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My name is Jane Zill. I am a professional social worker with a Master's degree. I am licensed to practice independently in New Hampshire and Massachusetts. In 1991 I was a kidney donor for my brother, James Zill. From 2007- 2009 I was a member of the Living Donor Committee (LDC) of the Organ Procurement Transplant Network (OPTN). During my term on the LDC I was appointed to the 2008 Living Donor Data Task Force (LDDTF), which was formed to identify unmet data needs on living organ donors and to make recommendations for data collection going forward.

Thank you for the opportunity to present testimony today.

My testimony is about the profound conflict of interest of the transplant surgical community regarding living organ donors (including the OPTN), which has (a) negatively impacted data collection on donors and (b) has jeopardized public safety. And, I will suggest long overdue, first step public safety recommendations for living donors.

First, for the public record, let me briefly describe what is the OPTN. It is a membership organization of transplant centers and organ procurement organizations. Although it was established through congressional authority and the National Organ Transplantation Act (NOTA), it is an organization comprised solely of those who are professionally involved in transplantation. The OPTN is commonly referred to as UNOS, which stands for United Network for Organ Sharing. But UNOS is a separate organization contracted by HHS to oversee the OPTN. However, UNOS and the OPTN share the same Board of Directors. In short, since 1986 the United States government has allowed UNOS/OPTN to make policy for the regulation of its own industry, an industry whose viability is increasingly dependent on the altruism of those willing to donate an organ to help another.

Unethical and Unscientific Data Collection

Data collection on living organ donors has not been desired by UNOS/OPTN. Since the first living donor transplant in **1954**, the number of living organ donors that have died in the U.S. in the days, weeks, and months following donation is unknown. Also unknown are the number of donors with surgical, emotional, financial, and medical complications, for example, organ failure, cardiovascular disease (CVD), and renal insufficiency.

The 2008 Living Donor Data Task Force (LDDTF) of UNOS/OPTN found that data reported within three months of surgery are incomplete and anything beyond this three-month period is “woefully inadequate” for making any conclusions about the long-term safety of living organ donation. (See the attached Consensus Report of the LDDTF.) This “woefully inadequate” state of affairs exists despite the fact that in 1999 HHS contractually required UNOS/OPTN to collect data on donors and despite the fact that the deficiencies in donor data collection have been officially reported to the UNOS/OPTN Board of Directors since 2004.

Today, UNOS/OPTN continues to evade meaningful data collection on donors. For example, UNOS/OPTN created a policy proposal this year requiring that the transplant center that surgically removes a donor’s kidney also conduct the data collection on that donor for two years past donation. But given their track record on data collection, it’s appalling that the plan does not make provisions for independent oversight of data collection and reporting.

But it gets worse; UNOS/OPTN then proposed that centers are only required to report if the donor is alive or dead. This means that failure to report important biomedical markers and other findings would not be sanctioned through by-law or policy. Furthermore, data collection limited to two years is not enough time to understand the long-term effects of altered organ function. The net effect is that in another twelve years, in 2023, another living donor data task force will likely conclude that OPTN data is “woefully inadequate.”

The lack of data raises a critical ethical concern about the basis of the scientific information that has been used to obtain informed consent, an issue that won’t be resolved until meaningful data are gathered.

Nonetheless, living organ donation is continuously promoted to the public as a safe solution to address the nation's epidemic of organ failure.

UNOS/OPTN's Flawed Policies Regarding Living Organ Donors

It is a commonly held belief among donors and the public that living organ donors who progress to organ failure will go to the top of the national waiting list or be given priority on a national waitlist. However, there is not a national waiting list, only local and regional lists. Curiously, changes in allocation policy now under consideration do not incorporate donors who progress to organ failure in a new national ranking system. So what is the nation's plan to address the needs of former donors in need of a transplant? It seems that the plan is to do nothing for those who have helped another, rather they remain hidden away as a local problem, treated as an odd artifact, and a source of irritation, shame, embarrassment to their local transplant center, and vulnerable to "death by geography."

There are also other troublesome issues. Passage of the 2007 Norwood Inslee Bill paved the way for Kidney Paired Donation (KPD) and increased market interest in living donor transplantation. In anticipation of its passage and the increased market, UNOS/OPTN sought increased authority in living organ donation from HHS. Despite UNOS/OPTN's historic neglect of donors and its conflict of interest, in 2006 HHS granted UNOS/OPTN increased authority in matters of living organ donation. Instead of promoting public safety by protecting the "hens" from the "fox," the fox was allowed to run the roost.

In response to this criticism, UNOS/OPTN might attempt to cite their 2008/2009 safety initiatives created by their Living Donor Committee as evidence of their concern for living donors. But these safety initiatives are only voluntary "guidance" documents for transplant centers to use a model for a medical evaluation protocol and to inform donors of risk, as is stated in the preamble to the OPTN's document, "Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols";

"Since this resource is not considered OPTN or UNOS policy, it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, and it is

not intended to be clinically prescriptive or to define a standard of care. This resource will not be used to determine member compliance with policies or Bylaws... It is intended for members' voluntary use." (*OPTN Guidance for the Development of Program-Specific Living Kidney Donor Medical Evaluation Protocols, 2008*)

Why is the guidance so voluntary? Because centers are dependent on living donors to make their programs viable, so there exists a powerful motivation for wide latitude in the evaluation, selection, and informed consent of donors, and the investigation of centers with poor outcomes. This latitude benefits centers by increasing living donor transplants and center revenues, while cloaking poor outcomes, all at the expense of living donors.

UNOS/OPTN might respond by highlighting a bylaw requiring centers to have an Independent Donor Advocate (IDA) to represent the best interests of donors. However, advocates employed by centers rank low on the medical hierarchy and there are negative financial consequences to the center when Independent Donor Advocates question the appropriateness of a donation going forward.

In the first 29 months after passage of these purported "safety initiatives" there were at least eight donor deaths, possibly more. Michael King, (29), New York, died after donating a kidney to his wife in October 2008. Myra Lee Martinez (28), Texas, died on February 8, 2011, after she donated a kidney to her mother. Ryan Arnold (34), South Dakota, died on August 2, 2010 after donating a portion of his liver to his brother, as did a liver donor in Boston in the spring of 2010. In addition, four kidney donor deaths were reported in the first seven months of 2010 at the August 2010 Advisory Committee on Organ Transplantation meeting, and other printed resources suggest two or three other live donor deaths in 2009.

Finally, there is not a clear path of resolution for donor complaints within the mission and structure of UNOS/OPTN. The development of the "The Patient Help Line" in 2008 leads the public to believe there is a safety net for donors, but nothing could be further from the truth. Because UNOS is dependent upon its relationship with OPTN centers for its viability, it is inappropriate to have UNOS employees staffing the "The Patient Help" line

and overseeing donor complaints. The staff has no leverage to act on behalf of individual donors and UNOS has no institutional motivation to act on behalf of living donors.

I have previously expressed the above and other concerns to UNOS/OPTN and this Advisory Committee, including a letter to the former chair of ACOT, Dr. Velma Scantlebury. This letter somehow never made it into the public record. I would like to attach that letter as part of my testimony today.

Recommendations to Enhance Public Safety in Living Donor Transplantation

Create separate, independent Boards of Directors for UNOS and the OPTN in order to reduce the undue influence and interests of a closed network of industry professionals on our nation's transplant system.

UNOS/OPTN needs major structural changes to limit the transplant surgical community's influence on our nation's transplant system. Representation from other disciplines, medical and non-medical, and from all walks of life, should be included to ensure that all stakeholders in the practice of transplantation are represented in policy creation.

It is nonsensical to promote living organ donation as a solution to the nation's epidemic of organ failure because human beings are not medical supplies. HHS needs to establish a coherent and comprehensive national agenda for prevention and treatment of chronic kidney disease that is powered equally to the national agenda to support organ transplantation.

Finally, the miracle of transplantation, the need for donor organs, and industry market expansion are not justifications to place the public at risk, exploit donor altruism, or treat donors with organ failure as odd artifacts or as expendable. Therefore, the public should not be asked to consider donating life in the current system.

The establishment of a comprehensive system of care to manage all phases of the living donation process; that is, recruitment, evaluation, selection, informed consent, and follow-up that is totally independent of UNOS/OPTN would do much as first steps to promote public safety in the

practice of living donor transplantation. Additional needed initiatives include prospective data collection that utilizes a registry of living organ donors and provisions for medical care for donors to forestall progression to organ failure or other serious health problems. The enforcement of the 1972 Medicare benefit for kidney donors would create a mechanism to both collect data and fund continued medical care, and is a right given to kidney donors in the End Stage Renal Disease Program. Donor altruism and commitment to public safety require nothing less.

Thank you for your kind attention to my testimony, the attached Consensus Report of the Living Donor Data Task Force, and 2010 letter to Dr. Velma Scantlebury, former Chair of the Advisory Committee on Organ Transplantation.

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.

- **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

Robert Gaston, M.D., Chair
Mark Barr, MD
Dolph Chianchiano
Matt Cooper, MD
Connie Davis, M.D.
Samantha DeLair
Mary Amanda Dew, Ph.D.
Ruth Ann Hanto, RN, MPH, CPTC
Cheryl Jacobs, ACSW
Arthur Matas, M.D.
Tom McCune, M.D.
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

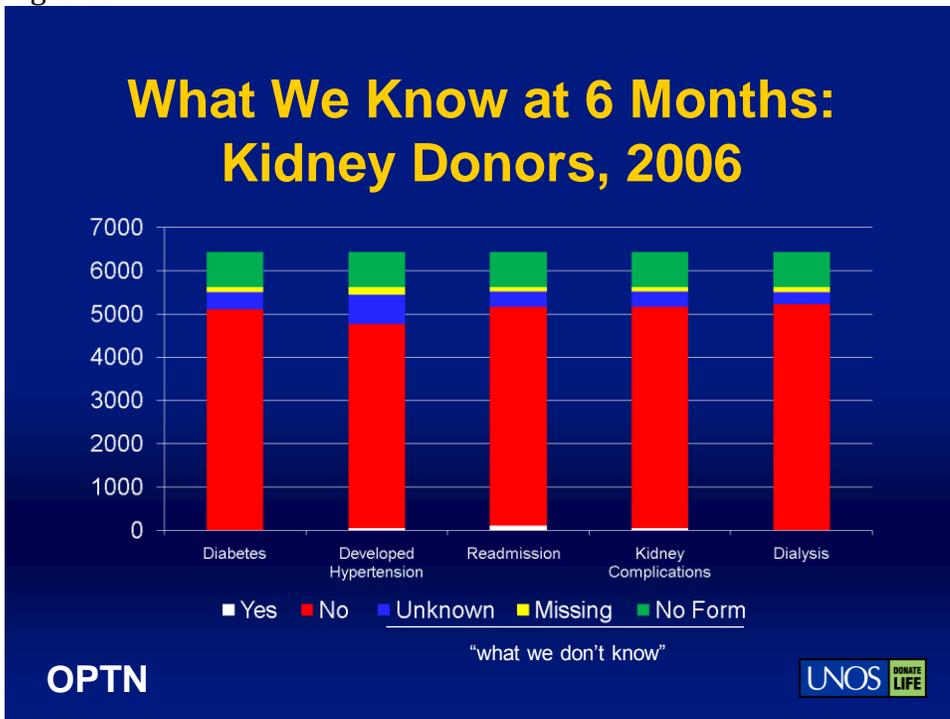


Figure 2

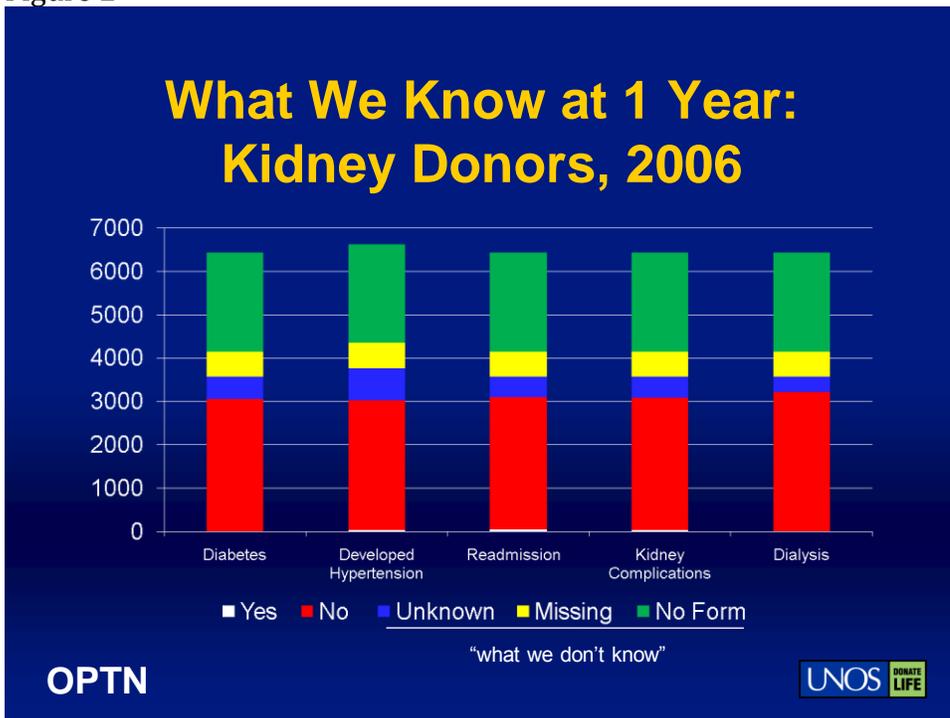
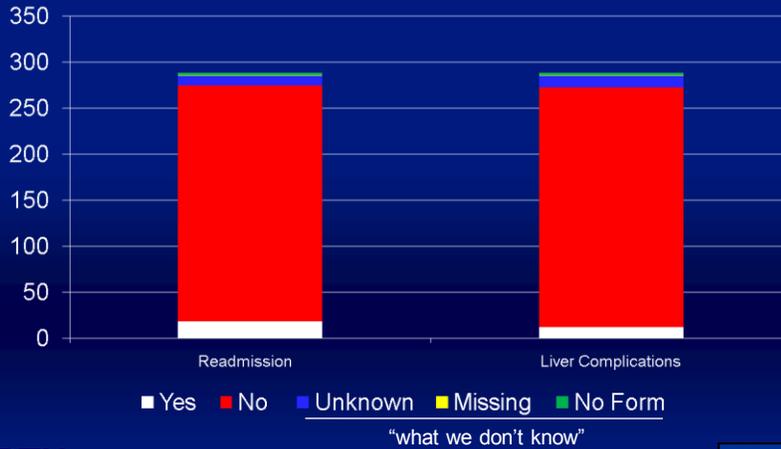


Figure 3

What We Know at 6 Months: Liver Donors, 2006

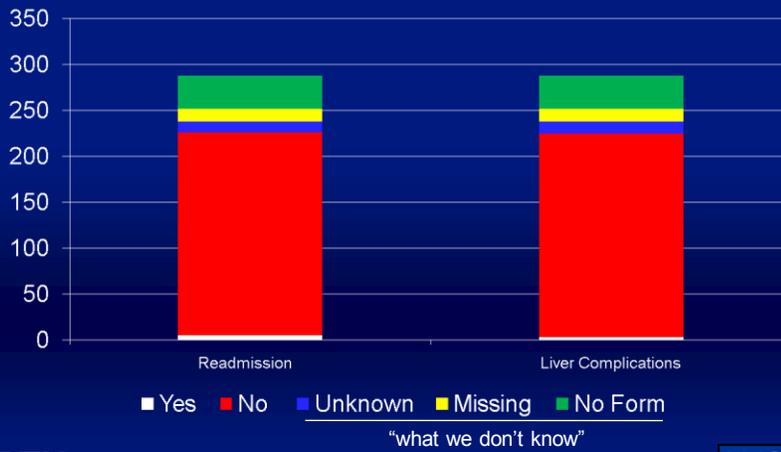


OPTN

UNOS DONATE LIFE

Figure 4

What We Know at 1 Year: Liver Donors, 2006



OPTN

UNOS DONATE LIFE

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August 31, 2010

Dear Dr. Scantlebury- White,

Thank you for your reply to my email message. I will welcome the inclusion of the ACOT Secretary in our communication.

I agree that the general surgical community does not have a conflict of interest regarding living organ donors; however, I believe that the transplant surgical community does. Therefore I recommend that those who are employed in connection to the transplant industry should divest themselves from a central role in the care and management of living organ donors, which would include management of data regarding living organ donors. Donor needs extend beyond pre-and postoperative care to include the pressing requirement for prospective data collection regarding short-term and long-term outcomes.

These needs are especially urgent because the transplant industry is increasingly dependent on living organ donors for the growth of transplantation as a therapeutic option and because the transplant industry, due to a limited supply of deceased donor organs, is focusing on living organ donation to expand their programs. In my opinion it is not humanly possible to address the many problems attending living organ donation, to inform the public of these problems, and, at the same time, to promote living organ donation as an elective surgery that involves minimal short and long-term risk.

Examples of transplant industry conflict of interest are pervasive. I would like to focus on the recent review by Davis and Cooper, *The State of US Kidney Donors* (Clin J Am Soc Nephrol 2010). The authors claim that living donors are extensively evaluated and highly selected. Yet, what is the evidence? Mandated guidelines for the evaluation and selection of living kidney donors do not exist. CMS regulations and OPTN bylaws regarding living organ donors only require centers to develop written protocols for the evaluation and selection of living donors; they do not require a standardized protocol.

As of March 2009 there were 262 transplant programs in the U.S., which means there were 262 different protocols for the selection and care of living organ donors.

But even more concerning is the apparent bias of the authors, a transplant nephrologist and transplant surgeon, when they cite a study by Mancilla et al. which reports on preimplantation biopsies of donor kidneys, that 119 of 219 *“were not completely normal.”* The authors conclude that, *“more detailed evaluation of donor outcomes, according to renal histology at donation, is required, preferably with quantification of the degree of nephrosclerosis, global sclerosis, and intersistital fibrosis. Likewise, genetic and proteomic studies will be helpful in evaluating the processes that lead to renal function loss.”* I believe that more detailed evaluation of donor candidates is required prior to donation. Renal biopsies are not routinely performed as part of the *“classic”* donor evaluation. Rather than concluding that donors should become research subjects, a recommendation focused on donor safety would have emphasized the importance of comprehensive pre-donation evaluation in light of the finds of Mancilla et al.

Similarly, the authors acknowledge that estimates of GFR for the donor population are unreliable pre-and post- donation. At least 15% of kidney donors do not sustain a GFR of 60 or more, and as the authors write, *“that cardiovascular risk increases with even small amounts of loss of kidney function, and that all kidney donors have a decrease in GFR.”* Despite uncertainty about long-term safety, the authors do not advocate for implementing more stringent selection criteria. Instead, they recommend more research and improved follow-up.

They also write, *“The anticipated changes in donor risk must be placed into context with the donor’s willingness to provide benefit to their recipient.”* In reality a donor cannot make an informed decision about risk unless he or she knows everything the transplant nephrologist knows about the short- and long-term risk associated with nephrectomy – including what is absent from the data.

Another conspicuous problem concerning data pertaining to the safety of live organ donation – and the many peer reviewed articles in which it is cited is this: the donors *“voice”* is lacking altogether. To date, self-reported experiences of organ donors have not been central to understanding the donor experience and have not been a source for generating new scientific inquiry about living organ donation. The transplant community has been allowed to define the experience of living organ donation narrowly and to market the personal meaning and experience of being a live organ donor. And yet, to date, I am aware of only one U.S. transplant nephrologist who has become a living organ donor.

The public is vulnerable to the media blitz promoting live organ donation that reflects to the market needs of the transplant industry. For the sake of public safety, it is imperative that funded research about living organ donors is conducted in an independent and highly scientific manner that is akin to the Framingham study or other prospective model registries of selected patient populations, and is done by those who are independent of any industry motivation to promote living organ donation.

You mention the Living Donor Subcommittee of the ACOT. I have not been able to identify a living donor on the ACOT. Would you kindly let me know if there are donors on the ACOT and if an agenda has been developed for the Living Donor Subcommittee?

After spending nearly two years on the OPTN LDC Subcommittee on Data Collection and approximately a year on the LDDTF, I have become aware of how easy it is to present and spin information to support an agenda with a foregone conclusion. The LDDTF has studied RELIVE and concluded that the data are deeply flawed. In addition to the problem of selection bias (three centers selected) other concerns include the small percentage of donors actually studied. RELIVE may be useful in describing possible risks but cannot be used alone to define risk. RELIVE captures less than 10% of U.S. donors (8,000 out of 100,000). Conclusions about the other 90+% cannot be based upon data gathered from a non-representative sample and should not serve as the basis for deciding if individuals are to undertake a surgery for which they will not receive benefit. The findings of the study cannot be generalized to centers across the country (and the world) because the centers and the donor population cannot be considered representative. As world leaders in transplantation, the U.S. has a responsibility to address the limits of this study when reporting outcomes -- once these data are published they will be used internationally and will continue to contribute to ethical violations involving living donors among the world's poor.

Similarly I am skeptical of the agenda of the September conference you mention in your letter because I am dismayed that RELIVE continues to be discussed, taking time and engendering public expense, when leaders in the field have extensively reviewed the project through the LDDTF.

In summary individuals employed by the transplant industry cannot be the voice, mentors, advocates, or leaders of living organ donors. A system of truly independent professional donor-advocacy must be established with funding sources independent of transplant units. Although Davis and Cooper did not address the importance of independent donor advocacy in their article, newly instituted CMS regulations and OPTN bylaws indicate an increasing awareness of the importance of protections of this nature.

I believe all centers practicing living donor transplantation must participate in a nation-wide system of continuing quality improvement. There must be ongoing efforts to collect comprehensive long-term data going forward, as well as to investigate and make public each short-term surgical complication or death. A nationwide registry of living donor outcomes is long overdue in the United States. Donor altruism and trust should be met with nothing less.

My best,

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