
New York State Committee on Quality Improvement in Living Liver Donation

**A Report to:
New York State Transplant Council
and New York State Department of Health**

December 2002

**State of New York
George E. Pataki, Governor
New York State Department of Health
Antonia C. Novello, M.D., M.P.H., Dr. P.H., Commissioner**

This report is available on the New York State Department of Health website (www.health.state.ny.us). Or, copies are available by writing:

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December 19, 2002

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner
New York State Department of Health
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Dear Dr. Novello:

On behalf of the New York State Transplant Council's Committee on Quality Improvement in Living Liver Donation, I am pleased to present to you the Committee's report.

The Committee worked diligently and intensively reviewing the issue of live adult donor liver transplantation and developing recommendations pertaining to the care of live liver donors for New York State. The distinguished 17-member panel extensively analyzed and reviewed donor and recipient selection criteria; informed choice processes; preoperative, intraoperative, and postoperative care plans; as well as discharge planning procedures. In addition, two representatives from the federal government assisted in Committee deliberations.

The full committee met in June, August, October, and November of this year. The October meeting included public comment on the draft report. Donors, donor spouses, and two widows whose spouses died during the donation process provided compelling testimonies. The Committee carefully considered the testimonies in making the recommendations included in this report.

At the initial meeting, the committee was divided into subgroups: Dr. Francis Delmonico chaired the Subcommittee on Informed choice, Donor/Recipient Selection and Evaluation; Dr. Lewis Teperman chaired the Subcommittee on Donor Perioperative Care and Facility Support; and Dr. Jean Emond chaired the Subcommittee on Donor Discharge Planning, Support and Long Term Follow Up. The efforts of these Subcommittee chairs was vital in the development of this report.

In addition, at the initial meeting of the full committee, the members unanimously rejected calls for a moratorium on live adult donor liver transplantation. The committee members recognized the 10-15% mortality rate of patients currently listed and waiting for cadaver donor liver transplantation and, in light of this, were adamant that live adult donor liver transplantation continue as transplant centers strive to improve the overall quality of care for both donors and recipients. The Committee felt strongly that such a moratorium would cost hundreds, if not thousands, of lives and thus rejected calls for a moratorium as morally and ethically unacceptable.

At its final meeting, November 13, the Committee unanimously approved the report and requested that it be presented to you and the full Transplant Council for final review and approval.

The Committee also collaborated with Health Department staff to develop a donor survey, which was sent to the more than 400 liver donors who had their surgery in New York State. Preliminary data from the survey indicates that donors welcome an opportunity to express their feelings about their experiences.

As chair of the Committee, I am pleased to deliver these comprehensive, landmark recommendations to you and the Transplant Council. The Committee is hopeful that this report will serve as a model for the entire country as this issue is examined on a national level.

Sincerely,

A handwritten signature in black ink that reads "David J. Conti". The signature is written in a cursive style with a long horizontal flourish extending to the right.

David J. Conti, M.D., Chair
Committee on Quality Improvement in Living Liver Donation
Professor of Surgery
Albany Medical Center

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Commissioner of Health Antonia C. Novello, M.D., M.P.H., Dr. P.H., appointed the New York State Committee on Quality Improvement in Living Liver Donation in June 2002 to review adult living liver donation in New York State. This Committee operates under the auspices of the New York State Transplant Council, New York's 21-member advisory body appointed by the Governor and the State Legislature to advise the Commissioner of Health on issues related to organ and tissue donation and transplantation.

The Committee met in June, August, October, and November 2002 to review existing requirements and develop new guidelines and protocols in accordance with New York State and federal laws concerning donor and recipient selection, informed consent, preoperative evaluation, intraoperative and postoperative care of living liver donors. Commissioner Novello asked the Committee members to forward their recommendations before the end of 2002.

Members of the Committee include transplant physicians, an organ procurement organization representative, a liver transplant recipient and donor, a registered nurse, a social worker, a psychiatrist with transplant experience, an ethicist, and representatives from the five liver transplant programs in New York State. Two federal government representatives serve in an *ex officio* capacity.

Three subcommittees were formed at the first meeting of the Committee:

- Subcommittee on Informed Consent, Donor/Recipient Selection and Evaluation (Francis L. Delmonico, M.D., chair):
- Subcommittee on Donor Perioperative Care and Facility Support (Lewis Teperman, M.D., chair);
- Subcommittee on Donor Discharge Planning, Support and Long-Term Follow-up (Jean Emond, M.D., chair).

This report represents the diligent work of the Committee and contains guidelines to help reduce morbidity and mortality associated with live adult liver donation (hemihepatectomy) in New York State. This report was unanimously approved by the Committee at its November 13th meeting. Members hope these recommendations and guidelines will serve as a model for the rest of the country.

The Committee recommends that this report be reviewed annually.

Appendix II is a flowchart of the recommended adult living donor liver donation process.

II. Background

The availability and quality of an organ obtained from a live donor combined with the continuing shortage of recoverable organs from deceased donors has propelled an extensive effort to promote live donor organ transplantation. The well being of the donor should be a primary consideration of any live donor organ transplantation. Although the possibility of injury to a live donor has been acknowledged since the inception of organ transplantation as a viable medical field, a basic tenet of medicine is to do no harm. Thus, transplantation of an organ from a live donor stands in ethical contrast to all other care that a physician provides. If a seriously ill patient does not completely understand a plan of treatment, the physician may still act in his or her best interest. However, if a living donor does not understand the process and risks of donation, the consequences of not assimilating this important information in their decision-making process are profound.

Competing interests arise in live organ donation that are unique. These include the interests of the donor, the needs of the recipient and society for tissues or organs for transplantation, the interests of the next of kin of both the donor and recipient, as well as the interests of the transplant center.

A. The Donor

Potential donors donate selflessly for the good of either a family member, loved one, or society. The potential donor, however, must understand the following points:

1. In contrast to the consent for donation at the time of death, the living donor is potentially faced with either immediate risk or unknown future medical problems related to his or her organ system. These risks may not be entirely known at the time a living donor procedure is undertaken (such as a right lobe liver donation or laparoscopic nephrectomy).
2. The financial and emotional consequences of the donation must be understood. At a minimum, the donation process may cause stress in the family. It may also limit the functionality of the donor for weeks or months following the operation. The financial impact of this loss of functionality must be assessed and addressed before the transplant is

performed. Complications of the donation procedure may have limited consequences or may evolve into a state of chronic illness and lead to loss of employment and loss of medical insurability. The donor's family must consider the possibility of such an outcome, even though it may be unlikely.

3. Emotional consequences are much harder to quantify, and may have a varying effect upon donor family members that may impact the ultimate decision on donation. For example, the decision to donate could have a positive emotional bearing upon siblings when a parent is in need of a transplant, while at the same time, having a negative effect on the donor's primary family (spouse, children).

B. The Recipient

At first glance, it may appear that the recipient would have every reason to encourage living donation. Because the wait for a life-saving or life-enhancing organ transplant is shortened, the transition to a more functional life is accelerated, and the emotional strain of waiting for a deceased donor's organ is eliminated. The recipient should, nonetheless, understand the following points:

1. Transplantation, whether via a deceased donor or living donor source, is not a process that can be successfully accomplished alone. The recipient outcome is uniquely dependent upon another individual's willingness to provide a gift to a specific individual or society. In addition, the family is critically important to the success of the endeavor as the transplantation process requires the sacrifice of time, effort, emotion, and functionality of at least one if not more family members
2. Although there are risks for a live donor, the selection process and the efforts of the medical, surgical, and associated health care providers are to minimize these risks and ensure that the donor proceeds voluntarily and safely with the decision to donate
3. There may be additional medical risks associated with receiving an organ from a living donor versus an organ from a deceased donor. These negative factors may be countered by fewer complications in the pretransplant period.

4. The recipient should not believe that living donation is the only option to successful transplantation. The recipient must be placed on the transplant waiting list and the team will make every effort to pursue a deceased donor source of an organ so that the recipient does not feel the need to apply pressure on the potential live donor and thus avoid the creation of a coercive environment.
5. The recipient should be aware that once the potential donor begins the evaluation process, the team will not be able to provide the recipient with any information regarding the potential donor's progress in the process. This will provide the potential donor with the confidentiality afforded to all patients.

C. The Family

The families (spouse, children, parent, or person with a significant relationship with the donor) of either the donor or recipient can be either supportive or coercive. Family members are an integral part of the decision-making process they will be affected regardless of whether the decision is to donate or not to donate. The decision not to donate could impact another family member's fate, while the decision to donate could have a direct impact on the donor and his or her immediate family.

The family must understand that living donation may not be the only option. This concept helps engender a noncoercive environment in which the potential donor can make an independent decision. Both the potential donor's and recipient's families should make their preferences and desires known to the potential donor with the understanding that it is solely up to the potential donor to make the decision.

D. The Transplant Center

The professional staff of the liver transplant center is committed to helping patients with liver disease. However, as the demand for organs continues to increase and the pool of organs recovered from deceased donors remains insufficient, there is a compelling incentive for the transplant center to identify a living donor source of organs. The forces influencing the transplant center to solicit live donors include:

- the paramount desire to help the patients who entrust their future to transplant professionals;
 - prestige/professional satisfaction; and
 - economic concerns.
1. The transplant center exists for the benefit of the recipient. However, when a potential donor is determined to be suitable and becomes a possible surgical candidate, the transplant team must develop an additional ethical and professional relationship with the potential donor.
 2. Liver transplantation is a highly visible program of a medical center that conveys a sophistication and technical expertise that is commonly associated with an outstanding institution. It fosters professional recognition, scientific publications, academic reward, and personal satisfaction.
 3. Liver transplantation generates significant revenue for a medical center. The need to generate financial revenues and maintain the skills of the clinical providers may propel the leaders of the program to consider living donation as an alternative source for transplantation.

An independent donor advocate team should be established for any live donor adult liver transplantation program. This team's interests must be centered on the well being of the live donor; it must be constituted to assist donors in making informed decisions, and balance external/family pressures to donate. While centered on the interests of the donor, the team may not be totally independent of the recipient events, as there must be interaction with the transplant surgeon of the recipient team. However, at least one member of the donor advocate team should be independent of the recipient and designated solely to the interests of the donor.

Individuals presenting as potential donors should have an initial consultation at the transplant center prior to meeting the independent donor advocate team. This meeting should include an informational discussion with the surgeon who would be performing the partial hepatectomy. This surgeon, likely has the most in-depth clinical knowledge regarding this procedure and the possible risks and complications. The potential donor's family and persons with significant relationship to the potential donor should be included in this meeting.

A. Team Responsibilities

The independent donor advocate team's main responsibility is to support the donor. The independent donor advocate team's role begins with the donor evaluation process and continues through donation, the postoperative period, to discharge and postdischarge. Team members should complement the surgical team ensuring that the needs of the donor are fulfilled in a prompt manner and in accordance with best medical practice.

The team should:

1. structure the process of informed choice (specifically stating informed "choice" instead of preordained "consent") and emphasize that the decision to donate is not a foregone conclusion;
2. protect the interests and well being of the donor;
3. inform the potential donor that the independent donor advocate team will be discussing his or

her case with the transplant team and that the independent donor advocate team may override the potential donor's wishes;

4. provide information regarding the medical, psychosocial, and financial implications of the live donation for the potential donor;
5. explain the evaluation process, what to expect, what it means to be a donor, and that the donor may opt out at any time in the process;
6. decide on medical and psychosocial donor suitability; if the team does not have unanimous agreement, the donation will not occur;
7. discuss with the donor the formal conclusion regarding his or her medical and psychosocial suitability for the surgery;
8. assure there is continuity of care during hospitalization and assure that there are appropriate referrals for postdischarge care including follow-up from medicine, psychiatry or social work, as needed.

B. Team Characteristics

1. The independent donor advocate team should receive no direct financial or personal gains from approving the donor's participation.
2. The independent donor advocate team's status at the transplant center should not be affected by decisions made on behalf of the donor.
3. The independent donor advocate team must be medically sophisticated in transplantation and aware of relevant statistics such as center volume and outcome data, and be able to explain such information to the potential donor.
4. Each member of the team must have sufficient stature and preparation in his or her role to have the capacity to absolutely exclude a specific donor candidate when appropriate.
5. The independent donor advocate team should consist of, at a minimum, an internal medicine physician, a transplant coordinator/nurse clinician, a medical social worker with the participation of a psychiatrist and/or ethicist as appropriate. The Committee recommends the following:

- a. All team members should have a comprehensive working knowledge of liver disease and transplantation.
 - b. The social worker (who should have at least a master's degree) should be skilled in individual and family counseling, should understand the entire donation process, and should be able to provide information on financial issues and community resources.
6. Once team members are designated by the center to serve on the independent donor advocate team, they should participate in at least three donor evaluation processes per year.

C. Education

The independent donor advocate team should take the lead in educating the potential donor about the entire donation process. The team should begin with the existing known facts about the donation process, discuss these facts, and then explain how these issues relate to the potential donor's personal beliefs and values. This should be a long and thorough discussion that helps the potential donor recognize that only certain persons can and should be permitted to donate. A brochure or written materials regarding the donation process should be developed and provided to all potential donors.

The team should:

1. Evaluate the intellectual and emotional capacity of the potential donor to exercise legally and ethically adequate informed choice. This process is far more complex than the process involved in evaluating the capacity of a patient to provide informed consent to a treatment that is offered in his or her own best interest.
2. Devise a process appropriate for each individual potential donor to inform him or her about the risks of medical interventions, which makes clear that the benefits are speculative while the risks serious and measurable.
3. Balance the hopes of donors, such as expectations of recipients' gratitude, and the sense of well being from the altruistic behavior of donation, against the real medical risks of the donation procedure.
4. Ensure that there is a thorough understanding of the elements of the decision. When the risks are great, the team should interact with the potential donor to be certain that all intellectual and emotional considerations have been discussed and that the patient has understood the risks and benefits and applied them to his or her personal situation and core beliefs and values.
5. Determine that the potential donor's decision is voluntary. The donor should feel free to choose an option. Others should not try to influence the donor toward a particular decision.
6. Encourage the potential donor to contact his or her insurance company in advance.

IV. Informed Choice

The forces that influence a donor are numerous and complex. The donor must be free to make an informed independent choice. The informed choice process refers to that part of the donation decision that helps to focus on the technical elements of the donation, surgery, recovery, and on the unknown and unforeseeable consequences that might in the short- or long-run change the patient's life, health, employment, or emotional situation. The person who gives consent to be a live organ donor should be:

- competent;
- willing to donate;
- free from coercion;
- medically and psychosocially suitable;
- fully informed of the risks and benefits as a donor;
- fully informed of the risks, benefits, and alternative treatment available to the recipient; and
- likely to benefit in a specific, nonmonetary way.

The benefits to both the donor and the recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.

A. Informed Understanding

1. Written and verbal presentations should be in lay language, in accordance with the person's educational level, and in a language he or she can understand.
2. The potential donor should be able to demonstrate that he or she understands the essential elements of the donation process, especially the risks associated with the procedure.
3. Adequate time should be allowed for the potential donor to understand and assimilate the information provided, ask questions, and have questions answered. This may require several consultations for the donor to absorb the information and formulate questions.

4. Written material provided to the potential donor should not only serve as a basis for consent but also as future reference for the donor.
5. The donor's family/loved ones should be given the opportunity to openly discuss their concerns in a safe and nonthreatening environment.
6. The potential donor should understand, agree to, and commit to the need for postoperative, long-term follow-up and testing by the transplant center.

B. Disclosure

1. The transplant team and the independent donor advocate team should disclose their institutional affiliations to the potential donors.
2. The relationship of the donor and the recipient should not alter the level of acceptable risk.
3. There should be a two-week period of reflection and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and final approval to proceed by the independent donor advocate team before the potential donor signs the consent for the donation procedure.
4. Non-English speaking candidates and hearing-impaired candidates must be provided with a nonfamily interpreter who understands their language and culture.
5. A member of the independent donor advocate team should witness the potential donor signing the consent document for the donor hemihepatectomy.

The overall donation process and experience should be explained to the potential donor and should include:

1. donor evaluation procedure;
2. surgical procedure;
3. recuperative period;
4. short- and long-term follow-up care;
5. alternative donation and transplant procedures;
6. potential psychological benefits to donor;

7. transplant center and surgeon-specific statistics of donor and recipient outcomes;
8. confidentiality of the donor's information and decision;
9. donor's ability to opt out at any point in the process;
10. information about how the transplant center will attempt to follow the health of the donor for life.

C. Risks

Risks should be fully explained to the potential donor.

1. Physical

- a. potential for surgical complications including risk of donor death;
- b. potential for liver failure and the need for liver transplant;
- c. potential for other medical complications including long-term complications;
- d. scars;
- e. pain;
- f. fatigue;
- g. abdominal and/or bowel symptoms such as bloating and nausea.

2. Psychosocial

- a. potential for problems with body image;
- b. possibility of recipient death;
- c. possibility of recipient rejection and need for retransplantation;
- d. possibility of recurrent disease in recipient such as hepatitis C or hepatocellular carcinoma;
- e. possibility of adjustment disorder postsurgery;
- f. impact on donor's family;
- g. impact on recipient's family;
- h. potential impact of donation on lifestyle.

3. Financial

- a. out-of-pocket expenses;
- b. child care costs;
- c. possible loss of employment;
- d. potential impact on ability to obtain future employment;
- e. potential for disability benefits and need for assistance completing relevant paperwork;
- f. impact on ability to obtain health and life insurance (may be denied or have higher future premiums).

D. Choice

1. Determine, to the extent possible, that there is no monetary enrichment for the donor.
2. Determine that there is no coercion to donate by family or others.
3. Assist donor with a general statement of unsuitability for donation if requested by donor. Medical information regarding the donor should not be falsified to provide the donor with an excuse to decline donation.
4. Ensure that the donor is intellectually and emotionally capable of participation in a balanced discussion of potential risks and benefits.
5. Provide adequate information to the recipient to ensure his or her understanding regarding the risks to the donor.
6. Educate donor about recipient's options for cadaveric transplant, including risks and outcomes.
7. Ensure the donor understands that he or she may decline to donate at any time.

E. Documentation

1. Disclosure and consent process should be documented.
2. Donor should have a medical record separate and distinct from the recipient's to protect donor confidentiality.

F. Decision to Donate

Once the independent donor advocate team determines the suitability of the donor, then, further evaluative processes may proceed: medical assessment, psychological assessment, assessing the family dynamics, and assessing the level of social support.

1. Before the independent donor advocate team presents its decision to the potential donor, the team should discuss the decision with the transplant team.
2. If the potential donor wishes to donate, but the independent donor advocate team does not agree, the donation should not occur. The reasons for the independent donor advocate team's objections to donation should be explained to the donor. For example, the donor may have an inability to assimilate or process the information provided to him or her, the donor may be unable to integrate the degree of risk pertinent to his or her situation, or there may be a lack of equipoise between the risk to the potential donor and potential benefits to the recipient.
3. If the independent donor advocate team and the potential donor agree to donate, final review rests with the transplant team.

A. Primary Medical Evaluation

A medical evaluation of the potential donor should be made by a senior member of the medical staff to diminish the possible susceptibility to covert pressure. The following are recommended minimal initial criteria that should be met before proceeding with further evaluation:

1. absence of systemic disease or its likely occurrence should be considered (consider genetic and environmental vulnerability);
 2. absence of current or past impairment to any vital organ (for example, mild chronic obstructive pulmonary disease or history of coronary artery disease); when appropriate, a liver biopsy should be performed to determine the presence of nonseropositive hepatitis and steatohepatitis;
 3. absence of special vulnerability to infection, blood loss, or delayed wound healing; because of the risk of peptic ulcer disease in the donor, a significant documented history of peptic ulcer disease should be considered a contraindication.
 4. Minors younger than 18 should not be donors. While the exact upper age limit for donation is difficult to define, it is recommended that potential donors over age 55 not be considered, as the liver regeneration process may be compromised in this age group. When considering donors over age 55, special consideration should be carefully documented and detailed by both the independent donor advocate team and the transplant center.
- ### B. Psychiatric and Social Requirements
- The transplant center should have a dedicated medical social worker. In some instances, a transplant center may choose to engage a psychologist. In all instances, there should be access to psychiatric consultation either through participation of a dedicated psychiatrist or general hospital psychiatric consultation liaison service.
1. There should be a vital emotional relationship between the potential donor and the recipient, therefore, Good Samaritan donation is not recommended. Although this may change in the future, current assessment of right lobe liver donation does not justify Good Samaritan donation at this time. There should be no coercion by those close to the donor or recipient.
 2. The donor should be free of current psychiatric disorders. In situations where a past history of psychiatric illness exists, the illness should be in full remission with a low likelihood of reoccurrence as documented by a psychiatric evaluation.
 3. There should be no evidence of financial incentive or profit motive in the donor's participation.
 4. The donor should not have a history of physical or sexual abuse unless the recipient's survival is essential to donor welfare (for example, a twin brother and sister have experienced childhood abuse and suffer from stress disorders, but depend on each other for emotional sustenance).
 5. The donor should be able to acknowledge and understand the attendant risks of live donor adult liver transplantation and there should be appropriate documentation of that acknowledgement.
 6. If the donor has a history of alcohol addiction or substance abuse, there should be evidence of long-term stable abstinence with low risk of exacerbation.
 7. The donor should have the right and the capacity to withdraw participation at any time prior to the surgery.

VI. Liver Transplant Recipients

A patient may not be considered as a recipient of a live donor adult liver if he or she is not an eligible candidate for a cadaveric liver transplant. The patient should meet the eligibility criteria set forth by the United Network for Organ Sharing (UNOS), must be listed on the cadaveric liver transplant waiting list, and must have suffered at least one significant complication related to his or her liver disease (e.g., variceal hemorrhage, spontaneous bacterial peritonitis, encephalopathy, or severe impairment to his or her quality of life due to fatigue, pruritis, etc.). The UNOS recipient exclusion criteria for transplantation should be supplemented by the following exclusions for live donor adult liver transplantation (these exclusions may change as more data become available):

- A. a model for end-stage liver disease (MELD) score of greater than 25;
- B. adult fulminant hepatic failure;
- C. cholangiocarcinoma;

D. hepatocellular carcinoma if:

- 1. there is evidence of metastatic disease;
- 2. comorbidities exist;
- 3. the recipient can expect less than a one-year disease-free outcome.

E. retransplantation for hepatitis C;

F. need for dialysis;

G. simultaneous combined liver/kidney transplantation (however, in cases involving hyperoxalosis or other specific metabolic disorders, special consideration should be given to allowing simultaneous liver/kidney transplantation from two different donors);

H. acute alcoholic hepatitis.

The following information should be provided to the recipient:

- A. specific risks and benefits;
- B. alternative treatments available;
- C. expected outcome of transplantation.

VII. Perioperative Care and Facility Support

The donor surgeon should have primary concern and responsibility for the donor's care and welfare throughout his or her entire hospital stay.

A. Preoperative Preparation

1. Transplant centers should have the ability to allow donors to bank a minimum of one unit of blood before surgery. Facilities should have the ability to handle autologous blood donations.
2. Surgeries should be scheduled only when sufficient staffing will be available for the postoperative period (preferably the early part of the week). If surgery is scheduled during the latter part of the week, the hospital should ensure that there is adequate attending, resident physician, physician extender, and registered nursing coverage during the weekend.
3. The transplant coordinator or another team member should be assigned the responsibility of providing updates to the families of both the donor and recipient during the surgical procedures.

B. Operative Teams

1. There should be two liver transplant attending surgeons with live donor adult liver transplantation experience attending the live donor procedure. One such surgeon should be present for the entire procedure and both of these surgeons should be scrubbed and present for the critical portions of the procedure.
2. A third liver transplant attending surgeon should be present in the recipient operating room. This surgeon should have experience in cadaveric liver transplantation but does not necessarily need expertise in live donor resectional surgery.

C. Qualifications of Surgical Team Surgeons

1. All three surgeons should be board certified in general surgery or an equivalent foreign certification acceptable to the New York State Department of Health.

2. All three surgeons should have demonstrated experience in liver transplant surgery.
3. Two surgeons should have demonstrated experience in live donor hepatectomy (15 procedures) or demonstrated experience in major hepatobiliary resectional surgery (20 procedures) or surgical fellowship at an American Society of Transplant Surgeons (ASTS) approved liver transplant fellowship program with demonstrated experience (15 procedures) with live donor hepatectomy. This should include written verification by the fellowship program director or by the director of the supervising transplant program of hands-on training at an institution performing live donor hepatectomy.
4. For a new program with no experience in live donor adult liver transplantation, surgeons should have demonstrated experience in major hepatobiliary resectional surgery (20 procedures). Surgeons should also visit an established program and observe a minimum of five cases. Written verification should be obtained from the director of the hosting program.
5. Two liver transplant attending surgeons with live donor liver resectional experience should operate on the donor. These two surgeons should be present for the critical parts of the surgery including the liver parenchymal transection. They should be available and scrubbed if needed for complications, however, only one surgeon need be present for the remainder of the donor operation. One experienced surgeon and a resident or a fellow operating on the donor during the critical parts of the surgery would not be acceptable.

Anesthesia

1. There should be two separate anesthesia attending physicians for the live donor adult liver transplantation donor and recipient operations. These anesthesia attendings should be present for the critical anesthetic and surgical portions of the procedures and immediately available at all other times. As one case is completed, either anesthesia attending can take responsibility for the ongoing case. The

anesthesia attendings should have experience in liver transplant anesthesia and/or major hepatic resection surgery and/or cardiac surgery anesthesia.

2. There should be two separate anesthesia teams in two operating rooms (one for the donor, one for the recipient).
3. These teams should be directed by a separate anesthesia attending for the live donor and the recipient procedure. The team should consist of anesthesia attendings, chief residents and fellows (postgraduate year 3, 4 or 5), and/or qualified certified registered nurse anesthetists. They should have ongoing education and training in liver/cardiac surgery and have had anesthesia responsibility for major liver resections.

D. Postoperative Care

1. Day 0-1: Live adult liver donors should receive intensive care (ICU or PACU).
2. Day 2: If stable and cleared for transfer by the transplant team, donors should be cared for in a hospital unit that is dedicated to the care of transplant recipients or a hospital unit in which patients who undergo major hepatobiliary resectional surgery are cared for. Liver donors should not at any time be cared for on any other unit unless a specific medical condition of the donor warrants such a transfer.
3. The donor should be evaluated at least daily by one of the qualified liver transplant attendings with documentation in the medical record.
4. The transplant team should be responsible for the pain management of the donor. In institutions where a pain management team is available, the transplant team may delegate its responsibility to this team. However, there should be a written protocol in place for assessment and management of donor pain.
5. If there is an identified member of the anesthesia care team with specific education and training in pain management of liver donors, that person should be available for consultation with the transplant team regarding the pain control of the donor.

6. Since days 3 and 4 are generally the time when complications may occur (for example, gastric dilatation, wound infections, severe hypophosphatemia), the patient care staff should be familiar with the common complications associated with the donor and recipient operations and have appropriate monitoring in place to detect these problems should they arise.
7. If there is an emergent complication requiring reoperation, these patients should be prioritized for access to the operating room by the institution.

E. Medical Staffing

1. There should be 24 hour/seven day-a-week continuous coverage of the transplant service by general surgery residents at the postgraduate year 2 level or higher, transplant fellows, or physician extenders (nurse practitioners or physician assistants). Between the hours of 6 p.m. and 8 a.m. and at all times on weekends and holidays, the covering residents, fellows, nurse practitioners, or physician assistants should be dedicated to the transplant service and not covering other surgical and nonsurgical patients. An attending transplant surgeon should be available immediately as a resource for the residents, fellows, or physician extenders at all times.
2. Any patient with abnormal vital signs or unusual symptoms as identified by the registered nurse should be evaluated immediately by the medical staff. Notification to the appropriate senior medical staff (fellow, chief resident, attending) should be made within 30 minutes. Facilities should have policies in place to assure this response occurs in an expedient manner.

F. Nursing Staffing

1. Nursing staff should have ongoing education and training in live donor liver transplantation nursing care (donor and recipient). This should include education on the pain management issues particular to the donor. The registered nursing ratio should be 1:2 in the ICU/PACU level setting, adjusted as appropriate for the acuity level of the patients.

2. After the donor is transferred from the ICU/PACU, the registered nursing ratio should be 1:4 on all shifts, adjusted as appropriate for the acuity level of the patients.
3. The same registered nurse should not take care of both the donor and the recipient. This will minimize confusion if the surnames of the two are the same and will allow the nurse to focus solely on the needs of either the donor or the recipient.
4. The nursing service should provide the potential donor with presurgical information including, if possible, a tour of the unit before surgery.
5. The names and beeper numbers of the transplant team should be posted on all units receiving transplant donors.

G. Radiology

Institutions performing live adult liver transplantation should have adequate radiological staff support including:

1. a radiologist with demonstrated experience in evaluating preoperative imaging studies of a potential liver donor including computerized tomography (CT scan) and/or magnetic resonance imaging (MRI) with respect to liver volume estimates (right and left lobe) and detailed vascular and biliary anatomy;
2. a radiologist with expertise in reviewing imaging studies in liver transplant recipients;
3. radiologists with experience in interventional procedures (angiography) and ultrasound imaging studies in the live donor and liver transplant recipient (available on weekends and between the hours of 6 p.m. and 8 a.m.).

If there is an emergent complication requiring radiology services, these patients should be prioritized for access to radiology services by the institution.

VIII. Discharge Planning

The Committee recommended a comprehensive survey of all donors in New York State to more completely understand issues surrounding donation and, in particular, to help identify ways to improve the discharge planning process and the posthospital experience. The surveys were mailed by each transplant center in October 2002. Donors were provided with business reply envelopes addressed to the New York State Department of Health where a confidential analysis is underway. (See Appendix IV for a copy of the survey.) Results of the survey will be used to further refine the Committee's recommendations.

A. Predonation

1. Discharge planning should be viewed as a comprehensive process beginning with the decision to donate.
2. The independent donor advocate team should be available to provide support to the donor from preadmission to postdischarge, as outlined in this report.
3. The potential donor should be referred to others who have donated in the past. Consideration should be given to encouraging the creation of a voluntary statewide or national live adult liver donor consumer organization to provide support for potential donors and their families, as well as for those who have gone through the surgery.

B. Discharge

1. A detailed written discharge plan should be developed, given to the donor, and provided to all health care professionals involved in the donor's care including the donor's primary care physician.
2. This plan should be reviewed with the donor by a health care professional designated by the program, such as the primary care nurse, social worker, or transplant coordinator.
3. Instructions should include:
 - a. restrictions on activities (no heavy lifting for one month, no driving for four weeks, etc.);

- b. activities permitted (showering, walking, other activities as tolerated);
- c. diet (in most cases will be regular);
- d. medication for pain;
- e. wound care;
- f. a 24-hour contact number that donors can call with questions, concerns, and/or problems; this contact person should be available when needed and be knowledgeable about live adult liver donation;
- g. name, address, and telephone number of the surgeon and instructions for the follow-up visit; and
- h. instructions for family members or caregivers.

C. Postdischarge

1. Medical follow-up should be appropriate for someone who has undergone a major liver resection procedure. This follow-up should include:
 - a. postoperative visits with the donor's surgeon(s);
 - b. follow-up coordinated with the donor's primary care physician to assess wound healing, monitor for signs/symptoms of infections, and monitor liver function;
 - c. serum liver chemistry tests at discharge or at six weeks (whichever is sooner) and six months and annually for the first five years; three dimensional liver scan with volume assessment at one year should be performed on all donors of full right or full left lobes;
 - d. written summary of the donor's condition which should be provided to the donor and his or her primary care physician upon the donor's discharge from the hospital; this will ensure continued appropriate medical care.
2. Follow-up social/psychological supports which may include measures such as:
 - a. visits with a social worker;
 - b. visits with a psychologist or psychiatrist;

- c. participation in a professionally run support group, similar to support groups for cadaveric donor families;
 - d. participation in a center-sponsored computer donor listserv or bulletin board to share patient concerns;
 - e. invitation to a donor recognition event, such as an annual recognition ceremony or presentation of a donor medal.
3. There should be follow-up on financial/insurance concerns, possibly by the transplant center's financial coordinator.

Adult liver donors should be followed for the donor's lifetime to determine if there are any long-term health issues associated with the donation. A data collection system should be established to track and analyze the long-term (lifelong) outcomes of live adult liver donation in New York State. Centers should be required to report data on an ongoing basis, and verify accuracy of data for report generation to New York State and the New York Center for Liver Transplantation on a quarterly basis. The data system should be available to the New York State Department of Health. (See Appendix III.)



STATE OF NEW YORK DEPARTMENT OF HEALTH

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Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

March 18, 2002

I am writing this letter to the six hospitals in New York State authorized to perform liver transplant surgery as a result of serious quality of care issues that the Department of Health identified during a recent investigation into the death of a living liver donor at the Mount Sinai Medical Center.

All liver transplant programs in New York State need to ensure that the following quality of care and patient support measures are in place for liver transplant donors and recipients:

- 1) All policies and procedures for living liver donors must be re-examined to ensure that there are appropriate safeguards for both pre and post-operative care. Informed consent protocols should be included in this assessment to assure that potential donors are not subject to any coercion in making their decision to become a living donor. Hospitals also should assure that staff understands and adheres to these policies and procedures.
- 2) There must be sufficient medical and nursing staff to ensure that patient needs are met and quality care is continually provided.
- 3) Surgeries should be scheduled only when maximum staffing will be available for the post-operative period. If surgery is scheduled during the latter part of the week, the hospital should ensure that there is adequate attending physician and nursing coverage during the weekend.
- 4) There must be continuous supervision and monitoring by senior staff and attending physicians of patient care provided by interns and residents.
- 5) There must be continuous monitoring by nurses of patient condition; significant changes in patients' conditions must be promptly reported to the patient's attending physician.
- 6) There must be periodic review of communication policies within and between medical, nursing and other specialties.
- 7) All staff providing care to transplant donors or recipients must be prepared for their responsibilities through education, experience, demonstrated competence and completion of in-service programs.
- 8) Hospitals must establish protocols and devote the necessary resources to ensure that there are counseling and support programs for donors and their families.

Hospitals are expected to conduct this re-assessment of their liver transplant programs. Implementation of necessary improvements is to be completed within thirty (30) days. Department staff will monitor hospital compliance with this directive.

22 The New York State Transplant Council will review all issues involving living liver donations and transplantation. The Council will provide the Department with any necessary policy or regulatory recommendations that will improve the care and well being of individuals who wish to become living donors. I trust that the hospitals performing liver transplants will actively support and be engaged with the Transplant Council in this comprehensive review.

Your cooperation with this directive will ensure that liver transplantation in New York State meets the highest standards of quality and safe patient care.

Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Antonia C. Novello M.D. M.P.H. Dr. P.H.".

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner of Health

Live Adult Liver Donation Process Map

Recipient meets criteria for live donor adult liver transplantation.



Potential donor with vital emotional relationship presents to transplant center as potential donor.



Potential donor has initial meeting with surgeon who would perform donor surgery.



Potential donor is evaluated by independent donor advocate team.



Independent donor advocate team:

- structures process of informed choice and protects interests and well being of potential donor;
- explains surgery, and medical, psychosocial, and financial implications of procedure;
- refers potential donor to previous donors;
- evaluates intellectual and emotional capacity of potential donor;
- performs independent medical and psychosocial evaluations of donor;
- determines potential donor's choice is voluntary and ensures no monetary compensation is involved in decision.



Independent donor advocate team makes decision:

- if no, process ends.
- if yes, donor is referred to the transplant team for further evaluation.



Potential donor undergoes any further required medical/surgical evaluation by the transplant team.

- if donation contraindicated, process stops.
- if donation cleared and recipient meets criteria for live adult liver donation, process continues.



Potential donor has reflection and reaffirmation period of two weeks to make decision.



Potential donor signs consent form; independent donor advocate team member witnesses signing.



Donor surgery occurs.

- Two liver transplant attending surgeons with live donor adult transplant experience attend the procedure.
- A third liver transplant surgeon is present in recipient operating room.
- Qualifications for surgical and anesthesia team are met.



Day 0-1:

- Donor sent to ICU or PACU for initial recovery.
- RN ratio 1:2.



Day 2 – discharge: transferred from ICU or PACU if stable:

- Donor sent to transplant unit if stable and cleared for transfer.
- RN ratio 1:4.
- Donor is evaluated at least daily by qualified liver transplant attending.
- Pain management is a priority.
- 24/7 continuous coverage of service (including off hours shifts) by PGY2 or higher level physician or PA/NP.
- Any donor with abnormal vital signs or unusual signs/symptoms identified by the RN is evaluated immediately and senior medical staff notified within 30 minutes.



Donor discharged with pain medication and information on:

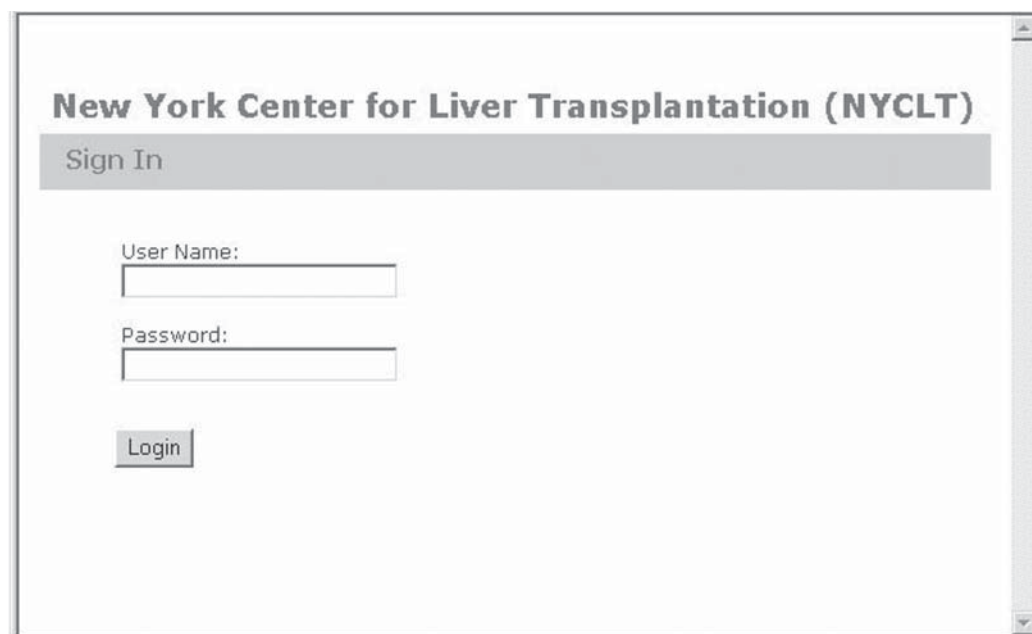
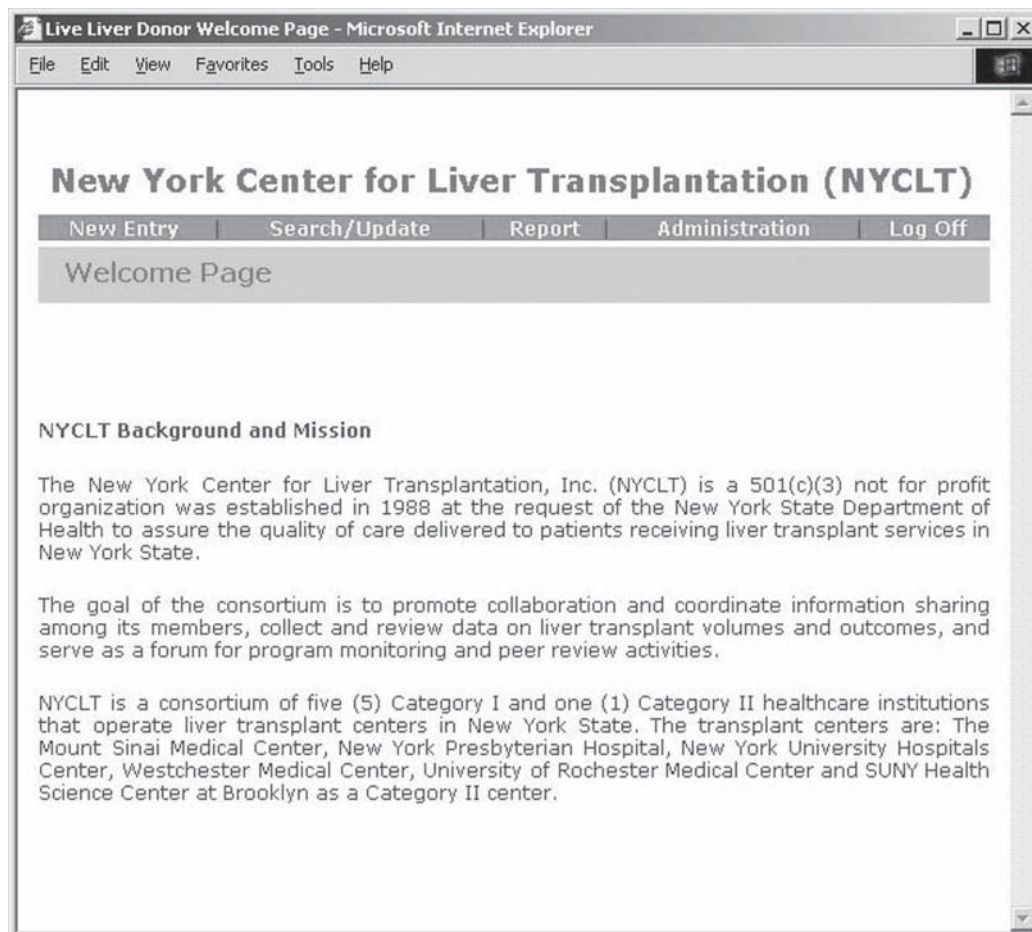
- permitted and restricted activities;
- diet;
- wound care;
- 24-hour contact telephone number for problems;
- instruction for family members.



Follow-up:

- post-op visits with surgeon;
- coordination with donor's primary care physician;
- donor recognition;
- periodic survey of donor's physical condition;
- data submitted to statewide and/or national registry.

NYCLT Online Data Collection Instrument



Provider Information

Provider Information

Assessment Time Frame Post Surgery
Discharge / 6 Weeks

Date of Assessment
(mm/dd/yyyy)

Donor Information

Donor Social Security Number
 - -

UNOS Identifier

Hospital ID Number

New Donor / New Survey

Provider Information

Provider Information

Assessment Time Frame Post Surgery
Discharge / 6 Weeks

Date of Assessment
12/04/2002

Donor Information

Donor Social Security Number
123 - 45 - 6789

UNOS Identifier

Hospital ID Number

Donor Demographics

Donor Gender

Male Female

Date of Birth

(mm/dd/yyyy)

Is Donor Related to Recipient?

Yes No

Does Donor Have Health Insurance?

Yes No

Surgery Information

Date of Hepatectomy

(mm/dd/yyyy)

Was Procedure Aborted After Donor Received Anesthesia?

Yes No

If Yes, Please Indicate Reason?

- Cardiac Issues
- Anesthesia Issues
- Donor Anatomy Issues
- Recipient Issues
- Other :

Did Donor Experience Any Vascular Complications Requiring Intervention?

Yes No

If Yes, Please Indicate Type(s) of Vascular Complication

- Portal Vein
- Hepatic Vein
- Hepatic Artery
- Pulmonary Embolus Requiring Anticoagulation or Filter
- Deep Vein Thrombosis Requiring Anticoagulation or Filter
- Other :

Did Donor Receive Any Non-Autologous Blood Transfusions?

Yes No

If Yes, Please Indicate Number of PRBC Units Donor Received**Did Donor Experience Any Other Complications Requiring Intervention?**

Yes No

If Yes, Please Indicate Type of Complication

- Ascites Requiring Treatment
- Line or IV Complication Requiring IV Antibiotics or Intervention
- Pulmonary (Pneumonia Requiring Antibiotics/Reintubation/Pleural Effusion Requiring Therapy)
- Wound Complication (Infection Requiring Antibiotics or Other Intervention)
- Brachial Nerve Injury
- Other :

Did Donor Have to Have a Re-Operation?

Yes No

If Yes, Please Indicate Type of Operation and Associated Date

- Liver Failure Requiring Transplant Date (mm/dd/yyyy)
- Bleeding Date (mm/dd/yyyy)
- Biliary Date (mm/dd/yyyy)
- Hernia Repair Date (mm/dd/yyyy)
- Bowel Obstruction Date (mm/dd/yyyy)
- Vascular Date (mm/dd/yyyy)
- Other : Date (mm/dd/yyyy)

Was Donor Readmitted to Hospital After Initial Discharge?

Yes No

If Yes, Indicate Reason and Date of Readmission

- Wound Infection Date (mm/dd/yyyy)
- Fever Date (mm/dd/yyyy)
- Bowel Obstruction Date (mm/dd/yyyy)
- Pleural Effusion Date (mm/dd/yyyy)
- Dehydration Date (mm/dd/yyyy)
- Ileus Date (mm/dd/yyyy)
- Dehiscence Date (mm/dd/yyyy)
- Portal Vein Thrombosis Date (mm/dd/yyyy)
- Intrabdominal Adcess Date (mm/dd/yyyy)
- Other : Date (mm/dd/yyyy)

<p>Did Donor Experience Any Vascular Complications Requiring Intervention?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If Yes, Please Indicate Type(s) of Vascular Complication</p> <p><input type="checkbox"/> Portal Vein <input type="checkbox"/> Hepatic Vein <input type="checkbox"/> Hepatic Artery <input type="checkbox"/> Pulmonary Embolus Requiring Anticoagulation or Filter <input type="checkbox"/> Deep Vein Thrombosis Requiring Anticoagulation or Filter <input type="checkbox"/> Other : <input type="text"/></p> <hr/> <p>Did Donor Receive Any Non-Autologous Blood Transfusions?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If Yes, Please Indicate Number of PRBC Units Donor Received</p> <p><input type="text"/></p> <hr/> <p>Did Donor Experience Any Other Complications Requiring Intervention?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If Yes, Please Indicate Type of Complication</p> <p><input type="checkbox"/> Ascites Requiring Treatment <input type="checkbox"/> Line or IV Complication Requiring IV Antibiotics or Intervention <input type="checkbox"/> Pulmonary (Pneumonia Requiring Antibiotics/Reintubation/Pleural Effusion Requiring Therapy) <input type="checkbox"/> Wound Complication (Infection Requiring Antibiotics or Other Intervention) <input type="checkbox"/> Brachial Nerve Injury <input type="checkbox"/> Other : <input type="text"/></p>	
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Did Donor Have to Have a Re-Operation?

Yes No

If Yes, Please Indicate Type of Operation and Associated Date

- Liver Failure Requiring Transplant Date (mm/dd/yyyy)
- Bleeding Date (mm/dd/yyyy)
- Biliary Date (mm/dd/yyyy)
- Hernia Repair Date (mm/dd/yyyy)
- Bowel Obstruction Date (mm/dd/yyyy)
- Vascular Date (mm/dd/yyyy)
- Other : Date (mm/dd/yyyy)

Was Donor Readmitted to Hospital After Initial Discharge?

Yes No

If Yes, Indicate Reason and Date of Readmission

- Wound Infection Date (mm/dd/yyyy)
- Fever Date (mm/dd/yyyy)
- Bowel Obstruction Date (mm/dd/yyyy)
- Pleural Effusion Date (mm/dd/yyyy)
- Dehydration Date (mm/dd/yyyy)
- Ileus Date (mm/dd/yyyy)
- Dehiscence Date (mm/dd/yyyy)
- Portal Vein Thrombosis Date (mm/dd/yyyy)
- Intrabdominal Adcess Date (mm/dd/yyyy)
- Other : Date (mm/dd/yyyy)

Did Donor Have Any Other Interventional Procedures?

Yes No

If Yes, Please Indicate Type and Date(s) of Intervention Procedure

1. Date (mm/dd/yyyy)

2. Date (mm/dd/yyyy)

Mortality

Mortality?

Yes No

If Yes, Indicate Cause and Date of Donor Death.

30 (chars left)

Date (mm/dd/yyyy)

Did Donor Have Any Other Interventional Procedures?

Yes No

If Yes, Please Indicate Type and Date(s) of Intervention Procedure

1. Date (mm/dd/yyyy)

2. Date (mm/dd/yyyy)

Return to Work

Did Donor Return to Work?

<input type="checkbox"/> Full Time	Date (mm/dd/yyyy) <input type="text"/>
<input type="checkbox"/> Part Time	Date (mm/dd/yyyy) <input type="text"/>
<input type="checkbox"/> Homemaker	Date (mm/dd/yyyy) <input type="text"/>
<input type="checkbox"/> Unemployed, Seeking Work	Date (mm/dd/yyyy) <input type="text"/>
<input type="checkbox"/> Retired	Date (mm/dd/yyyy) <input type="text"/>
<input type="checkbox"/> Disabled	Date (mm/dd/yyyy) <input type="text"/>

Mortality

Mortality?

Yes No

If Yes, Indicate Cause and Date of Donor Death.

30 (chars left)

Date (mm/dd/yyyy)

Liver Donor Survey

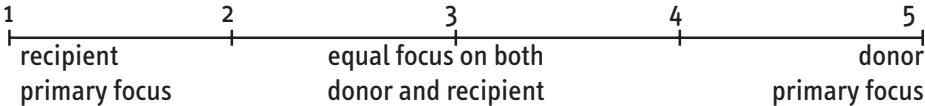
Before Your Surgery

- 1 = excellent information
- 2 = useful information
- 3 = somewhat useful information
- 4 = inadequate information
- 5 = no information at all

1. Using the scale on the left, rate the information you received before your surgery.
 - risks and complications of the surgery
 - surgical procedure itself
 - physical effects of the surgery (for example, pain, bloating, scars, fatigue, etc.)
 - possible emotional/psychological effects of the surgery
 - possible expenses or insurance costs as a result of the surgery

2. Based on your experience before surgery, do you think the hospital medical staff you came in contact with were primarily focused on you or the recipient?

Please circle the number on the scale to indicate where you believe their concerns were focused.



3. Were you given the opportunity to speak to other donors before your surgery? Yes No
 If yes, was it helpful? Yes No
 If no, do you think speaking to other donors would have been helpful? Yes No
4. Did the hospital staff give your family members the opportunity to discuss their concerns about your surgery? Yes No

Hospital Experience

- 1 = totally agree
- 2 = somewhat agree
- 3 = agree
- 4 = somewhat disagree
- 5 = totally disagree

5. Using the scale on the left, indicate your agreement with the following statements:
 - The surgeon answered all my questions before surgery.
 - The anesthesiologist answered all my questions before surgery.
 - My family/loved ones were kept informed of my progress during surgery.
 - I received good care from the doctors in the hospital.
 - I received good care from the nurses in the hospital.
 - While in the hospital, my pain was controlled adequately.
 - I was prepared for the way I would feel after surgery.

Before Discharge From the Hospital

- 1 = very useful
- 2 = somewhat useful
- 3 = less than useful
- 4 = not useful at all
- 5 = no information provided

6. Did a hospital staff person discuss your needs on the day you were sent home and help you plan to meet those needs? Yes No
If yes, who? (please check all that apply)
- Surgeon
- Social Worker
- Transplant Coordinator
- Unit Nurse
- Other (please specify) _____
7. Using the scale on the left, indicate how useful you found the information hospital staff provided to you before you were sent home from the hospital.
- what you should expect after surgery _____
 - primary care physician follow-up _____
 - wound care _____
 - pain management _____
 - physical activity _____
 - instruction for family members _____
 - referral sources for emotional issues _____
 - referral sources for financial issues _____
8. Was there other information you would have liked to receive? ... Yes No
If yes, please specify:
- _____
- _____

After Discharge From the Hospital

9. Was your primary care physician contacted by someone from the transplant team? Yes No
Don't Know
10. Were you instructed to see your primary care physician? Yes No
11. Did you receive a follow-up phone call from the transplant center? Yes No
If no, do you think a phone call would have been helpful? Yes No
12. How many times did you return for post-operative visits with the surgeon/transplant team? _____
13. Did the hospital staff address all your concerns before you were sent home? Yes No
If no, please explain:
- _____
- _____
- _____
- _____
- _____

Emotional Support After Discharge

14. Did you feel the need for any emotional support after discharge? .. Yes No
15. Did the hospital staff refer you to any support groups? Yes No
If yes, did you participate in a support group? Yes No
If no, do you think a professionally led group would have
been helpful? Yes No
16. Did you speak with any other donors after surgery? Yes No
If no, do you think that would have been helpful? Yes No
17. Would you like to have public recognition for your donation? Yes No

Financial Issues

18. When you were considering surgery, were you told that there
might be unexpected expenses as a result of the surgery? Yes No
19. Did you have any unexpected financial problems after discharge
as a result of your hospitalization? (for example, inadequate
insurance, out-of-pocket expenses, loss of wages, child care costs,
transportation costs) Yes No
If yes, please specify.
-
-

Demographics

20. How old were you when you donated part of your liver?
- 18 or younger
- 19 – 25
- 26 – 34
- 35 – 44
- 45 – 54
- 55 or older
21. Are you:
- male
- female
22. Where was your surgery performed?
- Mt. Sinai Medical Center
- New York University Medical Center
- New York Presbyterian Hospital
- Westchester Medical Center
- Strong Memorial Hospital

