Mount Sinai

SPECIALTY REPORT | WINTER 2017

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Division of Nephrology

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MESSAGE FROM THE CHIEF

John Ci-jiang He, MD, PhD

The Division of Nephrology of the Mount Sinai Health System is pleased to share with you our outstanding achievements of 2016, a year in which we increased our *U.S. News & World Report* ranking from No. 23 to No. 11 nationally and our NIH funding to $12 million per year.

In this report, you will read about our achievements in home dialysis—with more than 90 patients, our peritoneal dialysis program is New York City's largest, and our home hemodialysis unit continues to grow as well—and about advances in our uptown hemodialysis clinic, which expanded from 180 to 210 patients over the last year. In 2016, we struck an agreement with DaVita Inc. to open three new dialysis centers in Brooklyn and successfully organized two CME meetings, one on peritoneal dialysis and the other a joint conference with the Renal Research Institute on chronic kidney disease.

The Mount Sinai Hospital is one of four medical centers in the country with federal approval to perform liver and kidney transplants under the HIV Organ Policy Equity (HOPE) Act. We are now performing transplants from HIV-positive donors to HIV-positive recipients under this act, expanding the pool of organs for all.

We are also pleased to describe a new tool that could dramatically improve the process of recruiting patients for clinical trials, as well as a complex case of vasculitis that was solved through a team effort of the many skilled specialists who make up the Mount Sinai Health System. The vasculitis case is but one example of the excellent care that the clinicians and researchers of the Division strive to provide every day, to every patient.

And you will read about breakthrough research by Barbara Murphy, MD, Chair of the Mount Sinai Health System Department of Medicine, whose recent paper in *The Lancet* describes a set of genes that may predict outcomes in renal transplant cases. This study should have a significant impact on the future management of kidney transplant patients. Dr. Murphy has been elected a Councilor of the American Society of Nephrology. When she becomes President of the Society in 2023, she will become the first person to have held leadership positions both there and at the American Society of Transplantation, which she led in 2008–2009. ■

Screening Patients Fast

Tool Simplifies Clinical Trial Enrollment

Researchers in the Mount Sinai Health System's Division of Nephrology and The Charles Bronfman Institute for Personalized Medicine are leading a new initiative to dramatically accelerate the clinical trial prescreening process for kidney patients and to help researchers meet increasingly complex and numerous sets of trial criteria set by pharmaceutical companies.

The Mount Sinai Health System is the first academic institution in the nation to partner with Clinithink, a software developer that has designed a tool known as CLiX ENRICH, a set of algorithms capable of quickly processing large volumes of quantitative and qualitative data from electronic health records (EHRs), including notes handwritten in natural language. The innovative tool has been proven to read 95 percent of medical notes correctly.

Deployment of the tool will greatly reduce the time researchers typically spend sifting through EHRs to identify eligible trial candidates. The tool also generates a far more complete list of candidates than was possible previously.

"This software is a solution to the challenge of manual screening of patients by chart review and in the clinics," says Steven Coca, DO, Associate Professor of Medicine at Mount Sinai and executive sponsor of an evaluation of the program.

The Bronfman Institute and Clinithink conducted a proof-of-concept evaluation for the software in spring 2016. They applied the tool to an ongoing phase III randomized controlled trial run by Bayer for the drug finerenone, a nonsteroidal antimineralocorticoid to treat diabetic kidney disease. CLiX ENRICH located 97 highly eligible patients in three weeks compared with just 6 patients found over three months using standard methods. The trial designated 31 criteria (13 for inclusion and 18 for exclusion), out of which just 7 could be rapidly identified and matched from EHRs using structured data. The remaining 24 unstructured criteria included complex descriptors such as "Subjects with a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II–IV) at the Run-in Visit (class 1A recommendation for MRAs)."

The evaluation team also retrospectively applied CLiX ENRICH to a trial evaluating the drug fresolimumab, developed to treat steroid-resistant focal segmental glomerulosclerosis, a rare kidney disorder. The team found that CLiX ENRICH would have increased trial enrollment from two eligible patients identified over nine months to five patients found within two weeks.

The Mount Sinai Health System plans to roll out the tool, which can read notes scanned into the EHR from outside providers, across various specialties. CLiX ENRICH is compatible with all types of EHR systems as long as they include unstructured data such as progress notes or reports.

"The major bottleneck in clinical trials is finding participants," says Girish N. Nadkarni, MD, Assistant Professor of Medicine (Nephrology) at Mount Sinai and lead investigator for the CLiX ENRICH evaluation. "Generally the problem is not enrolling patients quickly enough. Now our problem will be having a sufficient number of staff to enroll all of the eligible patients." ■

FEATURED STORY

Transplanting HIV-Positive Kidneys

Pioneering Procedure Means More Organs for Everyone

Kenneth Teasley waited five years for a kidney transplant before becoming eligible for an HIV-positive organ.

As an HIV-positive man with end-stage renal disease, Kenneth Teasley has faced more than his share of challenges. Beyond the disease itself, there was the weekly grind of three trips to the dialysis center and "having an 18-gauge needle pushed into your arm each time," as he puts it. So when Mr. Teasley, who had been on a waiting list for a kidney transplant for five years, learned from The Mount Sinai Hospital in the spring of 2016 about his eligibility for an organ from another HIV-positive patient, he leapt at the opportunity.

Recipients need to have well-controlled HIV and no opportunistic infections.

Mount Sinai is the first hospital in New York State and only the second in the country approved to perform kidney and liver transplants from a deceased HIV-positive donor to an HIV-positive recipient under the new federal HIV Organ Policy Equity (HOPE) Act, signed by President Obama in November 2013. That legislation was prompted by a number of factors, including studies (one of them involving Mount Sinai) demonstrating the safety of transplantation in HIV-positive recipients, outcomes of HIV-to-HIV transplants performed in South Africa, the fact that people with HIV were living longer and often dying not from AIDS but from end-stage organ failure, and the ever-growing waiting list and shortage of organ donors in the United States. The act authorized research into HIV-to-HIV transplantation, which is led at Mount Sinai by Sander S. Florman, MD, Director of the Recanati/Miller Transplantation Institute (RMTI).

More than 80 patients with HIV are currently on the waiting list for a kidney at Mount Sinai. The average wait for an organ from a healthy deceased donor in New York State is approximately 8 to 10 years. "We think the HOPE Act could potentially have the greatest impact on increasing the organ donor pool in many, many years," says Brandy Haydel, Clinical Research Program Director at RMTI. "It benefits everyone, including patients who do not have HIV, since when HIV patients are transplanted using HIV-positive donors, more organs become available to others on the waiting list."

Mr. Teasley, who is 50 and has lived with HIV for 23 years, became an early beneficiary on July 13 when he received the kidney of a 46-year-old donor who had HIV but no other complications. The surgery, performed at RMTI, went smoothly, and after a week in the hospital Mr. Teasley returned to his home in the Bronx.

He continues to do well on a standard regimen of immunosuppression medicines and prophylactic antibiotics to prevent infection, according to Rebecca Kent, MD, an assistant professor and nephrologist at Mount Sinai, who has closely managed Mr. Teasley's post-discharge care.

Also supporting the success of HIV organ recipients like Mr. Teasley is the rigorous screening they undergo at Mount Sinai prior to being accepted into the transplant program, along with the careful selection of donors. "Recipients should have well-controlled HIV with no active opportunistic infections, and in the case of donors we want to know their viral load and CD4 counts and whether they have a history of opportunistic infections or [multidrug] resistance," explains Ms. Haydel, who helps oversee the clinical research in which each HIV transplant patient must participate under criteria set by the National Institutes of Health. "Only when we are confident the benefit vastly outweighs the risk will we move forward with the transplant."

Because protease inhibitors are known to interact with calcineurin inhibitors, the main class of antirejection drugs used in these cases, patients are taken off protease inhibitors when possible and switched to other types of antiretrovirals prior to surgery. Patients who cannot be safely taken off protease inhibitors because of resistance or other reasons can remain on that class of medication, but post-transplant immunosuppression management becomes more difficult.

Currently, Mount Sinai is one of 13 hospitals across the country approved to do HIV kidney transplants—a growing network that researchers say could make available up to 2,000 new organs a year in the United States.

For his part, Mr. Teasley says he is "ecstatic" about the outcome. "From day one I was able to get off dialysis and found myself sleeping longer and better. I was also able to get back to cooking and other projects I loved but could only half-complete before." ■

Cover photo: Mount Sinai surgeons conduct a kidney transplant.
Photo credit: Ruth Fremson/ The New York Times/Redux

Taking Dialysis Home

Treating Blood at Night Lets Patient Hold a Full-Time Job

Patients on traditional hemodialysis typically need to take three days out of their week to spend hours in a dialysis center, hooked up to a machine. But Marguerite Niles is able to be dialyzed at home while she sleeps.

Ms. Niles does peritoneal dialysis, in which two liters of fluids are infused into her abdomen to absorb waste products from the blood before being drained two hours later. The process repeats automatically overnight while she sleeps. During the day, she is completely free to move about, go to work, and conduct her life.

"The fluid remains in the belly, and the substances that are in the blood, like urea and creatinine, move across the pores of the peritoneal membrane into the fluid, because there's a diffusion gradient," says Ms. Niles's doctor, Jaime Uribarri, MD, Professor of Medicine (Nephrology) at the Icahn School of Medicine at Mount Sinai. "The peritoneal membrane acts like the artificial kidney we use for hemodialysis."

Only about 10 percent of dialysis patients in the United States are treated with peritoneal dialysis, Dr. Uribarri says, in large part because relatively few doctors are trained in it, even though data collected by the United States Renal Data System show that the long-term prognosis for patients on peritoneal dialysis is the same as for those on hemodialysis. "Medically, there's no significant difference," he says.

For Ms. Niles, 53, a sales representative at a New York City hotel, the benefit is clear: "I'm able to work full-time, which I wouldn't be if I had to go to the clinic for dialysis," she says.

The Mount Sinai Hospital's peritoneal dialysis program, with about 100 patients, is the largest in the New York City metropolitan region. About 60 percent of the patients are on automated peritoneal dialysis (APD) and use some version of a "cycler" machine, such as the AMIA APD system made by Baxter, which Ms. Niles uses. The remainder use continuous ambulatory peritoneal dialysis, which infuses the fluids without a machine throughout the day.

Ms. Niles has sickle cell disease, which resulted in a decline in kidney function starting about two years ago. She learned that she needed to start dialysis in August 2016.

She administers her APD through a plastic tube placed in her abdominal cavity. Because the line is briefly open to the air while being connected to and disconnected from the machine, hygiene is important. "She needs to be very careful to wash her hands, turn off the air conditioning, and close any windows to keep particles out of the air," Dr. Uribarri says.

Ms. Niles says the biggest drawbacks for her have been the length of time the process takes—nine hours per night, which leaves her little time for personal errands after work, since she usually gets up at five o'clock in the morning—and occasional disruptions to sleep while the machine is running. "It's a little disconcerting when I get the prompt from the machine that says I'm either sleeping on top of one of the tubes or need to change my position," she explains.

But learning the system was easy. "The machine tells you what to do. You just have to be aware of your surroundings and remember to put on your mask when you're connecting yourself," she says.

Every month, Ms. Niles sees Dr. Uribarri as well as a nurse, a dietitian, and a social worker. As with all dialysis patients, she takes phosphate binders, erythropoietin injections, and activated vitamin D.

This therapy allows Ms. Niles to have a reasonable life while waiting to receive a kidney transplant sometime in the future.

Peritoneal dialysis is relatively contraindicated for patients with abdominal damage, like colostomy, hernia, or scarring, as well as for those who have pets at home or cannot manage the hygiene regimen. But otherwise, Dr. Uribarri says, it should be offered to all patients who need chronic dialysis therapy. "The main decision has to be based on individual preference—whether to go to a hemodialysis unit where someone does it for them, or for us to teach them to do it at home." ■

Only 10 percent of patients nationally use home dialysis even though it allows much greater freedom.

Mary Grace Gonzales, BSN, RN, CNN, and Jaime Uribarri, MD, demonstrate a cycler machine of the type used in Mount Sinai's home dialysis program.

Improving Dialysis in the Clinic

Innovating to Improve Safety and Quality of Life

The Mount Sinai Health System, in partnership with the Renal Research Institute (RRI), continues to set the standard for the dialysis industry by introducing innovative new technologies that are making dialysis safer and the quality of life better for growing numbers of patients with kidney disease. These advances are taking shape at the Avantus Upper Manhattan Dialysis Center, owned and operated by RRI, under the medical direction of the Division of Nephrology of Mount Sinai St. Luke's and Mount Sinai West.

"Some of the most important innovations involve reducing the risk of infections to patients by delivering dialysate in a much safer way and through ultrapure water filtration," explains Ira Meisels, MD, Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai, Chief of the Division of Nephrology at Mount Sinai St. Luke's and Mount Sinai West, and Medical Director of Avantus Upper Manhattan Dialysis Center. "The new technologies we are piloting will, over time, work their way into dialysis units across the country."

Dr. Meisels and RRI, an arm of Fresenius Medical Care North America, have pioneered new equipment and services at the Center. For example, the emphasis on enhancing patient outcomes by reducing bacteria and other impurities has resulted in the use of an innovative new disposable bicarbonate bag (bi*b*ag®) that is secured to the connector of the hemodialysis machine. The sodium bicarbonate powder from the bag is automatically mixed with water, producing a saturated solution that is proportioned with purified water and an acid component (citrasate) to achieve the prescribed dialysate. In the past, this process took place in a back room in large tanks where the solution was stored and then pumped through lines to each dialysis station. This facility is the first in the country to be designed to eliminate backroom bicarbonate mixing, thus significantly reducing the risk of contamination and bacterial growth from solution storage and delivery.

The use of citrasate is another medically significant step for hemodialysis patients. Citrasate, a newer formulation of the acid component of dialysate, allows significantly lower doses of heparin anticoagulation than those used by most dialysis centers today. "Citrasate lets us avoid potential negative complications of heparin, including bleeding and platelet abnormalities," Dr. Meisels notes. Another patient safeguard that sets the Upper Manhattan Dialysis Center apart from most other units is a computerized water-purification system that helps to ensure microbiological purity. This on-site reverse-osmosis water treatment system converts tap water into ultrapure water for direct delivery to dialysis stations (versus tank storage) by reducing chemicals and impurities in the water by a factor of 100. The system is also heat disinfected and has a secondary loop at each station to prevent stagnant water from collecting in the lines. It further ensures safety and system integrity through continuous online monitoring of water and pressure.

Ira Meisels, MD, left, and Robert Levin, Director of Biomedical Services for the Renal Research Institute, at the Avantus Upper Manhattan Dialysis Center. The tanks behind them, where sodium bicarbonate powder is mixed with water, may soon be replaced by disposable bags that greatly reduce the risk of contamination.

A feature that's more obvious to hemodialysis patients is the state-of-the-art chairs they spend three to four hours in during each clinic visit. Patients can use hand controls to adjust the backs and leg rests for maximum comfort. Staff can also regulate the height of the chairs for injury prevention and better cannulation, and remove the non-porous upholstery for ease of cleaning after each patient.

Another way patients at the Upper Manhattan Dialysis Center benefit is through access to the Mount Sinai Health System's full range of services. "We have very close relationships with vascular surgery, interventional radiology, and cardiology divisions, as well as with Mount Sinai's kidney transplantation program," Dr. Meisels points out. "The Mount Sinai St. Luke's and Mount Sinai West Division of Nephrology, in addition to being the largest provider of dialysis on the Upper West Side, is uniquely equipped to offer patients all the advanced services they might need within the Mount Sinai Health System."

The Center, located at Amsterdam Avenue and 99th Street, is one of three dialysis units with a total of over 400 dialysis patients affiliated with Mount Sinai St. Luke's and Mount Sinai West. ■

Everything—from the chairs to disposable bags—gets a makeover at a Mount Sinai clinic.

Progress on Predicting Graft Loss

Genetics May Help Fine-Tune Transplant Medication

Clinical researchers who are exploring gene expression profiling as a way to identify renal transplant patients in danger of graft damage or loss continued to break important new ground last year, led by Barbara Murphy, MD, Murray M. Rosenberg Professor and Chair of the Samuel Bronfman Department of Medicine at the Icahn School of Medicine at Mount Sinai.

In one major project, the team pinpointed genetic signatures in the blood that were able to show which individuals had underlying rejection inflammation of the graft that was not being picked up by routine lab tests. Through this so-called subclinical rejection approach, researchers were able to stratify transplant patients immunologically into three groups: 1) those with inflammation in their kidneys that was not being detected, 2) an intermediate mix of patients expected to develop fibrosis, which can lead to severe tissue damage and kidney rejection, and 3) those with normal kidney function for whom the prognosis was good.

"By stratifying patients' immunological risk," Dr. Murphy explains, "we've come up with a potential mechanism for managing their immunosuppression in a more appropriate and personalized way than the current standard approach for everybody." That could mean, she elaborates, tailoring therapies to maximize the use of immunosuppressants when people are at risk, and to minimize them when they're not.

Dr. Murphy's lab has also identified several novel mediators of fibrosis in the allograft, with the overarching goal of long-term graft survival. These mediators include the SHROOM3 gene as a potentially important therapeutic target to prevent kidney fibrosis and chronic allograft nephropathy, which results in a progressive decline in function in the renal allograft.

And in a first-of-its-kind finding, a multicenter team of researchers led by Dr. Murphy identified a set of 13 genes that are accurately able to predict whether a transplanted kidney will develop fibrosis at one year, thus making this method superior to standard baseline clinical and pathological variables. Investigators also narrowed the genes down to a predictive set that could be used to identify patients at risk for renal function decline and kidney loss beyond one year.

Results of Dr. Murphy's study, "Genomics of Chronic Allograft Rejection (GoCAR)," were published in July 2016 in *The Lancet*. The study, launched in 2007 at five hospitals in the United States and one in Sydney, Australia, was based on biopsy samples from kidneys at 3 and 12 months after transplantation. Using microarrays, the researchers determined which genes correlated with biopsy samples showing an increased Chronic Allograft Damage Index score at one year and beyond one year.

"This study shows the potential to identify renal-transplant recipients at risk for organ loss prior to the development of irreversible damage," says Dr. Murphy, who joined Mount Sinai in 1997 as Director of Transplant Nephrology and has since become one of the nation's leading transplant researchers. "And that could eventually give doctors the opportunity to change their therapeutic approach to prevent fibrosis from progressing at all. In short, it could change how we monitor and manage all renal transplant patients." ■

Genes are linked to the likelihood that a transplanted kidney will develop fibrosis.

Researcher Is Honored

The American Society of Nephrology (ASN) has elected Barbara Murphy, MD, Murray M. Rosenberg Professor of Medicine, System Chair for the Department of Medicine, and Dean for Clinical Integration and Population Health, as its newest Councilor. Dr. Murphy's seven-year term began during ASN's annual meeting in November 2016 and will culminate in her becoming President of ASN in 2023. At that time, she will be the first and only person to have held leadership positions in the two most prestigious renal associations in the world, the ASN and the American Society of Transplantation. Dr. Murphy was President of the AST in 2008–2009.

Solving a Complex Vasculitis Case

ANCA-Positive and Anti-GBM Disease in the Same Patient

When she fell and broke her shoulder in November 2015, A. had no idea that she'd end up being treated for a combination of kidney problems that few nephrologists ever see in one patient.

Shortly after the shoulder injury, she sought care with a local provider because of increasing shortness of breath, cough, and fever. She was treated with antibiotics but found little relief. So the 75-year-old retired schoolteacher was referred to the noted pulmonologist at The Mount Sinai Hospital, Neil Schachter, MD. The physical findings were nonspecific, and X-rays showed a small right-sided pleural effusion. There were no clinical or laboratory signs of a systemic disorder. By March 2016, however, Dr. Schachter had identified a new rise in her serum creatinine levels, so he referred A. to a Mount Sinai nephrologist, Jonathan Winston, MD.

Teamwork solves "a great teaching case."

A., who asked that her full name not be used, presented with a background of hypertension and pheochromocytoma but otherwise appeared healthy. "When I saw her, she was clinically well," Dr. Winston says. But the combination of breathing and kidney problems led him to suspect ANCA-associated vasculitis. Within three days of that initial visit, ANCA-positivity was identified, a kidney biopsy confirmed vasculitis, and A. was treated with Solu-Medrol (500 g/3 days). Rituximab, as per the PAVE protocol, was scheduled, but a few days later, immunofluorescence studies of the biopsy showed linear staining: evidence of anti–glomerular basement membrane (anti-GBM) antibody disease. An anti-GBM antibody titer came back positive.

The combination of anti-GBM antibody and ANCA-associated vasculitis is unusual, to say the least. "Dr. Winston was shocked," A. says.

The next step was clear: lower the anti-GBM titer. So Dr. Winston switched gears, putting A. on cyclophosphamide and ordering plasmapheresis.

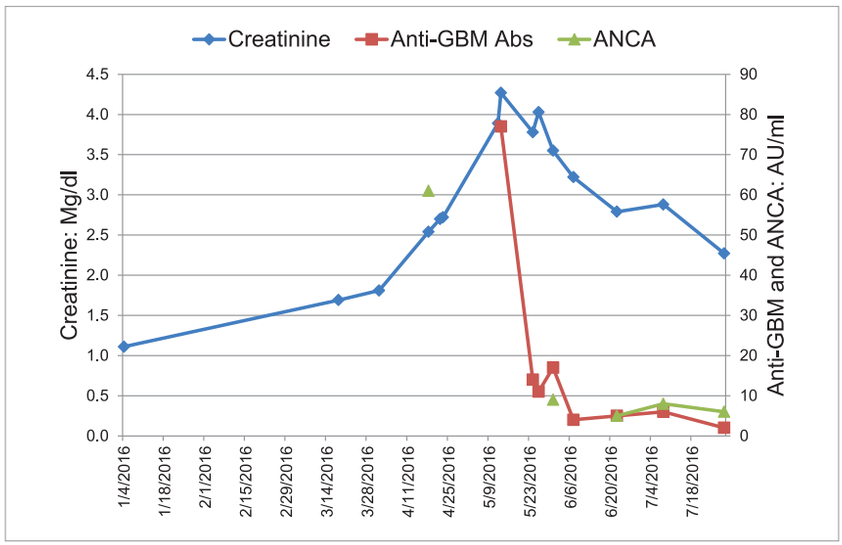
"Once you see the anti-GBM, your goal is to literally get that out of the system," he says. "That's why we did the plasmapheresis. Then we shifted back to the rituximab."

Plasmapheresis is rarely used in renal cases, and because a blood bank is often involved, not every hospital can provide it on short notice. But the Mount Sinai team treating A. was able to begin this treatment within 24 hours of the positive anti-GBM antibody titer.

"This was a great teaching case," Dr. Winston says, crediting colleagues in the Department of Pathology and Laboratory Medicine for identifying the anti-GBM staining of the biopsy. "There is an institutional commitment at Mount Sinai to teaching, research, and patient care, and those complement each other. Our faculty are physician-scientists, researchers, and clinicians. There's such a plethora of outstanding physicians that you can push a button and everybody recognizes that a real problem exists and the most complex care gets mobilized immediately."

A.'s labs tell the story (see chart below). Her anti-GBM was 77 AU/ml when first tested but fell to 14 within two weeks of therapy and below 10 by four weeks. She was maintained on cyclophosphamide and switched over to rituximab. A.'s ANCA was 61 AU/ml but became undetectable, and her creatinine, 2.54 mg/dl when she first saw Dr. Winston, climbed as high as 4.8 but weeks later was at 2.31.

"I was at renal failure, actually, when I first went to Dr. Winston. But you'd never know it by looking at me," she says. "I knew something was wrong with me, but I didn't know what. In the beginning, this was very, very scary. I didn't know if I needed dialysis. I didn't know if I needed a kidney transplant. I'm very happy and lucky. Dr. Winston is an excellent doctor." ■



Patient A.'s creatinine and anti-GBM antibodies responded rapidly to plasmapheresis and rituximab.

BEST HOSPITALS U.S.News & WORLD REPORT HONOR ROLL 2016-17

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QUICK FACTS

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

RANKED No.1
AMONG PRIVATE MEDICAL SCHOOLS IN TOTAL RESEARCH DOLLARS PER PRINCIPAL INVESTIGATOR

$290 MILLION
IN TOTAL NIH FUNDING

MOUNT SINAI HEALTH SYSTEM

7,100+
PHYSICIANS

THE MOUNT SINAI HOSPITAL
RANKED No.15
NATIONALLY BY *U.S. NEWS & WORLD REPORT*

4 MILLION
ANNUAL PATIENT VISITS

2016 OUTCOMES HIGHLIGHTS

43 PERCENT
REDUCTION IN C. DIFFICILE INFECTIONS

22 PERCENT
REDUCTION IN PATIENT SAFETY INDICATOR INPATIENT HARM EVENTS
(Medicare patients)

2016 DIVISIONAL HIGHLIGHTS

RANKED No.11
NATIONALLY IN *U.S. NEWS & WORLD REPORT*

90,000+
CKD PATIENTS CARED FOR EACH YEAR

Faculty Practice Associates
212-241-4060

Mount Sinai Kidney Center at East River Plaza
520 East 117th Street
Fourth Floor
New York, NY 10128
212-987-7208

Mount Sinai Kidney Center Home Dialysis Programs
1450 Madison Avenue
(at 99th Street)
New York, NY 10029

Peritoneal Dialysis
212-241-5537

Hemodialysis
212-241-4967

Mount Sinai Kidney Center B1 Renal Unit
1450 Madison Avenue
(at 99th Street)
New York, NY 10029
212-241-8081

Kidney Disease Associates
5 East 98th Street
(between Madison Avenue and Fifth Avenue)
New York, NY 10029
212-241-4060

Mount Sinai Renal Clinic Center for Advanced Medicine Internal Medicine Associates
17 East 102nd Street
(between Madison Avenue and Fifth Avenue)
New York, NY 10029
212-659-8551

Dialysis for Traveling and International Patients
212-241-9780

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