Cleveland Clinic

GLICKMAN UROLOGICAL & KIDNEY INSTITUTE

2019 Year in Review

CONTENTS

ON THE COVER

Georges Nakhoul, MD, Director of the Center for Chronic Kidney Disease, launched a virtual reality program to enhance the renal physiology learning experience for trainees.

AT A GLANCE

Glickman Urological & Kidney Institute

The Glickman Urological & Kidney Institute's activities encompass a unique combination of high-volume and challenging clinical cases, extensive basic and translational scientific efforts, and innovative laboratory research conducted in an environment that nurtures the future leaders of its specialties.

BY THE NUMBERS

(2019)

132,663
OUTPATIENT VISITS

14,098
SURGICAL CASES

21,255
DIALYSIS TREATMENTS

3,029
ADMISSIONS

12,116
PATIENT DAYS

4.0
AVG. LENGTH OF STAY (DAYS)

VITAL STATISTICS & RANKINGS

INSTITUTE VITAL STATISTICS	
65	Urologists
28	Nephrologists
33	Advanced Practice Providers
30	Urology Residents
22	Urology Fellows
9	Nephrology Fellows
292	Caregivers

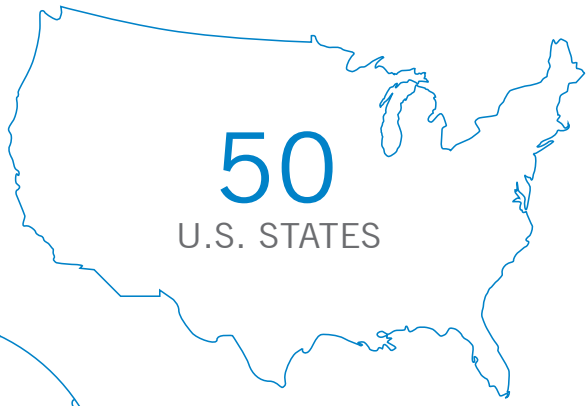
SURGICAL CASES	
532	Benign Prostatic Hypertrophy
1,157	Endourology and Stone Disease
1,555	Female Pelvic Medicine and Reconstructive Surgery
235	Male Fertility
642	Pediatric Urology
429	Genitourinary Reconstruction
204	Renal and Pancreas Transplant
3,256	Urologic Oncology

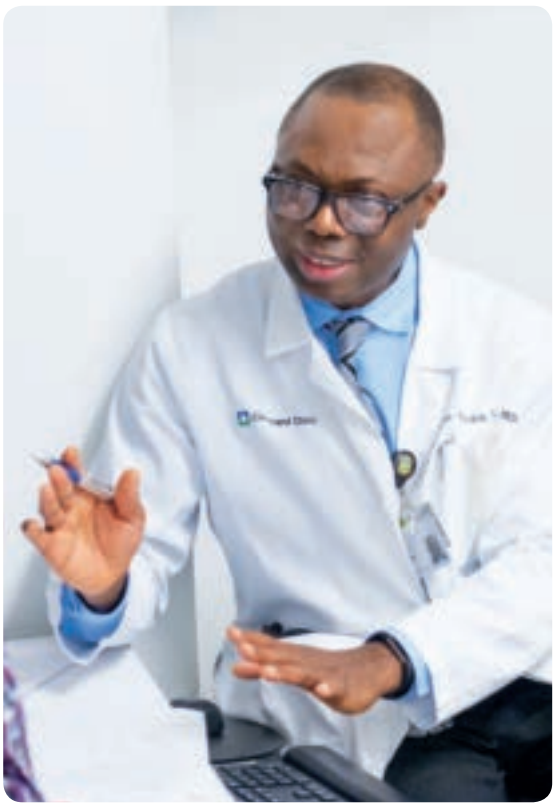
BEST HOSPITALS U.S.News & WORLD REPORT NATIONAL UROLOGY 2019-20

BEST HOSPITALS U.S.News & WORLD REPORT NATIONAL NEPHROLOGY 2019-20

U.S. News & World Report has consistently ranked Cleveland Clinic urology and nephrology among the country's top programs for the past two decades.

PATIENT ORIGINS





CENTERS

DEPARTMENT OF NEPHROLOGY

- Blood Pressure Disorders
- Chronic Kidney Disease
- Dialysis
- Kidney Stones
- Renal and Pancreas Transplant
- Renal Diseases

DEPARTMENT OF UROLOGY

- Endourology and Stone Disease
- Female Pelvic Medicine and Reconstructive Surgery
- Genitourinary Reconstruction
- Male Fertility
- Men's Health
- Minority Men's Health
- Pediatric Urology
- Renal and Pancreas Transplant
- Robotic and Image-Guided Surgery
- Urologic Oncology

MESSAGE FROM THE CHAIRMAN

DEAR COLLEAGUES,

I am humbled and honored once again to present Cleveland Clinic Glickman Urological & Kidney Institute's 2019 *Year in Review*. I hope you will view this publication as a reflection of our commitment to advancing patient care, leading research discoveries and training the next generation of physicians.

We are extraordinarily proud to have received the distinction of best nephrology and urology programs, respectively, in Ohio in the 2019 *U.S. News & World Report* "Best Hospitals" survey. Our training programs also continue to attract rising stars within the two fields.

Our nephrology fellowship programs (nephrology and hypertension, and kidney transplant) offer a unique, didactic training experience. As you will read, we recently announced a virtual-reality program through the Oculus Quest® platform to enhance the learning experience and knowledge base for our nephrology fellows. We are also proud to share that our urology residency program once again earned a top ranking in the Doximity Residency Navigator for the 2019/2020 academic year.

Our team continues to demonstrate innovation in robotic and image-guided surgery. This year we were the first in the world to perform a kidney transplant using the daVinci SP® Surgical System. Our kidney and pancreas transplant program, a collaborative effort between Nephrology and Urology, had another record-breaking year in transplant volume and outcomes.

We are also pleased to be at the helm of clinical innovation in our female pelvic medicine program. Our team recently launched a clinical trial using the UroMonitor, a wireless device that is designed to monitor bladder function in real time.

In other clinical innovations, our nephrology and hypertension team, which was again recognized as a Comprehensive Hypertension Center — one of only eight in the nation — continues to expand its ambulatory blood pressure monitoring program. The center provides 24-hour monitoring for a large cohort of patients to accurately diagnose and treat blood pressure disorders.

In 2018, we launched the Center for Genitourinary Malignancies Research, a virtual center designed to accelerate research findings to advance diagnostic and therapeutic approaches for patients with cancers of the prostate, kidney and bladder. The generosity of patients has allowed us to establish two endowed chairs for this program, which we will use to recruit new faculty to expand this work.

These achievements, above all, illustrate our commitment to delivering the best possible care to patients. As Teddy Roosevelt once observed, "Nobody cares how much you know, until they know how much you care." Everything we do is in the service of caring for patients.

Thank you for your interest in our program. I hope you enjoy reading about the Glickman Urological & Kidney Institute.

Sincerely,

Eric A. Klein, MD

Chairman, Glickman Urological & Kidney Institute
Professor, Cleveland Clinic Lerner College of Medicine

LEFT — ERIC A. KLEIN, MD

2019 HIGHLIGHT

TWO CLINICAL TRIALS, ONE AMBITIOUS GOAL TO PERSONALIZE KIDNEY MEDICINE

Cleveland Clinic began enrolling its first patients in two multicenter, NIH-sponsored studies this year. Both trials aim to develop personalized strategies to prevent, treat and manage kidney disease.

John Sedor, MD; Emilio Poggio, MD; and John O'Toole, MD, nephrologists in the Glickman Urological & Kidney Institute, lead the Cleveland Clinic arm of the Kidney Precision Medicine Project (KPMP) as one of six recruitment sites — and 14 institutions overall — involved in the study.

The primary goal of the KPMP is to understand and differentiate kidney disease phenotypes at a genetic and molecular level. The leaders of this initiative hope this information, taken together with clinical data, will lead to personalized approaches to treat diabetes, hypertension, and acute and chronic kidney diseases.

"This is where we must improve. Therapeutic development for kidney disease has lagged behind over the last decade or so," says Dr. Sedor. "There is no one-size-fits-all approach to treating patients with kidney disease. We need more targeted therapies."

The strategy is to build a robust repository of patient samples and leverage new research technologies to investigate kidney disease in a patient — or a particular set of patients — in the context of environment, lifestyle and genetics.

Dr. Poggio is also an investigator on the APOL1 Long-term Kidney Transplantation Outcomes Network (APOLLO) study. It also just enrolled its first patient this year. Cleveland Clinic is one of 13 clinical centers in the U.S. that will prospectively enroll living kidney donors and recipients of kidney transplants from donors of African descent. These transplants have an increased risk of carrying *APOL1* gene mutations.

"We know the *APOL1* genetic variant has origins in West African countries and is associated with chronic and progressive kidney disease," says Dr. Poggio. "We are examining the implications of the mutations on kidney transplant recipient outcomes."

This work complements the ongoing basic investigations in Cleveland Clinic Lerner Research Institute to identify the mechanisms by which *APOL1* causes progressive kidney diseases, in the laboratories of Drs. Sedor, O'Toole and Leslie Bruggeman, PhD, another staff member working in this area. They are all consultants on this project.

Patient and community-centered involvement

Further, Dr. Poggio notes that both the KPMP and APOLLO studies foster patient and community-centered involvement, something he has seldom observed in studies at this scale. There is a council of patients and community members who work alongside the team to develop study protocols, including consent documents. "They come to every meeting. They participate in every phone call," he says. "It is very helpful for them to be involved in the entire process — from the question to the answer."

For KPMP, patients are chiefly concerned with shaping safety protocols, which is important as biopsy does have some inherent risk. *APOL1* disproportionately affects patients in the African American community, so having these patients involved in the conversation about protocol development for the trial has been very helpful and important, notes Dr. Poggio.

Dr. O'Toole remarks that both research initiatives illustrate a tipping point in kidney medicine. "The prevalence of large multisite, federally funded trials like KPMP and APOLLO, in addition to growing patient and community advocacy efforts, is undoubtedly proof of this."

RIGHT — EMILIO POGGIO, MD; JOHN SEDOR, MD; AND JOHN O'TOOLE, MD


Cleveland Cl
Nima Sharifi, M.

2019 HIGHLIGHT

A NEW PARADIGM FOR ADVANCED PROSTATE CANCER CLINICAL TRIALS

The current paradigm for advanced prostate cancer clinical trials is based on an imperfect framework, says Nima Sharifi, MD, oncologist and prostate cancer researcher.

Along with focusing on evidence, like whether patients have metastatic disease and had previous treatments, he is calling for prioritization of the mechanistic underpinnings of the individual patient and tumor in clinical trials.

Dr. Sharifi, Director of Cleveland Clinic's Center for Genitourinary Malignancies Research and the Kendrick Family Endowed Chair for Prostate Cancer Research, notes that the path to curative therapies may be more efficient if researchers begin with the genetic context of the host — the patient in whom the tumor is growing — and the genetic context of the tumor, which is enabling its growth.

"It's essential that we aim to understand what's driving tumor progression, what treatment will have benefit and for which patients," he says.

His landmark research has focused on prostate oncogenesis, the biology of androgen metabolism and mechanisms of androgen deprivation therapy resistance in advanced prostate cancer. The androgen receptor is a primary driver in advanced prostate cancer and should be central to these investigations, he asserts.

What questions should researchers ask?

Dr. Sharifi proposes that the following questions be central to the framework of these investigations: "Does the tumor need androgen?" and "Does the tumor get androgen?"

There are a variety of studies, he says, that address the first question to determine whether a tumor expresses the androgen receptor and whether it's dependent on androgens. Gene expression signatures have also been developed, using the somatic context of the tumor itself. Other studies have shown that when certain tumor suppressor genes are eliminated, tumors are less addicted to androgens and are basically autonomous.

Whether the tumor gets androgen is a different question. Adrenal DHEA (dehydroepiandrosterone, an androgen precursor) can be sequentially converted by enzymes to testosterone or DHT (5α-dihydrotestosterone). The enzyme 3βHSD1 is required for all pathways to get from extragonadal androgen precursors to the most potent DHT. The gene that encodes for the enzyme is *HSD3B1*.

There's a very common germline variant where the protein coding change differs substantially and, in some cases, may even be associated with race. This protein coding can be categorized as an adrenal-restrictive genotype or an adrenal-permissive genotype. The former encodes for a protein that's rapidly degraded, so there is very slow conversion from DHEA to DHT, leading to low levels of DHT synthesis. The latter encodes for a stable protein, with rapid conversion from DHEA to DHT and high levels of DHT in the tumor tissue. This opens the floodgates to DHT, allowing for clinical progression to castration-resistant disease.

Putting it in context

"Patients with an adrenal-permissive genotype and an androgen receptor-dependent tumor probably would respond better to androgen annihilation, while patients who are adrenal restrictive and whose tumor is androgen receptor indifferent may benefit to a greater extent from something else — maybe taxanes or an experimental agent," says Dr. Sharifi.

As for changing the clinical trial design, he notes that it's up to the stakeholders. "My hope is for continued discourse that enables us to recast the aims of clinical trials to expedite personalized therapies for patients with advanced prostate cancer."

LEFT — NIMA SHARIFI, MD

2019 HIGHLIGHT

ANOTHER LANDMARK YEAR FOR CLEVELAND CLINIC'S KIDNEY TRANSPLANT PROGRAM

Cleveland Clinic's Kidney Transplant Program had another landmark year, completing nearly 230 kidney transplants — the most the program has performed in a single year to date. Adding to that, the team led the world's first single-port robotic kidney transplant in 2019.

Alvin Wee, MD, MBA, Surgical Director of the Renal Transplantation Program, notes that this growth and innovation is, in large part, due to several strategic developments, including increased living donor utilization, more patient and community outreach, and new virtual clinics.

Strong living donor program

In 2019, the program had 75 living kidney donors, a number that puts Cleveland Clinic among the most prolific living donor programs in the U.S. "For patients, this means there is a higher chance for doing internal pair exchanges at Cleveland Clinic," says Dr. Wee.

Two years ago Dr. Wee led the institution's first three-way internal swap. While the team is accustomed to frequent two-way kidney swaps, a three-way exchange at a single institution is more logistically cumbersome. The renal team continues to move the program in this direction and is actively planning larger internal pair kidney chains in 2020.

While the external pair exchanges program remains a resource for donors and recipients across the country, there are significant considerations, including the time and logistics associated with organ transportation. "The bottom line is that internal kidney exchanges give clinicians and patients more autonomy and, as a result, an improved clinical experience," says Dr. Wee.

Education and outreach for patients

The team has also aligned efforts to bring greater education and awareness about kidney transplant to patients in the community, which has helped create a meaningful dialogue about living and nonliving transplant.

Cleveland Clinic hosted an interactive workshop in partnership with the National Kidney Foundation. The event provided strategies and resources for patients on how to educate family and friends about the transplant process. Dr. Wee notes that with more education and discussion around the living donor conversation, the more normalized it will become for both donors and recipients.

The team also hosted a second successful kidney symposium with allied medical partners. The symposium provides education about the process and hurdles of transplant. Ultimately, the goal of the collaboration is to make more patients aware of transplantation options.

Virtual clinics support clinical efficiency

Additionally, telehealth initiatives, like virtual transplant clinics, have helped create efficiencies in the evaluation of potential recipients who live away from Cleveland Clinic's main campus. Historically, this assessment required the entire care team (nephrologist, surgeon, nurse coordinator, social worker and dietitian) to see the patient. Web-based technology, web cameras and electronic medical records allow one team member to interview the patient on-site while the virtual session is made available to the entire care team for evaluation.

"The goal is to utilize this technology and expand our virtual platform to provide clinics in different regions around Ohio," says Dr. Wee. "It's all a part of our goal to make kidney transplant accessible for those who need it most."

RIGHT — ALVIN WEE, MD


Cleveland Clinic

2019 HIGHLIGHT

GETTING IT RIGHT: NEPHROLOGISTS ARE WORKING TO MINIMIZE THE 'WHITE-COAT EFFECT' FOR PATIENTS WITH HYPERTENSION

When it comes to blood pressure screenings, clinical settings are not ideal. This is due to a variety of factors — notably, patient anxiety, or the "white-coat effect" — which may affect measurement accuracy and contribute to misdiagnosis.

Studies show that between 20% to 30% of patients who exhibit hypertension in a clinician's office are normotensive in nonmedical settings.

To address this, nephrologists in Cleveland Clinic's Glickman Urological & Kidney Institute emphasize the use of ambulatory and home blood pressure (BP) monitoring to diagnose and confirm hypertension.

George Thomas, MD, Director of the Center for Blood Pressure Disorders, notes that this is also in response to new hypertension guidelines from the American College of Cardiology and American Heart Association (ACC/AHA) that redefined hypertension as BP ≥ 130/80 mm Hg and revised the target BP to < 130/80 in most patients.

The team is also involved in a pilot project for remote home BP monitoring that automatically transmits home BP readings to the patient's Cleveland Clinic electronic medical record to assist with ongoing assessment of their care plan.

Ambulatory and home monitoring to diagnose and manage hypertension

"Ambulatory blood pressure monitoring (ABPM) and home monitoring programs are typically more representative of a patient's usual blood pressure," notes Dr. Thomas.

For ABPM, patients are provided with a wearable, automated device that collects measurements during a 24- to 48-hour period, with a frequency of every 30 minutes during daytime and every 60 minutes while the patient sleeps.

ABPM is the preferred methodology for out-of-office blood pressure monitoring, according to ACC/AHA guidelines. However, due to cost, minimal insurance reimbursement and many clinicians' unfamiliarity with its utility, it is not routinely available in medical offices. This makes home monitoring — cost-efficient and a solution to office-induced hypertension — a viable option in the diagnosis and management of high BP.

However, it's essential that patients are trained on how to accurately obtain the measurement at home. The clinician should check the patient's home monitor for accuracy initially and at least yearly thereafter. Patients or their caregivers should learn correct BP measurement techniques.

Optimize in-office measurements

ABPM and home monitoring aren't always available due to issues of cost and access. Dr. Thomas urges clinicians to explore how in-office evaluations can be optimized to minimize the white-coat effect and/or user errors.

For example, oscillometric devices that use an electronic pressure sensor to record arterial pressure oscillations and calculate BP are preferable to auscultatory devices, which are largely dependent on the operator's training and experience. Automated devices that are capable of measuring and averaging multiple readings with the patient alone in the room are preferred. Cuff size and placement, patient position, pain, and stress and anxiety associated with the office visit are other variables that can influence the accuracy of the measurement.

"There are some variables we do have control over," says Dr. Thomas. "We should focus on optimizing those for improved results, including proper cuff size and patient positioning, and use of automated devices to minimize the white-coat effect."

LEFT — GEORGE THOMAS, MD

2019 HIGHLIGHT

‘A FITBIT FOR THE BLADDER’: UROMONITOR TAKES MONITORING OUT OF THE CLINIC

A wireless, insertable pressure sensor to assist in the diagnosis of urinary incontinence is now one step closer to clinical application in patients. The team is actively recruiting patients for a trial that began in early 2020.

“Our vision is to take the monitoring out of the clinic and take the catheter out of the monitoring,” says Margot Damaser, PhD, who created and oversees development of the UroMonitor.

Dr. Damaser, staff in the Biomedical Engineering Department of Cleveland Clinic’s Lerner Research Institute, likens the device to a “Fitbit® for the bladder.” The flexible device, shaped like a coil, is inserted into a patient’s bladder lumen. It tracks physiological data over a four- to seven-day monitoring period and wirelessly transmits the information to the patient’s electronic medical record to inform a physician’s diagnosis and clinical management. The patient can then remove the device by a string and dispose of it completely.

Dr. Damaser works closely with urologists, including Howard Goldman, MD, staff in Cleveland Clinic’s Glickman Urological & Kidney Institute and clinical lead on the study, along with researchers and physician collaborators at Case Western Reserve University and the Louis Stokes Cleveland VA Medical Center.

Dr. Goldman notes that the short-term goal of the trial is to validate whether the UroMonitor demonstrates clinical value comparable to that of urodynamic testing, with comparable or greater comfort. The team will insert the device in eight to 10 patients and monitor their activity in the clinic to determine the safety and efficacy of this diagnostic approach.

“This study will allow us to evaluate whether the device provides, at a minimum, the same or similar effects as standard urodynamic testing,” he says. “That’s the first step.”

Implications for urodynamics

If the study shows improved outcomes for patients, the UroMonitor could represent a sea change in urodynamics.

Current diagnostic testing with a catheter is painful and embarrassing for some patients. After the catheter is inserted into patients’ bladders, they are required to force urination to simulate the issues they face during their daily activities. This simulation may also propagate artifactual data, notes Dr. Goldman, which is problematic for physicians.

The device would counter these issues. “It’s more comfortable for patients. A clinician inserts it, wirelessly turns it on and sends the patient home. For clinicians, there is more data to confirm the diagnosis and no need for specialized equipment or personnel to administer the test,” says Dr. Damaser.

What’s next?

The device also has the potential to play a therapeutic role for patients with neurogenic etiologies. Possible applications include controlled drug delivery and feedback to neuromodulation or electrical stimulation systems. It may restore sensation for patients with pelvic floor dysfunction or inform them as to when to empty their bladder.

With the recent enrollment of the first patient, Dr. Damaser is already looking ahead to improve the device. She and her team are currently investigating volume sensing capabilities in the lab. “To fully realize a wireless, catheter-free ambulatory urodynamics device, we need to know how much is in the bladder — we need volume,” she says. “So that will be our next step.”

RIGHT — MARGOT DAMASER, PHD


Clinic
Margot S. Damuser,

2019 HIGHLIGHT

VIRTUAL REALITY TOOL TO OFFER NEW WAY OF UNDERSTANDING RENAL PHYSIOLOGY

Soon medical students, residents and fellows will have access to an immersive, virtual reality teaching tool to enhance a renal physiology curriculum. The device will integrate 3D printing and holographic computing to simulate mechanistic processes in nephron physiology and pathology.

The project, led by Georges Nakhoul, MD, Director of Cleveland Clinic's Center for Chronic Kidney Disease and Associate Director of the Nephrology Fellowship Program in the Glickman Urological & Kidney Institute, will bring greater accessibility to a discipline that is often perceived as difficult to teach and learn.

The rigor of renal physiology

According to a national survey of U.S. internal medicine nonnephrology subspecialty fellows, 31% of respondents reported that nephrology was the most difficult physiology course taught in medical school.[1] The implication of this rigor — whether real or perceived for aspiring physicians — may negatively impact recruitment and training within the specialty.

"This challenge led us to consider new approaches to teach nephrology," notes Dr. Nakhoul, "by taking advantage of novel technology in the marketplace and engineering expertise within our institution."

Partnering to create a learning experience

Dr. Nakhoul is partnering with Karl West, MS, Director of Medical Device Solutions in Cleveland Clinic's Department of Biomedical Engineering, Lerner Research Institute, to leverage this virtual learning platform. Mr. West and his colleagues have been closely involved with similar projects that use this technology, although this is the first to focus expressly on renal education.

Using a virtual reality headset, Facebook's Oculus Quest, learners will be able to see animations of select parts of the nephron and observe physiologic and pathologic processes. They will also be able to interact with 3D models of enlarged nephron replicas to better understand the anatomy of the renal unit.

There will be several modules targeting different learning goals, notes Dr. Nakhoul. "For example, one will allow learners to experiment virtually with medications like diuretics and observe the effects of these interventions."

He hopes this simulated experience will make scientific concepts, including the physiology and pathology of electrolytes, proximal tubule, water balance regulation, and acid/base, more comprehensible than conventional learning modalities do.

Measuring success and fostering access

An important step, says Dr. Nakhoul, will be to measure the utility of the program. "It's great to implement innovative teaching technologies, but we must ascertain whether it's actually making a difference for learners. We have developed an evaluation plan to determine that."

And if it proves beneficial, Dr. Nakhoul and his collaborators hope to make the software freely available (to those who have access to Oculus Quest). "The goal would be to make the program available to those who want it by downloading the app on their phone."

"We saw an opportunity to meet an unmet need, helping not only Cleveland Clinic students and trainees but also the specialty at large," he remarks. "We are eager to see its impact."

Reference

1. Jhaveri KD, Sparks MA, Shah HH, et al. Why not nephrology? A survey of US internal medicine subspecialty fellows. *Am J Kidney Dis.* 2013;61(4):540-546.

2019 HIGHLIGHT

FIRST KIDNEY TRANSPLANT PERFORMED USING SINGLE-PORT ROBOT

In 2019, Cleveland Clinic became the first hospital in the world to successfully perform a robotic single-port kidney transplant, which enables all surgical instruments and the donor kidney to be placed through one 4 cm abdominal incision.

The Glickman Urological & Kidney Institute surgical team included Jihad Kaouk, MD, Director of the Center for Robotic and Image-Guided Surgery and the Zegarac-Pollock Endowed Chair in Laparoscopic and Robotic Surgery; Alvin Wee, MD, Surgical Director of Renal Transplantation; Mohamed Eltemamy, MD; David Goldfarb, MD; and Eric Miller, MD. These surgeons combined their expertise in minimally invasive, robotic and kidney transplant surgery to accomplish this first successful operation.

This approach limits incision points which results in quicker recovery and, in this case, eliminated the need for opioids after surgery. This most recent procedure follows a series of surgical innovations with the daVinci SP Surgical System last year, also led by Dr. Kaouk, including single-port extraperitoneal surgeries through a small incision in the bladder to remove cancerous prostates and enlarged benign prostates blocking the urinary system.

Single-port approach demonstrates improved outcomes in urologic procedures

"Our aims are to decrease the morbidity of procedures, move surgeries that are inpatient to outpatient and minimize the use of drains and pain medications," says Dr. Kaouk.

Robotic radical prostatectomies are now performed through a 2.5 cm intraumbilical incision. Using the single-port robot, the surgery is limited to the extraperitoneal space and, thus, avoids touching the bowel. The patient is kept in a flat position without the need for stirrups. Patients are typically discharged home a few hours after the procedure, which is done without narcotics.

For patients who have had numerous abdominal procedures, a transperineal approach is used with the single-port robot. This is the shortest route to reach the prostate, and the surgical field is confined to the prostate area. Patients with colostomies may be good candidates for this approach.

For benign prostatic hyperplasia, surgical excision is recommended for very large prostates. Dr. Kaouk modified the robotic simple prostatectomy approach and performed transvesical simple prostatectomy from within the bladder, without going through the abdomen, to successfully remove an enlarged prostate. "The plan is not to touch the bowel for a quick postoperative recovery," he says.

Innovator in robotic and image-guided surgery

Dr. Kaouk got an early start in using single-port robotic surgery. In 2010, he led a team that performed the first single-port urologic procedures in Europe to determine safety and clinical feasibility, which was published in the *European Journal of Urology*. He coined the term robotic laparoendoscopic single-site (R-LESS) surgery, and he also received the Best Surgical Movie award in 2019 at the American Urological Association Annual Meeting in Chicago for "Robotic Single-Port Partial Nephrectomy."

"It's all about thinking outside the box and using the system for new procedures. Single-port is a valuable tool to add to our surgical options," he says.

RIGHT — JIHAD KAOUK, MD

2019 ACHIEVEMENTS

Center for Blood Pressure Disorders

The Center for Blood Pressure Disorders was again recognized as a Comprehensive Hypertension Center by the American Heart Association — currently one of only eight centers nationally that have received this distinction. Certified Comprehensive Hypertension Centers are recognized as leaders in providing the most up-to-date, effective treatment strategies based on current evidence-based research in hypertension.

The center remains involved in a pilot project for remote home blood pressure monitoring that automatically transmits readings to the patient's Cleveland Clinic electronic medical record to assist with ongoing assessment of their care plan. The team hopes to examine the data from this project and assess next steps in 2020.

Finally, the team recently examined a cohort of patients with chronic kidney disease (CKD) to investigate the prevalence and prognostic significance of treatment-resistant hypertension, utilizing both office blood pressure measurement and ambulatory blood pressure monitoring. Findings, which were presented at a meeting of the American Society of Nephrology in Washington, D.C., reaffirm that there is a high prevalence of treatment-resistant hypertension in CKD, and patients who have this condition should be monitored more closely as they are at greater risk for poorer cardiovascular and renal outcomes.

Participating clinicians: Alison Heider, NP; Michelle Lard, NP; George Thomas, MD; Robert Heyka, MD

Center for Chronic Kidney Disease

The center published several studies in 2019 that examined patient outcomes in chronic kidney disease (CKD). In a first-of-its-kind study, the team analyzed the comparative risk of contrast-induced nephropathy (CIN), a leading cause of hospital-acquired acute kidney injury, following intra-arterial contrast versus intravenous contrast. The study showed that while there are potential risks associated with both agents, there was not a statistically significant difference. Findings demonstrated that CIN did not appear to be associated with increased mortality or progression to end-stage renal disease. Two other notable studies published by the group include an investigation of atrial fibrillation in the CKD patient population and the role of high-density lipoprotein cholesterol in mortality associated with CKD.

Participating clinicians: Georges Nakhoul, MD; Susana Arrigain, MA; Jennifer Hyland, CNP; Priscilla Davis Dann; Joseph V. Nally, MD; Jesse Schold, PhD

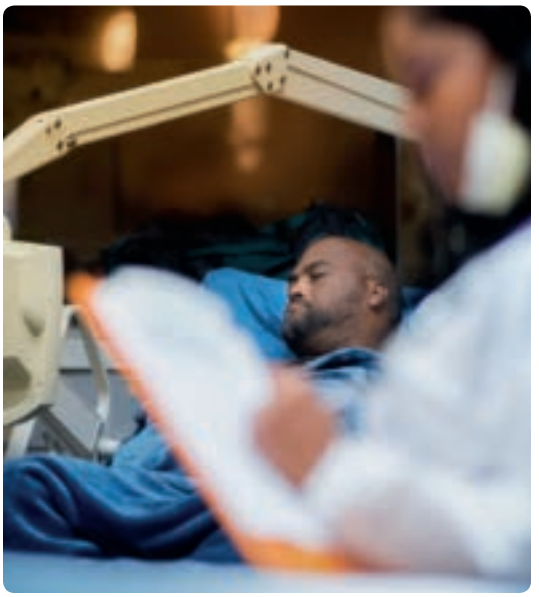
Center for Dialysis

End-stage kidney disease (ESKD) is a significant driver of healthcare expenditures. To address this, Leslie Wong, MD, MBA, Director of ESKD and the Center for Dialysis, is leading new population health efforts to improve outcomes and reduce costs for ESKD as Associate Director for Cleveland Clinic's Medicare Accountable Care Organization. Additionally, he continues to chair an executive committee for Nephrologists Transforming Dialysis Safety, one of the major initiatives for the American Society of Nephrology Alliance for Kidney Health.

The center also welcomed Tushar Vachharajani, MD, interventional nephrologist and Director of Global Nephrology, in early 2019. He has been instrumental in efforts to improve vascular access rates and is working with Dr. Wong to improve nephrology collaboration with vascular surgery and interventional radiology. He also led the launch of the interventional nephrology service in October 2019.

The Center for Dialysis team operates through the Ohio Renal Care Group to help improve outcomes at dialysis centers in the Cleveland area, and now in Ashtabula County. The team is committed to expanding and seeking out relationships and new partnerships to strengthen kidney care throughout Cleveland Clinic health system.

Participating clinicians: Leslie Wong, MD, MBA; Tushar Vachharajani, MD



Center for Endourology and Stone Disease

The Center for Endourology and Stone Disease was selected as one of six clinical centers in the Urinary Stone Disease Research Network, sponsored by the National Institutes of Health and National Institute of Diabetes and Digestive and Kidney Diseases. It is currently enrolling patients in a randomized clinical trial called PUSH, which evaluates innovative methods to improve compliance with fluid intake for stone prevention.

The translational laboratory for kidney stone research has made great strides to better understand how dysbiosis, a microbial imbalance caused, in part, by diet and antibiotics, may play a role in stone disease. Through this work, the team hopes not only to elucidate the pathophysiology of stone disease and its associated comorbidities but also to identify novel biomarkers for stone recurrence in order to potentially develop innovative therapeutic approaches to prevent the disease.

In collaboration with the Department of Biomedical Engineering within Cleveland Clinic's Lerner Research Institute, center staff are studying the design and application of energy-gated nanoparticles and drug-loaded nanomaterials for targeted delivery as a novel therapeutic approach to kidney stones and other benign urologic conditions.

Clinically, the center remains one of the highest-volume kidney stone centers in the country, with five endourologists focused on stone disease. In addition to offering tubeless percutaneous nephrolithotomy (PCNL) and mini-PCNL, staff are embarking on new clinical trials to evaluate recent innovations in shockwave lithotripsy.

Participating clinicians: Sri Sivalingam, MD; Juan Calle, MD; Smita De, MD, PhD; Vijay Krishna, PhD; Aaron Miller, PhD; Manoj Monga, MD

Center for Female Pelvic Medicine and Reconstructive Surgery

The members of the Center for Female Pelvic Medicine and Reconstructive Surgery consistently aim to innovate and help define the field of complex female urologic surgery. To that end, they have several unique projects underway.

In neuromodulation, they are studying the use of a novel implantable tibial nerve stimulation device. There are clinical trials in this space for appropriate patients who are refractory to standard overactive bladder management and are interested in an implant. The team is also taking an innovative approach to urodynamic testing, and is working closely with Cleveland Clinic collaborators to launch a clinical trial using the UroMonitor device.

Additionally, the national and international dialogue on mesh use in the vagina has spurred the development of cell-based therapies for stress incontinence. Glickman Urological & Kidney Institute, along with several other institutes around the country, is part of the Cook MyoSite® sponsored trial looking at muscle-derived stem cells for the treatment of stress incontinence.

Finally, to aid in optimizing follow-up protocols for patients who undergo post-sling surgery, two of the center's members helped develop the American Urological Association/ SUFU Foundation Stress Urinary Incontinence Guidelines. Those guidelines recommend that patients undergoing sling surgery have follow-up after the surgery, but the optimal method has not been elucidated. The center is also exploring how telemedicine, already a successful program in the institute, can be utilized for patient follow-up for those who have undergone synthetic midurethral sling surgery.

Participating clinicians: Sandip Vasavada, MD; Howard Goldman, MD; Raymond Rackley, MD; and Courtenay Moore, MD

Center for Genitourinary Reconstruction

As a national and international leader in the field of urologic congenitalism, Hadley Wood, MD, continued her efforts to improve the transition process and overall care of adolescents and adults with congenital urologic disorders. She was extensively involved in the International Consultation on Urologic Diseases (ICUD) review of this specialty area as it convened in October 2018. The findings were published in *Congenital Lifelong Urology: Caring for the Adolescent and Adult Patient with Congenital and Childhood GU Conditions*, and is a major resource for all health professionals caring for this challenging group of patients. In addition, Dr. Wood, working with members of the Pediatric Institute, was awarded a Quality Improvement Grant from the American Association of Pediatrics for a project designed to improve transition from pediatric- to adult- centered care for youth living with spina bifida.

Clinical research in the Center for Genitourinary Reconstruction this year dealt with a range of topics. Team members reviewed their experience with the use of postoperative imaging following buccal graft urethroplasty, and the findings have had a beneficial impact on patient management. Additional areas of research included a determination of the radiologic incidence of parastomal hernia following ileal conduit urinary diversion, and the spectrum of urologic morbidity in patients with Crohn's disease undergoing colorectal surgery. Team members were involved in other projects including book chapters on technique of urethrectomy, rectourethral fistula, and staged urethroplasty. The center's mission of resident and fellow education continued with the 15th Annual National Urology Resident Preceptorship in Adult and Pediatric Reconstructive Urology along with education by colleagues from Cleveland Clinic Children's and Rainbow Babies and Children's Hospital.

Participating clinicians: Kenneth Angermeier, MD; Hadley Wood, MD

Center for Male Fertility

Under the direction of Sarah Vij, MD, the Center for Male Fertility has expanded to serve a growing clinical and surgical practice. The center performed 175 fertility surgeries in 2019, a 35% increase from 2018. To address this growing demand, the center welcomed Neel Parekh, MD, to provide fertility services in the Akron region. In addition to clinical practice, the team also has a well-developed research program. This year, Dr. Vij published data that identifies predictive outcomes in microdissection testicular sperm extraction. She is studying the predictive value of prolactin in men with hypogonadism for findings on pituitary MRI, and has presented this work at national meetings. She is also investigating the microbiome of semen and its impact on semen parameters and infertility. Dr. Parekh recently co-authored a study investigating the clinical utility of over-the-counter male fertility supplements.

Notably, Ashok Agarwal, PhD, who leads the center's Andrology Lab, was named the IVF Expert of the Year by the American College of Embryology. Selection for this award is based on significant contributions to human reproductive embryology. Dr. Agarwal and co-researchers recently investigated the effect of oxidation-reduction potential on sperm vitality and mitochondrial membrane potential. The findings were presented at the annual meeting of the American Society for Reproductive Medicine in Philadelphia. He is also first author on the study "Male Oxidative Stress Infertility (MOSI): Proposed Terminology and Clinical Practice Guidelines for Management of Idiopathic Male Infertility" in the *World Journal of Men's Health*. Importantly, this article introduces the concept of MOSI in the diagnosis and treatment of idiopathic male infertility, and is a collaboration with 91 authors from six continents and 26 countries. A MOSI diagnostic test was recently developed by the Andrology Lab and will be integrated into clinical practice at Cleveland Clinic.

Participating clinicians: Sarah Vij, MD; Ashok Agarwal, PhD; Neel Parekh, MD

Center for Men's Health

The Center for Men's Health continues to offer a broad range of therapies for prostate enlargement, erectile dysfunction, low testosterone, and chronic pelvic and genital pain. For prostate enlargement interventions, it offers minimally invasive treatments done under local anesthetic (UroLift®, Rezum™), laser enucleation (HoLEP), standard transurethral approaches, and robotic removal when the prostate is very large or other bladder surgery is required at the same time. The center also recently added thulium laser therapy to treat enlarged prostates. It can be used to remove or vaporize prostate tissue and can also treat coexisting bladder stones. Frequently, this is performed as an outpatient procedure or overnight stay.

The center's experience with low-intensity shockwave therapy for erectile dysfunction continues to progress. This painless procedure involves application of energy pulses to the penile skin and can lead to improved blood flow and return of erections. The team's data comparing the success with two different devices (Urogold™ and Zimmer) and the interim results of its clinical trial using shockwave to aid return of erections after radical prostatectomy were presented at the Sexual Medicine of North America conference in Nashville, Tennessee.

Chronic pelvic and genital pain are common and frustrating conditions, and the center is internationally recognized for developing diagnostic and treatment algorithms that are safe and effective. Members recently led a multicenter team that developed the first validated symptom index for chronic testicular pain. The center now has three surgeons who perform microscopic spermatic cord denervation surgery. In properly selected men, the cure rate for chronic testicular pain is about 80%. In addition, the center's study on identification of nonculturable bacteria in urine and prostate fluid of men with chronic pelvic pain is ongoing.

Participating clinicians: Daniel Shoskes, MD; Khaled Fareed, MD

Center for Minority Men's Health

The Center for Minority Men's Health (CMMH) hosted another successful Minority Men's Health Fair (MMHF), now in its sixth year, across four different locations. This event represents a best practice in population health innovations designed to improve health outcomes with a particular focus on minority and underserved males, thus benefiting minority and socioeconomically challenged families and communities at greatest risk for health disparities. To date, the event has served over 35,000 men.

In 2019, approximately 2,000 men attended the MMHF, a record turnout. The CMMH continues to perform research to investigate ways to improve health outcomes in minority populations. Research highlights in 2019 included a survey of the top 10 characteristics that make doctors patient centered; the incidence and impact of stress, depression and anxiety in minority men and end-of-life choices in African Americans. In 2019, the *History of the Minority Men's Health Fair 2003-2019* was completed, and the CMMH provided research and shadowing mentorship for four students for the summer nine-week Office of Civic Education internship.

Participating clinician: Charles Modlin, MD, MBA

Center for Pediatric Urology

One of the many benefits of being housed within a large medical enterprise is the opportunity to care for an entire family at the same time. The center's team members meet parents whose fetus has a urologic anomaly found on screening ultrasound. They collaborate with other multidisciplinary teams to prepare for possible interventions, such as posterior urethral valves and bladder exstrophy once the child is born — or in some cases through fetal intervention in partnership with Cleveland Clinic Children's Fetal Care Center. The team establishes a relationship with the family before the child is born to provide medical evaluation and recommend potential proactive therapies for the child.

Participating clinicians: Audrey C. Rhee, MD; Jeffrey M. Donohoe, MD

Center for Renal Diseases

Cleveland Clinic began enrolling its first patients in two multicenter, NIH-sponsored studies this year: the Kidney Precision Medicine Project (KPMP) and APOL1 Long-term Kidney Transplantation Outcomes Network (APOLLO).

The team continued its involvement in research into Alport syndrome, a rare genetic disease that causes kidney failure and hearing loss. The CARDINAL trial, a phase 3 placebo-controlled trial using bardoxolone, completed enrollment and is following patients through the study. In addition, the team is currently enrolling patients in HERA, a phase 2 placebo-controlled trial using an anti-microRNA-21 medication.

Participating clinicians: Emilio Poggio, MD; John Sedor, MD; John O'Toole, MD; James Simon, MD

Center for Renal and Pancreas Transplant

The Kidney Transplant Program had a record-breaking year, completing nearly 230 kidney transplants. The team also led the first single-port robotic kidney transplant. Additionally, the center continues to focus on its living donor program, completing 75 such transplants in 2019. A number of new initiatives, including patient- and community-centered events and virtual transplant clinics, have contributed to increased patient volumes and more education around both internal and external kidney exchange.

Participating clinicians: Alvin Wee, MD; Emilio Poggio, MD; David Goldfarb, MD; Venkatesh Krishnamurthi, MD

Center for Advanced Robotic and Image-Guided Surgery

In partnership with members from the Center for Renal and Pancreas Transplant, Dr. Kaouk led the first kidney transplant in the world using the daVinci single-port robot. The center continues to pioneer robotic surgeries, in the past year completing almost 200 single-port extraperitoneal radical prostatectomies and transvesical simple prostatectomies using the daVinci SP robot. Dr. Kaouk was invited to lead several courses in robotic single-port surgery at the American Urological Association's 2019 Annual Meeting in Chicago and Society of Urological Robotic Surgeons meetings in multiple cities around the nation. Dr. Kaouk holds the prestigious Zegarac-Pollock Endowed Chair in Laparoscopic and Robotic Surgery.

Participating clinicians: Jihad Kaouk, MD; Georges-Pascal Haber, MD, PhD; Ryan Berglund, MD; Khaled Fareed, MD; Amr Fergany, MD; Michael Gong, MD; Robert Stein, MD

Center for Urologic Oncology

Steven Campbell, MD, PhD, published a paper comparing outcomes associated with partial nephrectomy and radical nephrectomy for renal cancer. Robert Abouassaly, MD, examined data from the National Cancer Database to create and validate a hospital quality scoring system for radical cystectomy that is both disease specific and associated with patient-centered outcomes. Eric Klein, MD, published a study confirming use of the novel IsoPSA™ prostate-specific antigen assays as compared to conventional tests to detect high-grade prostate cancers. Cleveland Clinic and other select medical centers are currently recruiting for the clinical trial Metacure: a Multi-arm Multi-modality Therapy for Very High Risk Localized and Low Volume Metastatic Prostatic Adenocarcinoma. Nima Sharifi, MD, and his lab continue to explore the role of the *HSD3B1* gene in prostate cancer. Dr. Sharifi recently published a review of current literature on the mechanisms conferred by the gene and discusses the need for continued exploration into additional phenotypes associated with *HSD3B1* (1245C).

Participating clinicians: Steven Campbell, MD, PhD; Eric Klein, MD; Nima Sharifi, MD; Robert Abouassaly, MD

RESOURCES FOR PHYSICIANS

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Glickman Urological & Kidney Institute

The Glickman Urological & Kidney Institute is a world leader in treating complex urologic and kidney conditions in adults and children. Our internationally recognized staff has pioneered laparoscopic and robotic surgical techniques and developed innovative procedures for urologic cancers and transplantation. We provide advanced management of kidney disease, hypertension, infertility and congenital malformations to help patients worldwide.

About Cleveland Clinic

Cleveland Clinic is a nonprofit, multispecialty academic medical center integrating clinical and hospital care with research and education for better patient care. More than 3,900 staff physicians and researchers in 180 medical specialties provide services through 26 clinical and special-expertise institutes. Cleveland Clinic comprises a main campus, 11 regional hospitals and more than 150 outpatient locations, with 19 family health centers and three health and wellness centers in northern Ohio, as well as medical facilities in Florida, Nevada, Toronto and Abu Dhabi. Cleveland Clinic is currently ranked as one of the nation's top hospitals by *U.S. News & World Report*.

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Year in Review

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