

EVALUATION ACKNOWLEDGEMENT ADULT LIVER TRANSPLANT

OVERVIEW

The following information is provided to inform you of the liver transplant evaluation process and provide information regarding liver transplantation. It is our goal to help you understand transplantation. This includes the benefits and risks of receiving a transplant so you can make an informed decision about proceeding with the transplant evaluation process. The Transplant Team will review all aspects of this Evaluation Acknowledgement form with you.

When you come to the hospital for your evaluation, you will be asked to sign a copy of this document to confirm you have read and understand the information given to you. You will have time with a Transplant Nurse Coordinator to ask questions prior to signing.

PURPOSE

You have been diagnosed with irreversible liver disease that will not improve with other surgical or medical therapies. A liver transplant has been identified as a possible option for you. The purpose of transplantation is to restore a *meaningful quality of life to you, as well as to extend your life.*

SELECTION CRITERIA

Guidelines for selecting patients to be placed on the liver transplant Wait List are as follows:

- Must have chronic *irreversible* liver disease which has not responded to other medical or surgical treatments.
- Patients with acute fulminant liver failure are accepted as transplant candidates when it is determined recovery without a transplant will not be possible.
- Patients with certain types and stages of liver cancer are considered for transplantation on a case-by-case basis.
- Must qualify for and be able to tolerate major surgery.
- Patients and their appropriate family members must be able to have a full understanding of transplant therapy, including the long-term need for close medical follow-up and life-long anti-rejection medication.
- Must be able to accept the responsibility to be involved in the long-term care including covering all associated financial costs and accepting all potential risks.

Guidelines for denial of transplantation for a potential candidate:

- Psychosocial instability of patient or care provider that would interfere with compliance;
- Severe psychiatric impairment which would interfere with the ability of the patient or care provider to understand informed consent and compliance with therapeutic regimen;
- Severe neurological impairment;
- Active systemic infection;
- Active cancer;
- Severe cardiovascular disease;
- Active alcohol, narcotic abuse or illicit drug use;
- Absence of funding for the transplant procedure and/or medications post-transplant;
- Pregnancy.

Possible exclusion criteria:

- HIV (patients will be referred to a center specializing in HIV positive transplant procedures).
- History of cancer – The Israel Penn International Transplant Tumor Registry (IPITTR) will be consulted on an individual basis regarding recommendations for waiting time prior to transplant consideration.
- Chronic pulmonary disease necessitating oxygen supplementation or mechanical ventilation.
- BMI greater than 40.

EVALUATION

Evaluation generally takes 3-4 days, but more days may be added if additional tests are needed. Evaluations are generally done on an outpatient basis. During the evaluation you will receive an extensive medical and psychosocial examination including, but not limited to: blood work, abdominal ultrasound, chest x-ray, EKG, echocardiogram/dobutamine stress echo (DSE), heart catheterization if indicated.

Consultations include but are not limited to: hepatologist, transplant surgeon, transplant nurse coordinator, dietician, psychologist, psychiatrist, social work, financial coordinator, cardiologist if age 50 or older or otherwise indicated, pulmonary if indicated, endocrinology if indicated, and nephrology if indicated.

WAITING PERIOD

There is no way to know when donor organs will become available. There is a system in place through a national organization – United Network for Organ Sharing (UNOS) – to ensure all patients in need of a transplant are given fair and equitable access to available donor organs. You will be placed on the liver transplant Wait List by blood type, body size and medical necessity score. This is called the MELD score or Model for End-Stage Liver Disease score. UNOS is notified when all donor organs become available throughout the United States. At that time UNOS will coordinate the placement of the liver organ based on the medical necessity, blood type and body size with the proper transplant center. From the time you are placed on the Wait List, you need to be prepared and ready to be called in for transplant.

During the waiting period you may become too sick to receive a transplant. At that time the Transplant Team may decide to make you inactive on the transplant list. The Transplant Team will monitor your condition and will re-activate you if your condition improves. There is a possibility your condition will not improve and you will no longer be eligible to receive a donor organ. If your listing status is changed at any time during the waiting period, you will be notified of this change and the reasoning for it will be discussed with you. In addition, if you are removed from the Wait List, you will receive written notice within 10 days.

Not all patients on the transplant list in the United States are transplanted due to the lack of available organs. Many patients die each year while waiting for a donor organ to become available.

RESPONSIBILITIES AND EXPECTATIONS WHILE ON THE TRANSPLANT WAIT LIST

If you are eligible and agree to be placed on the Wait List for transplantation, you will be responsible to:

- Update the Transplant Team regarding changes in your medical condition including any hospitalization;
- Update the Transplant Team with current contact phone numbers where you can be reached 24 hours a day;
- To stay as healthy as medically possible to stay active on the Wait List;
- Be compliant with your current medical care, including but not limited to: medical appointments, procedures, tests, and medications;
- Maintain substance abuse compliance, as instructed by the Transplant Team;
- Have a care partner during the full transplant evaluation process;
- Have a care partner to assist in your care following transplantation and will be required to stay with you while you recover at The Nebraska Medical Center. A care partner will be expected to be with you for extensive pre- and post-transplant education.

CALLED IN FOR TRANSPLANTATION

When a donor organ becomes available, you will be called by a member of the Transplant Team. You should have arrangements in place to arrive at The Nebraska Medical Center within 4-6 hours of notification. Transportation arrangements and costs are the patient's responsibility. At the time you are called in for transplantation, information regarding the donor will not be shared with you in accordance with guidelines protecting confidentiality of the donor and the donor family. Some exceptions to this guideline are listed below in the Risks section of this document. If needed, a Transplant Team member will review pertinent information about the donor organ with you in order for you to make an informed decision about accepting the organ. You always have the option to decline the organ. However, there is no guarantee that another donor organ will become available to you.

TRANSPLANT OPERATION

During the transplant surgery, you will be put under general anesthesia, which means you will be given medications to put you to sleep, to block pain, and to paralyze parts of your body. You will also be placed on a machine to help you breathe. Before surgery, the anesthesiologist will talk with you in more detail about the risks of anesthesia. The surgeon will make an incision across your abdomen and then proceed with the complete removal of your liver replacing it with the donated liver. The gallbladder is also removed.

Drains (tubes) will be inserted into your abdomen at the time of surgery to allow fluids to be removed and to help you heal. You will also have an intravenous line (IV) for fluid and medication administration, a urinary catheter to drain your bladder, and a nasogastric tube placed down your nose into your stomach to empty your stomach fluids. Special mechanical boots or sleeves for adult patients are placed around the legs to keep blood flowing to try and prevent dangerous blood clots. You will be in the operating room approximately 4-12 hours. During and after your surgery, your family will be updated regarding your progress.

TRANSPLANT RECOVERY

After transplant surgery, your hospitalization recovery will depend on your medical condition at the time of transplant and post-transplant complications, if any. Average hospital stay is between 7 and 14 days. Post-transplant education will be started during your hospital stay with you and your care partner. Physical rehabilitation will be started while you are hospitalized and will continue after you are discharged. You and your care partner will be required to stay in Omaha for a **minimum** of four to six weeks after your transplantation. This time frame will be extended if you experience complications. You will be responsible for the cost of staying in Omaha during this time. Costs will include the hotel cost for your care partner while you are still hospitalized and then the ongoing cost of the hotel once you are discharged from the hospital for at least four to six weeks. In some cases you may stay longer if required by your medical condition. The cost of meals is the responsibility of the patient and care partner. Some insurance companies will assist in the cost of the hotel and meals. If this is available for you, the financial coordinator will discuss this with you.

RISKS

Donor Screening: Before the transplant, both you and the potential donor will be tested for hepatitis and other viruses, including HIV (the virus that causes AIDS). An extremely thorough and complete screening process is done to ensure that the donor's organs are appropriate and safe to be transplanted. Despite this process, the donor may still have unknown risk factors that could affect your long-term health. Unknown risk factors may present due to the inability to obtain detailed donor social and medical history. This may include, but is not limited to, potential risk of contracting the HIV virus and other infectious diseases that were not detected at the time of transplant.

High-Risk Donors: If an organ becomes available from a donor with a known history of a riskier lifestyle (IV drug use, jail time, multiple sexual partners, etc.) and is offered to you, you will be told it is a high-risk donor and you have the option to refuse the organ. If you accept the organ, HIV and Hepatitis C testing will be done six months after your transplant date. Safe sex practices for the six month time period is highly encouraged.

Donation after Circulatory Death (DCD): Most of our organs are donated by brain dead patients whose organs had continuous blood flowing throughout the body until the organs were removed. Organs may also be obtained from donors after a cardiac death (donation after cardiac death – DCD). DCD organs are not removed from the donor until 5 minutes after the heart stops. There is no blood flow during the 5 minute time period. If a DCD organ becomes available for you, you will be notified that it is a DCD organ, and you will have the option to accept or turn down the organ. A DCD liver can have the possibility of a 30% chance of bile duct complications. *A second transplant may be needed if complications cannot be medically or surgically treated, though this is rare. The long-term outcomes for organs transplanted after cardiac death are similar to those for organs transplanted after brain death.*

Hepatitis B and Hepatitis C Organs: Organs from donors who have a history of Hepatitis B or C are allowed to be used for transplantation. Patients on the transplant list who have a diagnosis of Hepatitis B or C can be offered Hepatitis B and Hepatitis C organs. Research has shown that there is no difference in outcomes with Hepatitis B or C patients receiving B or C donor organs compared to non-B or C donor organs. You will be informed if you are

being offered a donor organ from a patient with Hepatitis B or C, and you will have the option to accept or turn down the organ:

- Hepatitis C antibody positive donor can be offered to a Hepatitis C antibody positive patient.
- Hepatitis B core antibody positive donor can be offered to a positive Hepatitis B surface antibody patient.

Surgical Complications: The transplant surgery itself has many risks and these will be discussed in detail with the transplant surgeon. Surgical risks include, but are not limited to: death, heart attack, stroke, infection, bleeding, wound/skin breakdown, bile leaks, or blood clots in the blood vessels leading to and from the liver.

Blood Products: Bleeding during or after surgery may require blood products to be transfused. Blood products go through an extensive screening for bacteria and viruses that can cause infections. These infections include, but are not limited to: the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV). Although rare, all patients who receive blood products have the risk of developing these infections.

Organ Function: There may be a delay in the function of your transplanted organ. Such a delay may increase the length of your hospital stay and increase the risk of other complications. There is a slight chance that the transplanted liver will not function. When this occurs, a second transplant is needed. You would then be placed on the UNOS Wait List in the highest priority category allowed. If a second liver does not become available, death may occur.

Hepatic Artery Thrombosis: Hepatic artery thrombosis (clotting within the hepatic artery) occurs in a small percentage of liver transplants. This is a clot that develops in one of the major blood vessels going to the liver. Hepatic artery thrombosis can cause liver failure, liver abscesses, and /or biliary strictures. Some patients that develop hepatic artery thrombosis will require a second operation to remove the clot. Some patients will require a second transplant if the liver has been damaged due to the clot.

Biliary Complications: Some patients experience biliary complications, such as leaks and strictures (narrowing) of the ducts transporting bile. Most bile leaks (leakage of bile from the cut surface of the liver) get better without the need for surgery. Occasionally tubes will be placed through the skin to aid in correcting the leak or stricture. In some cases, surgery is necessary to correct the bile leak or stricture. Some transplant patients may have long-term biliary complications.

Rejection: Rejection is when the patient's immune system responds to foreign tissue being present. Patients are given anti-rejection medications to help the immune system accept the transplanted organ. All transplant patients are at risk for rejection throughout their life. The risk for an episode of rejection is the greatest in the first three months. The incidence of rejection is never zero. The Transplant Team will monitor you for indications of rejection. Compliance with medications and blood work are required in reducing the risk for rejection. Biopsies are the only accurate way to determine rejection.

Re-occurrence of Disease: In some cases your original disease may recur after transplant. Diseases that may recur include, but are not limited to: autoimmune diseases (primary biliary cirrhosis, primary sclerosing cholangitis, etc.), hepatocellular carcinoma (HCC), and Hepatitis B. For certain diseases, such as Hepatitis C, recurrence is to be expected. Sometimes a second transplant may be indicated. Some patients may not be appropriate candidates for a second transplant.

Other Risks Associated with Transplantation: Side effects from immune suppressing (anti-rejection) drugs include, but are not limited to: kidney dysfunction, gastrointestinal complaints, blood count abnormalities, nervous system complications, high blood pressure, bone damage, weight gain, and diabetes. There is a slight increase in the risk of certain kinds of cancer (skin cancer, lung cancer, and post-transplant lymphoproliferative diseases or lymphoma) due to anti-rejection medications.

Infections: Your immune system is suppressed with the anti-rejection medications. When the immune system is suppressed you are at an increased risk for infections. Risks of infection include, but are not limited to: wound infections; infections related to tubes, catheters, or other objects; infections within your blood system; urinary infections; pneumonia and other bacterial, viral or fungal infections. The risk of infection is the greatest in the first

few months after surgery, but risk remains throughout your life. Most infections are treatable with medications and other therapies though sometimes overwhelming infections may result in death.

Stress: Organ transplantation can be stressful for both you and your family members. You may experience stresses related to and including, but not limited to: depression, body image changes, changes in interpersonal relationships, and finances. Multiple Transplant Team members are available to assist you and your family with these issues.

BENEFITS

A successful transplant may improve your quality of life and help you live longer. The SRTR (Scientific Registry for Transplant Recipients) provides patient and graft (organ) survival rates for transplantation at the following website: www.ustransplant.org.

The SRTR data for our transplant program will be provided to you as a separate document.

ALTERNATIVES AND VOLUNTARY PARTICIPATION

The treatment plan you receive from the Transplant Team is based upon our experience and ongoing review of the scientific literature related to care of transplant patients. Following evaluation, our team will make recommendations to you regarding your medical plan. You may choose not to proceed with transplantation or you may decide to withdraw from transplantation at any time prior to receiving a transplant organ without adversely affecting your relationship with the Transplant Team. The decision to proceed with transplantation will always be your choice to make. If you choose not to proceed with transplantation, it is your right to continue with the current medical treatment you are receiving. It is also your right to choose stop treatment if you so wish.

CONFIDENTIALITY

We are required by law to maintain the privacy/confidentiality of your health information. All information that is obtained in connection with this procedure will remain as confidential as possible within the requirements of state and federal law. The results of this procedure will be reviewed and may be published in a scientific journal, book, or report without identifying you by name. Records will be kept regarding this procedure and will be made available for required reviews/audit by representatives of the Food and Drug Administration (FDA), members of the University of Nebraska Medical Center transplant program, and representatives of the United Network for Organ Sharing (UNOS) under the guidelines established by the Federal Privacy Act. Federal and State reviewers/auditors may also have access to your medical records, which contain your identity; however, they are required to maintain confidentiality. Your insurance company may also review your record.

RESPONSIBILITIES AND EXPECTATIONS AFTER TRANSPLANT

Donated organs are a limited and precious resource that can offer you a longer and improved quality of life. When you accept the gift of donation, you are accepting responsibilities to ensure the optimal survival of you and the gifted organ. You will be responsible for having laboratory studies and other necessary tests performed as ordered. You will be responsible for complying with the medical treatments necessary for your care and survival. It is expected you will take these responsibilities seriously in order for us to maximize your health and the health of your donated organ.

MEDICATIONS

You will be responsible for the cost of all medications prescribed at the time of discharge and throughout your life span. You will be responsible for understanding and managing your pharmacy coverage for medications.

CMS INFORMATION

Specific outcome requirements are expected by transplant centers. We are required to notify you if we do not meet those requirements. Currently, The Nebraska Medical Center meets all Center of Medicare and Medicaid Services (CMS) requirements and is an approved Medicare and Medicaid transplant center. If placed on the transplant Wait List at our center and we do not meet CMS transplant criteria, we will notify you in writing. If you receive a transplant at a non-Medicare-approved transplant center, it could affect your ability to have your anti-rejection drugs paid for under Medicare Part B.



Place Patient Sticker Here

LIABILITY AND COMPENSATION

Adverse complications and outcomes are possible in any transplant procedure despite the use of high standards. We are unable to predict all complications that may develop. Despite all best efforts by you and the Transplant Team, unexpected complications or outcomes may occur.

You and/or your insurance company will be billed in accordance within the guidelines of the physicians and hospital billing system.

You do not give up any of your legal rights by signing this document. Your signature indicates members of the Transplant Team have informed you about transplantation, your questions have been answered sufficiently, and you agree to proceed with transplant evaluation.

You can obtain further information by calling the Transplant Office at 1-800-401-4444.

AUTHORIZATION

Your signature below indicates your decision to proceed with the liver transplant evaluation and that you understand the information contained in this Evaluation Acknowledgement. However, it is important that you understand by signing this document you are not being placed on the transplant Wait List.

_____ Patient (Guardian/POA) Signature	_____ Date	_____ Time
_____ Transplant Representative	_____ Date	_____ Time
_____ Physician Signature	_____ Provider #	_____ Date
_____ Interpreter Signature (if applicable)	_____ Provider #	_____ Date
		_____ Time

In the event a Telephone Signature is required to complete this form, **two persons must witness the consent of the patient.**

Name/Relationship of Person One

Name/Relationship of Person Two

Date _____

Time _____

Place this form in Patient Chart under the Education Tab/Section