



Hartford Hospital Liver Transplant Program

Informed Consent for Liver Transplant Evaluation Process

The evaluation process begins when you are first identified as a potential transplant candidate in the Hartford Hospital Liver Transplant Program and continues until a decision is made and you are either listed or declined for listing for a liver transplant.

This document is to help you be informed of the steps in a liver transplant evaluation. It is part of what we call the "informed consent process". It is important that you read and understand this document before you sign it. You should ask questions about any information that you do not understand. In fact, we expect and encourage questions throughout your transplant experience.

Evaluation Process

An evaluation for a liver transplant involves having many tests, procedures and meeting with members of the Transplant Team. You may also have visits with other health care providers. All these consultations, tests and procedures will help us decide if a liver transplant is the right treatment for you. It will also help us to know if you are well enough to have a liver transplant which is considered major abdominal surgery. These tests will also help us know if there is any other treatment besides a liver transplant than can help you.

Transplant Team Members

The professionals who make up the Transplant Team come from different specialties to make sure to address the many issues experienced by a patient requiring a liver transplant. This team is referred to as the "Multidisciplinary Transplant Team". The members of this team include:

- The **Hepatologist** is a medical doctor with expertise in gastroenterology who specializes in liver disease. The hepatologist will assist in the medical management of your liver disease. They are part of the multidisciplinary team that will determine if you are medically suitable for a transplant.
- The **Transplant Coordinator** is often an individual with a nursing background who provides education regarding the transplant evaluation process, listing and waiting for transplant and required follow up care. They will explain the patient responsibilities before and after transplant. This meeting is intended to provide you with an opportunity to ask questions and to become fully informed about the liver transplant process. The coordinator is your **advocate** throughout the transplant process. You are encourage to bring family members and significant others to this meeting.
- The **Transplant Surgeon** is a surgeon with special training and expertise in liver transplantation and will meet with you after your testing is done and discuss the appropriateness of a transplant based on the information obtained during your evaluation. The surgeon will also discuss the significance of undertaking a liver transplant, the various types of livers available, the risks of the surgery and the possible complications associated with the transplant surgery.
- The **Transplant Social Worker** is a licensed social worker with special training in transplant issues and will meet with you to evaluate your ability to cope with the stress of transplantation and your ability to follow a rigorous treatment plan, both before and after transplantation. The social worker will also help to identify your support network and coping strategies. If you need assistance in these areas, they will work with you to try and find what is available to you.



- The **Financial Coordinator** has special training in the financial issues associated with transplant and will discuss the costs associated with your transplant and with the medications you will require after transplant. They will be sure you understand your insurance coverage. It is important that you understand the costs that may not be covered by insurance. It is also very important that any changes in insurance coverage is reported to them immediately so that you do not risk being placed on a financial hold for transplant.
- A **Psychiatrist** is the physician who will conduct a more in-depth psychiatric evaluation and assessment if our social worker or other physician members of the Team feels this would be appropriate. Some patients with a history of drug or alcohol abuse may be required to participate in a formal rehabilitation program. All patients sign a Drug and Alcohol Contract prior to listing. Patients with recent substance abuse must meet abstinence requirements prior to and after transplant listing.
- The **Transplant Dietitian** has special expertise in the nutritional issues associated with liver disease and will perform a detailed nutritional assessment and provides nutrition education to patients. Most people with end stage liver disease have problems meeting their nutritional needs and maintaining muscle mass because of their illness.
- The **Transplant Pharmacist** has knowledge of the multiple medication requirements of transplant patients and will review all of your medications throughout the transplant process. They look for medication interactions and may suggest changes to maximize results or minimize side effects. They are also available to both patients and staff as a resource.
- Some patients may be referred to another specialty physician for consultation. For example, a nephrologist (kidney doctor), pulmonologist (lung doctor) or cardiologist (heart doctor). Even if you are seeing a local specialist in your community, unless they are on staff at Hartford Hospital, they would not be available to care for you during your admission. This is why we will often have you see one of our specialists who understand the unique needs of liver transplant patients and can follow you in the hospital. Be assured we will work with your community physicians to provide you with the best care possible.

Many different tests are done to determine if you are a suitable transplant recipient. Some of the following tests may be included in your evaluation process. Remember, other tests may need to be done on an as-needed basis depending on results of these tests.

- Blood tests help to determine the extent and/or cause of your liver disease. Other tests performed include; determining your blood type for organ matching and screening tests for immunity to or the presence of specific viruses, including HIV. Additional blood tests help us determine how well your other organs are functioning.
- A chest x-ray and pulmonary function tests will allow your physician analyze lung capacity and function.
- A urine test is used to screen for the presence of urinary tract diseases as well as drugs and alcohol in your system.
- An EKG, echocardiogram and nuclear stress test will show how well your heart muscle works, if you have high pressure in the lungs that can cause heart failure and if you have any abnormalities with your heart valves. This will assist your physicians in deciding if your heart is strong enough for transplant surgery.



- A MRI, CT scan or ultrasound can help determine the extent of your liver disease, the presence of any tumors, and define the blood supply to your liver.
- A liver biopsy may be requested by your transplant team. During a liver biopsy a needle will be used to remove a tiny portion of your liver. This is an outpatient procedure. A microscopic examination of the tissue will provide information to your physicians regarding the cause and severity of your liver disease.
- After completing the evaluation process the members of the Multidisciplinary Transplant Team will meet to present your results and determine if you meet the Hartford Hospital selection criteria for placement on the United Network for Organ Sharing (UNOS) Liver Wait List. You will be notified of this decision in writing. Our inclusion and exclusion criteria are available in writing to all patients. At Hartford Hospital we review each person as in individual. Our criteria for placement on our list include:
 - Unacceptable quality of life (fatigue, itching, mental confusion, fluid in your abdomen which may become infected)
 - Portal hypertension (high pressure in the blood vessels in your abdomen that causes bleeding in your throat or rectum)
 - Problems with liver function-delayed clotting, low blood protein levels
 - Jaundice- yellowing of the skin and eyes caused by high bilirubin levels in your blood
 - Deterioration in your kidney function that is caused by your liver disease
 - Muscle wasting and bone disease
 - Repeated infections in the bile ducts in your liver
 - Some forms of liver cancer

In addition, the candidate must have the ability to pay for the transplant and post transplant medications, no evidence of significant, untreatable heart or lung disease, must be abstinent from alcohol or drugs for 6 months , when this is the primary cause of liver disease, must be cancer free, except for primary liver cancer/hepatocellular carcinoma (HCC) and certain skin cancers, must be free of systemic infection, and must show that there is sufficient social support to maintain the often difficult post transplant follow up.

Risks of Surgical Procedure and Allocation

Liver transplantation is often a life-saving therapy; however, the potential benefits cannot result from surgery alone and are dependent upon your following the rigorous treatment plan prescribed by your physicians. You must be aware of the potential risks and complications outlined in this document that can result in serious complications and death. Your physicians cannot predict exactly how your body will respond to a liver transplant. Sometimes the condition that caused your underlying liver disease will affect your transplanted liver. The operation is complex and the risks are high. The success rate varies according to how sick the patient is prior to the transplant surgery with sicker patients having a lower chance of a successful outcome.

Livers are allocated according to the policy of United Network for Organ Sharing (UNOS). Livers are allocated according to how sick a patient is and not how long they have been on the wait list. Being put on the waiting list for a liver transplant does not guarantee the availability of a liver or receiving a transplant. You will be offered the opportunity to be considered for a type of donor liver called an ECD (extended criteria donor). This may improve your chances for transplantation and will be discussed in detail by the surgeon.



The Transplant Operation

When a donor organ becomes available, you will be called and you must come to the hospital right away. If the organ is considered an ECD organ your surgeon will review the details of this particular organ with you at this time and assist you in making your decision. At this point your surgeon has a clear picture of the cumulative risks associated with this particular organ versus the risk of waiting for the next available donor and can base their specific recommendations on this information. You always have the option to decline a specific ECD organ even if you have consented to consider them.

During the transplant surgery you will be put under general anesthesia, which means you will be given medications to put you to sleep, block pain and paralyze parts of your body. You will also be placed on a machine to help you breathe. The anesthesiologist will talk with you in more detail about the risks of anesthesia. The transplant surgeon will make an incision in your abdomen. Through this incision your liver and gallbladder will be removed and a donated liver graft (without a gallbladder) will be placed into your abdomen.

During the surgery you may be placed on venous bypass. If this is required, your surgeon will make an incision in your underarm or neck and groin for the placement of intravenous tubes. These tubes will be connected to a machine that will allow your blood to bypass your liver during surgery. The transplant surgeons will decide if this machine will be used based upon your condition.

Drains will be put into your body to allow fluids to be removed and to help you heal. Special mechanical boots or sleeves around your legs will be used to keep blood flowing through your legs to try to prevent dangerous blood clots. You will be in the operating room approximately 4-12 hours.

Post-Surgical Care and Recovery

After the surgery you will be taken to the intensive care unit where you will be closely monitored. You will be on a machine to help you breathe and you will have many tubes and drains in place. Intermittent pressure boots or sleeves around your legs will be used to prevent blood clots.

Immediately following the surgery, you will experience pain. This will be carefully monitored and controlled. The goal of pain control is to keep you as comfortable as possible so you can move, take deep breaths and begin the recovery process.

When your medical condition has stabilized you will be transferred to the transplant floor. Your length of stay in the hospital will depend on the rate of your recovery. You will remain in the hospital as long as your physicians feel hospitalization is necessary. Most patients stay in the hospital for a period of 7 to 14 days. The hospitalization time varies depending on the severity of your illness prior to transplant or complications after surgery. You may benefit from a stay at the rehabilitation unit for additional physical therapy to regain your strength and level of function prior to discharge home.

After you leave the hospital you will still be recovering. For the first 4-6 weeks you will have some restrictions on your daily activities. During the recovery period the transplant team will closely monitor your progress. You will require life-long follow up and must make yourself available for examinations, laboratory tests and scans of your abdomen to see how well your transplanted liver is working. Biopsies may be done routinely and as needed to diagnose possible complications including rejection or recurrent liver disease.

The Transplant Team will see you regularly for three to six months post transplant. Every effort is made to transition your routine medical care to your primary care physician. However, you will be followed in the Transplant Clinic for life. For most patients this involves frequent lab work (usually monthly for life) and a yearly clinic visit. Patients who develop complications may need to be seen more often by the Transplant Team.



Alternative Treatments

Alternative treatment therapies may be available for your medical condition. Please feel free to discuss your condition and any possible alternative therapies with your Transplant Team.

Potential Medical and Surgical Risks and Complications

There are inherent risks in all surgeries, especially surgeries conducted under general anesthesia. Many complications are minor and do not require additional treatment. In some cases, the complications are serious enough to require additional surgery or medical procedure but severe complications can result in prolonged coma or even death.

Bleeding during or after surgery may require blood transfusions or blood products that can contain bacteria and viruses that can cause infection. Although rare, these infections include, but are not limited to, the Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

There may be a delay in the function of your transplanted liver. Such a delay may increase the length of your hospital stay and increase the risk of other complications. There is a possibility that the transplanted liver will not function. When this occurs a second transplant is needed and you will be placed on the UNOS waitlist in the highest priority category allowed. If a second liver does not become available death may occur. The chance of primary non-function (liver not working right after surgery) is about 3%. Re-transplantation is required emergently for cases of primary non-function.

Hepatic artery thrombosis occurs in a small percentage of liver transplants. This is a clot that develops in one of the major blood vessels going to your liver. Hepatic artery thrombosis can cause liver failure, liver abscesses and/or biliary strictures. Most patients that develop hepatic artery thrombosis will require a second operation; some will require re-transplantation.

Some patients experience biliary complications such as leaks and strictures (narrowing). Most bile leaks get better without the need for surgery. Occasionally, a bile drain called a t-tube is placed through the skin to aid in the healing process. In some cases surgery is necessary to correct the bile leak. Liver transplant patients can have both short and long term problems with biliary strictures. A biliary stricture is a narrowing of the ducts transporting bile. Some of the strictures can be repaired by non-surgical means such as dilation and insertion of a stent that is changed on a regular basis until the problem resolves. Occasionally, the surgeon will have to do a surgical procedure to correct the stricture.

Some liver diseases can return after transplant. Diseases that may recur include autoimmune disease, hepatocellular carcinoma (HCC), and hepatitis B and C. For certain diseases, such as hepatitis C, recurrence is universal. In certain cases, we may recommend that you consider a donor who had a history of hepatitis B or C. We generally offer these livers to recipients who already have a diagnosis of hepatitis B or C or are so ill they cannot wait for another donor organ. Sometimes a second transplant may be indicated. Unfortunately repeat transplants have a lower chance for success and not all patients are appropriate candidates for a second transplant.

There are other risks associated with transplantation. Infections from bacteria, viruses, or fungi, acute rejection, side-effects from drugs that suppress the immune system are all possible complications. Side-effects from immune-suppressing drugs include, but are not limited to: kidney problems, gastrointestinal complaints, blood count abnormalities, neurologic toxicity, high blood pressure, weight gain, higher risk of infection, diabetes, and others. There may be a need for repeated liver biopsies, surgeries, and other procedures, or a prolonged intensive care unit or hospital stay after a liver transplant.



Transplant recipients have a slight increase in the risk of certain kinds of cancer (including skin cancer and post-transplant lymphoproliferative diseases or lymphoma) because of the immune suppressing medications you will take to prevent rejection.

Rejection can occur following liver transplantation. It occurs when your body sees your new liver as foreign (not a part of your body) and tries to attack it. Your body will then try to attack and destroy the new liver. You will take medication for the rest of your life to prevent rejection from happening. Although you are taking anti-rejection medication, it can still occur. There are two types of rejection. They are acute rejection and chronic rejection. Acute rejection usually happens in the first 3 to 6 months after your transplant but can occur at any time. It is usually diagnosed by a liver biopsy and treated with increased doses of your anti-rejection medicines. If needed you may also be treated with stronger intravenous medications. If acute rejection responds to treatment it usually does not do permanent damage or scarring in the transplanted liver. Chronic rejection occurs over time. It causes scarring of the liver that is not reversible. The causes of acute and chronic rejection are not totally understood but it may be caused by not taking the correct doses of your anti-rejection medicines or from missing doses over time. It is very important that you take your anti-rejection medicine as directed. If you have difficulty affording your medications-you should discuss this with the Transplant Team right away.

Psychosocial risks

This can be a very stressful time for you and your family. Possible psychosocial risks may include, but are not limited to, depression, generalized anxiety, post traumatic stress disorder, feelings of guilt and anxiety related to loss of control, dependence on others and suicidal thoughts. Our social workers and others will be available for support should you or your family need help with any of these feelings.

Miscellaneous risks

Despite the use of compression boots, blood clots may occasionally develop in the legs and can break free and occasionally move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period of time or a filter that is placed in a large blood vessel leading to your lungs.

The risk of infection is higher for transplant recipients than other surgical patients because the treatments needed to prevent organ rejection make the body less capable of fighting infection. Also, liver disease itself decreases the body's ability to fight infection. The abdominal incision for the liver transplant and any incision needed for the liver bypass machine (neck, underarm, and groin) are potential sites for infection. Infections in the sites where tubes are placed in your body (tubes to help you breathe, tubes in your veins to provide fluids, nutrition and to monitor important body functions) can cause pneumonia, blood infections and local infections.

In rare cases, nerve damage may occur. This can happen from direct contact within the abdomen or from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.

Other possible complications related to any abdominal surgery include: injury to structures in the abdomen, pressure sores on the skin due to positioning, burns caused by the use of electrical equipment during surgery, damage to arteries and veins, pneumonia, heart attack, irregular heart beat, stroke, permanent scarring at the site of the abdominal incision, multiple organ failure and even death.

If you are a woman of childbearing age, It is important to understand that pregnancy before and after a liver transplant can endanger both your life and health as well as and that of your fetus. Although pregnancy after liver transplant has been successful, it is not recommended during the first year after transplant. Pregnancy may injure your new liver and even cause it to fail. Prior to becoming pregnant, you should inform the Transplant Team of your plans and discuss the risks and benefits.



National and Transplant Center-Specific Outcomes for Adult Liver transplantation:

I have been informed and have received information about national and Hartford Hospital transplant center specific outcomes related to liver transplantation.

Notification of Medicare Outcome Requirements Not Being Met By Center:

Specific outcome requirements need to be met by transplant centers and we are required to notify you if we do not meet those requirements. Currently, the Hartford Hospital Adult Liver Transplant Program meets all requirements for transplant centers does not meet the following requirements _____

If you have your transplant at a facility that is not approved by Medicare for transplantation, your ability to have your immunosuppressive drugs paid for under Medicare Part B could be affected.

Organ Donor Risk Factors

You should be aware that all donors are screened for communicable diseases or problems, such as cancer, that may affect the liver and your health. There is no guarantee as that all contagious diseases or problems have been detected. There may be unforeseen factors including undetected cancer or undetectable infectious disease that may affect the success of your transplant or your health. These include; HIV, Hepatitis B virus, Hepatitis C virus, malaria or other bacterial, viral or fungal infections. There are other factors related to the specific organ donor, such as the donor's history, the donor's age and condition of the donated organ that can affect the success of the transplant and your health. The surgeon will discuss the specific donor risk factors with you in detail as part of your decision to consent to the transplant surgery.

Right to refuse transplant

You always have the option not to undergo transplantation and can choose to be removed from the list. If you choose not to have a transplant, your option is to continue with medical management. Keep in mind there is no guarantee that another organ will become available to you. If you do not undergo the transplant surgery, your condition is likely to worsen and limit your life expectancy. If the Transplant Team is concerned about the reason you declined a particular organ, you will need to come in and meet with them to discuss this.

Life and Health Insurance

It is very important that you notify the Transplant Team immediately of any insurance changes so that the Financial Coordinators can verify my benefits and coverage. Failure to do this can result in lack of payment for your transplant and/or medications.

After you have a liver transplant, health insurance companies may consider you to have a pre-existing condition and refuse payment for medical care, treatments or procedures. After the surgery, your health insurance and life insurance premiums may increase and remain higher. In the future, insurance companies could refuse to insure you.

Patient Relations

The patient relations department provides information to patients and their families about services at Hartford Hospital. They help patients and their families interpret hospital policies and procedures, provide a formal mechanism for the investigation, resolution and recording of patient complaints and assure the observation of patient's rights, and handle certain special requests. You can reach the Patient Relations office at Hartford Hospital at (860) 545-1400.



You also have the right to notify the Organ Procurement and Transplantation Network at 1-888-874-6361, if you have any concern or grievance about the Hartford Hospital Transplant Program.

General

In addition to the information provided in this document, I have been informed and have received information about wait time transfer and multiple listing and the possibility of receiving a living donor liver transplant.

I will receive a letter of notification concerning my status at the end of this evaluation process indicating that either:

- a. I have been accepted and am active on the UNOS waitlist*
- b. I have been conditionally accepted and placed on hold status on the UNOS waitlist, pending completion of evaluation or treatment*
- c. I am not an acceptable candidate for transplantation and the reason(s) for this decision*

I understand that the Hartford Hospital Liver Transplant Program may remove a candidate from the waitlist for changes in their medical condition or inability to comply with medical care.

I have received this information from the Transplant Team. I have been provided an opportunity to read the information and ask questions. I understand the information that has being provided to me. I also consent to have my photograph taken and scanned into my electronic chart in the Liver Transplant Office.

_____ Date: _____ Time: _____
Patient:

_____ Date: _____ Time: _____
Nurse Coordinator:

_____ Date: _____ Time: _____
Transplant Surgeon/Hepatologist