

Consensus Report of the Living Donor Data Task Force, January 2009

I. Background: OPTN Living Donor Data Collection

In October 1987, the OPTN began to collect information about living organ donors (name, gender, age and relationship to the recipient) on the Donor Histocompatibility Form. The Living Donor Registration (LDR) form was created in October, 1990, and added some histocompatibility and basic demographic information. In April 1994, the donor SSN was added to LDR. The six month and one year Living Donor Follow-up (LDF) forms were implemented in October, 1999. The LDR was expanded at that time to include pre-discharge complications, donor education level and source of payment, along with requests for donor status, rehospitalizations, complications such as dialysis and bile leaks, and laboratory values such as creatinine and bilirubin, along with cause of death if indicated. A June, 2004 update included requests for additional data about the donor's pre-donation insurance and functional status, and the LDR was expanded to include more details on complications, including events occurring in the first 6 postoperative weeks. Additional changes to the LDR and LDF were implemented in March 2008, and will capture more information about the center's attempts to contact the donor. As the OPTN contract issued in September 2005 extended this requirement to 2 years, a 2-year follow-up form is also being implemented¹.

Thus, the OPTN has been collecting data on living donors for over twenty years; however, no comprehensive evaluation of the completeness and utility of these data for research has been undertaken. Further, many questions remain unanswered regarding the short and long-term impacts of living donation. In June 2006, the Secretary of HHS directed the OPTN to develop living donor policies that would have the same force as other policies developed by the OPTN. At the same time, there have been considerable objections from some sectors within the transplant community regarding the feasibility, benefit, and cost of reporting requirements. (REF: Roberts et al, Am J Transplant 3: 1316, 2003) In June 2007, the OPTN/UNOS Board approved a resolution from the Policy Oversight Committee stating that, "Resolved, that a joint OPTN Committee be established to evaluate the use of living donor data." As a result, the Living Donor Data Task Force (LDDTF) was established in late 2007. The Task Force consists of 19 members with varied expertise in living donation. LDDTF member involvement includes:

- OPTN/UNOS Living Donor and Policy Oversight Committees, Kidney Paired Donation Working Group, and Board of Directors;
- ASTS, AST;
- Adult to Adult Living Donor Liver Transplantation Cohort Study (A2ALL), Renal and Lung Living Donors Evaluation Study (RELIVE), NYCLT, LODN, NKF; and
- Clinical, Social Work/Psychology, patients and donors.

¹ 2-year follow up forms will begin generating in March 2010, for the cohort of individuals that donated beginning in March 2008.

The idea behind creating the LDDTF was to assemble an expert panel representative of the transplant community with “all the answers present in the room.” Task Force members were not asked to represent a specific entity (i.e., AST, OPTN), but rather to bring their experience and expert opinions to the group. The LDDTF was asked to take an objective look at the various needs for living donor data, and to propose an appropriate approach for each need. The LDDTF reviewed the data currently available from the OPTN as well as other sources. Members were then asked a series of questions intended to form the basis for recommendations to the Board of Directors regarding appropriate approaches for obtaining and/or reporting data for each of the purposes for which living donation-related issues that have been identified.

Task Force members were generally in agreement that the overarching concern of the LDDTF was to examine data collection in the context of ensuring donor safety during the selection process, the surgery itself, and potential long-term impact on health and quality of life. The primary utility of collecting data regarding live donors is to enhance the informed consent process, with a secondary goal of evaluating and assessing center competence and quality. As one member noted, to achieve these objectives requires data of the highest quality and reproducibility.

II. An Overview of Information Currently Available or In Process Regarding Living Donor Outcomes in the United States

OPTN Data

The OPTN collects data on living donors at time registration (LDR) and at discharge/6 weeks (LDR), 6 months (LDF), 1 year, and 2 years post-donation. For the 6,433 individuals who donated a kidney in 2006, 12% had an LDR only, 17.6% have an LDR 6-month follow-up form, and 69.9% had an LDR, 6-month follow-up form, and 1 year follow-up. However, in some cases, a patient may be marked as ‘alive’ on the form but the follow-up date provided on the LDF may be the same date provided on the registration form (e.g., discharge date) or an earlier LDF. Looking at reported complications, the LDR had a very low rate of ‘not reported.’ However, the rate of those with ‘unknown’ or ‘missing’, or ‘no form’ increased to approximately 20% for these complications at 6 months, and 50% at 1 year. The data for liver donors appeared to be more complete, but was subject to the same caveats regarding the actual date of follow-up (Figures 1-4).

The OPTN has collected SSN since 1994, and both UNOS and Arbor Research can link to the Social Security Death Master File (SSDMF) and to CMS Medical Evidence Report form (CMS-2728) data to derive death and return to dialysis. UNOS has also developed a complex algorithm to enhance these linkages when the social security numbers (SSNs) of the donors are incorrect.

Non-OPTN Studies / Data

Living Liver Donor Quality Of Life Project, New York Center for Liver Transplant (NYCLT). Since February 2004, the New York State Department of Health (DOH) has required transplant centers in New York to monitor Quality of Life (QOL) for each living liver donor for the lifetime of the donor. Based on input from focus groups and interviews with LDs and transplant coordinators, the NYCLT developed a 53-item multiple-choice questionnaire that is filled out by the donors, with the intent that the data will be used to educate potential donors using peer input. At the time these data were presented to the LDDTF by Samantha DeLair, responses had been received

from 44 of 96 (46%) donors that the NYCLT contacted approximately 1-year post-donation. Data for 2006 and 2007 donors will be added to the analyses

Living Organ Donor Network (LODN) Registry and Donor Insurance Policy. LODN, originally established through SEOPF, is an insurance policy and a registry; the insurance policy funds the registry. (REF: McCune et al, Clin Transplant 18 (Suppl 12): 33-38, 2004). The transplant centers provide some limited information to the registry initially, and subsequent communications are between the donor and the registry through a short questionnaire. For centers participating in both the registry and the insurance program (at a cost to the center of \$550/donor), the response rate of donors to a 3-month donor questionnaire is 78.5%; this decreases to 68.6% and 62.0% at 6 months and 1 year. Across all time periods, this represents a one-time response rate of 82.0%. This rate declines with each year of follow-up. The majority of complications are to be found in the 3 month report, and about one-third of the donors will report the same complication on subsequent forms, so the duplicate reports need to be removed from the analyses. These data show a “serious complication” rate of 3.3% (those requiring overnight hospitalization or an operation), and “complications other than serious” at 17%. While these rates are much higher than those reported by Matas, et al (REF: Matas AJ, Bartlett ST, Leichtman AB, Delmonico FL. Morbidity and mortality after living kidney donation, 1999-2001: survey of United States transplant centers. Am J Transplant 2003;3(7):830-834.), they are comparable to other more recent studies. These data show that the LODN cohort has higher rates of donor follow-up than the OPTN cohort.

Renal and Lung Living Donors Evaluation Study (RELIVE). This 5-year study, funded by the National Institutes of Health, began in 2006, with 3 living kidney and 2 living lung centers participating. The analyses will include data from living donor transplants between 1963 and 2008. Three types of studies are being conducted:

- Retrospective studies of vital status, and progression to ESRD/need for transplant;
- Cross-sectional studies of vital status, residual organ function and quality of life (QoL); and
- A prospective study of informed consent.

The studies include 400 lung donors, which is 80% of all known living lung donors in the U.S., and just fewer than 9,000 kidney donors dating back to 1963.

Adult to Adult Living Donor Transplantation Cohort Study (A2ALL). In 2002, A2ALL initiated a retrospective study of living liver donors and recipients from 1998 to 2002. A prospective study began in 2004. Enrollment was to end in July of 2008 but may be extended. These are observational cohort studies. There are also several government-funded ancillary studies, including a quantitative liver function study, which is a combination of volumetric studies with MRI/ CT and metabolic studies. Another study will focus on the genomics of hepatic regeneration in the donor and recipient.

There are 1,283 recipients and 1,543 donor candidates in the A2ALL study. A primary aim for the prospective cohort is to determine the short and long term health and QoL impact of donation. Another aim is to standardize and assess the role of informed consent, and to assess motivations of donors with a standardized instrument. This may help determine if certain personality traits predispose individuals to donation. The study will also attempt to correlate donor satisfaction with measureable outcomes.

Initial findings of the retrospective study are being published. One paper finds that complications occurred in 38% of the 405 donors in the cohort (graded by Clavien classification)[REF: Ghobrial RM et al. Donor morbidity after living donation for liver transplantation. *Gastroenterology* 2008;135:468-476.]. A paper by Trotter, et al, reported surprisingly high rates of *de novo* psychiatric morbidities in the A2ALL cohort [REF: Trotter, JF, et al, *Transplantation* 2007; 83: 1506-1508]. The retrospective study will also report on aborted donations and re-hospitalization.

III. Deliberative Process

LDDTF members were asked to answer a series of questions related to the time frame and mandate for living donor data collection, and for potential sources of data needed to answer specific questions. Responses were reviewed from 14 members. These are summarized in Appendix A. The Task Force met by teleconference to review the consensus recommendations drawn from the responses. Members were in agreement as to the current state of living donor data collection, and made five primary recommendations for improvement of the data collection system. In the absence of unanimity, minority views are also included in this report in the “other comments” section.

IV. Consensus Recommendations

In summary, the Task Force agreed upon the following statements and recommendations:

Consensus on Existing Data collection Mechanisms:

1. As currently collected, the OPTN data are incomplete beyond the point when the discharge form is submitted (up to 6 weeks post donation) and therefore data collected beyond these time points are useless for research or making conclusions about living donor safety.
2. Major limitations to high quality data collection include:
 - a. absence of funding for living donor follow up visits and laboratory studies at individual transplant centers, and
 - b. as indicated in the experience of the NYCLT, difficulty in enlisting previous donors in the follow up process, particularly beyond the first year post-donation.

Consensus Recommendations

1. The Task Force recommends:
 - a. Continued use of OPTN data supplemented by data from the SSDMF, NDI, and CMS/ESRD as the mechanism for tracking short- and long-term deaths.
 - b. Required center reporting and completion of data through a limited time interval (discharge through 6-12 months), with the duration dependent on whether funding is made available to

the centers; this would strengthen the requirement for centers to report a limited set of data elements.

- c. Development of a self-reporting mechanism for donors of a longer duration than that required of centers.
2. The Task Force supports utilizing both OPTN and non-OPTN sources of data to determine donor risk for the purpose of generating accurate informed consent regarding medical and Quality of Life issues.
 3. The Task Force supports a requirement for center-specific reporting of deaths and major complications, and recommends that these data elements be included in the UNOS auditing processes to ensure accuracy and completeness. This would include correction of SSNs.
 4. Data reported to or collected by the OPTN regarding donor deaths and adverse events (e.g., return to waiting list or dialysis) should be provided back to the transplant programs.
 5. The OPTN should investigate existing registries (LODN, LDAP) to determine how the OPTN could partner with and/or promote their efforts.

Other Comments:

- One member expressed concerns about a conflict of interest regarding the OPTN/UNOS collecting and managing data on living donors and felt that data collection efforts on living donation would best be served outside the purview of the OPTN/UNOS.
- One member felt strongly that input from the general medical community (e.g. internists and primary care physicians) is necessary for information regarding long-term donor outcomes.
- Several members requested the OPTN expand the scope of the LDDTF (or convening some other group) to address the many remaining questions, including creation of a living donor registry.

Appendix A:

1. From what you have learned while on the LDDTF, as well as through your own personal and professional experiences, what is your recommendation to the OPTN regarding the current/near-term approach to reporting the following for educational purposes and public information?

- **Aggregate short-term living donor deaths**

There is strong consensus that these data must be reported by the transplant centers and also verified and/or supplemented by non-OPTN sources such as the Social Security Death Master File (SSDMF) and the National Death Index (NDI).

- **Aggregate long-term living donor deaths**

There is strong consensus that these data must be obtained from non-OPTN sources such as the SSDMF, NDI, and CMS/ESRD, with the caveat that linkage via SSN is often problematic.

- **Aggregate short-term living donor complications.**

The response to this question was split between proposals for a living organ donor registry (LODR) that would obtain data from centers and/or donors, with others stating that these data are best obtained from studies such as A2ALL and RELIVE. Respondents discussed possible linkage to the donors' health insurance records; however, issues of donor consent/HIPPA compliance, accuracy of data, and following donors who switch health insurance plans were noted as problematic.

- **Aggregate long-term living donor complications.**

Many respondents felt that these data would be best collected from some form of donor self-reporting, either through the centers or directly to a LODR, although several noted that this mechanism can be incomplete/inaccurate and expensive. Further, donors may not always know what data are important to report.

1a. What is the role of funded research regarding donor outcomes (i.e., RELIVE) in answering these questions?

Some respondents stated that these studies are "extremely valuable," "integral," "essential" for obtaining detailed, meaningful long-term data on living donors. However, several other respondents noted that these data cannot be generalized to the experiences of all living donors: while providing important information about effective educational methods to obtain informed consent, these data, from a handful of centers, may not be representative of living donor outcomes at most centers. Several respondents noted that these studies will be of value in delineating practice at model centers, which may come to be considered exemplary practice.

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- **Are the data obtained from these studies of value to the OPTN? Is it possible to utilize these data to determine donor risk as required by OPTN mandates?**

There was strong consensus that these data are of value, but many noted that the data are limited and may only capture specific patient populations, or represent the characteristics of larger or more experienced programs.

1b. Do you feel that there is some time point after which the OPTN data are incomplete for research and for making conclusions about living donor safety? If so, at what point? For what duration of time should transplant centers be responsible for reporting donor outcomes?

The majority of respondents felt that the data are woefully incomplete beyond 3-6 months. However, there was support for reporting of death, organ failure, and donation-related readmissions for one year or more. There was some support for no time limit on reporting.

2. From what you have learned while on the LDDTF, as well as through your own personal and professional experiences, what should the OPTN do now in preparation for addressing the following data 10 years from now?

- **Aggregate short-term living donor deaths.**

There is consensus that the existing reporting mechanism, supplemented with data from the SSDMF, should be maintained.

- **Aggregate long-term living donor deaths.**

There is consensus that these data should be obtained from extra-OPTN sources such as the SSDMF and NDI.

- **Aggregate short-term living donor complications.**

Most agreed that centers should be responsible for reporting short-term living donor complications, perhaps to six or twelve months post-donation. However, several respondents indicated that direct donor self-reporting, either to the OPTN or to a yet-to-be-established LODR, might be one mechanism for obtaining these data. Two respondents recommended a short term - arrangement with LODN/LDAP, etc, until a LODR is established.

- **Aggregate long-term living donor complications**

There was no clear consensus on this question, with answers ranging from direct donor-reporting to UNOS or another LODR, to reliance on A2ALL/RELIVE studies or other sources such as the ESRD data.

- **Options: The OPTN could propose to make living donor follow-up mandatory for transplant programs for some period of time post-donation. If so, for what length of time?**

While no single time point was suggested by the majority, five members suggested that the data should be collected through time of discharge, or at the most, 3-6 months. Six suggested that 1-2 years is appropriate, depending on whether funding is available for living donor follow up visits and laboratory studies. One respondent felt that follow-up should extend to 5 years. However, there was near-universal opinion that mandated reporting beyond the early post-donation period (3-6 months) without commensurate funding was unlikely to generate meaningful responses.

- 3. The OPTN could continue to seek funding for a census registry for some period of time post-donation. If so, where will these data be obtained? If so, for what length of time?**

The majority of responses indicated that data should be obtained from the donor. The most recommended time frame was “for as long as the donor wishes,” with several recommendations for 5-year follow-up.

- 4. Is the data requirement for assessing donor risk the same as for assessing center-specific performance? Does the LDDTF have any recommendations related to data needed for assessment of center-specific performance?**

The majority of responses indicated that the requirement is not the same, as the center is not responsible for donor's long-term care.

Appendix B. LDDTF Members

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Samantha DeLair

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Bob Merion, M.D.

Kim Olthoff, M.D.

Robin Pierson, M.D.

John Roberts, M.D.

Gigi Spicer, R.N.

Judy Jones Tisdale, Ph.D.

Betsy Walsh, JD, MPH

Jane Zill, LICSW

Figure 1

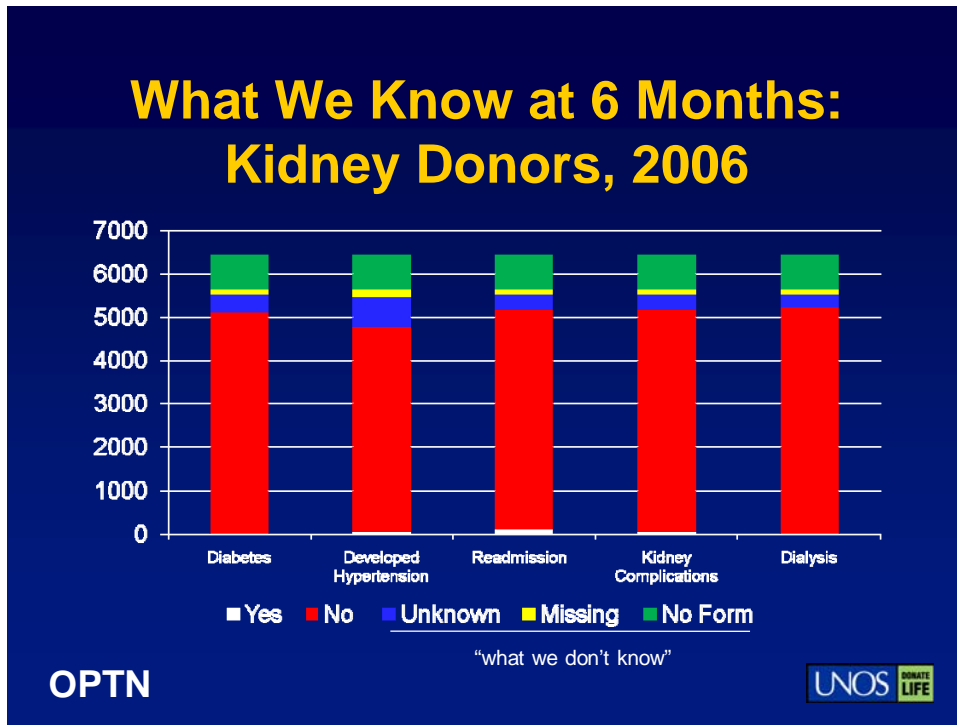


Figure 2

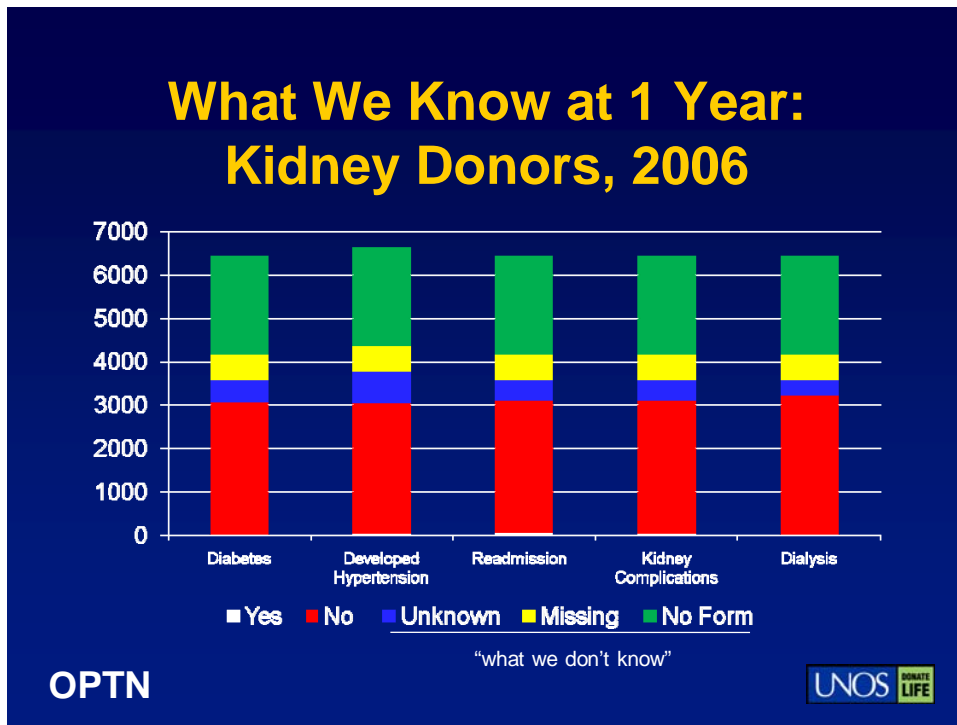


Figure 3

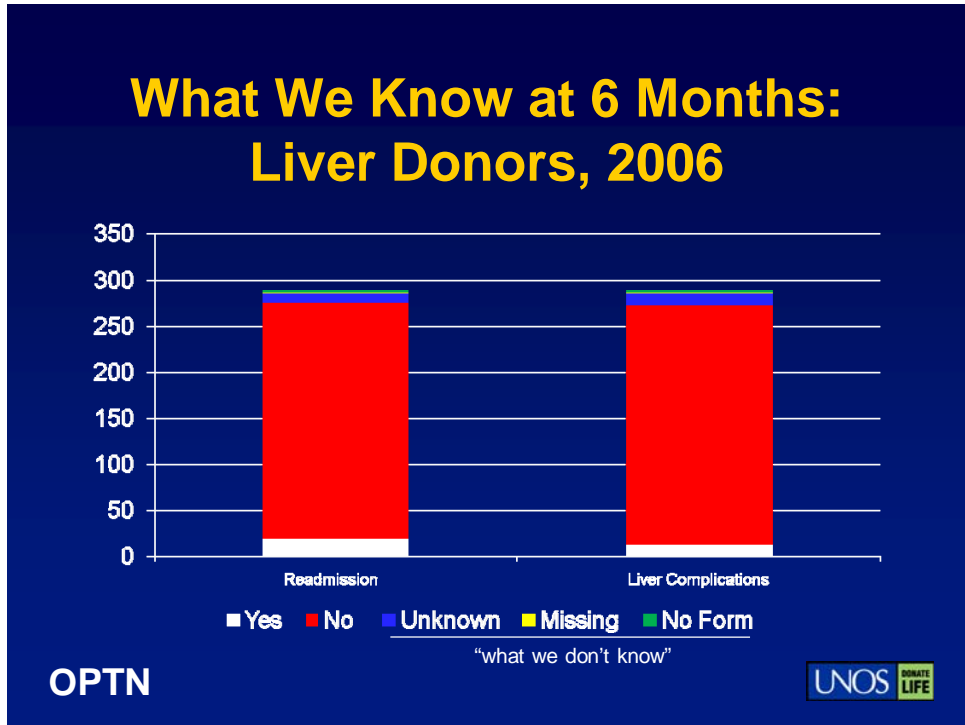


Figure 4

