A year of two milestones

In 2013, Cleveland Clinic marked the 50th anniversary of its first kidney transplant while achieving another milestone by performing the most kidney transplants in a single year — 184 — in the program’s long history.

The kidney transplant program’s graft and patient survival rates compare favorably with national norms, as detailed in the graphs on the following pages. Notable outcomes from the January 2014 report of the Scientific Registry of Transplant Recipients (SRTR) include:

- 36.3-month median time to transplant, one-third shorter than the national median of 54.3 months (see graph, p. 14)
- One- and three-year adult graft survival rates of 94.61 and 89.71 percent, respectively, which are at or above risk-adjusted expected levels and national averages (see graphs, next page)
- Three-year adult patient survival rate of 95.25 percent, exceeding the risk-adjusted expected level and the national average by 3 percentage points
- 100 percent one-year kidney graft survival for simultaneous kidney-pancreas transplants
- 11.3-month median time to transplant for kidney-pancreas transplants (vs. national median of 14 months)

Rise in living-donor transplants bucks national trend

The 184 kidney transplants in 2013 represent a 12 percent increase from 2012. The growth was partly due to an increase in living-donor transplants, which totaled 81 in 2013, representing 44 percent of overall kidney-only transplants.

The program’s rise in living-donor transplants bucks a national trend of declining living-donor kidney transplants. Living donation is generally the best option for recipients because it can provide a very high-quality kidney and the ability to optimally plan the transplant surgery.
More than 90 percent of living-donor procedures in 2013 were performed using laparoscopic techniques. Cleveland Clinic surgeons were instrumental in the development of such techniques beginning in the 1990s, and the program has performed more than 1,000 laparoscopic living-donor nephrectomies to date.

Dual-organ transplant is a setting in which deceased-donor kidneys continue to be essential. In 2013, the surgical team performed 20 dual-organ transplants:

- 11 kidney-pancreas
- 7 kidney-liver
- 1 kidney-heart
- 1 as part of a multivisceral transplant

National Kidney Registry brings more paired donations

One reason Cleveland Clinic has defied the trend against living-donor growth is its participation in the National Kidney Registry to facilitate paired donation, which allows most participating patients to receive a living-donor kidney within six months. Since the program began working with the National Kidney Registry in 2011, it has enabled Cleveland Clinic to perform 22 living-donor kidney transplants (as of the end of 2013) that otherwise would not have been done.

In 2013, Cleveland Clinic ranked seventh out of 75 programs nationally in National Kidney Registry participation volume.

Incompatible donors' kidneys are procured in Cleveland and shipped to recipients elsewhere in the U.S. In return, Cleveland Clinic recipients have received organs from as far away as California. Recipients have fared well, and all grafts have functioned.

In 2013, Cleveland Clinic participated in the second-longest chain of paired donations to date, the 28-patient “Chain 221.” Starting donation chains with altruistic donors has resulted in some transplants in the absence of a reciprocal donor through the registry’s CHIP (Children and High PRA) program for children and highly sensitized patients.

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When Cleveland Clinic marked the 50th anniversary of its kidney transplant program in 2013, Patricia Kunkle was the most appropriate person on hand for the celebration.

A 66-year-old resident of Rocky River, Ohio, Patricia embodies the program’s longevity better than anyone alive today, as the kidney she received from her mother at Cleveland Clinic in 1968 is still serving her well, 46 years later. Since her mother was 46 at the time of the transplant, that means Patricia’s healthy kidney is 92, a remarkable transplant achievement. In the decades since her transplant, Patricia has been able to give birth to and raise three children, earn bachelor’s and master’s degrees, and retire after a career spanning more than 30 years.

“I remember waiting a long time for the transplant surgery because they didn’t have the tissue matching like they do now,” recalls Patricia, who needed the transplant after her kidneys began to shut down secondary to lupus.

“It was just unbelievable how good I felt after the transplant,” she says. “It was like night and day. From there, every day has been a good day.” She adds: “Cleveland Clinic looked at my whole being, not just my kidney. I would never go anywhere else.”

Patricia Kunkle with her mother and kidney donor Jane Malloy one month after her 1968 transplant (left) and last year at the 50th-anniversary celebration for Cleveland Clinic’s kidney transplant program (right).

Patricia Kunkle: A Thriving Testament to Five Decades of Transplantation

PATRICIA KUNKLE: A THRIVING TESTAMENT TO FIVE DECADES OF TRANSPLANTATION

RYAN HULEC: PROOF OF THE POWER OF THE NATIONAL KIDNEY REGISTRY

Full-time student Ryan Hulec struggled with chronic kidney disease but managed to avoid dialysis, thanks to Cleveland Clinic’s participation in the National Kidney Registry and his mother’s generosity.

While not a match for her son, Ryan’s mother agreed to donate her kidney, enabling Ryan to more swiftly obtain a kidney from another living donor. Ryan’s transplant at Cleveland Clinic was a success, and the now 23-year-old Valley View, Ohio, resident is back at school — and his mother is back at work. Both are grateful for Ryan’s renewed health — and for their opportunity to help another patient who was in Ryan’s shoes somewhere else in America.

Ryan Hulec with his mother and kidney donor Carol Badinger one month after his 2012 transplant (left) and last year at a National Kidney Registry celebration (right).
Short wait times, rapid evaluation, declining length of stay

These aggressive efforts to support living-donor transplants have helped give Cleveland Clinic the shortest kidney waitlist time in Northeast Ohio and a transplant rate that exceeds expectations based on SRTR data. Cleveland Clinic’s median wait time of 36.3 months for patients listed from July 1, 2007, to December 31, 2012 (the most recent data period), is:

- One-third shorter than the national median of 54.3 months
- Shorter than the regional (OPTN Region 10) median of 40.7 months and the local Donation Service Area median of 46.7 months

A number of additional efforts have contributed to the program’s success in trimming wait times:

- To counter the nationwide organ shortage, the program has extended use of the deceased donor pool by using pediatric en bloc and dual adult kidneys and has increased use of organs donated after determination of cardiac death.
- A waitlist IV immunoglobulin desensitization program has been started to enhance transplant opportunities for highly sensitized patients.
- The program takes a proactive, highly communicative approach with patients on the waitlist to ensure that as many as possible are fully ready to be transplanted on short notice.

Additionally, recent operational efficiencies in the program resulted in 60 percent reductions from 2010 to 2013 in:

- Mean time from referral to evaluation for transplant (reduced to 45 days in 2013)
- Mean time from evaluation to wait-listing (reduced to 33 days in 2013)

Post-transplant hospital length of stay (LOS) was also on the decline for the program in 2013. Improved management of the transition from hospital to outpatient care resulted in a reduction in LOS to 5.71 days, the lowest in four years.
Cleveland Clinic’s kidney transplant program has become one of the widest-reaching programs of its kind in the world, with one of the largest collective volumes in the nation — 278 across all U.S. locations in 2013. In addition to the flagship program in Cleveland, kidney transplants (living-donor as well as deceased-donor procedures) are performed by Cleveland Clinic transplant physicians at the following sites:

**CLEVELAND CLINIC FLORIDA**
155-bed Cleveland Clinic hospital in Weston, Fla.
- Program launched in April 2013 under the directorship of world-renowned transplant surgeon Andreas Tzakis, MD, PhD, with an experienced team of surgeons and nephrologists (see p. 7)
- Operated in close collaboration with Cleveland Clinic’s Cleveland program under a “one program” model involving shared protocols, some shared staff, joint patient selection meetings, shared EMR and transplant database, and regular and frequent communications
- 7 kidneys transplanted in 2013
- Patient and graft survival of 92 percent during first 11 months of operation
- Approved by CMS and UNOS

**CHARLESTON AREA MEDICAL CENTER**
Charleston, W.Va.
- An affiliation with Cleveland Clinic since 1987 for kidney transplants and urologic care
- Program team includes Cleveland Clinic transplant surgeon Joseph Africa, MD (program director), certified clinical transplant coordinators, a dietitian, a social worker, attending nephrologists and other clinical support personnel with a supporting histocompatibility lab
- More than 1,000 kidney transplants to date, including 43 in 2013
- Only kidney transplant program in West Virginia
- Approved by CMS and UNOS

**ST. VINCENT TRANSPLANT SERVICES**
Indianapolis
- A partnership between Cleveland Clinic and St. Vincent Indianapolis Hospital since December 2008 for kidney and pancreas transplant services
- Program comprises a dedicated 11-bed unit for kidney transplant patients, an outpatient transplant clinic and a histocompatibility lab
- Directed by Alvin Wee, MD, with support from attending surgeon Islam Ghoneim, MD, PhD, both of whom are renal and pancreatic transplant surgeons with Cleveland Clinic’s Glickman Urological & Kidney Institute
- More than 200 kidney transplants to date, including 44 in 2013, and more than 400 referrals for evaluation annually
- Median time to transplant of 14.8 months, one of the shortest in the nation (national median of 54.3 months)
- Program performed its first simultaneous kidney-pancreas transplant in 2013
- Approved by CMS and UNOS

**SHEIKH KHALIFA MEDICAL CITY**
Abu Dhabi, United Arab Emirates (UAE)
- Cleveland Clinic has provided clinical and logistical support for the kidney transplant program at Sheikh Khalifa Medical City in Abu Dhabi, UAE, the only transplant program in the country, since the program’s inception in 2007
- Longtime Cleveland Clinic transplant surgeon Bashir Sankari, MD, took part in Sheikh Khalifa Medical City’s first cadaveric kidney transplant in 2013 after moving to Abu Dhabi in 2012 to practice at Cleveland Clinic Abu Dhabi
- Performed 30 kidney transplants in 2013, its highest annual count to date, including the program’s 100th kidney transplant
- UAE’s legal adoption of a brain death policy laid the groundwork for development of a multiple-organ deceased-donor transplant program at Cleveland Clinic Abu Dhabi after that facility opens in 2015 (see photo above)
Collaborative expert care — conveniently delivered

Kidney transplant patients benefit directly from the multidisciplinary nature of Cleveland Clinic’s Glickman Urological & Kidney Institute, which brings together urologists and nephrologists in an organizational structure designed to pool expertise and promote collaborative management.

Transplant services are also supported by a large dialysis program and the collective clinical acumen of the Urological & Kidney Institute, whose surgeons bring long-standing expertise in complex renal vascular anatomy and renal anomalies. That expertise is reflected in the institute’s ranking among the nation’s top 2 urology and nephrology programs by *U.S. News & World Report* for multiple consecutive years — and as the No. 1 urology program in 2014-15.

When a patient with end-stage kidney disease is evaluated for transplant, he or she meets in a single care space with a team comprising transplant urologists, transplant nephrologists and other providers. The patient’s evaluation day includes an educational session and visits by transplant physicians, transplant coordinators, social workers, financial counselors and nutritionists.

Advancing the science of kidney transplantation

Cleveland Clinic has a rich history of advancing the care of patients with kidney failure — from the work of Willem Kolff, MD, PhD, to perfect his dialysis machines here in the 1950s, to establishment of one of the first kidney transplant programs in 1963, to pioneering contributions in minimally invasive kidney surgery in the 1990s and beyond.

That tradition continues today across many areas of kidney transplant-related research. Below is a sampling of projects active or published in 2013.

**Building a biorepository.** Novel biomarkers are fast emerging in basic kidney and pancreas transplant research, but their validation for clinical application requires repetitive tissue sampling in a sizable patient cohort. Cleveland Clinic is one of the few centers that can combine tissue samples from large numbers of transplant recipients with the advanced infrastructure and expertise needed to meet the challenge.

The kidney transplant program got started on that challenge in 2012 by establishing a Renal Transplant BioBank. The goal is to create a patient-linked repository for biologic samples (blood, urine and graft biopsy tissue) for use in research studies related to metabolic, inflammatory and immunologic markers relevant to kidney and pancreas transplant.

**Leading a trial of a targeted approach to acute rejection.** Organ recipients receive induction therapy with antibodies to make their immune system less able to mount an initial rejection response. Unfortunately, current induction agents, such as anti-thymocyte globulin, have drawbacks related to long-term immune suppression and other immune-mediated side effects.

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In search of a safer approach for preventing acute kidney rejection, researchers are studying TOL101, a novel monoclonal antibody that targets a highly specific immune cell type critical to the acute organ rejection response. Cleveland Clinic kidney transplant surgeon Stuart Flechner, MD, is serving as national principal investigator for a multicenter study comparing TOL101 with anti-thymocyte globulin for preventing kidney graft rejection when used as part of an immunosuppression regimen including steroids, mycophenolate mofetil and tacrolimus.

**Using big data to assess safety of living kidney donation.** Living-donor kidney donation is safe and has been getting safer. Those are among the conclusions of a Cleveland Clinic-led research team that published two unprecedented analyses of more than 69,000 living donors between 1998 and 2010. The team found that the incidence of perioperative complications among donors fell from 10.1 to 7.6 percent over that period and that donors’ length of hospital stay declined from nearly four days to less than three days. Complication rates and length of stay were highly comparable with those of other low-risk abdominal surgeries, such as appendectomy. A second analysis found that rehospitalizations among living donors were lower than among patients with comparable surgical procedures but were higher among donors with particular characteristics. The data are assisting in the counseling of living donors around the nation.


**Deep-rooted pediatric program**

In April 1963, just three months after completing its first adult kidney transplant, Cleveland Clinic performed its first pediatric kidney transplant — one of the earliest successful pediatric transplants in the nation.

Since then, the program has transplanted 363 kidneys in patients under age 21. It is northern Ohio’s only pediatric program with a dedicated outpatient pediatric dialysis unit, located at Cleveland Clinic Children’s Hospital for Rehabilitation.

A team of kidney transplant surgeons with expertise in pediatric transplant is supported by a dedicated pediatric kidney transplant medical director, three additional pediatric transplant nephrologists and a growing team of pediatric urologists.

Their collaboration helps produce routinely positive outcomes in pediatric patients, including 100 percent one-year and three-year pediatric patient and graft survival rates in the January 2014 SRTR report.