

INFECTING A PATIENT TO SAVE HIS LIFE

Montefiore became the first New York health system to use hepatitis C-infected livers in transplants for uninfected patients who might otherwise die waiting for a match. Alvin Fisher was first in line

BY ROBIN D. SCHATZ

PHOTOGRAPHY BUCK ENNIS



THE PROS AND CONS: Fisher discussed all aspects of the transplant decision with the Montefiore team, which included Sigal, Bellemare and Kinkhabwala.

Alvin Fisher was back at Montefiore Health System on March 23, hospitalized again for problems related to his failing liver. He expected to be discharged the next day, but early that morning a doctor delivered the news: After 14 months, the Bronx hospital had found the 21-year-old a new liver. A man in his early 30s had died in a fall, and a team from Montefiore was heading upstate to examine the organ.

Fisher contained his emotions. "I didn't get my hopes up too much, because they could say at the last minute it was too damaged for me to have," he said.

There was reason for Fisher to be circumspect. Until then he had been behind about 30 New Yorkers waiting for a liver, giving him just a 50-50 chance of surviving long enough to get a transplant. But five weeks earlier, doctors at Montefiore had made an offer that dramatically expanded his options: He could get a liver faster if he agreed to accept one with a potentially fatal disease. He said yes.

On March 24 Fisher became the first patient in New York City to be willingly infected with hepatitis C in order to obtain a liver that might otherwise have gone to waste. For Fisher that meant taking a leap of faith that the Montefiore doctors could cure him of hep C, a blood-borne virus that could itself cause cancer and liver failure.

Fisher is among the lucky. An average of 20 people die each day in the U.S. waiting for a donated organ. With more than 14,000 people in need of a liver, demand far outstrips supply. The statistics are even worse in New York. In part because livers have a short shelf life—just eight to 12 hours from recovery to transplant—they are first allocated to a person in the donor's state or region. And because the share of New York residents who are registered organ donors is last in the nation, available organs are even harder to come by. "If Alvin had lived in another state, like Virginia or South Carolina, he would've been transplanted much sooner," said Dr. Milan Kinkhabwala, chief of transplantation at Montefiore.

Those odds have motivated doctors to push the envelope of what's an acceptable donor organ. Around the country, physicians have begun transplanting HIV-positive organs into HIV-positive patients, thanks to the reversal in 2013 of a 1998 law

that banned their use. And it has become standard for transplant centers to give hep C-positive organs to patients who already have a hep C infection. Now doctors, led by those at Montefiore and a handful of other medical centers around the country, have crossed a medical threshold—and an ethical one: giving infected kidneys and livers to people who had no trace of hep C to help them get an organ sooner.

The shift is being made possible by powerful drugs approved in the past few years that can cure hepatitis C with a success rate exceeding 95%. "We probably feel the way doctors felt when penicillin was invented," said Dr. Samuel Sigal, Fisher's hepatologist, or liver specialist, at Montefiore. "Hepatitis C therapy should be considered one of the miracles of medicine. If we had not given this liver to [Fisher], he probably would've died."

One reason that more hep C-positive organs are becoming available for patients like Fisher is that

up Montefiore's Center for Bioethics. "There will be some organs available for transplant, and if they are organs with hepatitis C, I hope they'll be able to do some good."

Still, as Fisher awaited his new liver, he knew what his doctors know: that any donor organ comes with caveats. "By definition, all donor livers are in used condition," Sigal said. "There's no factory-perfect liver in a box. They all have a story."

Ethical considerations

Fisher and Montefiore agreed to share the story of his liver transplant to call attention to the shortage of registered donors and to the lifesaving potential of transplanting organs infected with hepatitis C.

Montefiore's path toward the groundbreaking surgery reflects the quandaries in the transplant field. The program has transplanted 23 livers this year through the end of June and 276 since it began in 2008. Offering the option of accepting an infected liver presents an opportunity for patients and the hospital but was preceded by a rigorous review that included ethical implications and the establishment of protocols to ensure patients are informed of the risk of being infected with the disease.

If the practice becomes more widespread, it's certain to spark debate about who should foot the bill. Dr. John Reinus, a hepatologist at Montefiore who helped craft the hospital's policy on hep C-positive transplants, said he's aware of colleagues around the country who are starting to do these procedures, but most are happening under the radar. "People haven't become vocal, mostly because of their concerns with how the insurance industry will respond to this," he said. "I don't think people wanted to draw attention to the fact that we're giving people this disease."

The new hep C treatments are not cheap. Pharma company Gilead's drug, called Harvoni, a combination of two medications, has a list price exceeding \$1,000 a pill. A 12-week treatment of three bottles can cost up to \$94,500 if someone has to pay out of pocket, according to a Gilead spokesman. Most insurers negotiate a lower price with the drugmaker, and the net cost is closer to \$45,000 per treatment, or even less for some Medicaid plans, according to Gilead. Insurance

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"I'M GOING TO LIVE, BUT I'M GOING TO GET A LIVER WITH A DISEASE THAT COULD ALSO POSSIBLY KILL ME"

many of the people who once had the disease and might have accepted an infected organ have dropped off that list because so many of them are now cured. Another factor in the supply of infected organs is the surge in the numbers of otherwise healthy younger people dying from drug abuse, particularly of opioids. Some of those individuals contracted hep C from sharing dirty needles.

The United Network for Organ Sharing said drug-intoxication deaths accounted for 34% of transplanted donor hearts and 21% of transplanted donor livers in New York state last year. A January report from the American Society of Transplantation said the use of hep C-infected organs could "result in an increase in transplants and lives saved for patients with end-stage organ failure." The group noted that there could be 300 to 500 opportunities nationwide for donation among hep C-positive people who died of drug-related causes.

"Opioid overdose is a major cause of death in America right now," said Dr. Tia Powell, who heads

through his father's union has picked up most of Fisher's expenses.

Still, compared to the higher cost of caring for patients waiting for organs or treating those who are dying, the price of hep C therapies "appears to justify the practice," the transplantation society's report read. They also noted that well-designed clinical trials with conclusive findings will be necessary to convince insurers to pay for such therapies routinely.

Childhood interrupted

Fisher's journey was marked by one obstacle after another. As he suffered from two autoimmune disorders, his poor health curtailed his growth, sidelined his education and even dulled his senses. The likelihood that he would die before receiving a donation meant he was even willing to take a liver from someone with cancer.

The liver is the largest gland in the human body, performing hundreds of vital functions. It detoxifies and removes waste products, makes bile to help absorb fat and ensures that the body maintains a normal blood-glucose level, among other things. Kidneys come in pairs, but each person has only one liver. When kidneys fail, dialysis can keep a patient alive while he waits for a transplant. No such option exists when it comes to liver failure. Some patients can accept a piece of a liver from a living donor, usually a close relative whose blood type is a match. But neither Fisher's father, an electrician, nor his mother, a family advocate at a preschool, were options.

Fisher, who is from Newark, has known since he was about 13 that he would need a liver transplant. He was diagnosed with systemic lupus, an autoimmune disorder, and primary sclerosing cholangitis, another autoimmune disorder, which affects the ducts that carry bile from the liver to break down fat in the gall bladder and the small intestine, his physicians explained. PSC causes the bile ducts to scar and narrow, leading to recurrent infections.

"My friends knew I was always sick, but I tried to play like nothing was wrong with me," he said. "I didn't like when people would show pity."

As a kid Fisher was on a steady dose of drugs to control inflammation, and he believes they might have stunted his growth. His mom is 5 foot 11, his dad is 6 feet tall, but Fisher is just 5 foot 5. By the time he got to high school, he started noticing that other players on his baseball team were growing. "I'm like, When is my growth gonna happen?" he recalled. "I started noticing it was affecting my playing time. That's what really got me very sad."

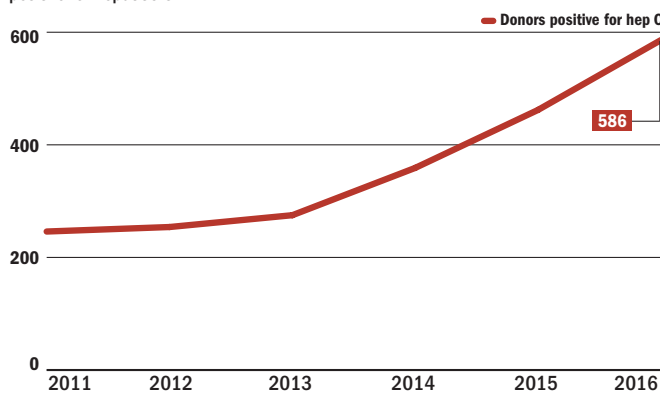
Despite the health challenges that frequently interrupted his studies, Fisher graduated from high school and set off for Stockton College, a state school in southern New Jersey. Excited for his future, he signed up for marine biology and philosophy classes. But three weeks into his first semester, he fell ill—"the sickest I've ever been in my life," he said.

He could barely feel his heartbeat and was so exhausted, he could hardly walk. He had a massive stomachache but went to the cafeteria to try to eat something. He found some dry cereal; it didn't help.

"I was walking back to my apartment, and I'm thinking to myself, I'm probably not going to make it back there." He called one of his friends and the school police. An ambulance took him to the hospital. He lost three weeks of classes "right off the bat," he said.

HEP C DONORS ON THE RISE

NUMBER OF LIVERS recovered from deceased donors in New York state that were positive for hepatitis C



As he spent time in and out of hospitals, the hardest part was seeing all his friends on social media talking about the fun they were having. By the spring semester of his freshman year, though, he was feeling "way better." He took six classes to try to make up for what he'd missed. But the improvement didn't last. By his junior year he had become too sick to attend classes. His physicians recommended he take a leave of absence.

Getting a score

Fisher first went to Montefiore for treatment in August 2015, after his mother lost her job and the family changed insurance policies. To get there, Fisher and his mother commuted two hours by public transportation to the Norwood section of the Bronx. But the change proved to be a stroke of good fortune.

"There's a group decision that's made about whether the patient is sick enough to be put on the [organ-donation] list and whether they would benefit from a transplant," said Sigal, who became Fisher's physician in January 2016.

"ALL DONOR LIVERS ARE IN USED CONDITION. THERE'S NO FACTORY-PERFECT LIVER IN A BOX. THEY ALL HAVE A STORY"

It was Sigal's task to evaluate Fisher's fitness for transplantation. That included checking his heart and performing an MRI to make sure there was no cancer in his liver. Social workers interviewed Fisher to make sure that he had a strong support system so he could care for his new organ after the transplant and deal with side effects and complications that could arise.

"He was extremely sick from the very beginning," said Sigal. "His numbers we looked at were always quite bad." Patients with PSC are prone to recurrent cholangitis, bacterial inflammation or cirrhosis of the liver. "Alvin had both," Sigal said. He determined the young man was a good candidate for a transplant. The team of doctors at Montefiore moved aggressively to save Fisher's life.

Fisher was placed on the United Network for Organ Sharing list for a liver transplant on Jan. 13, 2016. Like all patients with advanced liver disease, his spot on the list depended on the Model for End Stage Liver Disease score, which ranks the severity of a patient's illness. Despite his grave condition, his score did not catapult him to the top in part because it did not fully

take into account his underlying autoimmune diseases and other conditions.

To increase his chances of getting a donor organ, Fisher agreed to take what the Centers for Disease Control and Prevention considers a high-risk organ because of disease or lifestyle, which includes those from cancer patients, drug users, people who abuse alcohol and individuals who were incarcerated. This designation didn't include hep C-positive organs.

Risks and benefits

In the fall Fisher's situation grew critical. He developed life-threatening enlarged veins in his esophagus, known as esophageal varices, that result from blocked blood flow to the liver. By winter he was hospitalized with another serious infection. The bacteria were beginning to resist antibiotics. If the infection stopped responding to treatment, Fisher would become too sick for a transplant.

It was clear to Sigal and the rest of the Montefiore team that Fisher might not live long enough to make it to the top of the organ-donation list.

"He kept getting infections in his bile ducts with fever," said transplant surgeon Dr. Sarah Bellemare. "He was jaundiced and losing weight, but he was never high enough on the list to get an organ."

Physicians in Montefiore's transplant program considered how to increase Fisher's chances. The doctors had begun to hear more about successful transplantation of hep C-infected organs.

"It became obvious to everyone that the way we look at hep C needed to change," said Reinus, the hepatologist. "Whereas in the past it was largely an incurable disease with a potentially fatal outcome down the line with treatments that had enormous side effects, it had been transformed into a very treatable disease. As that realization sank in, everyone in the transplant field understood there were a lot of patients who would be much better off with hepatitis C than with the disease that had led them to a transplant."

As the hospital weighed the pros and cons of expanding the definition of what was an acceptable transplant organ, bioethicist Powell sprang into action. "We were very concerned about addressing the threat to this young man's life," she said. The challenge was "how can we creatively invent some options that are legitimate, that are ethically viable and that will help save his life." It also meant crafting more general policies that could be applied to other gravely ill patients who also didn't have a high-enough position on the transplant list.

Informed consent is particularly important in discussing options with patients who are facing the prospect of contracting a new disease.

"What we need to be careful about, particularly when you're using high-tech interventions, is not to get caught up in a kind of triumphal narrative, where this is great and the technology is perfect," Powell said. "You don't want to say, 'I have a medication that can absolutely fix hepatitis C,' because that's not a true statement. You can say, 'We've got a pretty effective treatment.' And you've got to compare that against a person's other choices."

When the Montefiore doctors first spoke to Fisher about receiving an infected donor liver, he was understandably nervous. "I looked at my mom to see her reaction," Fisher said. His first thought was "I'm going to live, but I'm going to get a liver with a disease that could also possibly kill me."



BELLEMARE TOOK THE LEAD
on Fisher's almost-seven-hour surgery.

But then they explained how they would vigorously attack the virus with two drugs, Harvoni and ribavirin, for 24 weeks. While the chances of a cure were extremely high, Fisher was told that the medications do not work for a slim percentage of people and the hep C could reappear at a later date.

Sigal told him to take some time to think about it. Fisher called two of his closest friends. Both said to go for it. "I'd rather see you with hep C than see you dead," they told him. Montefiore's bioethics team made sure Fisher was informed of the risks. "When I spoke to Alvin, he was just super articulate about the risks and benefits [of the surgery]," said Adira Hulkower, a bioethics consultant at Montefiore, "and he had such a desire to continue his life."

His mother, Virginia, was torn. "I was debating it," she said. "But my son made the decision. He's my only son, my life."

Ready for surgery

Soon after Fisher was told that a donor with hep C had been identified, he got another piece of good news. The team of doctors that had been sent upstate to examine and biopsy the liver found that, despite the infection, it had no signs of damage. It was, in fact, a perfectly healthy specimen. The team packed it up in a specially insulated box and rushed back to the city, traveling by plane. The whole process took six hours.

Fisher, meanwhile, had to stop eating in preparation for the surgery. He tried not to think too much about it. His mother, a friend and her mother came to stay with him. While he lay on a stretcher in the waiting area, they took turns by his side.

"The last person to see me was my mom," he said.

Once in the operating room, the doctors turned on the bright lights and strapped him to the table. "That's when I started to get nervous," Fisher recalled.

Bellemare, his lead surgeon, began the operation at 2:39 a.m. March 24. His surgeons clamped the major vessel leading to the heart and removed the entire diseased liver though a large incision, a step that took several hours. For about 40 minutes, Fisher survived with no liver at all as they raced against the clock to connect the new organ to blood vessels. New bile ducts from the donor liver were also attached, and the old damaged ducts were removed. Fisher remained stable during the entire procedure, Bellemare said.

Six hours and 39 minutes later, at 9:20 a.m., the surgeons closed up Fisher, and he was wheeled into recovery. The surgery had been a success. But immediately they began a regimen of medications to keep his immune system from rejecting the foreign liver. Shortly after he started the drugs, he had a seizure, so they adjusted his meds.

When he woke up, Fisher had tubes snaking through his nose and mouth, and he wasn't allowed to drink any water for three days. When he finally sipped his first glass of apple juice, "it tasted so sugary," he said. "It never tasted that way before. And colors seemed more vibrant for some reason."

His heightened perceptions were not surprising to Kinkhabwala, the transplant chief, because liver disease changes one's appetite and taste. The new liver would restore many normal sensations.

By the fourth day, Fisher was gaining some weight and getting restless. "I was able to get up. I could start to walk." He took a stroll through the hospital wing. He passed a patient with brain trauma and

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Turner

Invitation to Prequalify and to Bid: Updated Notice
Rehabilitation and Flood Mitigation of the New York Aquarium, Brooklyn, NY

Turner Construction Company, an EEO Employer, is currently soliciting bids for the Rehabilitation and Flood Mitigation of the New York Aquarium from subcontractors and vendors for the following bid packages:

- BP # 29A Installation of Power, and Building and Theatrical Lighting. (*Bid, Payment & Performance Bonds Required*)
- BP #13A Supply and Installation of Drywall, Rough Carpentry and Installation Only of Doors, Frames and Hardware. (*Bid, Payment & Performance Bond Required*)
- BP #13B Supply Only of Doors, Frames and Hardware.

Only bids responsive to the entire scope of work will be considered and, to be successful, bidders must be prequalified by Turner. The construction schedule is expected to last 24 months starting in the 4th quarter of 2017. Certified M/WBE and Small Business (13 CFR part 121) companies are encouraged to submit.

In order to receive the bid packages, potential bidders must submit a complete Subcontractor/Vendor Prequalification Statement. Prior prequalification submissions that remain current will be considered as previously submitted or may be updated at this time. All bidders must prequalify by the bid deadline by **August 15, 2017** and submission of a Prequalification Statement not later than July 31, 2017 is strongly encouraged. All bidders must have an acceptable EMR, and will be subject to government regulations such as 44 CFR and federal Executive Order 11246. Successful bidders will be required to use LCP Tracker compliance verification software. Note that while this is a New York City prevailing wage project, union affiliation is not required.

To obtain further information about contracting opportunities and/or the prequalification package and bid solicitation package/s, please contact Kahli Yaba-Baker (kbaker@tcco.com) or 212-629-6000.)

The new due date for prequalification and for submission of bid(s) is **August 15, 2017**. All bids will be publicly opened at office of the Purchasing Department, Bronx Zoo, 2300 Southern Boulevard, Bronx New York, on **August 17, 2017 at 11 am**.

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others recovering from heart transplants. Only then did the gravity of the state he had been in hit him.

"I was shocked to know that I was in the same critical-care unit as those people," he said. "I had never really thought [about] how terrible a condition I was in until I saw other people who looked like they were dying."

Eleven days after surgery, Fisher went home with a 15-drug regimen. "Which medication am I not on?" he joked. A few weeks later, Sigal started Fisher on the hep C treatment. His plan was to treat Fisher with two medications at the same time. While most patients tolerate Harvoni very well, a small number don't respond to it, Sigal said. So he gave Fisher ribavirin to increase the chance for a cure. "Alvin is really exceptional," said Sigal. "Most kids his age don't do well with their illness. They're very bitter; they just don't take their medicine. Alvin is a model patient."

Fisher's insurer has so far covered the surgery (around \$600,000) plus the antirejection drugs he will have to take for the rest of his life. After originally approving eight weeks of hep C therapy, there was a "little bit of pushback" before the insurer extended coverage to 12 weeks, Sigal said. Now Sigal is seeking to increase treatment to 24 weeks. Already there is no sign of hep C in Fisher's bloodstream, he said.

Another hospital follows

Since Fisher's surgery, Montefiore has transplanted two other infected livers into patients who did not already have the disease, and the patients have begun the same treatment regimen that Fisher is on.

EmblemHealth, a nonprofit insurer based in Man-

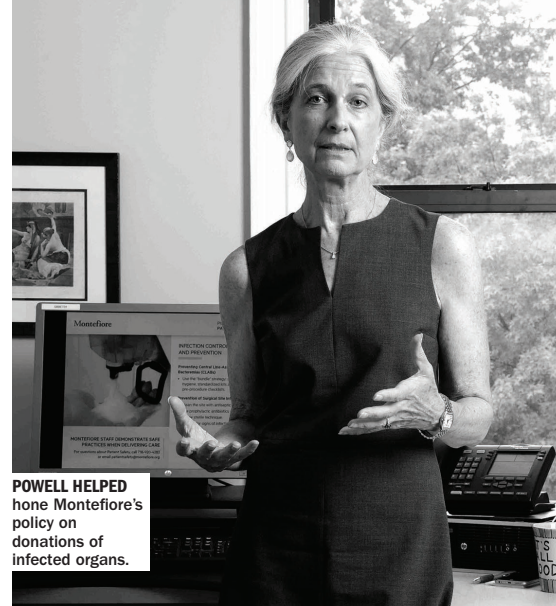
hattan, recently covered a case involving a transplant of a hep C-infected organ, according to a spokeswoman. "If this trend starts to take off, I'm sure it's something that we'd need to address moving forward," she said. "The cost of prescription drugs, especially specialty drugs like Harvoni, is a big driver in our increasing medical costs. If this type of transplant becomes a more widely accepted solution, all plans are going to have to figure out how to approach this."

In July Mount Sinai became the second hospital in New York to transplant a hep C-infected liver into a patient who did not have the disease. Others say it is only a matter of time before they do such procedures. Dr. Nabil Dagher, director of the abdominal-transplant program at NYU Langone Health's Transplant Institute, said that in the next few months he plans to establish a protocol for transplanting hepatitis C-positive kidneys and eventually livers.

Dr. Lewis Teperman, head of transplantation at Northwell Health, said he is also considering it. "I think when you have medications that are so powerful that they can cure 99%-plus of the disease, then it would be best for the patients to accept these organs, especially if they are sick or dying," he said.

Others urge caution. "I think it's great to be thinking about ways to expand the pool of transplantable organs," said Art Caplan, a professor in the division of medical ethics at NYU Langone Health. But he said such transplants should first be viewed as "an experiment, not a treatment."

By this past June Fisher felt good enough to start a part-time internship with an education program for high school students aiming for health care careers.



POWELL HELPED
hone Montefiore's
policy on
donations of
infected organs.

In September he plans to resume his education, albeit closer to home, at William Paterson College, a state school in Wayne, N.J.

Fisher believes others should have the opportunity Montefiore gave him. Already he has watched one fellow patient he befriended in the hospital die while waiting for a liver. "If they have the cure for hepatitis C, I don't know why this isn't the first option for those who are very sick," he said. "It really doesn't make any sense to me to have people waiting when they could have just done this." ■

Additional reporting by Gerald Schiffman

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