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Trial Signals Machine Perfusion's Evolution

To James Guarrera, MD, using hypothermic machine perfusion of liver grafts for transplantation is an idea whose time has come—again.

Dr. Guarrera decided to apply the lessons learned from the success of machine perfusion in kidney transplantation to machine preservation of livers.

He and colleagues at NewYork-Presbyterian Hospital/Columbia University Medical Center completed a clinical trial of 20 patients who underwent transplantation with livers preserved through machine perfusion. The control group consisted of 20 patients whose transplanted livers had undergone the standard static cold storage on ice. It was the first clinical study to test the safety of machine preservation in human liver transplants.

The results of the trial are encouraging and demonstrate that the utility of machine perfusion is “something that has swung back,” Dr. Guarrera said. The machine perfusion grafts functioned immediately in all 20 patients, with no episodes of primary nonfunction, early allograft dysfunction, or vascular complications occurring.

Whereas 4 patients (20%) in the control group had a minor biliary complication, this occurred in only 1 perfusion patient. Preservation-associated injury to the organ was significantly less in the perfusion group than for control organs, said Dr. Guarrera.

“It is our hypothesis that the machine perfusion platform developed here will permit ex vivo resuscitation, expanded criteria, and suboptimal liver grafts, thereby expanding the donor pool and improving outcomes,” he said.

According to Dr. Guarrera, the slow progress of clinical use of machine perfusion in liver transplantation is attributed to the difficulty in developing a

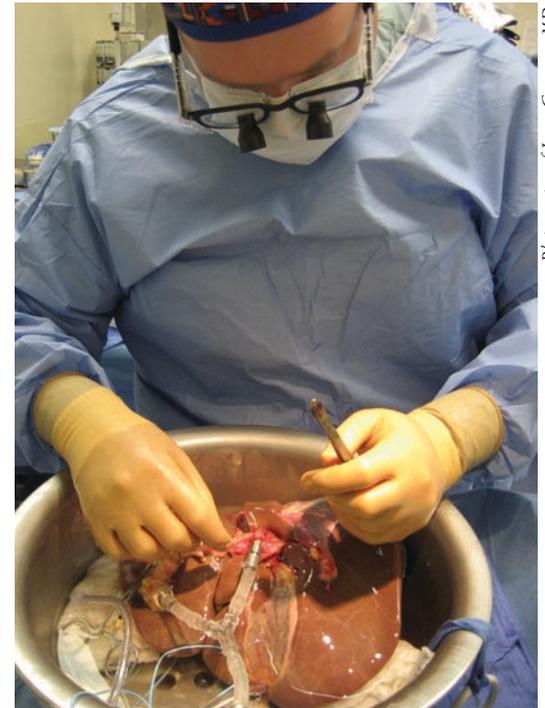


Photo courtesy of James Guarrera, MD.

James Guarrera, MD, performs a liver transplant using a liver that was preserved through machine perfusion.

user-friendly and portable system, the more severe ramifications of primary nonfunction and poor early function in liver transplantation, and the culture of liver transplant surgeons.

The machine perfusion method essentially is a pump device that has been modified for ex vivo perfusion of a single organ, similar to cardiopulmonary bypass.

see **Perfusion**, page 5

Innovative NEAD Chain Approach Makes News

On February 14, 2008, the transplant team at NewYork-Presbyterian Hospital/Weill Cornell Medical Center and The Rogosin Institute successfully performed one of the nation's first never-ending altruistic donor (NEAD) “chain” renal transplants. The chain was continued in 2 sets of procedures—first in May, then this fall. The innovative NEAD approach may forever change the way transplants are performed in the United States.

“In the process of a NEAD-type transplant, an altruistic donor initiates a chain of transplants and the potential donor from the last transplant serves as a bridge donor to initiate another chain of transplants,” said Sandip Kapur, MD, who coordinated the successful triple transplant procedure. “In the case of the first procedure, Gareth Hill, who founded the National Kidney Registry, identified an altruistic donor in California.

see **NEAD**, page 7

Non-heart-beating Donors Expand Lung Transplant Pool

The lung transplantation program at NewYork-Presbyterian Hospital/Columbia University Medical Center has grown rapidly since 2001, but the program is on the threshold of becoming even larger.

The growth is possible because of expanded eligibility criteria that allow hospitalized patients whose hearts have stopped beating but who are not yet brain-dead—the usual legal requirement for organ donation—to be considered as lung transplant donors.

These non-heart-beating lung donations, or donations after cardiac death (DCDs), as the category is often called, have the potential to increase the lung donor pool by 5% to 10%, according to Joshua R. Sonett, MD.

“That is huge, if you think of 10% of the patients on the waiting list for lung transplants,” Dr. Sonett said. As of October 24 2008, 2,146 people in the United States with intractable lung disease were awaiting new lungs, according to the Organ Procurement and Transplantation Network (www.optn.org/data).

The lung transplantation program at NewYork-Presbyterian/Columbia currently ranks as No. 4 in the United States in number of transplantations performed, according to Dr. Sonett. It also boasts the best 3-year

patient survival record among the top 10 programs in the country. In 2007, the team of Columbia physicians undertook 55 lung transplant procedures with a high degree of success. The program moved cautiously to extend its boundaries to include DCD patients, according to Selim M. Arcasoy, MD. Eighteen months ago, the team performed a successful double-lung transplant procedure involving a non-heart-beating donor, but none since then, Dr. Arcasoy said, although other donor lungs have been considered but rejected because of their less-than-acceptable quality or the travel time needed to procure them.

“We have been looking for really perfect ones,” Dr. Arcasoy said. But now, he added, “because of the success [of DCD transplants] overseas and because of our initial success, we are looking to expand our use of non-heart-beating donors. We’re also waiting for the infrastructure in the United States to catch up to some extent because each hospital has to have its own legal protocol as to how to handle these patients so that everything is aboveboard.”

The use of such lungs has advanced faster in Europe than in the United States since the first successful operation by a Swedish

team in 2000 (*Lancet* 2001;357[9259]:825-829). Overseas growth also has benefited from generally more liberal guidelines governing donor eligibility. In several countries, for example, patients who die suddenly are presumed to be donors unless their next of kin say otherwise. That is not the case in this country.

“If we can keep lungs alive for a couple of days, ultimately we will have something like a lung bank, where lungs are procured, fixed, and then go to the best recipient.”

—Joshua R. Sonett, MD

Expanded efforts at NewYork-Presbyterian/Columbia may also benefit from the development of a new device that can assess the quality of donated lungs outside the donor’s body and recondition less-than-perfect ones to the point at which they can be grafted successfully. A Swedish team from the same hospital that performed the first DCD lung transplant reported last year on the successful use of an ex vivo reperfusion and reconditioning apparatus for a lung donation that would have been considered unacceptable according to previous standards (*Ann Thorac Surg* 2007;83[6]:2191-2194).

“The biggest problem in procuring lungs after cardiac death,” Dr. Sonett explained, “is that you have no idea how viable those lungs are, especially if they are coming from a patient in an emergency room who died suddenly.”

The device, developed in Sweden, allows the transplant procurement team to keep lungs alive long enough to ensure their viability and then transplant them. Dr. Sonett is part of a working group that is developing ex vivo lung perfusion to the stage at which it can be used clinically. “We’ve done experimental ex vivo perfusion at Columbia,” he said. “We just haven’t made the jump to clinical use.”

Dr. Arcasoy agreed that technologic improvements making it possible to take lungs from a patient after complete cessation of cardiopulmonary function and assess blood flow pressure, permeability, oxygen

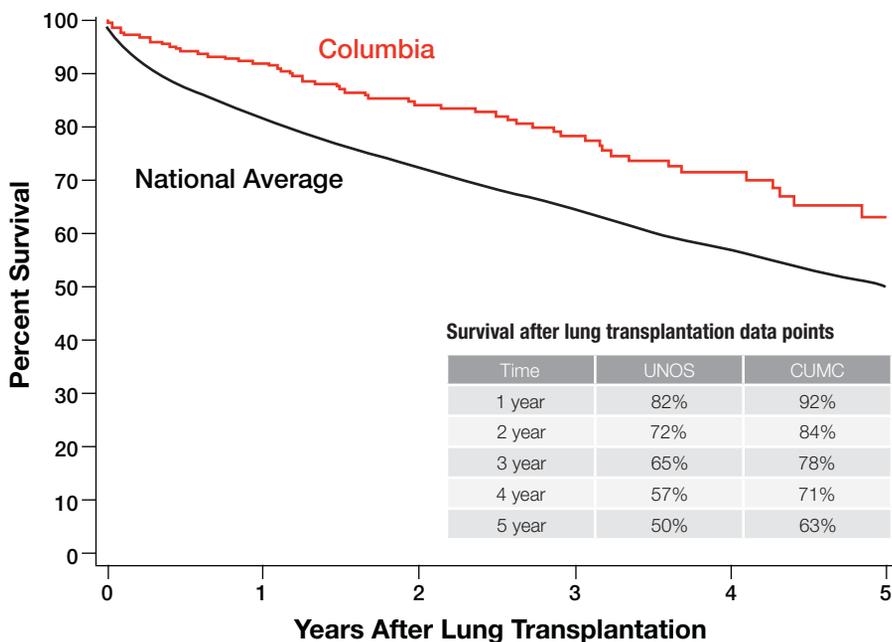


Figure 1. Survival of 274 consecutive patients transplanted at NewYork-Presbyterian/Columbia compared with 8,179 patients transplanted nationwide between July 1, 2001 and July 31, 2008 ($P < 0.001$).

National average data source: United Organ Sharing Network (UNOS).

levels, and other physiologic factors inside a sterile box would help expand the use of non-heart-beating donations.

A second category of non-heart-beating lung donations may serve to increase the supply even more. These lungs are from patients whose hearts stop suddenly outside the hospital setting and are not resuscitated. "There is a huge pool there," Dr. Arcasoy said. "Even if you can procure 1% or 2% of the organs of patients who die suddenly in motor vehicle accidents or from gunshot wounds and other causes, you may still end up with a lot of potential donors."

Often, however, the narrowness of the available window in which to obtain next-of-kin consent and cool the lungs sufficiently to limit ischemia prevents the use of such donations. A new law in New Jersey may eventually help to relieve the next-of-kin consent challenge. It requires people applying for



a driver's license to consider becoming organ donors, and it also incorporates education about organ donation into the high school curriculum beginning in the 2009-2010 school year. College clinics also will be required to distribute information.

Any benefits from the new law may be years in coming, and other states may be slow to follow New Jersey's lead, but the technologic promise of the lung perfusion device in non-heart-beating donors is on the verge of fulfillment.

"You can imagine what that will eventually mean," Dr. Sonett said. "If we can keep lungs alive for a couple of days, ultimately we will have something like a lung bank, where lungs are procured, fixed, and then go to the best recipient."

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Renal Transplant Recipient Operations Receive a Facelift

Recent advances in minimally invasive surgery have made the laparoscopic donor nephrectomy possible. Now, advanced technology and techniques are being tested in renal transplant recipient operations. A combination of minimized incisions and laparoscopic surgery will decrease complications and pain, speed recuperation, and reduce scarring, said Lloyd E. Ratner, MD. “For thin people, now we’re able to do the recipient operation through a 5- to 7-cm incision, and we’ve been able to provide better retraction and strategize the operation a little bit better,” said Dr. Ratner, who performs renal transplant procedures at NewYork-Presbyterian Hospital/Columbia University Medical Center. “In the lab, we’re working on a laparoscopic operation for heavier recipients so we’ll be able to get by with about a 7-cm incision to put the kidney in, and then do the rest of the operation laparoscopically.”

Dr. Ratner pointed out that renal transplant recipient operations have been performed in essentially the same way since the 1950s. He believes it’s time to update the procedure with the latest tools and techniques for minimally invasive operations. “With the goals of decreasing wound complications, reducing pain, speeding up recuperation, and producing a better cosmetic result, we’re trying to minimize the scar and the incision necessary,” he said. “I performed the first minimally invasive laparoscopic operation for kidney donors [at NewYork-Presbyterian/Columbia], and now we are trying to expand those minimally invasive techniques to recipients. For the minimally invasive operation, there are only 2 or 3 other centers in the world that we know about that

are using these techniques on the recipient. And as far as we know, there’s really no one else currently working on a minimally invasive laparoscopic operation for recipients. So this is really pretty unique.”

Dr. Ratner described 2 minimally invasive operations for transplant recipients; the better documented of these is performed through a small incision no larger than 7 cm, and sometimes as small as 5 cm. Patients with a body mass index (BMI) below 30 kg/m² are the best candidates for the simple minimal incision, and those with a BMI of 28 to 30 kg/m² should be evaluated on a case-by-case basis, noted Dr. Ratner. “In some people with BMIs of 29 or 30 we can’t perform the operation, but in some of them we can. In patients with a BMI higher than 30, it becomes too difficult, and they are candidates for the laparoscopic operation.” Dr. Ratner and his colleagues have performed hundreds of these procedures and are currently revising a paper for publication that discusses their results.

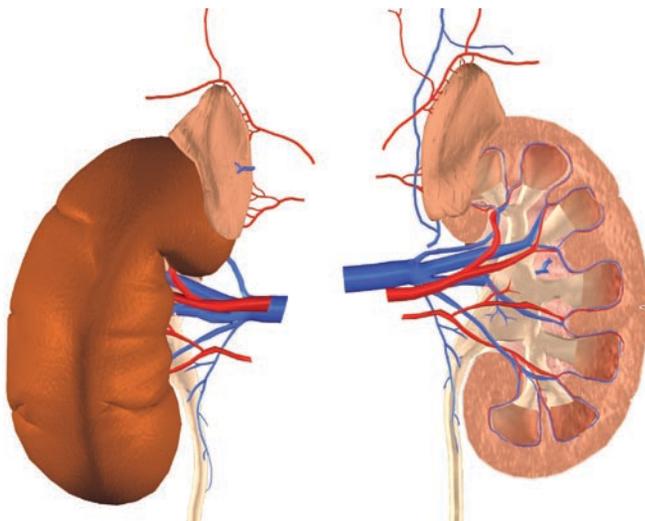
The more experimental operation, which Dr. Ratner and colleagues are testing in pigs, begins with a 7-cm Pfannenstiel incision, through which a hand port is placed to maintain the pneumoperitoneum. The surgeon performs a retroperitoneal dissection, dissects out the iliac vessels, and occludes them with atraumatic clamps. After the kidney has been inserted through the hand port, the arterial and venous anastomoses are sewn laparoscopically to the iliac vessels. “The incision is right over the bladder, so we could actually do the bladder anastomoses just as we would now, using non-laparoscopic techniques,” he said. “In the

pigs, we’ve gotten to the point where we can consistently sew the arterial and the venous anastomoses together in less than 50 minutes and have the kidney reperfuse and begin making urine. From a technical standpoint, it’s very doable. It’s within a suitable time frame of warm ischemia. We think that we’ll be able to transfer it to humans fairly easily. It’s well refined; we just need to practice it a little bit more and demonstrate in the animal model that the kidney will work well. We’ve worked out most of the technical details.”

The next step will be to add the use of a surgical robot, which Dr. Ratner said would be an excellent fit for the laparoscopic part of the operation. “We haven’t been able to use robotic techniques because we can’t get a clinical robot up to the pig lab, but I think that ultimately the laparoscopic operation will be done using surgical robotics. Since we have to sew all of the vessels together, it’s a perfect application for it. So it’s sort of a stepwise process: minimally invasive incision in thin people using standard techniques, then progress to the laparoscopic operation for heavier people, and then apply robotic techniques to that laparoscopic operation.” He added that the surgeons in his group are waiting to perfect the procedure and perform it successfully on human patients before publishing their results, but they did present a video titled “Minimally Invasive Renal Transplant Recipient Operation in Humans and Laparoscopic Renal Transplantation in a Porcine Model” at the 94th Annual Clinical Congress of the American College of Surgeons in October.

Although Dr. Ratner expects that the majority of renal transplant recipients will eventually undergo 1 of these 2 minimally invasive procedures, a small percentage may require the full operation as it is currently performed. “For instance, if a patient had prior surgery on both iliac fossae, that would preclude laparoscopic surgery,” Dr. Ratner said. “If a patient had extensive atherosclerotic disease, that would preclude a laparoscopic transplant. If the kidney had a lot of anatomic anomalies, that would preclude performing it laparoscopically. But I think that 75% to 80% of people ultimately will be able to benefit from one of the minimally invasive operations.”

Contributing faculty for this article:
Lloyd E. Ratner, MD



continued from *Perfusion*, page 1

Introduced 41 years ago, machine perfusion represented the best way to preserve kidneys for transplant. By the 1980s, it had been supplanted by the cold storage method, which was considered cheaper, easier, more practical, and not as cumbersome because less equipment and fewer technicians were needed.

But when “perfect” kidneys became less available by the early 1990s, age requirements were loosened and “imperfect kidneys” were being transplanted, requiring the reduction of preservation injury to ensure a successful outcome. As a result, the older technique was reconsidered and machine perfusion “came back into vogue in the late 1990s,” said Dr. Guarrera, prompting his team to investigate its application in liver transplants.

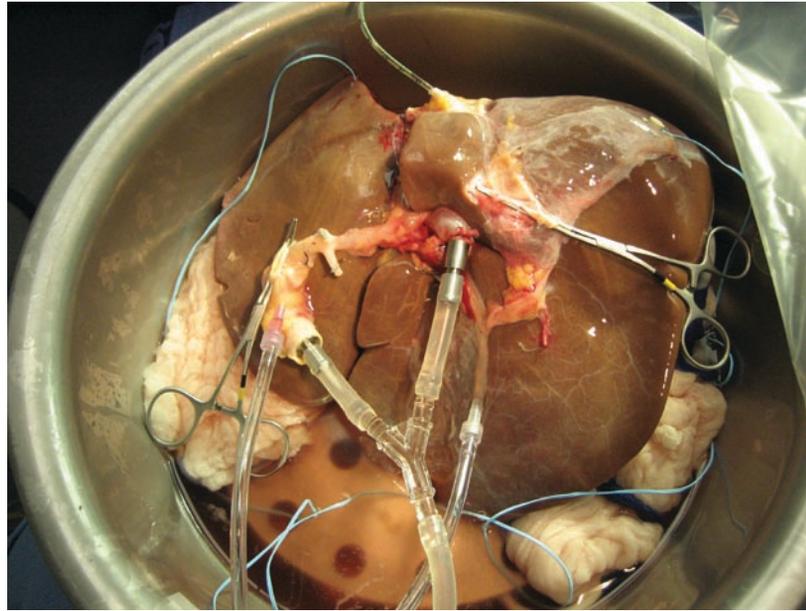
Dr. Guarrera and his study investigators—Jean Emond, MD, Benjamin Samstein, MD, and organ procurement coordinator Ben Arrington—were “always big advocates of the perfusion technique because we saw its success in kidney transplantations,” he explained. “We adapted it and made it applicable for liver transplantations.”

“What we’re doing that’s different is that we’re applying some of the basic principles of kidney perfusion and have pioneered some new techniques for perfusing livers,” said Mr. Arrington. “In the clinical setting, this will allow us to access more organs that are associated with the extended-criteria donor.... This technology, we believe, will help resuscitate these livers, increase the chance of viability for our patients, and improve patient outcomes.”

Despite its effectiveness, the cold storage method sometimes damages the organ by depriving it of continuous circulation of metabolic substrates. Machine perfusion, by comparison, reduces damage to the organ and increases the chance that it will be healthier for transplant.

The clinical trial was designed to prove that machine perfusion in liver transplants is “not inferior to cold storage”—and the result showed that “it’s certainly not inferior,” Dr. Guarrera said.

Since the trial, Dr. Guarrera has fielded inquiries and received many lecture invitations to speak about machine perfusion in liver transplantation. He would like to spread the word: “People are starting to believe that in the next few years, this can change the way we do business—that this will be readily available equipment.”



Photos courtesy of James Guarrera, MD.



Dr. Guarrera recently applied for a U.S. Department of Health and Human Services Health Resources and Services Administration grant for a Phase II trial with 25 patients. The trial will examine the effect of perfusion on the function of high-risk livers, which come from older donors or have a fatty infiltration.

“If you can improve their early function, you can improve their long-term function—and this makes them a viable option to increase the donor pool,” Dr. Guarrera said.

“Our results suggest at least equivalence to cold storage, but likely superiority. With a sample size of 20 patients, it is difficult to prove superiority, but the encouraging, preliminary results motivate us to further

develop and study clinical liver machine perfusion. In the last 20 years, there has been no significant clinical change in liver preservation, which further highlights the need for improvement and development of new techniques.”

As of October 24, 2008, 16,658 people nationally were waiting for a liver transplant, according to the Organ Procurement and Transplantation Network.

“It does give us a reason to keep going and continue to study it,” said Dr. Guarrera. “There hadn’t been a real advance in liver preservation since the University of Wisconsin storage solution was developed [in 1988].”

Contributing faculty for this article:
James V. Guarrera, MD, Ben Arrington

Center Boasts High Survival and Low Waiting-List Rates

Since it was founded, the Center for Liver Disease and Transplantation (CLDT) at NewYork-Presbyterian Hospital/Columbia University Medical Center has been a pioneer in living donor transplant surgery. Although it cannot affect the overall availability of livers, the CLDT carefully considers how it can use the organs that do exist, noted Robert Brown Jr, MD, MPH. “If you can recognize who the patients are who can benefit from expanded-criteria donation, the small risk is more than realized by the huge incremental benefit.

“It’s not just our ability to do the operation, [but to deal with] the organ shortage and with access to treatment,” added Dr. Brown.

The CLDT was one of the first centers in the United States to perform adult living donor transplants, and it has one of the largest and most successful living donor programs. It also successfully performs transplants on small babies with a high risk of adverse outcomes. It can do so, in part, because its team of experienced clinicians in medicine, hepatology, surgery, psychiatry, oncology, radiology, and nursing provide a multidisciplinary approach to adult and pediatric care. Dr. Brown, Dianne LaPointe Rudow, DNP, Patricia Harren, DNP, Steven Lobritto, MD, and Jean Emond, MD, launched the Center in 1998. At many institutions, the medical and surgical components often are separated into pre- and post-transplant care. At the CLDT, the transplant team works as an integrated unit: 6 surgeons, 6 hepatologists, 7 nurse practitioners, and 5 physician assistants. All are full-time employees.

The transplant team at the Center for Liver Disease and Transplantation works as an integrated unit: 6 surgeons, 6 hepatologists, 7 nurse practitioners and 5 physician assistants.

The proof is in the results. The CLDT has the highest patient waiting list survival rate and shortest waiting time in the New York State region.

According to the Scientific Registry for Transplant Recipients, the CLDT’s waiting list mortality rate is 7%, compared with 13% overall at the other 4 transplant centers in its region, all of which are in New York.

From January 2004 to June 2006, the CLDT had a 98% survival rate for the 267 adults and 43 children on whom it performed liver transplants; the national rate was 96%. In that period, the 1-year post-transplant survival rate was 88% for adults (87% nationally) and 94% for children.

“We’re proactive instead of reactive by developing an individualized plan with each patient to maximize access to transplant. This may be with standard criteria livers, expanded criteria livers, and living donors,” said Ms. LaPointe Rudow.

Specialists at the CLDT are experts in determining organ suitability. Surgeons and fellows often will travel out of state to procure livers that will go unused in that area of the country, for patients in whom the organ will be suitable. That affords patients a greater chance of being offered a liver. “We’re a very innovative program when it comes to considering all types of organs that other places may not consider,” added Ms. LaPointe Rudow.

The CLDT offers patients continuity of care not often found elsewhere. As a result, “every time we see our patients, we’re assessing their risks of staying on the waiting list versus the risks of getting a transplant now,” she said. “We call it the ‘early access plan for transplant.’ We teach patients about living donation and ask them to consider expanded-criteria donation. It’s a very active participation by our team.”

“We’ve reduced the pre-transplant chance of dying by far more than any potential small increase in the post-transplant risk of dying,” said Dr. Brown.

Patients and their families are assigned psychiatrists and social workers and attend weekly workshops or support group meetings. Patients are followed every 3 months through a “very active participation” that enables the team to “better predict who’s getting sicker and [who] needs to be prioritized for transplant,” Ms. LaPointe Rudow explained.

Part of the reason for that is location. In a metropolitan area as densely populated as New York City, where there are so many patients waiting for transplants, “we have to be innovative and think outside the box for successful outcomes,” Ms. LaPointe Rudow said.

“It’s not just our ability to do the operation, [but to deal with] the organ shortage and with access to treatment.”

—Robert Brown Jr, MD, MPH

Dr. Brown agreed that the Center’s model was aggressive from the start and that that is a key factor in the CLDT’s success. “Our program was built from the get-go with the multidisciplinary approach. We’ve known for a while that we could lower our mortality on the waiting list with our approach to transplantation, but it was never validated by the government,” he said. “We think that by working together, we’ll deliver superior, better-integrated services to all our patients. That’s a philosophy that isn’t followed all over the country.”

To Dr. Brown, that “seems such an obvious way to do it” because “with a team that’s integrated clinically and financially, you have another set of eyes on the patient and an ongoing discussion that challenges you to do everything better. As a result, we don’t get into any issues of who has ‘ownership’ of the program. We discuss cases twice a week to make sure that everyone is delivering the best care possible.”

The CLDT is the only program in the New York City area in which “the expected rate of death on our waiting list is *higher* than what we actually provide. Our results are better than what would be expected statistically,” Dr. Brown said. That is because “we’re able to take the sickest patients and, through our multidisciplinary approach, transplant them safely and more quickly.

“The better you take care of patients, and the fewer patients there are on your waiting list, the better you’re doing.”

Contributing faculty for this article:
Robert S. Brown Jr, MD, MPH, and
Dianne LaPointe Rudow, DNP

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“Both his parents were incompatible donors. We’re not at the point where we can do these special desensitization treatments for a child, so he would have been stuck without a donor and receive a deceased donor transplant (statistics show that they only last about half as long). Instead, he got a kidney from a donor who was a complete stranger. Then his father became the bridge to the second chain that we had. The family was utterly thrilled, to the point that his mother decided to donate

a kidney herself and start a new chain,” said Ms. Hambleton.

“Without the amazing generosity of these donors, none of this would be possible,” said Ms. Charlton. “It is one thing to improve the life of a loved one; however, to improve the life of someone and not even know their name takes a very special person.”

The logistics of the 3-way chain transplant were undoubtedly complicated. “As you can imagine, it was very difficult coordinating 6 different operating rooms,” said Dr. Kapur,

“making sure that the proper recipient and donor combinations occur as they should; and then there is the postoperative care. It becomes a very complex task to arrange all of this, and it is very resources-intensive. But fortunately, we have a very large, skilled team here, with dedicated professionals who have been in the field for 15-plus years, and we had the capabilities of pulling it off.”

Contributing faculty for this article:
Marian Charlton, RN, CCTC, Judith A. Hambleton, RN, SRN, CCTC, Sandip Kapur, MD, and David Serur, MD

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NEWYORK-PRESBYTERIAN TRANSPLANT

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Important news from NewYork-Presbyterian Hospital—at the forefront of heart, lung, liver, kidney, and pancreas transplantation and clinical research to advance transplant surgery and organ health.

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