

UPDATE

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2019 Survivorship Symposium

Toward a Precision Medicine Approach for Tinnitus

Thanos Tzounopoulos, PhD, is working to conquer the mysteries and complexities of tinnitus. As professor and vice chair of research in the Department of Otolaryngology, and as UPMC Endowed Professor of Auditory Physiology and director of the Pittsburgh Hearing Research Center, Dr. Tzounopoulos' basic and translational studies have provided significant new insights in recent years with respect to the pathological and mechanistic drivers of this common, highly heterogeneous, and often disabling condition.



About 10 to 15 percent of the entire U.S. population has experienced some variation and degree of tinnitus, with nearly 10 million seeking out medical care for the condition. Upwards of 2.5 million individuals are debilitated by the condition with severe effects on their quality of life. "We have no cure and limited therapies that can provide relief for these individuals. But we are making progress in understanding the cellular and molecular mechanics of what triggers the condition, and how we may be able to intervene pharmacologically," says Dr. Tzounopoulos.

In tinnitus, there is usually a triggering event, for example an acoustic trauma such as an explosion or prolonged exposure to high levels of sounds, or age-dependent hearing loss, that set off a cascade of events — some known, others still a mystery — that leads to an individual's experience of the condition which can be highly variable, from mild to outright unbearable. Additionally, there are mechanisms that work from a maintenance perspective that allow the continuation of the tinnitus leading to a permanent presence. Much of Dr. Tzounopoulos' research has been focused on the triggering mechanisms and molecular changes that occur in the brain, and how to intervene at an early stage to cut short and prevent a long-term or permanent manifestation of the condition.

Dr. Tzounopoulos' and colleague's research over the last 10 years has uncovered, among other aspects, a specific class of potassium channels responsible for the onset process of tinnitus. His work also has shown that modulation of this channel in his murine model of tinnitus via pharmacological intervention can prevent the development of the condition.^{1,2,4}

Working in collaboration with University of Pittsburgh chemist Peter Wipf, PhD, Distinguished Professor and director of the Combinatorial Chemistry Center and the Center for Chemical Methodologies and Library Development, the duo has discovered and continues to actively investigate the ability of a potassium channel activator known as RL-81³ — derived by them from the compound retigabine, an epilepsy medication — that may be able to function as a treatment for tinnitus because of its ability to target the potassium channel associated with the condition. Initial studies are underway in preclinical animal model trials.

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Toward a Precision Medicine Approach for Tinnitus Continued from Page 1

Tinnitus and a Multidisciplinary Pathway to Precision

In order to further the research into the mechanistic causes of tinnitus, and to define more accurately what will likely be numerous phenotypes of the condition, ultimately establishing an evidence-based differentiation of tinnitus and its underlying mechanisms, Dr. Tzounopoulos has assembled a team of multidisciplinary researchers from the University of Pittsburgh and Carnegie Mellon University to investigate and collaborate to develop new models of care.

“As it currently stands, tinnitus is thought of as being idiopathic or secondary in nature. We do not have a systematic characterization of the different paths of tinnitus,” says Dr. Tzounopoulos.

These new efforts aim to establish a path for replacing the empirical classification of tinnitus with a taxonomy from precision medicine. The goal of a classification system is to understand the inherent heterogeneity of individuals experiencing and suffering from tinnitus, and to identify what differentiates potential subgroups.

More importantly this differentiation will reveal what the members of a subgroup share in common based on the network, cellular, and molecular properties of their peripheral and central auditory and nonauditory networks involved in tinnitus. As such, this classification requires the understanding of the underlying mechanisms of tinnitus and will lead to a mechanistic-driven personalized medicine approach to the care of tinnitus patients.

“The goal is to move to a precision medicine approach because different patients, based on the damage that they have, are going to need different kinds of treatment. This is no different than, for example, how we are starting to conceive and approach other diseases, for example, cancer. This effort will be a first of its kind with respect to the study and treatment of tinnitus,” says Dr. Tzounopoulos.

Zinc: Neurotransmitter and Signaling in the Auditory Cortex

Zinc is a critically important micronutrient that facilitates the function of thousands of

proteins in the human body. Unbound zinc has been shown in recent years to act as a neurotransmitter in the brain in concert with glutamate. This has turned out to be an important process in the auditory cortex in the brain where this unbound form of zinc is responsible for modulating or adjusting the responsiveness of the brain to sound through a process called gain modulation.⁵

Dr. Tzounopoulos’ research group was the first to identify this role of zinc in the auditory cortex.

“It has revolutionized a part of my research, because we have been able to unmask the role of zinc in the auditory cortex and how it affects how we perceive sound.”

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- NIH, Tzounopoulos, Cell-Specific Synaptic Plasticity in the Auditory Brainstem, 5R01 DC007905, March 2016 - February 2022
- NSF, Tzounopoulos and Aizenman, NSF-IOS-BSF: Influence of neuronal zinc homeostasis on cortical responses to sound, IOS-1655480, September 2017 - July 2021

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Head and Neck Cancer Survivorship Update:

Recent Findings in Post-Treatment Neck Disability, and the Effects and Prevalence of Inadequate Health Literacy in Patients

Head and neck cancers (HNC), even if cured from a primary disease standpoint, can leave lasting and severe morbidities and quality-of-life issue for patients. Head and neck cancers (HNC) constitute the sixth leading cause of cancer worldwide, and there are approximately 60,000 new cases diagnosed annually in the United States. The majority of new cases are diagnosed as late-stage disease and typically have been associated with older adults — over the age of 50. However, with the rising rate of human papillomavirus-associated HNC, the overall trends are leading to an increase in cases and more cases diagnosed in younger individuals.



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Helping to prepare patients for these potentials before treatment and working with them to help them cope with the post-treatment management of their condition after the fact is the domain of the UPMC Head and Neck Cancer Survivorship Clinic in the Department of Otolaryngology.

The burdens of these cancers for afflicted patients are significant, from diagnosis through treatment, to post-treatment survivorship. The physical, emotional, psychological, and financial implications of a diagnosis of head and neck cancer tend to be overwhelming for many, and they persist long after the diagnosis and initial therapies have been provided.

Encompassing a range of disciplines and services, the Survivorship Clinic tackles all aspects of HNC patient care prior to and after treatment. Physical therapy, dental health, swallowing therapy, and audiology, are combined alongside other disciplines to create a cohesive, individualized program of care designed to deal with the biopsychosocial complexities of HNC patients.

Beyond and behind the Clinic's multidisciplinary care structure is an active research program that is investigating crucial aspects of HNC patient care — some of which receive little attention in the field but are nonetheless critical to long-term outcomes, patient satisfaction, and quality-of-life measures, and the oft-burdensome continuing costs of care and financial impacts associated with HNC. Some of the newest findings related to neck disability after treatment, and how a patient's health literacy can affect their ongoing treatment, have been a focus of both **Marci Nilsen, PhD, RN**, a researcher at the University of Pittsburgh School of Nursing and one of the

nurses in the Survivorship Clinic (and who initially worked to launch it with a group of colleagues, including department chair **Jonas Johnson, MD, FACS**), and **Leila Mady, MD, PhD, MPH**, who is currently a fifth-year resident in the Department of Otolaryngology.

HNC Treatment and Neck Disability

Surgical treatments for HNC can present patients with substantial morbidity in relation to various aspects of neck disability and concomitant declines in quality of life. Dysphagia and potential complications, fibrosis and accompanying pain and limited range of motion, disruptions to sleep patterns, and other issues are potential, serious, long-lasting complications that patients may experience. Coupled with the growing population of younger HNC patients due to the increasing incidence of human papillomavirus-associated HNC, post-treatment morbidities such as neck disability may present as a much longer consequence of treatment as treatment efficacy increases and more survivors are living longer.

But what about neck disability after non-surgical treatment approaches to HNC? This aspect of neck disability post-HNC treatment has been a recent focus of Drs. Nilsen and Mady and their colleagues in the Survivorship Clinic. "Nonsurgical treatments for HNC and resulting neck disability has not attracted a lot of research, and there are few studies in the literature that have been devoted to the subject," says Dr. Nilsen.

A new study, for which preliminary results were presented in an abstract at the 2018 AHNS annual meeting (the full study is

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currently under review for publication), sought to provide a basis for and determine the prevalence of neck disability in three cohorts of HNC patients: 1) those that received nonoperative treatments of radiotherapy or chemotherapy, or a combination thereof, 2) surgical resection only, and 3) surgical resection plus adjuvant therapy.

Preliminary prospective study¹ findings examined 173 cases of squamous cell carcinoma of the head and neck in the primary setting. Highlights of the study include the following outcomes. More than half of the patients in the study reported some form of neck disability. Of that total, more than a third reported a degree of disability from moderate to complete. More than half of the nonoperative treatment cohort reported neck disability. Those individuals that had both surgery and adjuvant therapy were more likely than others to report neck disability.

These findings speak to the growing body of evidence of the substantial impacts to quality of life that HNC treatments can pose to patients. And both Drs. Nilsen and Mady say that clinicians need to be able to not only screen patients for treatment-related toxicities but to better advise them in advance of the potential complications. “I’ve heard many — perhaps too many times — from patients who have experienced severe treatment toxicities, that if they had known how bad it could get, or how burdensome these potential outcomes could be, they would have been better prepared and understood this possible symptom burden, and may have made different decisions or preparation for their care. We have to set proper expectations with these patients, because under-communicating the risks leads to bad outcomes for both patient and provider,” says Dr. Mady.

And while this communication and ongoing assessment of the patient is critically important to the care process, it has to be conducted in a disciplined and clear manner, and take into account the patient’s health literacy. This notion of the importance of managing to a patient’s health literacy is another ongoing research area for the Survivorship Clinic, and an area in which its clinical practice and measurement are being tested and refined.



Health Literacy and HNC — Perspectives and Practice

Understanding and managing to a patient’s health literacy level is virtually as important to their overall care as their actual treatment. If a patient cannot fully comprehend their care instructions, they are at higher risk for treatment noncompliance which inevitably leads to decreases in quality of life and morbidity. “As clinicians, we likely assume a much higher level of literacy than our patients actually have. The communication process is complex, intense, and can happen quickly. Many of our patients present with advanced disease that will require complex treatment. Proactively assessing literacy and managing the patient to that level ought to happen much more frequently than it likely does. Dr. Nilsen’s work in this area, with the implementation of a screening tool in the Clinic, and her ongoing research into the impact health literacy has on HNC survivorship, is an important aspect of how we care for our patients,” explains Dr. Mady.

From a clinical perspective, the Survivorship Clinic implements the screening protocol as part of the initial patient intake process. “We use the three-question Brief Health Literacy Screen (BHLS), which assesses a patient’s perception of their health literacy. It’s subjective, so there are some limitations, but it gives us a score and a starting point for how we may need to communicate with the patient. The entire multidisciplinary care team that the patient is going to see during their Clinic visit has instant access to this information — before they even lay eyes on the patient for the first time,” says Dr. Nilsen.

This work, of course, is also being rigorously tested and analyzed as part of ongoing studies. An initial analysis of the use of the

BHLS in the Survivorship Clinic by Dr. Nilsen and one of her students, Anna Dainauski, looked at the prevalence of inadequate health literacy in a cohort of patients from the Clinic. Of the 232 subjects, 17 percent (40) scored low enough on the BHLS to be deemed to have inadequate health literacy. Interestingly, age seems to play a role, in that the mean age of these individuals was 68 compared to 63 for the group deemed to have an adequate level of literacy. Other factors such as type of disease and stage, marital status, and gender did not appear to be significant with respect to literacy levels.

“This small study shows us a couple of things. First, that our screening protocol works, and second, that our study seems to be consistent with those in other patient populations,” says Dr. Nilsen. And this is but the first step in building the body of evidence that will be needed to reshape practice in the long term. Dr. Nilsen has recently secured a grant to study health literacy in an inpatient population using a different, more objective assessment tool. “We’re also now interested in looking at readmission rates in patients deemed to have lower health literacy levels to see if we find a correlation. The implications for that ought to be obvious — if we can prove there is a relationship. Beyond that, we’re also taking a look at outpatient data related to how well outpatients adhere to our treatment and therapy plans from the recommendations we send home with them.”

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Pittsburgh CREATES: Research, Training, and Innovation in Surgical Technology

The science and art of surgery — the techniques and technologies, the training and teaching methods — have steadily progressed over millennia, from the crudest of forms to the highly sophisticated, technological discipline that continues to evolve and advance today.



Max Fedor
Executive Director
Pittsburgh CREATES



Umamaheswar Duvvuri, MD, PhD
Medical Director
Pittsburgh CREATES

“Our goal is to work with our strong network of industry partners to find new and disruptive ways to improve outcomes, while driving down the cost of surgical interventions through technology.”

Evolving and advancing the technological platforms that surgeons use now and those to come in the future, how surgeons are trained to perform surgery at its fundamental levels, how the marvel of robotic surgery will advance, and how new modalities such as machine learning and advanced imaging technologies will augment a surgeon’s practice is the mission of Pittsburgh CREATES, a new collaborative start-up from the University of Pittsburgh and partners UPMC and Carnegie Mellon University.

The scope of what Pittsburgh CREATES has laid out for itself in advancing surgical platform design and development, teaching surgeons how to use these platforms, and augmenting these platforms with new advances in technology is broad, multidisciplinary, and independent of any one surgical discipline. The mission goes far beyond just the worlds of robotic and minimally invasive platforms and the world of otolaryngology, where many of Pittsburgh CREATES members practice as physicians and researchers.

Starting with surgical robotics, a formerly niche field which has evolved to become a \$1.53 billion industry, Pittsburgh CREATES will pursue opportunities in computer-assisted image guidance, remote sensing, machine learning, and other technologies that will advance surgical practice and improve patient care and outcomes.

Umamaheswar Duvvuri, MD, PhD, who serves as the medical director of Pittsburgh CREATES, has a long, extensive history in the practice, design, teaching, and refinement of minimally invasive endoscopic and robotic surgical platforms. As director of robotic surgery in the Division of Head and Neck Surgery in the Department of Otolaryngology, and as director of the Center for Advanced Robotics Training (CART) at the University of Pittsburgh, Dr. Duvvuri has established himself as one of the leading practitioners, educators, and innovators in the field.

Together with **Max A. Fedor**, the executive director of Pittsburgh CREATES, and a staff of specialists working alongside an executive committee made up of a group of surgeons, administrators, and executives from both UPMC and the University of Pittsburgh, Pittsburgh CREATES has made rapid advances in its work since its launch in April 2018.

While Pittsburgh CREATES as an entity is new, the thinking behind it, the resources and expertise, the visionary leadership steering its course have existed for some time. Pittsburgh CREATES is a new embodiment of everything that its partners have been doing and accomplishing for a very long time. It’s the next logical step in the progressive growth and expansion of the ideas of its leaders and collaborators.

“Pittsburgh CREATES offers the opportunity to bring the unique strengths of our region to companies that are laying the groundwork for significant health care improvement in the surgical domain,” says Mr. Fedor. “Our goal is to work with our strong network of industry partners to find new and disruptive ways to improve outcomes, while driving down the cost of surgical interventions through technology.”

Industry Collaborations and Consultative Work

Innovation in a vacuum is typically not efficient, and it is even less so in the world of surgical device and platform design. Collaboration between the end users — the surgeons — and the engineers and industry members who bring technologies to market and the clinic is paramount. Bringing clinicians together with industry and engineers can make the development process more robust and expansive, and at the same time create more immediate and lasting value to the end users of the technology, and the patients who benefit from these efforts and advances.

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Pittsburgh CREATES *Continued from Page 5*

The Pittsburgh CREATES collaborative functions much like an institute or even a company. “One of our goals is to reach out to industry entities via business development pathways to bring in partners who will collaborate with our physicians. This is different than the traditional university/industry partnerships that happen through academic research. We do have that pathway, and we fully anticipate that we will have some collaborative or sponsored research projects evolve as time goes on, but we also have this great ability to function in a more consultative manner with industry because of our collective clinical expertise and resources,” says Mr. Fedor.

Pittsburgh Trains the Current and Next Generation of Surgeons

Training surgeons is a big component of Pittsburgh CREATES. It has also been a huge part of Dr. Duvvuri’s past work in the Department of Otolaryngology and specifically in the UPMC Center for Advanced Robotics Training, where he has trained surgeons from all over the world on how to use robotic surgical platforms.

“We embrace the idea of training within a simulated surgical environment. Within Pittsburgh CREATES, we have two surgical suites we can use to train physicians to do certain types of surgical procedures with robotic platforms. Currently, one lab has an Intuitive Surgical da Vinci robot, and the other one has a Medrobotics Flex Robotic System. The labs are flexible spaces we can configure for a number of possible setups, and surgeons can practice on either cadavers or physical models, with curricula that have been designed to measure the skills that are required to perform the procedure,” says Mr. Fedor.

“We see this as a means of evolving best practices and training techniques. Innovation in the education and credentialing of surgeons through the use of simulation and other technology-based approaches flattens the learning curve, leading to improved consistency, productivity, and outcomes,” says Jonas Johnson, MD, FACS, chair of the Department of Otolaryngology and member of the Pittsburgh CREATES executive committee.

“Surgery should be democratic, it should be egalitarian, it should be accessible to everybody. It shouldn’t be limited to just the select few people who happen to live in a place that has access to these kinds of resources, or that have the money to do this. So I think about robotics as a democratization of surgery,” explains Dr. Duvvuri. This is one of the reasons that much effort and resources are being allocated to not only help design and test simulation-based teaching tools with industry partners, but also to increase the number of surgeons who are able to effectively use these platforms for their patients. There are some parts of the world, and even many parts of the United States, where the expertise and resources to accomplish this simply do not exist. However, by creating innovative ways to train surgeons — be it directly through hands-on experience in Pittsburgh or through other means such as remote monitoring and training — Pittsburgh CREATES will help to spread the usability and practicality of robotic surgery to places in need.

Where and What Is the Future?

Pittsburgh CREATES and its leadership team are by definition forward-thinking, and are researching and working on technologies that will one day make it to the surgical operating theatre, the clinic, and the classroom.

Robotic surgical platforms in their current state are really master-slave systems at the control of the surgeon. They do what they are told, by and large. This of course will change in time as the world of machine learning and artificial intelligence grow and help to create new generations of tools that can function semi-autonomously. The benefits of this extend not only to practice surgery but also to how surgeons are trained, and how their training can be quantified.

Pittsburgh CREATES is working on related technologies that no doubt will one day improve the ability to do surgery. For example, molecular imaging during surgery has the potential to highlight the molecular characteristics of tumors, for example, so the surgeon can much more accurately delineate where a tumor stops and where normal tissue begins. This has the potential

for a more accurate initial surgery, perhaps cutting down on repeat procedures. It may one day better delineate which tumors are likely to be metastatic or aggressive. Used correctly, this kind of technology could have enormous potential to increase the accuracy of surgical care and create much more value for health systems and patients alike.

“We also have research happening right now on a new generation of robotics that will use artificial intelligence to improve existing platforms and help create semi- or autonomous robots. This won’t happen in the next two or three years, but long-term it will occur, and it will improve how we care for patients. And that is what it is about. Technology is great, but if it does not improve how we treat patients, and how well these patients do with our treatments, in my opinion the technology is useless. Value to the patient — and high value at that — is really the only metric that matters at the end of the day. This ought to be our guiding principle in the design or enhancement of any system we create or modify,” says Dr. Duvvuri.

To learn more about the Pittsburgh CREATES mission, plans, and current activities and partnerships, and for more biographic information on its leadership and partners, please visit PittsburghCreates.Pitt.Edu.

Pittsburgh CREATES Leadership and Staff

Max A. Fedor — Executive Director

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Free CME Courses in Otolaryngology

Biologics and Novel Therapeutics For Chronic Rhinosinusitis

Stella E. Lee, MD, discusses biologic therapies for chronic rhinosinusitis and current options for treatment.

Next Generation Sequencing of Locally Advanced WDTC

Umamaheswar Duvvuri, MD, PhD, gives a presentation on thyroid cancer and how to identify risk factors for progression.

Pediatric Sleep Disordered Breathing

Allison Tobey, MD, gives a presentation on how to better identify patients in need of perioperative polysomnography.

Survivorship: Lessons Learned from a Head and Neck Cancer Survivorship Clinic

Marci Nilsen, PhD, RN, gives a presentation on raising awareness of the needs of cancer survivors. Dr. Nilsen covers topics like prevention and detection of new or recurrent cancers and coordination between specialists and primary care providers.

Hemostasis During Endoscopic Sinus and Skull Base Surgery

Carl Snyderman, MD, MBA, gives a presentation on some of the techniques, materials and tools for intraoperative hemostasis.

Hearing, Cognition, and Health Outcomes

Catherine Palmer, PhD, gives a lecture on the role of untreated and unrecognized hearing loss.

An Overview on Tinnitus Research

Lori Zitelli, AuD, gives a presentation on Tinnitus, it's common characteristics, and the current standards of treatment. Dr. Zitelli also discusses the current state of evidence-based research into the condition, and how these findings are difficult to generalize and apply to treat this heterogeneous condition.

Endoscopic Endonasal Intracranial Surgery: Update

In this presentation, **Eric Wang, MD**, reviews the advantages of intracranial surgery via the endoscopic endonasal approach (EEA) with a specific focus on increased preservation of pituitary function. Dr. Wang's course reviews the relevant anatomy of the anterior skull base necessary for a transcribriform resection of a sinonasal tumor and other aspects of the EEA to skull base surgery.

Video Rounds

Researching a Viable Treatment for Tinnitus

Presented by: Thanos Tzounopoulos, PhD

Dr. Tzounopoulos discusses his search for a treatment for tinnitus, in addition to his cellular and molecular studies elucidating the basic biology and mechanisms for the causes and maintenance of the condition.

Update in Robotic ENT Surgery

Presented by: Umamaheswar Duvvuri, MD, PhD

Dr. Duvvuri discusses recent advances in robotic surgery for ENT patients at UPMC.

Head and Neck Cancer

Presented by: Jonas Johnson, MD, FACS

Furthering Education and Collaboration with Surgical Telementoring

Presented by: Carl Snyderman, MD, MBA

A Clinical Review of Balance Disorders

Presented by: Joseph Furman, MD, PhD

Benefits of Sublingual Immunotherapy

Presented by: Stella Lee, MD

Evaluating the Clinical Approach to Hearing Loss

Presented by: Catherine Palmer, PhD

Save The Date: 2019 Survivorship Symposium

August 5-6, 2019 – Pittsburgh, Pennsylvania

Overview

The purpose of this symposium is to provide fundamental information necessary for a comprehensive approach to survivorship care of head and neck cancer patients. This is intended to improve healthcare providers' ability to provide high-quality survivorship caring to the growing population of survivors.

Who Should Attend

Professional providers, cancer survivors, primary care physicians, nurses, residents, audiologists, speech-language pathologists, physical therapists, dentists and other interested health care professionals.



ABOUT OUR PROGRAM

The Department of Otolaryngology continues to be a national leader in the exploration of otolaryngology and human communication disorders. The department is highly ranked in research dollars awarded, and continues to provide faculty, residents, and students with the resources and support to generate new health care knowledge related to direct clinical practice and public health policy.

The department has more than 40 full-time faculty members, representing all the subspecialties of otolaryngology. While the primary mission continues to be providing high-quality patient care, we also are dedicated to advancing education and research within the field of otolaryngology.

To learn more about the UPMC Department of Otolaryngology, please visit UPMCPhysicianResources.com/ENT.

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A \$19 billion world-renowned health care provider and insurer, Pittsburgh-based UPMC is inventing new models of patient-centered, cost-effective, accountable care. UPMC provides more than \$900 million a year in benefits to its communities, including more care to the region's most vulnerable citizens than any other health care institution. The largest nongovernmental employer in Pennsylvania, UPMC integrates 85,000 employees, 40 hospitals, 600 doctors' offices and outpatient sites, and a 3.4 million-member Insurance Services Division, the largest medical insurer in western Pennsylvania. As UPMC works in close collaboration with the University of Pittsburgh Schools of the Health Sciences, *U.S. News & World Report* consistently ranks UPMC Presbyterian Shadyside on its annual Honor Roll of America's Best Hospitals. UPMC Enterprises functions as the innovation and commercialization arm of UPMC, and UPMC International provides hands-on health care and management services with partners around the world. For more information, go to UPMC.com.