

MINIMALLY INVASIVE UROLOGIC CANCER SURGERY



Beth Israel Deaconess
Medical Center



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

2015

Where State-of-the-Art Surgery, Patient-Centered Care and World-Class Research Go Hand-In-Hand

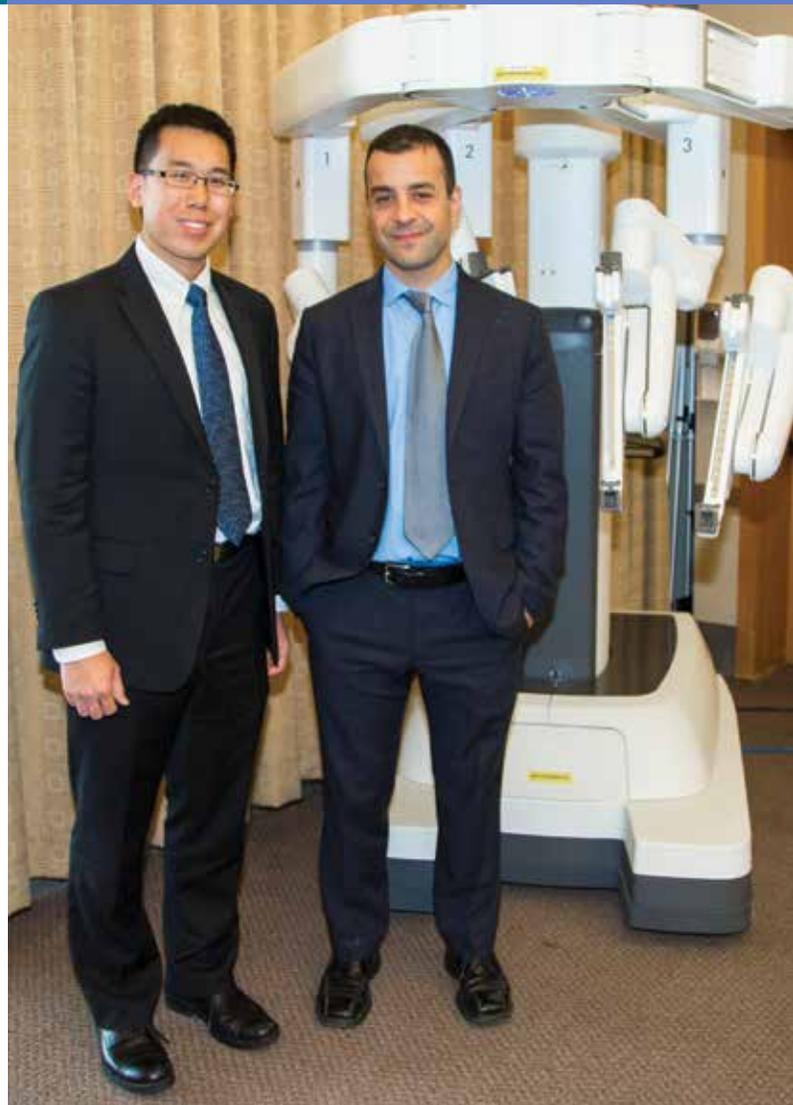
Welcome to the BIDMC Program in Minimally Invasive Urologic Cancer Surgery. We have the privilege of caring for patients with urologic cancer, and we are devoted to providing personal and compassionate care for each and every patient during a very stressful time. Our team offers the full range of treatment options, from non-surgical options, to the most technically advanced surgery performed by the most experienced robotic surgery team in Massachusetts. This newsletter describes the latest developments in our clinical and research efforts, as well as our goals and challenges for the future. We thank you for allowing us to care for you and your families. By doing so, you join our team as well, and we hope to show you how you are helping contribute to the BIDMC difference.

THE BIDMC DIFFERENCE

The motto of the BIDMC difference is “HUMAN FIRST.” We aim to live up to the philosophy behind this motto by making our care truly patient-centered; the goals, wishes and preferences of our patients are always our first priority. We develop a deep, personal connection with our patients so that each one feels that he or she is seen as a unique individual, not just a number.

We combine this philosophy with the most robust kidney, prostate and bladder cancer program in New England. Our multidisciplinary programs for kidney and prostate cancer were among the first to be developed in Boston, focusing on patient-centered care, and encouraging non-surgical approaches whenever possible. We are also justifiably proud of our robotic surgery team, the most experienced in Boston, having performed over 1500 minimally invasive surgeries for genitourinary tumors. This expertise has allowed us to develop the first minimally invasive urologic fellowship in Boston focusing on robotic surgery.

The co-leaders of our team, Drs. Andrew Wagner and Peter Chang, specialize in minimally invasive surgical approaches to malignant urologic conditions, in particular, kidney, prostate, and bladder cancer. Our research interests include evaluating the safety of active surveillance for low risk prostate and kidney cancer, evaluating health-related quality of life following cancer surgery, designing new tools to improve the education of patients after their cancer diagnosis, developing ablation techniques for small renal tumors, and evaluating totally robotic surgery for advanced bladder cancer.





Our Team

Left to right: Peter Renehan, BS; Ostap Dovirak, MD; Catrina Crociani, MPH; Kimberly Taylor, BS; Peter Chang, MD, MPH; Andrew Wagner, MD; Kyle McAnally, BS

Peter Chang, MD, MPH

Dr. Peter Chang specializes in minimally invasive and open approaches to urologic cancer surgery. He has a particular interest in prostate and bladder cancer, and is the Director of the BIDMC Prostate Cancer Care Center, a multidisciplinary program that emphasizes collaboration between urologic oncology, medical oncology, and radiation oncology and provides comprehensive care through all stages of disease to patients with prostate cancer.

Dr. Chang is also a promising research investigator. He was recognized as one of the nation's top 10 young Urologic Investigators in 2014, and served as a Urology Care Foundation Research Scholar from 2012-2014. He currently is the first recipient of the Martin and Diane Trust Career Development Chair in Surgery at BIDMC.

Dr. Chang is a world expert in quality of life assessment in prostate cancer, and is committed to bringing cutting-edge research findings to patients in the clinic. He developed the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) questionnaire, which is used to measure prostate cancer patients' quality of life in the clinical setting. He is also interested in prostate cancer patient education, and leads BIDMC's effort in helping patients learn about their cancer diagnoses and communicate their personal preferences to the doctor so that patient-centered treatment decisions can be made.

Andrew A. Wagner, MD

Assistant Professor of Surgery at Harvard Medical School and Director of Minimally Invasive Urologic Surgery at BIDMC, Dr. Wagner specializes in minimally invasive surgery for urologic cancer, in particular kidney, prostate, and bladder tumors. He completed a clinical fellowship in minimally invasive urology and robotics at the Brady Urological Institute of Johns Hopkins University. Dr. Wagner has performed robotic surgery since 2004 and is considered one of the country's most experienced robotic cancer surgeons.

Dr. Wagner is the director of the BIDMC Minimally Invasive Urologic Fellowship Program, the first such academic fellowship in New England. Dr. Wagner has also been the course director for the New England Robotics Teaching Course since 2012. This course allows surgeons and residents from around the country to come to BIDMC to learn from world-renowned faculty about advanced robotic surgery techniques.

Dr. Wagner has published over 50 manuscripts and book chapters on urologic surgery. His research interests include evaluating the safety of active surveillance for low risk prostate cancer and kidney cancer, evaluating quality of life after urologic cancer surgery (robotic prostatectomy, laparoscopic nephrectomy, robotic partial nephrectomy and robotic cystectomy), and developing ablation techniques for small renal tumors.

Catrina Crociani, MPH

Catrina is a Clinical Trials Specialist for the Division of Urology. She has worked on quality of life/outcome research studies for over 10 years. She reports directly to the principal investigators (Drs. Chang and Wagner) and provides guidance on all related study activities including day-to-day troubleshooting, regulatory affairs, study finances, and hiring/training of junior personnel.

Kimberly Taylor, BS

Kim is a Clinical Research Assistant with a BS in Biology from Emmanuel College. She is currently working on our kidney surgery databases and kidney quality of life studies, the PASS and MEAL prostate cancer active surveillance studies, the robotic vs open prostate cancer quality of life study and the bladder cancer database.

Kyle McAnally, BS

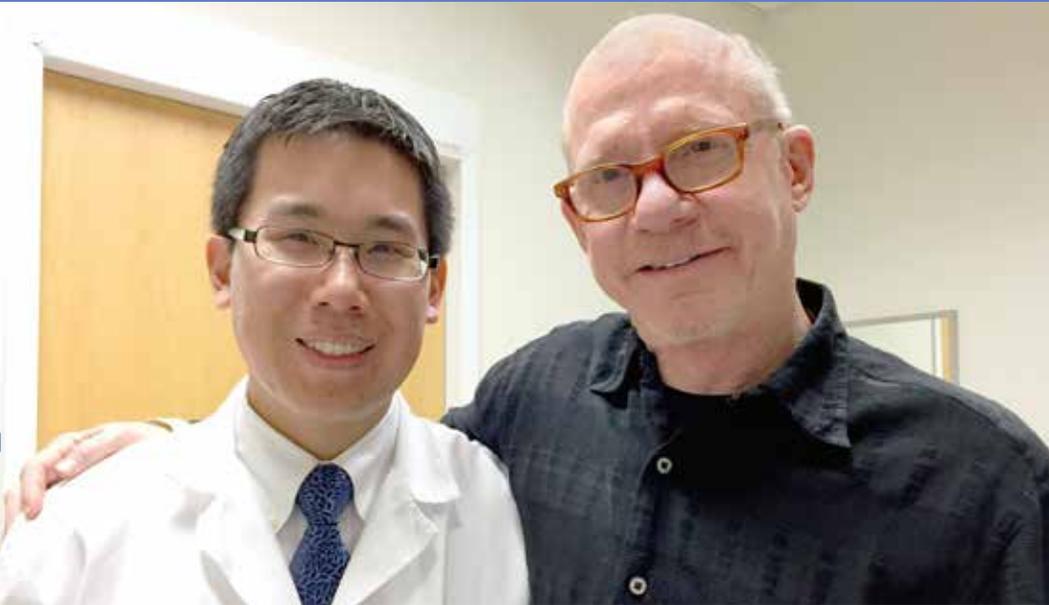
Kyle is a Clinical Research Assistant with a BS in Geography from the University of North Alabama. He is currently working on the Mazzone and P3P prostate cancer education trials, the robotic vs open prostate cancer quality of life study, and the PASS and MEAL prostate cancer active surveillance studies.

Peter Renehan, BS

Peter is a Harvard medical student with a research interest in surgical cost effectiveness. He is studying the return to work patterns of our patients and gathering data that will allow him to evaluate the overall societal financial impact from cancer care.

Prostate Cancer

Philosophy



Prostate cancer care at BIDMC features remarkably integrated clinical and research programs with a common thread: patient-centered care. Our philosophy is that every patient with prostate cancer has different priorities for his care, has a right to communicate those wishes to doctors clearly, and has the right to have the best quality-of-life possible. While our team has extraordinary surgical expertise, it is actually our efforts before and after treatment that set us apart from other institutions.

Surgical and Clinical Excellence in Prostate Cancer Care

We pride ourselves in being the most highly trained and most experienced robotic surgery program in the New England area. Every component of our team, from our surgeons, Drs. Wagner and Chang, our nurse practitioners Jodi and Analesa to our operating room nurses and technologists, to our pre-operative and recovery room staff, has been working together since our robotic surgery program started here at BIDMC in 2008. This combined experience allows us to offer a level of care that is unparalleled in this area. How do we know? We track every

outcome that occurs and constantly look for ways to make our surgery safer and better.

Our clinical excellence in prostate cancer goes far beyond our surgical excellence. We offer the most modern tools for diagnosis, including MRI-guided prostate biopsy, and urine/blood tests that may guide a patient towards or away from biopsy. After a patient finds out he has prostate cancer, we offer multidisciplinary care at the BIDMC Prostate Cancer Care Center, led by Dr. Chang, where patients can

receive comprehensive care from the surgeon, radiation oncologist, and medical oncologist in a single session. For patients with lower-grade cancer, we are committed to encouraging active surveillance in order to preserve quality of life for as long as possible. For patients whose tumor biology or behavior is unclear, we offer genomic tests to better understand the genes that make these tumors more or less aggressive. Lastly, no matter what treatment a patient chooses, we believe he has a right to have the best quality of life possible.

ROBOTIC PROSTATECTOMY AT BIDMC IS EXTRAORDINARILY SAFE





Quality of Life and Prostate Cancer

When a patient first hears that he has prostate cancer and begins to learn more about the disease, he will find out that, because of the prostate’s function and anatomical location, his urinary, sexual, bowel, and hormonal systems may be injured during cancer treatment. This raises questions, such as, “Will I still be able to have sex after treatment?,” and “If I have urine leakage after surgery, how long will it last?” BIDMC has long been a national leader in prostate cancer quality of life research, and we are proud of how we bring this expertise to the clinical setting so that every patient can expect to have his quality of life concerns addressed.

Prostate Cancer Surgery Database: Outcomes and Transparency

Our commitment to using patient-reported data to measure quality of life has allowed us to build a clinical database of patients who have undergone prostate cancer surgery at BIDMC. The information in this database assists us in analyzing our performance as surgeons, and helps us counsel patients about their expected outcomes based on our own experiences with previous patients. For example, we can tell patients that based on our last 400 operations, about 70% of those patients are no longer using any protective pads for urinary leakage six months after surgery and 92% are using either zero or one pad per day (see table).

Our techniques and outcomes after robotic prostatectomy have been accepted and/or presented at several scientific meetings.

Use of protective urinary pads after robotic prostatectomy at BIDMC, as reported using the EPIC-CP questionnaire in the last 400 patients

	6 months after surgery	2 years after surgery
Do not need any urinary pads	70%	79%
Use 1 or fewer urinary pads	92%	95%

We track every outcome that occurs and constantly look for ways to make our surgery safer and better.

Choosing No Treatment: Active Surveillance for Prostate Cancer

Not all prostate cancers are the same. Some tend to be very slow-growing and will never metastasize (spread to other organs) or cause problems. These cancers may not need to be treated. Indeed, BIDMC has been a national leader in an approach called *active surveillance*, one in which a patient with such a tumor is carefully monitored through regular rectal exams, PSA measurements, and most importantly,

repeat prostate biopsies, to determine whether the tumor is getting worse or staying the same. The rationale behind such active surveillance is that, for every year, month, or day that a patient can delay getting his prostate removed, he can preserve his current quality-of-life. Unfortunately, despite its proven safety, many doctors across the nation are not comfortable with this approach, and are over-treating low-grade prostate cancer.

At BIDMC, we not only regularly offer active surveillance, but we also offer participation in exciting national clinical trials for patients on active surveillance that are changing our understanding of these tumors.

Men's Eating and Living Study (MEAL)



"What can I do to help slow down my cancer? Does what I eat affect the growth of my cancer?" These are common questions from our patients, and ones that we do not have good answers to, as yet. The MEAL study aims to investigate how diet may (or may not) affect prostate cancer progression in men on active surveillance for their cancer. It is a national study run out of the University of California - San Diego, and we have recently started accruing patients. Patients are randomly chosen to receive either a strict phone-based dietary intervention or other information regarding diet using paper or web format. Being on the study does not change our clinical care of patients. It is an opportunity for patients to contribute to our understanding of this disease and how we may influence its course.

Prostate Active Surveillance Study (PASS)



The PASS study is the largest multi-center study in the U.S. dedicated to prostate cancer active surveillance, with over 1200 patients enrolled to date, and over 120 patients from BIDMC. This study aims to identify substances (called biomarkers) in the blood and urine that may predict whether a man on active surveillance will progress (and require treatment) or continue to meet the criteria for active surveillance. BIDMC is proud to be a top contributor to the PASS study, and we are the only institution that offers participation in the study in the Northeast. Once again, being on the study does not change clinical care, nor will it immediately benefit the participants. However, it is an important opportunity to contribute to science, and one of the unique aspects of receiving care at an academic center of excellence such as BIDMC.

Accurate and Consistent Quality of Life Measurement: EPIC-CP

Research has shown that doctors tend to overestimate their own outcomes and underestimate patients' symptoms after prostate cancer treatment. In order to limit this bias, and to give patients their own voice to communicate their problems clearly, Dr. Chang created the EPIC for Clinical Practice (EPIC-CP) questionnaire, which is now used worldwide by organizations such as the Movember Foundation and the American Urological Association (Chang P et al, *J Urol* Sep 2011).

Our team is committed to using EPIC-CP to evaluate quality of life for every patient, on every visit.

Bringing our quality of life research expertise to the clinic allows us to tell a prostate cancer patient, given his age, PSA level, and pre-surgery sexual function, his approximate chances of recovering sexual function after surgery.

(Chipman et al, *J Urol* Mar 2014)

Using EPIC-CP also allows us to identify a patient who may not be recovering more slowly than others and may require intervention. Most importantly, however, it allows our patients to tell us how they are doing in an objective, consistent way.



Prostate Cancer Treatment Decision-Making

The treatment decisions associated with certain cancers can be fairly straightforward. However, prostate cancer is more complicated. A patient most often has multiple potential treatment choices, each of which affects cancer control and quality of life differently and may have lifelong consequences. At BIDMC, we aim to achieve a shared decision-making approach and almost all of our prostate cancer patients are offered participation in an exciting research study that may aid in this shared decision-making.

Personalized Patient Profile-Prostate (P3P) Randomized Trial

Patient Testa Patient Report Date HW: 14343 DOB: 05/07/1963 03/03/2013		Influential Personal Factors A lot of influence: Spouse or Partner, Family Member, Sexual Function, Recreational Activities Some influence: Friend, Co-worker, Sexual Function, Bowler, Work Activities	
Baseline Treatment Preference Do you think you know which prostate care option you want? Yes External beam radiation therapy			
Decisional Control Preference "I prefer that my doctor and I share responsibility for deciding which care option is best."			
Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) Higher scores indicate worse QOL. Two most serious problems indicated with the care.			
Overall Prostate Cancer QOL Score 25 out of 60		Bowel Symptom Score 1 out of 12	
Overall Urinary Better Moderate Problem	Urinary Incontinence Symptom Score 2 out of 12	Bow Urgency No Problem	Bowel Control Very Small Problem
Drinking Occasional Drinking	Fecal Use None	Sexual Symptom Score 10 out of 12	Organ Ability Very Poor to None
Lacking Very Small Problem		Erections Not Firm Enough for Sexual Activity	Overall Function Big Problem

Patients seen at BIDMC are offered participation in the P3P randomized trial, an NIH-funded study that tests whether an individualized web-based program may improve the patient-doctor interaction and decrease the confusion that can occur during a patient's treatment decision. This program finds out what's most important to the patient (e.g. sexual function, cancer control, bowel function), and who he wants to be involved in the treatment decision and how much. Based on these responses, the P3P uses videos to advise the patient on how

to talk to his doctor about these concerns. **BIDMC is the only site in New England participating in this national study**, and is the highest accruing site in the nation, reflecting our dedication to helping patients make the best decision possible.

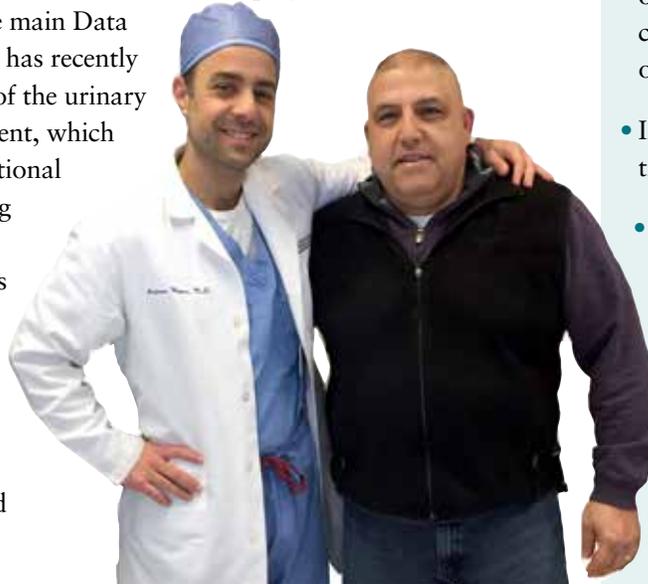


Future Goals and Directions

- Expand our clinical research program to include ALL prostate cancer patients in BIDMC — a multidisciplinary effort.
- Analyze results of the PROST-QA RP2 study — addressing the question of how robotic and open surgery compare in regards to quality of life outcomes.
- Implement electronic EPIC-CP throughout BIDMC.
- Evaluate the relationship between pelvic floor strength and post-prostatectomy urinary incontinence.
- Assess how use of EPIC-CP affects practitioner workflow and patient satisfaction.

Leading the Way in Understanding Quality of Life Changes after Prostate Cancer Treatment: The PROST-QA and RP2 studies

Dr. Chang is the Co-Overall Principal Investigator and Dr. Wagner is a Co-Investigator for the NIH-funded multi-center PROST-QA and RP2 studies. These studies aim to describe clearly how different prostate cancer treatments impact quality of life and patient satisfaction, and their results have been published in the *New England Journal of Medicine* and the *Journal of the American Medical Association*. They are arguably the most important prostate cancer quality-of-life studies ever performed, and BIDMC continues to play a critical role in their continued success, serving as the main Data Coordinating Center. Dr. Chang has recently completed an in-depth analysis of the urinary effects of prostate cancer treatment, which has been presented at several national scientific meetings and is pending submission for publication. The multi-center RP2 study evaluates patients after either robotic or open surgery and will allow us to compare how open and robotic prostatectomy affect patients' quality of life. We are currently analyzing this data and eagerly await these results.



Select Prostate Cancer Bibliography (2010-Present)

Alemezaffar M, Narayan R, Minnillo B, Matthes K, San Francisco I, Nguyen H, **Wagner AA**. A novel high fidelity robot assisted radical prostatectomy simulator. *J Endourol* part B, Videourology, Dec 2010

Chang P, Szymanski KM, Dunn RL, Chipman JJ, Litwin MS, Nguyen PL, Sweeney CJ, Cook R, **Wagner AA**, Dewolf WC, Bubley GJ, Funches R, Aronovitz JA, Wei JT, Sanda MG. Expanded prostate cancer index composite for clinical practice: development and validation of a practical health related quality of life instrument for use in the routine clinical care of patients with prostate cancer. *J Urol* 2011; 186: 865-72

Wagner AA, Sanda MG. Retropubic and robotic-assisted radical prostatectomy. In: Baker RJ and Fischer JE, editors. *Mastery of Surgery*. 6th edition, Lippincott Williams & Wilkins. 2012

Chipman JJ, Sanda MG, Dunn RL, Wei JT, Litwin MS, Crociani CM, Regan MM, **Chang P**; PROST-QA consortium. Measuring and predicting prostate cancer related quality of

life changes using the Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP).

Alemezaffar M, Percy AA, Narayan R, Minnillo BB, Steinberg P, Haleblan G, Gautam S, Matthes K, **Wagner AA**. Validation of a novel, tissue based simulator for robot assisted radical prostatectomy. *J Endourol* 2014, 28: 995

Carneiro A, Sasse AD, **Wagner AA**, Peixoto G, Kataguir A, Neto AS, Bianco BA, **Chang P**, Pompeo AC, Tobias-Machado M. Cardiovascular events associated with androgen deprivation therapy in patients with prostate cancer: a systematic review and meta-analysis. *World J Urol*. 2014 Nov 12 [Epub ahead of print].

Chang P, Carneiro A, Dovorak O, Taylor K, Crociani C, McAnally K, Percy A, Sanda M, **Wagner AA**. Real-world use of EPIC for Clinical Practice (EPIC-CP) to assess patient reported prostate cancer quality of life in the clinical setting. American Urologic Association Annual Meeting, New Orleans 2015

Skolarus TA, Dunn RL, Sanda MG, Chang P, Greenfield TK, Litwin MS, Wei JT, and the PROST-QA Consortium. Minimally important difference for the Expanded Prostate Cancer Index Composite Short Form. *Urology*. 2015 Jan; 85(1):101-6.

Chen RC, **Chang P**, Vetter RJ, Lukka H, Stokes WA, Sanda MG, Watkins-Bruner D, Reeve BB, Sandler HM. Recommended patient-reported core set of symptoms to measure in prostate cancer treatment trials. *Journal of the National Cancer Institute*. 2014 Jul 8 106(7).

Gay H, Michalski J, Hamstra D, Wei JT, Dunn RL, Klein E, Sandler HM, Saigal C, Litwin M, Kuban D, Hembroff L, **Chang P**, Sanda MG, PROSTQA Consortium. Neoadjuvant androgen deprivation therapy (NADT) leads to immediate impairment of vitality/hormonal and sexual quality of life: Results of a multi-center, prospective study. *Urology*. 2013 Dec; 82(6): 1363-8.

Kidney Cancer

Philosophy

Advanced Multidisciplinary Kidney Cancer Care

As Dana Farber/Harvard Cancer Center's (DF/HCC) lead site for kidney cancer, BIDMC has the largest team of specialists with a specific clinical and academic interest in kidney cancer in New England, and one of the only multidisciplinary kidney cancer clinics in the northeast. This includes surgeons, medical oncologists, radiologists, pathologists, radiation oncologists, social workers, nurse specialists, and psychiatrists. Patients with advanced disease see not just one doctor but a team of kidney cancer specialists. In weekly meetings, our team collaborates to discuss challenging cases to determine the best treatment options. This integrated approach to evaluation and treatment enhances patient care.

As DF/HCCs lead kidney site, we have received Kidney Cancer SPORE funding: this is the largest NCI-sponsored multi-center grant for kidney cancer in the country. Our team continues to make novel treatment and research breakthroughs in kidney cancer, advancing the field in Boston and around the world. Very few places, if any, have such a high concentration of kidney experts, providing you with the widest and most updated array of treatment options.

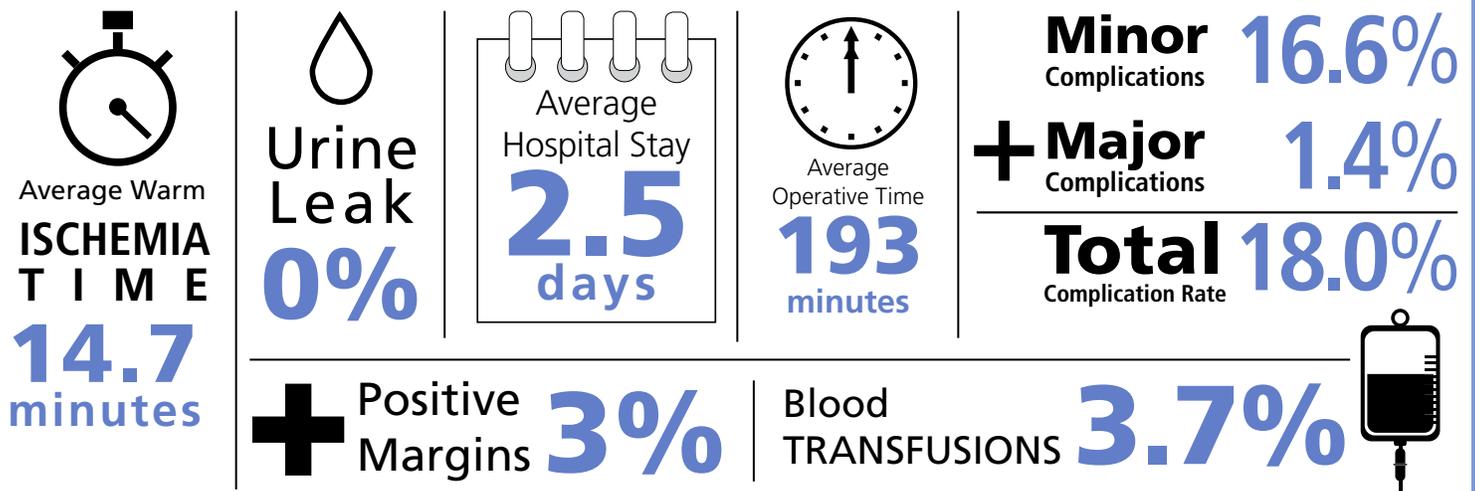
Robotic Partial Nephrectomy

Our team has **the most experience with robotic partial nephrectomy in Massachusetts**. We have pioneered novel approaches to this surgery, allowing for safe removal of tumors while sparing damage to the normal kidney and preserving kidney function. For the last five years, we have used an "early unclamping technique." This procedure allows the tumor to be removed while drastically reducing the amount of time blood flow to the kidney is stopped. Our results demonstrate complication rates and "ischemia time" among the best of all published series. We also published our novel approach to upper pole tumors, known as the "transposition technique." This allows safer access to difficult-to-reach tumors while allowing the surgeon excellent visualization of the tumor and kidney blood vessels.

Kidney cancer patients at BIDMC are cared for by New England's best multidisciplinary team of kidney cancer specialists. We provide the most technologically advanced surgical and medical care for our patients, and at the same time make each patient part of the team through open lines of communication and education. As we believe well-informed patients live longer healthier lives, we encourage our patients to learn about and become involved in their care whenever possible.

BIDMC urologic oncology surgeons are acknowledged as New England's leaders in robotic and laparoscopic surgery for kidney cancer. We perform 100 to 150 kidney cancer surgeries annually, and **90% of our surgery, even for complicated cases, is minimally invasive**. Because we see a large volume of advanced kidney cancers from around the country and beyond, we are especially skilled at removing smaller tumors robotically (robotic partial nephrectomy) and large tumors laparoscopically — even very large tumors that are starting to invade surrounding structures (laparoscopic radical nephrectomy).

ROBOTIC PARTIAL NEPHRECTOMY AT BIDMC BY THE NUMBERS



Kidney Cancer Surgery Research

With a large clinical volume of kidney cancer surgeries comes a responsibility to gain knowledge for future generations of patients and clinicians. Our research interests cover important areas such as developing novel surgical techniques, to finding non-surgical treatments using state-of-the-art technology, evaluating quality of life after surgery, and identifying ways to improve cost effectiveness of cancer care. Read on for more information on our studies.

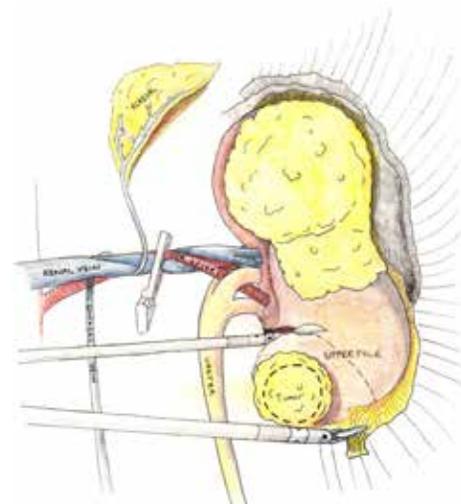
Small Kidney Masses: Choosing No Surgery When Possible

In 2012, we joined up with the kidney cancer team from Johns Hopkins University to evaluate the safety of “surveillance” of small kidney masses. This project, named “DISSRM” (Delayed Intervention and Surveillance for Small Renal Masses), has blossomed into a full-fledged collaboration, and is helping to change the way urologists approach the treatment of small kidney masses for select patients.

Together, we are following over 400 patients with small kidney masses and only a handful have eventually required surgery. We are also helping to design a scoring system to allow other doctors to determine when surveillance or surgery is more appropriate. We presented multiple abstracts describing our work at the 2014 American Urologic Association annual meeting in Orlando, and have recently published our results in *European Urology*, 2015.

Developing New Robotic Kidney Surgery Techniques

Our team has been performing robotic partial nephrectomy longer than any other team in Boston and we continue to pave the way. *We have developed even safer methods to remove kidney tumors while limiting ischemia time that can damage kidneys during surgery.* We have partnered with a multi-center group in France to share results using our “early unclamping technique,” in a first of its kind video manuscript. Also, a video describing our robotic kidney transposition technique won first prize at the World Congress of Endourology in Istanbul, Turkey in 2012.



This picture demonstrates transposition of the kidney during robotic partial nephrectomy. The kidney is transposed allowing for safer resection of hard-to-access upper pole tumors.

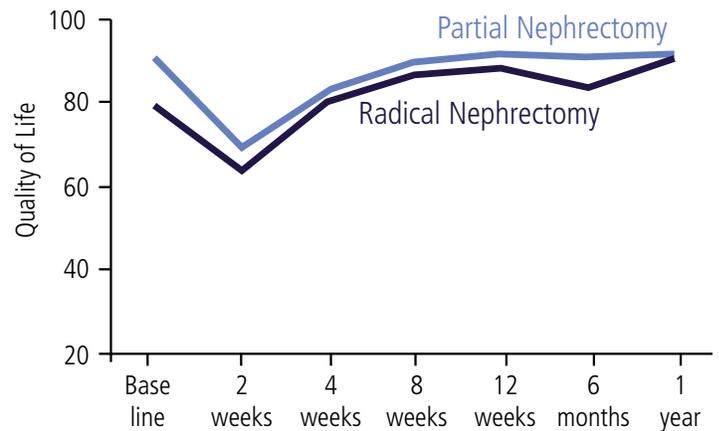
Cost Effectiveness Studies

There is still considerable controversy regarding the increased expense of robotics in surgery. Although we published on this topic in 2013, comparing the hospital costs of open, laparoscopic, and robotic partial nephrectomy, the overall financial impact of these surgeries has never been quantified and our team is currently evaluating several different ways to do this. This year we designed and carried out a pilot study to evaluate the societal impact of kidney cancer surgery. Our results showed the typical patient societal costs after kidney surgery were approximately \$10,000 and even higher in certain patient populations. We are very excited about this project and recently had our work accepted for presentation at both the American Society of Clinical Oncology Meeting in Orlando (Feb. 2015) and the American Urologic Association Meeting in New Orleans (May 2015). Future funding could help us study the overall financial impact of minimally invasive surgery on health care in the United States.

Quality of Life After Kidney Surgery: What is the Best Approach?

Through seed funding from the Kidney Cancer Association, and generous philanthropic support from BIDMC patients, we have developed a multi-center project to prospectively evaluate the quality of life in patients following kidney surgery. In particular, we are interested in objectively comparing recovery between different types of surgery, such as partial and radical nephrectomy. Also we are evaluating the differences in recovery between open and robotic surgery. Pilot data from this work was published in the journal *Urology*. More recent updates were presented in October 2014 at the New England Sectional meeting of the American Urologic Association annual meeting in Newport, Rhode Island and will be presented in 2015 at the American Association of Urology National Meeting in New Orleans. Through continued philanthropic support, we are now enrolling patients into our study from Maine Medical Hospital in Portland, Maine, making this one of the largest multi-center projects in the country specifically designed to study recovery after kidney cancer surgery. This combined database will allow us to answer questions about kidney failure rates after surgery, compare recovery and quality of life after open, robotic and percutaneous surgery

Recovery From Laparoscopic Radical Nephrectomy (RN) and Robotic Partial Nephrectomy (PN)



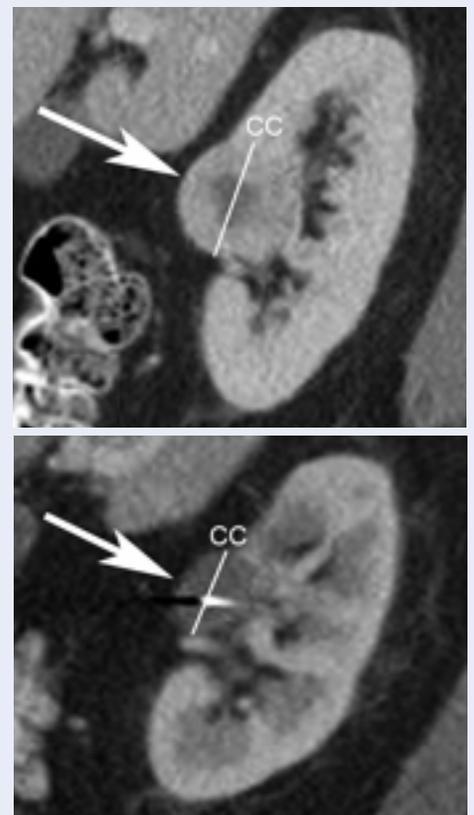
for kidney tumors, and evaluate cost effectiveness of different approaches to kidney tumors.

Above, we show a figure comparing the quality of life recovery of laparoscopic radical nephrectomy to robotic partial nephrectomy. We found that although most patients return to baseline by 4 weeks, many patients require longer than this for certain areas of quality of life.



Cyberknife® Radio-Surgery For Kidney Tumors

BIDMC is investigating innovative non-surgical treatments for smaller kidney tumors. CyberKnife is the newest technology to treat tumors without anesthesia or surgery. This approach offers superior targeting accuracy, sending pencil-thin beams of radiation into the tumor, while sparing the normal kidney and surrounding organs. BIDMC was the first center in New England to treat kidney tumors using the CyberKnife robotic stereotactic radiosurgery system. Our experience with this technology now exceeds 50 patients, but is still only offered to those patients who do not qualify for surgery based on existing medical or anesthesia risk. We have presented our early results with this approach at several national meetings including the GU ASCO meeting in San Francisco 2014, and submitted our data for publication. One patient's CAT scan is shown at right.



Patient with a 3 cm clear cell kidney cancer treated with CyberKnife radio surgery. 30 months after treatment there is significant decrease in tumor size and blood flow.



Future Goals and Directions

- Obtain external funding to allow us to expand our multi-center kidney cancer quality of life database to include patients from other Boston-area institutions.
- Evaluate different algorithms to examine societal costs after cancer surgery with help of investigators from Harvard School of Public Health.
- Collaborate with French researchers to evaluate robotic partial nephrectomy technique using early unclamping of renal artery.
- Continue to build on the DISSRM database with the Johns Hopkins team and evaluate active surveillance for small kidney masses.
- Develop a clinical trial to expand our indications for CyberKnife treatment of kidney tumors.

Laparoscopic Radical Nephrectomy and Cytoreductive Nephrectomy

Our surgeons can claim one of the most extensive experiences with advanced kidney cancer surgeries in the country. We are able to perform most of these surgeries laparoscopically, saving patients weeks or months of painful recovery. Cytoreductive nephrectomy is the removal of the entire kidney in patients with metastatic kidney cancer. Laparoscopic removal cuts down on recovery time and allows patients to return to work or receive drug therapy sooner (within weeks instead of months) than after traditional “open” surgery. Since 2006, 75% of the cytoreductive nephrectomy patients at BIDMC have had their surgery laparoscopically, a rate much higher than other area institutions.



Select Kidney Cancer Bibliography (2011-Present)

San Francisco IF, Sweeney MC, **Wagner AA**. Robot-assisted partial nephrectomy: early unclamping technique. *J Endourol* 2011; 25:305-8.

Williams SB, Kacker R, Alemozaffar M, Fancisco IS, Mechaber J, **Wagner AA**. Robotic partial nephrectomy versus laparoscopic partial nephrectomy: a single laparoscopic trained surgeon's experience in the development of a robotic partial nephrectomy program. *World J Urol* 2011; Jan 29.

Sun ME, **Wagner AA**, San Francisco I, Brook A et al. Need for intraoperative ultrasound and surgical recommendation for partial nephrectomy: correlation with tumor imaging features and urologist practice patterns. *Ultrasound Quart* 2012.

Kim SB, Williams SB, Cheng SC, Sanda MG, **Wagner AA**. Evaluation of patient-reported quality of life outcomes after renal surgery. *Urology* 2012; 79(6): 1268-73.

Alemozafar, M, Chang SL, Kacker R, Sun ME, Dewolf WC, **Wagner AA**. Comparing costs of robotic, laparoscopic, open partial nephrectomy. *J Endourology* 2013; 27(5): 560-5.

Kaplan JR, **Chang P**, Percy AG, **Wagner AA**. Renal transposition during minimally invasive partial nephrectomy: a safe technique for excision of upper pole tumors. *J Endourology* 2013;27(9):1096-00.

Chang P, Mao J, Taylor K, Dovorak O, Carneiro A, Percy A, Crociani C, **Wagner AA**. Patient-reported quality of life and convalescence after minimally invasive kidney cancer surgery. American Urologic Association Annual Meeting, New Orleans 2015.

Chang P, Renehan P, Taylor K, Dovorak O, McAnally K, Carneiro A, Crociani C, Percy A, **Wagner AA**. Societal costs after upper tract urologic surgery. American Urologic Association Annual Meeting, New Orleans 2015

Castaneda CV, Danzig MR, Finkelstein JB, RoyChowdhury A, **Wagner AA, Chang P**, Pierorazio PM, Allaf ME, McKiernan JM. The natural history of renal functional decline in patients undergoing surveillance in the DISSRM Registry. *Urologic Oncology*, 2015 in press.

Pierorazio PM, Castaneda CV, Danzig MR, Finkelstein JB, RoyChowdhury A, **Wagner AA, Chang P**, McKiernan JM, Allaf ME. Five year analysis of a multi-institutional, prospective clinical trial of delayed intervention and surveillance for small renal masses: the DISSRM Registry. *Eur Urol* 2015 in press.

Kaplan IK, **Wagner AA**, Mahadevan A, Dagoglu RN. Stereotactic body radiosurgery for primary small renal tumors: a retrospective analysis. GU ASCO, San Francisco, 2014.

Bladder Cancer

Robotic Radical Cystectomy and Totally Robotic Urinary Diversion

Although most patients with bladder cancer are successfully managed with local resections or bladder “washes” using local instillations of chemotherapy, a subset will progress to muscle invasive cancer and require a radical cystectomy — removal of the entire bladder and surrounding organs (prostate in men and uterus in women). Since 2009 we have performed the radical cystectomy for these patients using robotic assistance. Up until 2012, following the robotic removal of the bladder, we would make a traditional open incision to create the “urinary diversion.”

In 2012, we began a program to complete the entire operation (bladder removal and urinary diversion) robotically, thus sparing patients any large incisions. Since then we have been able to perform the cystectomy using the robotic approach in virtually all patients presenting with muscle-invasive bladder cancer. This has even included many patients with prior chemotherapy or pelvic radiation. Moreover, we are performing an extended pelvic lymph node dissection

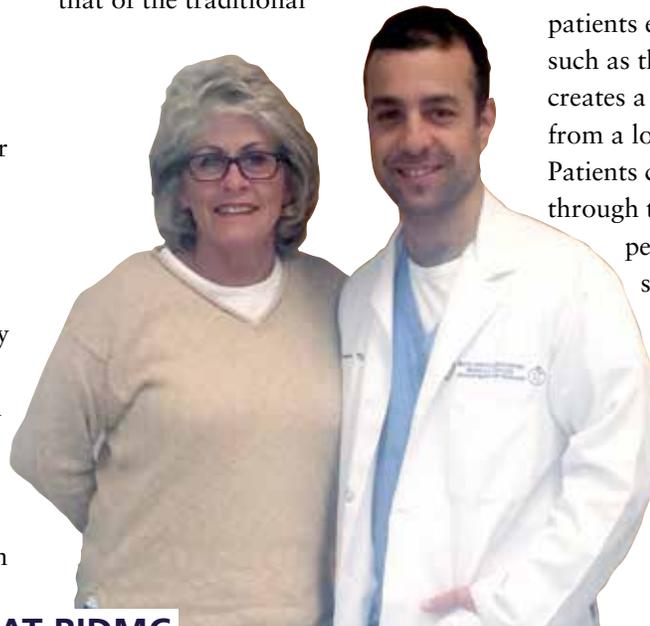
during this operation. A recent study documented that only 13% of patients received this extended lymph node dissection at academic institutions despite strong evidence showing that a higher lymph node retrieval during this surgery improves long term survival. Our extended lymph node dissection typically retrieves greater than 25 lymph nodes.

We have now been performing this operation successfully for two years with very promising results that mirror that of the traditional

open operation. To our knowledge we are still the only academic institution in Massachusetts performing this incredibly complex operation robotically. Our early clinical outcomes are displayed below.

All patients complete detailed questionnaires before and after surgery which help us understand the quality of life changes inherent to this major operation.

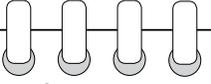
Moving forward we intend to expand our robotic approach to include patients electing “continent” diversions such as the neobladder. This procedure creates a new bladder pouch made from a longer section of intestine. Patients can void after the surgery through their native urethra. We have performed and published this surgery in an animal model previously. This procedure will require almost 8 hours to complete and there are only a few centers in the world currently pursuing a robotic approach for the neobladder.



ROBOTIC CYSTECTOMY AT BIDMC IS EXTRAORDINARILY SAFE


Average Operative Time
463
minutes


Preoperative Radiation
5%


Average Hospital Stay
8.6
days

 Positive Margins **11%**

Neoadjuvent Chemo
36%

Death Rate
0%


Blood TRANSFUSIONS
13%

 Average Blood Loss **396** cc

 Average Number of Lymph Nodes Examined **24**

The International Radical Cystectomy Consortium (IRCC)

In 2013, our team joined the IRCC, a multinational bladder cancer consortium headquartered at Roswell Park Cancer Institute in Buffalo, NY. With more institutions evaluating bladder cancer comes more research power — now we can evaluate recovery, complications and techniques more easily and more quickly, disseminating best practices and techniques to the rest of the consortium centers and the world. We are one of the few centers in this consortium to perform the entire operation using robotic surgical techniques. Several of our abstracts were presented at the 2014 American Urologic Association Annual Meeting in Orlando.

Select Bladder Cancer Bibliography (2010-Present)

Saar, M, Raza, SJ, Binkowski J, Richstone L, **Wagner AA**, et al. Oncologic safety after robot-assisted radical cystectomy: results from the international robotic cystectomy consortium. American Urologic Association Annual Meeting, Orlando 2014.

Raza SJ, Field E, Scherr D, Dasgupta P, **Wagner AA** et al. Long term survival outcomes of robot-assisted radical cystectomy: results from the International Robotic Cystectomy Consortium. American Urologic Association Annual Meeting, Orlando 2014.

Carneiro A, Dovirak O, Kaplan J, **Chang P, Wagner AA**. Robot-assisted ureteroileal reimplantation for post-cystectomy anastomotic stricture. American Urologic Association Annual Meeting, New Orleans 2015.



Future Goals and Directions

- Refine our technique for totally robotic cystectomy and urinary diversion.
- Develop a technique to perform a totally robotic neobladder operation.
- Develop a “point-of-care” bladder cancer quality of life instrument: With our expertise in creating point-of-care (in-office) instruments (questionnaires) to measure quality of life in prostate cancer patients, we would like to invest 1-2 years to create an instrument designed specifically to evaluate patients after their bladder cancer treatment. This instrument would be available at the “point-of-care” for clinicians, and represents a very unique and simple method to measure quality of patient care and allow comparison of different treatment approaches.



National and International Invited Teaching Presentations (2011-Present)

Dr. Wagner

05/2011 “Kidney cancer surgery in 2011... now what?” at Roswell Park Cancer Institute Grand Rounds – Invited faculty lecture, Buffalo, NY

11/2012 “Robotic prostatectomy, step by step” at Advances in Prostate Cancer Symposium: Research, Diagnosis and Treatment, Santiago, Chile

11/2012 “How to get a robotic surgery program off the ground” at Advances in Prostate Cancer Symposium: Research, Diagnosis and Treatment, Santiago, Chile

2010, 2011, 2012 Kidney Cancer Association Annual meeting – Invited faculty lecture, Chicago, IL

05/2013 Kidney Cancer “Take Home Messages” at the American Urologic Association plenary session, San Diego, CA

10/2014 “The carrot, the stick and the whip: optimizing training of our bedside assistants for robotic surgery” at NE-AUA state of the art lecture, Newport, RI

Dr. Chang

09/2011 “Building bridges: the identification of core symptoms and health-related quality of life domains for use in cancer research” at NCI Symptom Management & Quality of Life Steering Committee expert panel – Prostate Cancer

08/2013 “Measuring prostate cancer patient reported outcomes at the point of care” at Urology Grand Rounds, Emory University

05/2014 “Using patient reported outcomes to enable patient-centered prostate cancer care” Opening Speaker, Massachusetts Prostate Cancer Consortium annual symposium

05/2014 “Bridging the research and clinical realms in prostate cancer health-related quality of life management” at Early Investigators Showcase – AUA Research Forum 2014

New England Urology Training Course in Robotic Surgery

“(In the live case), we got to see the procedure play by play...we all know these surgeons by name but it was fantastic to have them so accessible... the presentations and hands on training was incredibly valuable... the course gave me insights, practical skills and confidence.”

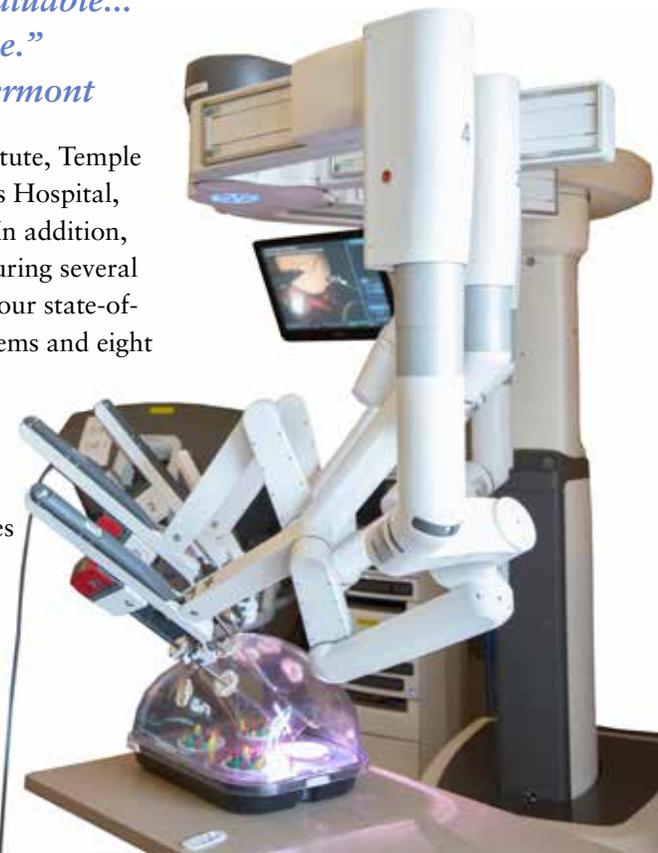
- Hagop Sarkissian, MD, resident, University of Vermont

As the demand for robot-assisted surgery increases so, too, does the need to train residents, fellows and attending surgeons. Yet there are just a small handful of courses in the nation that offer this training and, until very recently, none were in the Northeast. In November 2014, we offered the third annual New England Urology Training Course in Robotic Surgery. Led by Dr. Wagner, the two-day course attracted surgeons from throughout the country and from abroad.

This year’s course included lectures on robotic approaches to kidney, prostate, and bladder surgery and was taught by faculty from BIDMC, Lahey

Clinic, Roswell Park Cancer Institute, Temple University, Brigham and Women’s Hospital, and Boston Children’s Hospital. In addition, attendees were able to practice during several hands-on robotic sessions using four state-of-the-art, dual-console robotic systems and eight different simulation stations. As part of the course, an unedited robotic partial nephrectomy performed by the BIDMC team was shown to the course attendees in the BIDMC Carl J. Shapiro Simulation and Skills Center.

The New England Urology Training Course in Robotic Surgery will be offered again at BIDMC in 2015.



From past Urology training courses:



Chang Honored with Prestigious Award Made Possible by Generous Donors

In the fall of 2014, Dr. Peter Chang was selected to be the first incumbent of the Martin and Diane Trust Career Development Chair in Surgery, recognizing his promise as a young surgeon-investigator, and helping to support his research goals. Establishment of this career development chair was made possible through an incredibly generous gift of \$1 million to the BIDMC Department of Surgery by Mr. and Mrs. Martin and Diane Trust and the Trust Family Foundation. Through their generosity, Dr. Chang and future incumbents of the Trust Career Development Chair will have more opportunity to blend surgical expertise with scientific excellence.



Minimally Invasive Fellowship Training

In July, 2012, we began a urologic fellowship training program at BIDMC to train urologists in advanced techniques in minimally invasive urologic cancer surgery and research. Fellows spend 1-2 years at BIDMC pursuing advanced surgical techniques (much of which is robotic kidney, prostate, and bladder surgery), and urologic research in our department. Dr. Ostap Dovirak is our current fellow. He trained in urology at the SUNY at Buffalo School of Medicine and Biomedical Sciences Urology Residency Program and will be joining a private practice in Newport News Virginia at the conclusion of his training in July 2015.

Our robotic fellowship is the first of its kind in New England.

The minimally invasive fellowship is the centerpiece of our program. In addition to learning to perform complicated minimally invasive surgery, the fellow is involved in high-level teaching and research. For example, the fellow plays a major role in teaching our urology residents and medical students throughout the year in the operating room, simulation center, outpatient clinic, and in didactic lectures. Also, the fellow is the point person for every minimally invasive research project that is ongoing in our program and without the dedication, time, and involvement of the fellow, we could not move forward with many of these projects. Most importantly, after completion of our program, the fellow moves on to start his or her own minimally invasive urologic program and continue our tradition of outstanding clinical care, teaching and urologic research.

Funding of the fellowship is made possible through generous donations and grant support.



Dr. Peter Chang with Dr. William DeWolf, Chief of Urology



MINIMALLY INVASIVE UROLOGIC CANCER SURGERY

We Appreciate Your Support

A tremendous amount of resources are required to maintain an active clinical research program.

Without generous philanthropic support, we are unable to continue many of these projects. If you have any questions about the above projects or would like to become actively involved in our mission, please contact Dr. Wagner (awagner@bidmc.harvard.edu), Dr. Chang (pchang@bidmc.harvard.edu), or Michele Urbancic in the BIDMC Department of Surgery at 617-632-8388 or murbanci@bidmc.harvard.edu

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