

Montefiore

**Liver Disease and
Transplantation Program**



Dear Colleague,

It is my pleasure to introduce you to the outstanding Liver Disease and Transplantation Program at the Montefiore Einstein Center for Transplantation.

We have created a novel approach that integrates Montefiore's clinical hepatology and hepatobiliary surgical practices with the world-renowned faculty at The Marion Bessin Liver Research Center at Albert Einstein College of Medicine. Bessin at Einstein is one of the oldest continuously funded National Institutes of Health Digestive Disease Centers in the United States, with a 37-year track record of breakthrough translational research. Our liver program operates under the umbrella of our Center for Transplantation, a Center of Excellence with more than 40 years of experience.

Our goals extend well beyond integration of clinical practice and science. Both Montefiore and Einstein have committed substantial resources to the development of a comprehensive Liver Center. The Liver Center houses specialty programs in liver transplantation, liver cancer, pediatric liver disease, general consultative hepatology and hepatobiliary surgery. Each program offers multidisciplinary patient assessment and protocol-based management. We have built new outpatient and inpatient units, recruited more than 50 support staff members and developed unique critical care pathways, including a Rapid Response Team for treating acute liver failure.

Due in part to these efforts, Montefiore has been able to achieve an outstanding survival rate for liver transplant patients that is superior to the national average of 75-80%.

It is a sincere privilege to care for patients with liver disease and to be able to offer them a second chance at life. As a referring physician, you are considered a key part of our team.

I hope this will provide you with all the information you need to understand and utilize the extensive services we offer your patients with liver disease. We look forward to partnering with you in your patients' care and, when the patients are ready to return to your care, making the transition seamless.

Sincerely,



Milan Kinkhabwala

Milan Kinkhabwala, MD

Chief, Division of Transplantation

Department of Surgery

Professor of Surgery, Albert Einstein College of Medicine

Superior Outcomes

By combining a world-class team of specialists with a full range of standard and innovative therapies, Montefiore can offer transplant patients a survival rate of more than 90%—significantly higher than the national average of 75-80%. Additionally, we have performed multiple combined organ transplantations.

Quick Facts About Liver Transplantation at Montefiore

- The first liver transplant was successfully performed in a critically ill woman with fulminant hepatic failure in 2008.
- Within the first year of the Liver Disease and Transplantation Program, 50 patients were on the waiting list.
- Within the past two years, 34 patients, including two infants, have received liver transplants with a survival rate of more than 95%.
- Of the 34 transplant recipients, 15% had acute liver failure, UNOS status 1. The median natural MELD for all the other recipients was over 30.
- About 25% of the transplant recipients had unresectable liver cancer. As of 2011, all are alive and well, with no sign of cancer recurrence.
- In 2010, Montefiore performed a “split liver” graft, in which an adult donor liver was split in the donor and offered to two recipients.
- Montefiore was approved to initiate its live donor liver program in 2010.

The Montefiore Einstein Philosophy

The Montefiore Einstein partnership distinguishes itself through its commitment to research and community outreach, as well as patient and physician education. Our philosophy of patient care is fundamentally holistic in nature, with our primary goal to restore patients' overall functional health.

Compassionate, Personal Approach Is Highly Valued by Patients

All team members take a personalized approach to patient care by individualizing the experience and making it as warm, intimate and comforting as possible.

The team takes extraordinary steps to create a support system that makes patients and their families feel at home. Many types of special liaisons are available for support. Among the multiethnic, multilingual staff, patients often find speakers of their native languages. Translators are also available on the premises.

We have developed a robust relationship with the Orthodox Jewish community and offer many special services, including a separate waiting lounge with kosher food. Accommodations for the needs of other ethnic groups are willingly met.

Liver transplant patients highly value the fact that all aspects of pre- and post-transplant care, as well as the transplant procedure itself, are coordinated and performed by attending transplant hepatologists and surgeons. Patients are supported at every stage by a team of nurses, social workers, donor advocates, nutritionists and financial counselors, who, by working together, create a unique transplant experience.

Nationally Ranked Specialized Pediatric Care

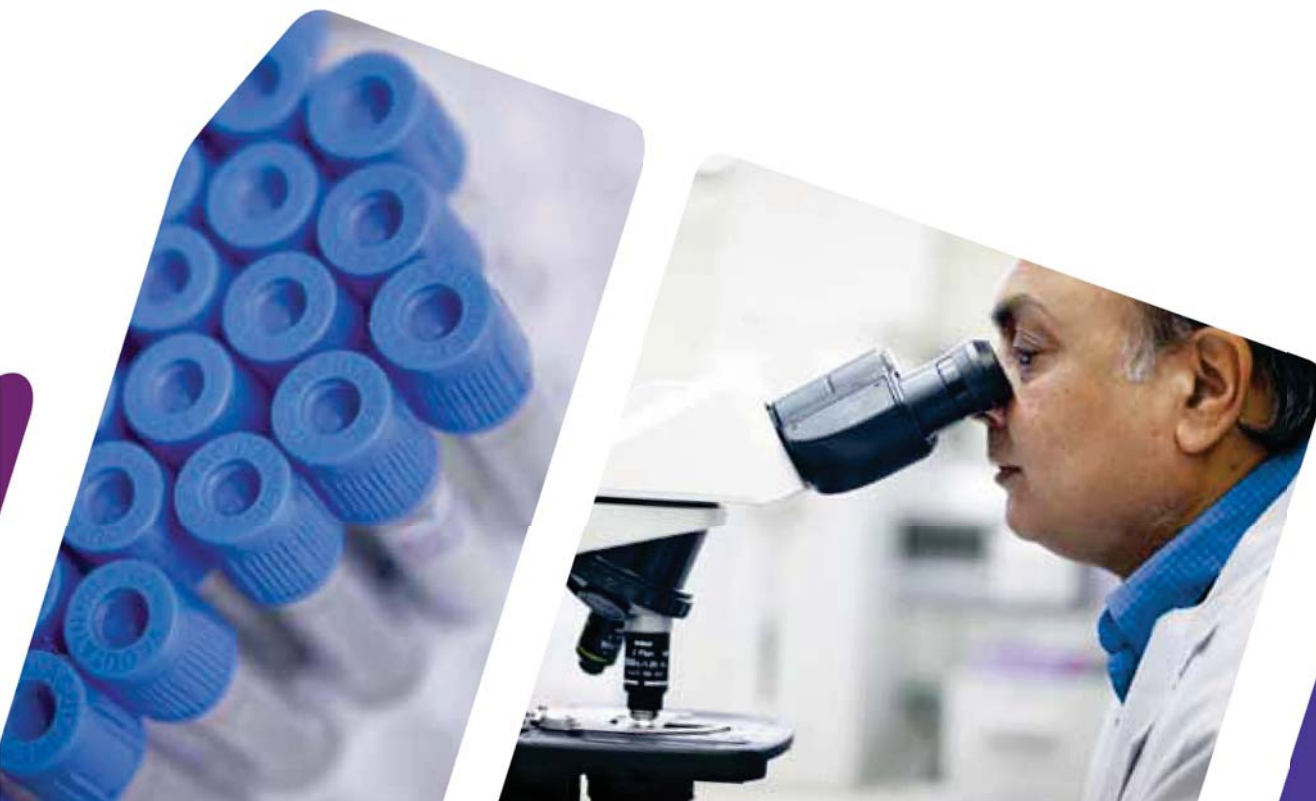
The Children's Hospital at Montefiore (CHAM) has one of the few dedicated pediatric hepatology and transplant services in the nation.

For the third consecutive year, CHAM is ranked among the top pediatric specialty hospitals by *U.S. News & World Report*. In 2009, John F. Thompson, MD, was recruited to lead the Division of Pediatric Gastroenterology and Nutrition, and was charged with growing the pediatric liver transplantation program. A renowned pediatric gastroenterologist and researcher, Dr. Thompson has an international reputation as a leader in the treatment of a full range of complex childhood gastrointestinal and liver conditions.

During his years at Holtz Children's Hospital/Jackson Memorial Hospital in Miami, Florida, he was instrumental in developing and operating the world's largest pediatric liver and intestinal transplantation center. At CHAM, he is responsible for creating programs for inflammatory bowel disease, intestinal failure and intestinal transplantation.

CHAM offers many resources for children with liver disease, including dedicated transplant social workers and nurse coordinators, a child-life specialist and a state-of-the-art pediatric ICU (PICU) with staff trained in multiorgan transplantation.

Children hospitalized at other centers are routinely transferred to CHAM's PICU for management of organ failure, and we offer one of the few comprehensive pediatric dialysis centers in the United States. The liver faculty from CHAM also participates in weekly combined conferences and works closely with the adult transplant staff on sequential transplants and adult-to-pediatric transplants.



Liver Disease: A Growing Public Health Crisis

Rates of subclinical and overt liver disease—particularly hepatitis C infection—are rising in this country. The hepatitis C virus (HCV) is the most common cause of end-stage liver disease (ESLD) in the Western world today. While new infections are expected to decrease over the next five to 10 years, the number of HCV-infected patients with cirrhosis and end-stage liver disease will increase dramatically. In addition, the epidemic of obesity and diabetes will likely increase the number of patients with non-alcoholic fatty liver disease (NAFLD) in the United States.

The Gap Between Need and Access

Chronic conditions that damage the liver can eventually lead to ESLD, which is incurable without liver replacement. At any time, approximately 16,600 adults and children in the United States are awaiting liver transplantation. According to the Organ Procurement and Transplantation Network, in 2009 only about 6,000 patients in the entire country received a liver transplant, and 426 of those transplants were performed in New York.

New York State has one of the highest rates of liver disease in the United States, with more than 1,800 patients in the state waiting for a donor liver. However, only 300 to 350 donor livers become available in New York every year, illustrating an alarming gap between need and access to lifesaving transplants.



Responding to the Crisis with a Multidisciplinary Approach

The prevalence of liver disease in New York and the complexity of decision-making for patients with advanced liver failure make early diagnosis and evaluation imperative. The multidisciplinary specialty programs offered at our Liver Center are designed to provide community-based gastroenterologists and primary care providers with rapid consultative assessments and interventions as needed. Care plans are individualized, and a full-time physician liaison is available to provide real-time feedback about patients to their referring physicians.

A physician-driven practice, the Liver Center has assembled a world-class team of specialists from leading institutions with a broad range of experience in the treatment of liver disease and research. This environment provides a unique combination of experience and innovation.

Our multidisciplinary transplant team is composed of advanced practice hepatologists, liver transplant and hepatobiliary surgeons, liver transplant anesthesiologists and advanced practice nurse coordinators, all of whom have earned a strong national reputation for management of abdominal organ failure. The quality of immediate post-transplant care is enhanced by an experienced team. The multispecialty Liver Team also includes a family practitioner, a full-time psychiatrist and a full-time nutritionist.

Our Integrated System Improves Care

The Liver Center is structured as an integrated delivery system (IDS) that allows for the comprehensive management of all types of liver disease in adults and children. The IDS model to care for patients with liver disease includes the participation of hepatologists, oncologists, surgeons, psychiatrists, critical care physicians, nutritionists, financial counselors and social workers who work as a team.

The Liver Center utilizes sophisticated techniques to facilitate rapid evaluation and assessment of patients. Critically ill inpatients are transferred within hours of referral, and patients needing urgent outpatient referrals may be seen the same day.

A similar team-oriented approach is used for children with liver disease, taking advantage of the outstanding pediatric specialists and outpatient facilities at The Children's Hospital at Montefiore.

Patients with acute liver failure are transferred within 24 hours to the critical care facilities at Montefiore, where a Rapid Response Team immediately evaluates and treats life-threatening fulminant liver failure to reduce mortality. This rapid access is designed to maximize positive outcomes in this high-mortality condition. Our Surgical Intensive Care Unit director is a trained liver transplant surgeon, so critical care services are linked with the Liver Center's liver failure protocols.

Taking a Multimodal Approach to Liver Cancer

For patients with liver cancer, the Liver Center takes an aggressive multimodal approach to therapy while patients await transplantation. In collaboration with the physicians of the Montefiore Einstein Center for Cancer Care, a variety of surgical and nonsurgical alternatives are considered for each patient. Choices include stereotactic radiosurgery, surgical resection, transcatheter intra-arterial injection (TACE and SIR Spheres) and systemic intravenous anticancer therapy.

The Liver Center Tumor Board evaluates each new patient with suspected liver cancer and develops an individualized treatment plan using a team approach. The full spectrum of therapeutic options is available, including advanced surgical intervention, interventional oncology procedures and clinical trials of cancer therapies.

These approaches may enable some patients previously considered unsuitable candidates for transplantation to qualify. In many cases, these therapies may avert the need for transplantation.

Improving Outcomes

The incidence of primary liver cancer in the United States is increasing. Fortunately, multiple therapeutic options have emerged in recent years. Selection of the most appropriate treatment regimen for each patient is based on staging as determined by cross-sectional images, as well as careful assessment of underlying liver disease by an experienced hepatology team. More recently, molecular markers have been utilized to individualize therapy.

Therapeutic intervention in liver cancer is always multimodal and is based on discussion of each case by a dedicated liver tumor board. Montefiore provides the entire range of standard and nonstandard tumor therapies, including complex hepatic resections, liver transplants, minimally invasive surgery, microwave and radiofrequency ablation, transcatheter embolization, stereotactic radiosurgery and radiolabeled embospheres.



Intraoperative view of a primary liver cancer during laparoscopic hepatic surgery.





Transplantation for End-Stage Liver Disease

Liver transplantation is often the only reasonable option for the treatment of end-stage liver disease (ESLD). Although chronic liver disease from hepatitis C is the most common cause, a wide variety of other liver conditions can result in ESLD.

ESLD is defined as acute or chronic liver failure that will be fatal without liver replacement. The United Network for Organ Sharing (UNOS) has adopted the Model for End-Stage Liver Disease (MELD), a severity-of-illness scoring system for ranking patients on the waiting list and allocating organs. MELD scores are closely correlated with short-term survival in patients with liver failure.

Transplantation offers a survival benefit for patients with a MELD score of 15 or higher. Most of these patients will exhibit some or all the stigmata of decompensated liver disease, including ascites, encephalopathy, jaundice and muscle wasting. For liver transplant candidates, the higher the MELD score, the higher the ranking on the waiting list.

Some patients may have greater functional disability than others. However, refractory ascites, for example, may be associated with significant morbidity and may not correlate with the MELD score. In patients who are underserved by MELD, access to organs may prove difficult, and an alternative, such as living donation, may be required.

The timing of transplantation in patients with liver cancer is complex and driven by many factors, including the risk of cancer progression and the severity of underlying liver disease. Complications of liver disease from cancer are not reflected in MELD scores. However, UNOS does permit MELD exceptions, which can shorten the waiting time for transplant candidates with liver cancer.

Reducing the Wait for a Donor Liver

The waiting time for a donor liver is based on severity of illness and blood type. Patients may be waitlisted in multiple centers in different regions to improve their chances of receiving a donor liver that is the best match.

Possible alternatives to transplantation are discussed with each patient during transplant education. One option is the identification of a healthy donor to provide a portion of his or her liver. Another option is to receive a deceased donor liver that may be at increased risk of poor graft function or disease transmission. In some cases, this type of “expanded criteria” organ may be acceptable and potentially preferable to long wait times.

A Comprehensive Transplantation Evaluation Process

The Liver Center will evaluate any patient referred for an opinion regarding liver transplant candidacy. Not every patient requires a full evaluation; patients who may be too well for transplantation may continue to be followed by their primary doctors, with a full evaluation initiated only when appropriate.

A full transplant evaluation is a comprehensive process that includes extensive patient and family education, multiple physician assessments by our multidisciplinary team and aggressive medical and psychosocial intervention to prepare the patient for liver transplantation.

Once a patient is listed for transplantation, our team becomes intimately and directly involved in all aspects of the patient’s care in order to prevent complications that could interfere with his or her active status on the waiting list.

Optimal Graft Selection Helps Ensure Success

To optimize post-transplant outcomes, attending transplant surgeons directly assess and procure most donor organs used for transplantation at Montefiore rather than relying on evaluations by trainees or outside medical personnel. All liver implantations are performed by two attending liver transplant surgeons to minimize the risk of complications, shorten operative time and reduce blood product utilization.

The liver anesthesia team utilizes advanced techniques such as blood recycling during transplantation to minimize use of blood products. This enables some liver transplants to be performed without a blood transfusion.

Better Immunosuppression Options

Post-transplant immunosuppression regimens are individualized, with an overall goal of minimizing immunosuppression whenever possible.

The aim is to discontinue steroids within the first week, rather than the first year, as is common in most programs. This protocol is based on recent findings suggesting that less immunosuppression may reduce recurrent disease related to HCV.

By the end of their first post-transplant year, virtually all patients are maintained on only one immunosuppressive agent.

Coordinated Follow-up Care for Life

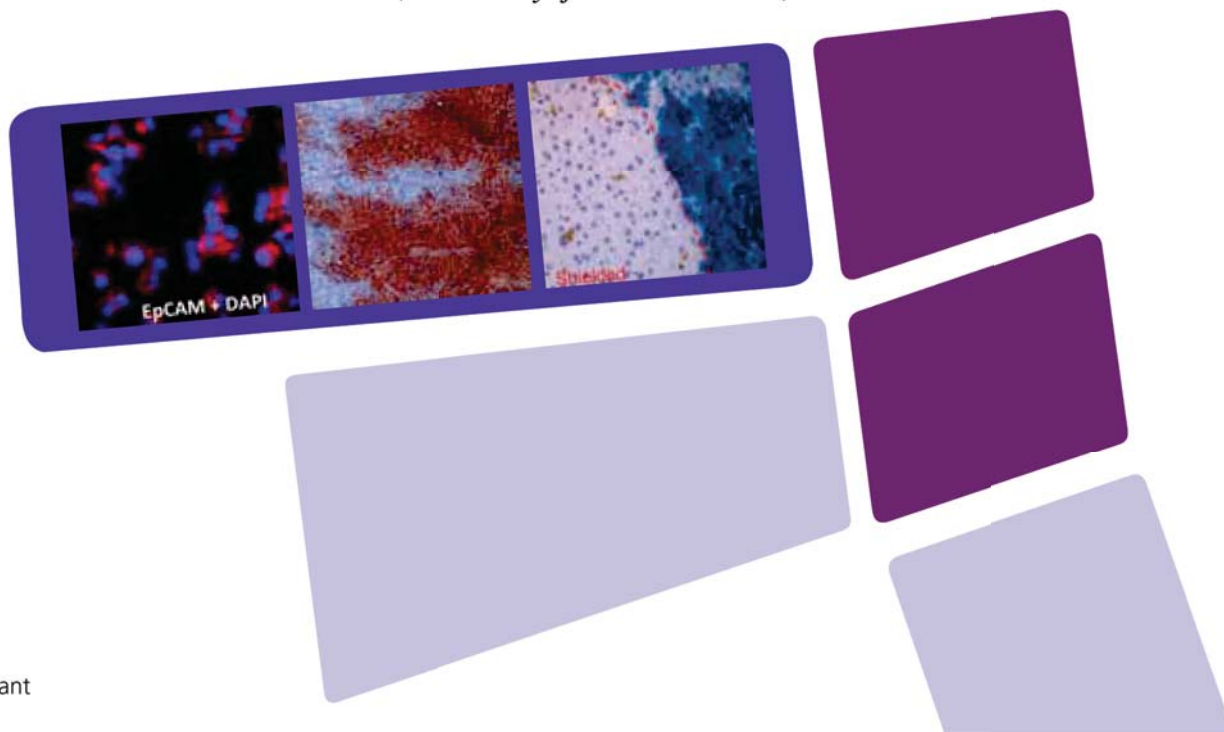
After transplantation, a full multidisciplinary team of medical and surgical specialists, nurse coordinators, nutritionists and psychosocial professionals will continue to provide care for life. In many cases, however, patients are able to return to their community physicians for routine care within a few months following successful transplantation.



Liver Stem Cells Hold Promise

The laboratories of David Shafritz, MD; Chandan Guha, PhD, MB, BS; Jayanta Roy-Chowdhury, MD; and Sanjeev Gupta, MD, at The Marion Bessin Liver Research Center at Albert Einstein College of Medicine are recognized worldwide for pioneering work in liver stem cells and hepatocyte transplantation for metabolic disease. Dr. Roy-Chowdhury participated on the team that performed the first successful human hepatocyte transplant in the world. Cell-based therapies offer tremendous opportunities for future development of novel applications in the treatment of liver disease.

These images depict a potential cell-based approach to liver disease, which is a major focus of translational research at the Liver Center. Investigators at The Marion Bessin Liver Research Center at Albert Einstein College of Medicine are studying ways to transform liver progenitor stem cells, which can be derived from a number of sources, including adipose tissue, as a means of repopulating a diseased liver (Slide courtesy of Dr. Chandan Guha).





State-of-the-Art Inpatient and Outpatient Facilities

Most patients require two weeks' hospitalization after liver transplantation. Some may need a longer stay, depending on the severity of their illness and any complications that may arise.

All abdominal transplant patients at Montefiore stay on a state-of-the-art, newly renovated unit. The unit is staffed by physician assistants and nurses who work solely with transplant patients and are familiar with their needs and desires, as well as the warning signs of complications.

Montefiore's outpatient facility for transplant patients provides a single location where patients may see a hepatologist, transplant surgeon, dietitian and social worker and have blood tests done. Centralizing services for this unique group of patients facilitates education and dialogue, reduces patient stress and helps ensure coordination of care.

Information for Referring Physicians

We are available at any time to discuss general hepatology and hepatobiliary surgical issues at 888-795-4837. Urgent cases requiring surgical or hepatologic consultation often can be accommodated the same day.

We are happy to discuss the timing of a referral with you by phone. Even if a patient is not a candidate for liver transplantation, we are available to see the patient in our office to discuss treatment options. After the patient has been examined, we will send you a letter detailing our recommendations and follow up with a phone call to discuss the case. Our full-time physician liaison can work with your office staff to expedite and facilitate referrals to our practice. Liaisons will provide you with timely feedback on the status of our patients.

Successful Rare Heart/Liver Transplant

Juan F. underwent a combined heart/liver transplant at Montefiore in 2010. Only a handful of such procedures have been performed worldwide for his unique condition: heterozygous familial hypercholesterolemia, an inherited metabolic condition causing irreversible atherosclerotic heart disease. Juan had failed maximal medical therapy and plasmapheresis to reduce lipid loads. Because replacing the heart without correcting the underlying enzyme defect would have accelerated a recurrence of ischemic cardiomyopathy, Juan was offered a heart and liver from the same donor. The successful operation was performed in 12 hours by two surgical teams, one for the heart and one for the liver. Ten days later, the 32-year-old patient was discharged and went home.

First Liver Transplant Performed on Patient in Fulminant Hepatic Failure

In 2008, Millicent P. received the first liver transplant at Montefiore. The 51-year-old Bronx native had presented with acute liver failure of unclear etiology, which rapidly progressed to coma, requiring urgent transfer and listing for liver transplantation. Montefiore Einstein's Rapid Response Team for liver failure, which includes specialists in critical care, medicine, hepatology, liver transplant anesthesia and transplant surgery, was mobilized. The patient was made hypothermic and had placement of an intracranial pressure monitor, transcranial Doppler monitoring and renal replacement with continuous veno-venous hemofiltration (CVVH). A donor liver became available less than 24 hours later and the diseased liver was replaced. Within another 24 hours, the patient regained consciousness and was discharged eight days postoperatively with normal functional status and no neurological deficits.

The Evaluation Process

We are flexible with regard to evaluation and testing. Many tests can be performed at your facility, at the facility of your choice or at Montefiore.

The evaluation process for liver transplantation includes:

- Mandatory education program attended by the patient and a family member or companion serving as the patient's healthcare proxy
- Consultation with a transplant surgeon, hepatologist, transplant coordinator, social worker and financial counselor
- Laboratory tests
- CT or MRI of the abdomen
- Doppler ultrasound of the liver
- Echocardiogram
- EKG
- Chest X-ray
- Pulmonary function tests
- PPD to determine exposure to tuberculosis
- Routine health screening, which may include mammography, colonoscopy and Pap smear
- Chest CT scan and bone scan (cancer patients)

Evaluation may also include:

- Consultation with a transplant psychiatrist, family physician, cardiologist, pulmonologist or infectious disease specialist
- Cardiac stress test
- Cardiac catheterization
- Head CT scan
- Liver biopsy

Because the evaluation process can be lengthy, we work with patients to make the process as convenient as possible.

All components of the evaluation must be completed before a patient may be placed on the waiting list. Each patient's case is discussed at a selection meeting attended by all transplant team members. The patient will be assigned to one of three categories: suitable for transplantation; possibly suitable, but requiring additional testing; or unsuitable for transplantation. In the event the patient is not considered a candidate for transplantation, alternative treatments will be recommended.

Patients found suitable for transplantation are immediately registered on the United Network for Organ Sharing (UNOS) waiting list, regardless of whether the organ will be procured from a living or deceased donor.

General contraindications to liver transplantation:

- Recent or active substance abuse, including alcohol or illegally obtained drugs
- Advanced or uncontrolled medical condition that would make recovery difficult or dangerous, such as serious cardiopulmonary disease, psychiatric disorder and infection
- Primary liver cancer beyond stage I or II
- Metastatic cancer spread to the liver
- Recent or active cancer outside the liver
- Inadequate social support/family assistance
- Undocumented immigration status (in certain cases, legal visitors to the United States may be able to receive organ transplants)

Montefiore Liver Disease and Transplantation Program Staff



Milan Kinkhabwala, MD
Chief, Division of Transplantation
Professor of Surgery
Albert Einstein College of Medicine

Specialty Interests: liver transplantation, hepatobiliary surgery

Medical Degree: Cornell University Medical College, New York, NY

Residency: Cornell Medical Center, New York, NY

Fellowship: University of California at Los Angeles Medical Center



Paul J. Gaglio, MD
Medical Director
Adult Liver Transplantation
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Albert Einstein College of Medicine

Specialty Interests: viral hepatitis following liver transplantation, novel treatments of hepatitis B and C, NASH, acute liver failure

Medical Degree: University of Medicine & Dentistry of New Jersey, Newark, NJ

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Fellowship: Columbia-Presbyterian Medical Center, New York, NY



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Albert Einstein College of Medicine

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Medical Degree: Université Pierre et Marie Curie, Paris, France

Residency: Assistance Publique-Hôpitaux de Paris, Paris, France

Fellowship: Université René Descartes, Paris, France



Javier Chapochnik-Friedmann, MD
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Albert Einstein College of Medicine

Specialty Interests: liver and pancreas transplantation, hepatobiliary surgery

Medical Degree: Universidad de Chile School of Medicine, Santiago, Chile

Residency: Hospital del Salvador / Universidad de Chile, Santiago, Chile

Fellowship: NYU Medical Center, New York, NY; Northwestern University Medical Center, Chicago, IL

“My experience [referring patients for liver transplantation] has been excellent. They are very prompt seeing patients. John Reinus and Paul Gaglio are extremely bright and have been helpful managing patients with problems that may or may not lead to transplantation. Milan Kinkhabwala and Sarah Bellemare are good surgeons and stay in communication with me the entire time my patients are in their care. They are most helpful and accommodating.”

Francis R. Weiner, MD
New York Associates in Gastroenterology

“I knew Drs. Kinkhabwala and Gaglio from our time on staff together at Columbia. I was familiar with their reputation, credentials, expertise and the work they had done. So when they moved to Montefiore, I continued to send them patients. My patients are very satisfied. They don't have to wait for an appointment and are happy with the multidisciplinary approach. I have not had a single complaint.”

David F. Stein, MD
*Riverdale Gastroenterology
and Liver Diseases*



Harmit S. Kalia, DO
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Specialty Interests: general hepatology, liver transplantation
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John F. Thompson, MD
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Residency: Wyler Children's Hospital, University of Chicago, Chicago, IL
Fellowship: Babies and Children's Hospital, Columbia-Presbyterian Medical Center, New York, NY



Allan W. Wolkoff, MD
Chief, Division of Gastroenterology and Liver Diseases
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Albert Einstein College of Medicine

Specialty Interests: hepatology, gastroenterology
Medical Degree: Albert Einstein College of Medicine, Bronx, NY
Residency: Jacobi Medical Center, New York, NY
Fellowship: National Institutes of Health, Bethesda, MD

How to Reach Us

To refer a patient for an outpatient hepatology consultation, hepatobiliary surgery consultation or liver transplant, please contact us through our referral line, **888-RX-LIVER** (888-795-4837). You can use the same number to speak with any of the doctors in our group at any time.

To transfer a patient to Montefiore for hospitalization or to speak with the attending on call, please call **888-RX-LIVER** (888-795-4837) and ask that the attending on call be paged directly to you.

Visit www.montefiore.org/transplant for more information.

Montefiore Einstein
Center for Transplantation

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Montefiore
THE UNIVERSITY HOSPITAL



Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

www.montefiore.org/transplant