Information presented to both the donor and the recipient must be presented in a manner that is clearly understandable and will vary dependent on the educational background and intellectual capacity of the individual. It is incumbent on the transplant center to provide accurate disclosure to potential donors of all pertinent information regarding known risks, as well as benefits to both the donor and the recipient.

Recognizing that transplant techniques are continuously evolving, the prospective donor needs accurate and coherent information regarding his/her risks for morbidity and mortality. In addition, the individual considering the option to donate needs to understand that the potential risks for donation extend beyond the event of the surgery. It is important to explain that the

¹ Consensus Statement for Live Organ Donors, page 2920.

procedure may carry long-term risks, which are not yet appreciated. The potential for psychological, financial, and insurance risks should also be disclosed and understood.

In addition to understanding the risks of the procedure, the potential donor should have a realistic understanding of the transplantation process. To this end, they should be made aware of pertinent patient and graft survival data, as well as possible risks to potential recipients post transplant. Additionally, they should be informed of organ allocation policies that will determine how the non-directed donation will be allocated.

Informed, valid consent must reflect autonomous and stable preferences. The transplant center should attempt to identify any potential sources of coercion that may influence a donor's decision. This process may actually be less complicated than in living-directed donation because non-directed donation lacks the inherent, potentially coercive nature present in the familial/emotional relationships. Therefore, the living non-directed donation decision may be considered more of a voluntary act. Given the absence of reproducible health benefits for the donor, the transplant team must ensure that the donor is free from coercion, particularly any form of illegal financial compensation. In living organ donation, a "cooling off period" between the consent decision and the scheduled donor operation is critical to the process of informed consent. This period will allow time for the transplant center to perform a thorough evaluation and for the potential donor to assimilate the information being provided.² Further, if the individual's commitment to donation persists through this period, it provides evidence of the stability of her/his preferences.

Living non-directed donors represent a unique subset of donors who do not medically benefit from the surgical procedure yet who elect to place themselves at risk for a stranger's benefit. Informed consent for living non-directed donation must be established at a strict standard to protect this unique group of donors. This standard of informed consent should resemble a research standard. The Institutional Review Board (IRB), Hospital Ethics Committee or Hospital Risk Management Program may assist in playing a key role in providing guidance in the development of the protocol and consent documents prior to implementation of the living non-directed donation program.

Risk/Benefit Analysis:

Primum non nocere ("First, do no harm") is one of the most widely recognized principles of medical ethics. Early opponents objected to living donor transplantation on the grounds that it violates a strict interpretation of this principle. In living organ donation, as in other areas of medicine, interpretation of this fundamental precept has evolved. The anticipated benefit is considered, rather than focusing solely on the avoidance of harm.

Thus, one of the primary ethical concerns in living donor transplantation is the need to achieve an appropriate balance of benefit and risk. In the case of living donors, this risk/benefit analysis is extremely complex because it requires deciding if the benefit to one individual justifies the risk to another. The recipient enjoys a disproportionate share of the benefits (improved health and life expectancy), while the donor assumes the burden of an invasive

² Consensus Statement for Live Organ Donors, page 2920.

surgical procedure and its potential long-term adverse consequences. In living related transplantation, just as the emotional connection between donor and recipient can introduce an element of coercion, that same connection makes more apparent the donor's participation in the benefits accruing to the recipient. In living, non-directed donation, absent that connection, the donor assumes risk without an obvious or immediate opportunity to share in the recipient's good fortune. This lack of obvious and direct benefit raises questions concerning the non-directed donor's motivation.

Not only should the theoretical and statistical risk for the donor and recipient be considered, but also the location where the donation is occurring plays a role in the ethical considerations of its appropriateness.

Donor Motivation:

The ethical issues discussed in preceding sections are pertinent to both non-directed donation and living-directed donation. However, discussions of these issues have traditionally taken for granted that a relationship exists between the donor and recipient. The unique challenge posed by non-directed donation stems from the difficulty understanding a person's motivation to donate an organ to a "stranger." When a relationship exists between the donor and the recipient, it is easy to appreciate the extent to which the donor is invested in the situation. The experiences of the two individuals are intertwined such that the donor stands to benefit directly from the improved health of the recipient or to suffer if the recipient's condition deteriorates.

Motivation to donate outside the context of such a relationship is more difficult to discern. For this reason, offers by non-directed donors are frequently met with skepticism. One potentially confounding factor is the expectation that a donor's motivation stems from pure altruism (i.e. the desire to help another person without expectation for personal gain). It is important to realize that, even in living-directed donation, attainment of the ideal may be rare.

Maintaining a standard based on altruism may result in a tendency to downplay the extent to which individuals benefit from the act of donating. Multiple publications over the past twenty-five years have explored the living donor's decision-making process, and authors have noted increased self-esteem and other beneficial changes.³ While most reports pertain to living related donation, one would expect non-directed donors to experience similar benefits. In fact, it has been suggested that non-directed donors may actually experience a greater sense of satisfaction because the act is considered beyond the call of duty. An individual may hope to achieve a heightened sense of meaning or feeling of accomplishment through the act of donating. Thus, the benefits of donating an organ may be unanticipated or they may actually serve as a source of motivation. Organ donation remains a morally commendable act despite the potential for benefit to the donor.

Considerations of donor motivation should acknowledge that many sources of motivation are ethically sound. Non-directed donation does not require strict adherence to an altruistic ideal. Rather than attempting to strictly define acceptable motivations to donate, it may be more useful to rule out unacceptable circumstances. For example, expectation for financial compensation or

³ Organ Donation-Psychiatric, Social and Ethical Considerations; page 338.

the desire to form an emotional bond with the recipient or to benefit a specific population would be unacceptable motivations. In addition, emotional or intellectual instability, which would impede the individual's ability to make an informed decision about donation, would be cause to refuse an offer from a non-directed donor. Most importantly, the evaluation process should be a collaboration between the potential donor and the transplant center to insure that the donor's goals and expectations are realistic.

Transplant programs need to respond to inquiries about non-directed donation following protocols and policies that will help to ensure that these requests are handled in an objective and thoughtful manner. Such offers should not be dismissed simply because they do not conform to the accepted explanation of why people donate organs. Offers of non-directed donation warrant serious consideration and a commitment to implement policy that would serve the best interests of the donor, recipient, and transplant community.

Anonymity:

Anonymity for either the donor or the recipient cannot be guaranteed. Nonetheless, attempts should be made to maintain anonymity, and donors and recipients should be advised that maintaining anonymity may be in their best interests. Anonymity should be maintained as a means to protect both parties from future potential coercion.

Transplant Program Considerations:

A significant number of transplant centers are reportedly performing these procedures with regularity. Therefore, various approaches dealing with non-directed donation are already operational and must be taken into consideration. Nonetheless, it is unacceptable for the transplant center to derive any gain through exploitation of the donor and/or the recipient or to achieve self-aggrandizement through improved economy, prestige, individual ego or career advancement due to this type of donation. Program marketing, advertising or the use of media appeals must follow strict standards to prevent the perception of conflicts of interest.

Allocation Considerations:

When allocating living non-directed organs, it is important that there be an intent to serve the entire transplant candidate pool. Allocation of organs recovered from living non-directed donors should follow the standardized policies of non-discrimination utilized for the allocation of deceased donor organs, which recognizes the option for individuals to direct donation in some cases. Since the potential good from non-directed living donation should be maximized, the transplant community should make an effort to match donors and recipients appropriately. Until such time, the organ being donated will presumably be allocated to the first compatible transplant candidate on the list as per the existing OPTN/UNOS allocation policies, within both clinical and logistical limits.

Currently, there is no policy governing the allocation of non-directed organs from living donors. Therefore, there may exist a presumption that organs recovered in this manner may be applied for the exclusive benefit of the recovering center's patients. The goal in pursuing non-directed organ donation from living donors should be to derive maximal benefit and equitable distribution. However, this goal needs to be reconciled with the need to ensure autonomy of the donor. For this reason, the OPTN/UNOS Ethics Committee proposes that, within both clinical

and logistical limits, non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of deceased donor organs within the appropriate sharing unit.

The proposed allocation policy for non-directed donor organs as currently articulated is restricted to kidney transplantation. The OPTN/UNOS Ethics Committee endorses the concept that this allocation principle be the expectation for the allocation of liver and lung segments recovered from non-directed living donors. However, it is the opinion of the Committee that technical considerations and limited experience and expertise in living donor transplantation of liver and lung segments preclude the broad application of the proposed allocation principle at this time.

Donor Follow-up:

The establishment of a living donor database is necessary as one means to collect information related to the donor, which includes demographic, clinical and outcome information on all living organ donors. The rationale for the development of a living donor database includes: concern for donor's well-being, limitation of current knowledge regarding the long-term consequences of donation, to evaluate the impact of donor variables on the outcome, and the need within the transplant community to develop mechanisms to provide for quality assurance assessments.⁴ Living non-directed donors could utilize this information in their decision-making process.

Conclusions:

Living non-directed donation is an ethically justifiable form of organ donation, so long as:

- The potential donor undergoes appropriate evaluation and screening;
- Donors are protected from coercion and undue influence;
- Respect is given to the individual's autonomous decisions while minimizing their exposure to risk;
- A strict standard of informed consent is followed;
- Safeguards are followed to ensure anonymity between the donor and the recipient;
- Organs are allocated in an equitable manner according to existing policies; and
- A donor follow-up database/registry is established with the goal of increasing available information on donor outcomes.

⁴ Consensus Document for Live Organ Donors, page 2925.