



MedStar Health
Research Institute



MEDSTAR HEALTH RESEARCH

Highlights

2016

Knowledge and Compassion
Focused on You

MedStar Health Awarded Membership into the CDC SHEPherRD Program

MedStar Health Research Institute was awarded membership to the second cohort of the Safe Healthcare, Epidemiology, and Prevention Research Development (SHEPherRD) Program funded by the Centers for Disease Control and Prevention (CDC). MedStar Health Research Institute is one of a select group of organizational members of this cohort.

SHEPherRD was developed as an indefinite delivery, indefinite quantity contract to provide CDC a mechanism to collaborate with healthcare systems, academic and other research partners to perform research and quality improvement projects. Membership is divided into eight specific research areas. Membership into specific domains qualifies MedStar Health Research Institute investigators to bid as the prime contractor on CDC-released task orders. Across the entire SHEPherRD program, the CDC will fund projects totaling up to \$200 million over five years.

MedStar Health Research Institute was awarded membership into *“Acute Inpatient Care Quality Improvement and Research Implementation Infrastructure”*, as one of only four organizations. As part of this award, MedStar Health Research Institute has partnered with Abt Associates, a research organization specializing in large-scale data collection, evaluation and analysis of health problems, policies and programs. **This award leveraged MedStar’s academic partnership with Georgetown University to access the expertise of the O’Neill Institute for National and Global Health Law in assessing legal and policy interventions as related to the impact of infection control interventions.**

In addition, MedStar Health Research Institute is also a partner on the Abt Associates SHEPherRD award under *“Healthcare-associated infection (HAI) and Other Adverse Healthcare Event Prevention Research Protocol Development and Implementation”*. Membership under this specific domain allows Abt Associates to bid as the prime contractor on CDC-released task orders that will focus on successfully answering research questions posed by CDC, including study design, protocol development, database development, statistical support, background literature review, study implementation and data management and analysis services. If interested, MedStar Health Research Institute investigators could be investigators and collaborators under SHEPherRD proposals submitted by either MedStar Health Research Institute or Abt Associates.



New Ankle Replacement System Shown to be Safe in Post-operative Study

Researchers Eric W. Tan, MD; Camilla Maccario, MD; Paul G. Talusan, MD; and Lew C. Schon, MD, Department of Orthopaedic Surgery at MedStar Union Memorial Hospital assessed early data from patients receiving a new total ankle arthroplasty to determine the potential for complications.

Published in *Foot & Ankle International*, the data addressed in “Early Complications and Secondary Procedures in Transfibular Total Ankle Replacement” was from patients who underwent ankle replacements with the Zimmer Trabecular Total Ankle, an ankle replacement system developed and patented by Dr. Schon and his co-inventors.

This innovative ankle replacement system uses a lateral transfibular approach, which helps to avoid potential issues and complications associated with the standard anterior approach.

It is important to assess the safety of novel procedures and implants.

“In the first clinical use of this new implant, we focused on vigilance for complications or hardware failure in the early postoperative period,” said Dr. Tan. The patients studied showed no signs of implant failure, fibular nonunion or delayed union. Two complications were resolved with secondary surgery to replace symptomatic hardware and two were resolved with other secondary treatment. The findings showed that this total ankle system is safe in the short-term follow-up period.

The 20 participants were evaluated between 12 and 27 months postoperatively, after approximately 12 weeks of restricted weight-bearing and strengthening exercises. Patients showed statistically significant changes in pain levels and increases in range of motion at final follow-up.

Future investigations will study range of motion, pain, and complications with at least 24 months of follow-up to determine the effectiveness of the procedure and arthroplasty system.



Study Sheds Light on Why Medical Students Choose to be Surgeons

Data from a new, local prospective study on the impact of gross anatomy labs on first-year Georgetown University medical students showed an increased desire to work with their hands, enjoyment of working with instruments and tools and likelihood of pursuing a surgical career.

"It's fascinating to see the impact of certain courses on a student's career choice and I think it serves a roadmap for choosing learning environments and curricula that will get students excited about surgery," said Sonya Malekzadeh, MD, FACS, co-author of the study and professor of otolaryngology (head and neck surgery) at Georgetown University School of Medicine and MedStar Georgetown University Hospital.

In the prospective study, 60 first-year Georgetown University medical students completed surveys before and after gross anatomy labs to determine the impact of the course and to identify influences in career decision making. Each survey was followed by a five-point Likert-type scale to survey participants' interests, specific personality traits, experiences during the course of gross anatomy and likelihood of pursuing a surgical career.



The study showed 31.7 percent of students were more likely to pursue a surgical career after gross anatomy, a decreased interest in 16.7 percent and unchanged interest in 51.7 percent of students; 21 percent of those who previously felt neutral agreed that they were likely to pursue a career in surgery at the conclusion of the laboratory.

This paper received the 2016 American Association of Clinical Anatomists Keith and Marion Moore Blue Box Award for the best student paper published in Clinical Anatomy.

Dr. Malekzadeh is a 2010 graduate of the first class of MedStar Health's award-winning Teaching Scholars program, a partnership between MedStar Health Research Institute and MedStar's Academic Affairs division that enables clinicians to utilize research methodology so they can apply it to the scholarship of education.

MedStar Health Selected by AHRQ to Evaluate Patient Safety Surveillance System

MedStar Health has been selected by the federal Agency for Healthcare Research and Quality (AHRQ) to study the accuracy, efficiency and usability of its patient safety surveillance system, Quality and Safety Review System (QSRS), to detect adverse events in medical records during its pilot phase in hospitals.

“QSRS has tremendous potential, and this research takes it a step further by facilitating validation and optimization of the system, so that its data can be used to understand adverse events in hospitalized patients, and subsequently to prevent future occurrences,” says Kathryn (Kate) Kellogg, MD, MPH, a principal investigator of the task order.

QSRS is being developed by AHRQ to replace the legacy Medicare Patient Safety Monitoring System (MPSMS). While the MPSMS has advanced the science of patient safety measurement, the current system has approached its limits, as it only has the capabilities to measure a specific set of safety events. The QSRS relies on clinical information recorded in medical records and applies standard definitions and algorithms to more easily identify events and generate adverse event rates and trends.



Raj Ratwani, PhD



Kathryn Kellogg,
MD, MPH

These features provide AHRQ and other users of the system the ability to measure all causes of harm and ensure that events can be accurately identified.

In addition, testing of QSRS in hospitals will establish an opportunity to evaluate the system in ways not available with the current MPSMS system, by enabling wider use and a process for users to make recommendations for system improvements.

“This pilot test is a critical step toward achieving a standard surveillance system that could be implemented in any hospital,” says Raj Ratwani, PhD, also a principal investigator of the task order.

The research and execution for this task order will be conducted by Drs. Kellogg and Ratwani with support from associates at MedStar Health Research Institute, MedStar Institute for Innovation and MedStar Health Institute for Quality and Safety.

MedStar Health Researchers are First in the World to Enroll in Lung Cancer Trial

Researchers at the Harry and Jeanette Weinberg Cancer Institute at MedStar Franklin Square Medical Center have enrolled the first patient in the world in a Phase III study of treatment for lung cancer.

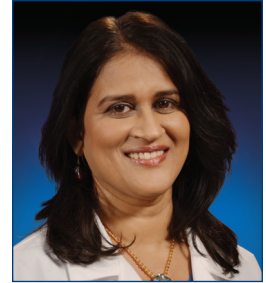
Estimated enrollment for “A Randomized, Double-Blind, Phase III Study of Carboplatin-Paclitaxel/Nab-Paclitaxel Chemotherapy With or Without Pembrolizumab (MK-3475) in First Line Metastatic Squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-407)” will be approximately 560 patients from around the world. These patients will be treated over three years. This study is sponsored by Merck Sharp & Dohme and is being conducted at MedStar Franklin Square and MedStar Union Memorial Hospital, both located in Baltimore.

This enrollment is a testament to the coordinated care that patients receive from the entire team, including front-line associates, pharmacy, administrative and clinical research staff, and Suman Rao, MD, and Kevin Chen, MD.

“I have seen the difficulties that other sites face trying to get studies started and patients scheduled to fit protocol requirements and I know that our site does a phenomenal job coordinating care,” said Jean M. Flack, BSN, OCN, CCRC, manager, Oncology Research at MedStar Baltimore Oncology Network. “Everyone does a superb job helping us with our research patients.”



Kevin Chen, MD



Suman Rao, MD

Effects of Stress in the Emergency Department Funded for Research on Simulation Training

The Agency for Healthcare Research and Quality (AHRQ) has awarded a \$100,000 grant to Kathryn Kellogg, MD, MPH, to research the effects of stress in emergency medicine. The project, "Identifying Stress-Associated Factors to Develop Advanced Emergency Medicine Simulation," focuses on the types and causes of stress that can affect patient outcomes in emergency situations.

Current research shows that stress not only has a negative impact on the well-being of patients and clinicians, but it also has a negative effect on decision-making, technical skills and team interactions, which can lead to patient harm. The existing literature on stress focuses on data collected through surveys and interview data.

This research will identify specific stress-associated factors within an emergency department (ED) situation. **Through a combination of physiologic responses and observational data, Dr. Kellogg and colleagues will produce a comprehensive list of stressors that can be correlated to physician physiologic response.** Following creation of this list of stressors, Dr. Kellogg and her team will conduct focus groups and interviews to validate the stressors.

This research will rely on an innovative method of measuring stress.

"We have pilot tested an innovative method of measuring stress that utilizes unobtrusive sensors to capture physician physiological response," said Dr. Kellogg.

This method allows for the combination of qualitative data with observational data to create a more complete picture of the environmental factors that may cause workplace stress in an ED.

Building on this research and MedStar Health's work in simulation, the results from this study will be used in subsequent projects to develop preliminary scenarios for simulation training, with the intention to improve stress-induced reactions by ED physicians. In addition to supporting training for current clinicians, this work will develop "stress-management training tools and higher fidelity simulations to better prepare physicians-in-training for their clinical practice," said Dr. Kellogg.



MedStar Health Community Clinical Research Center Achieves NIH Target With 150th D2d Participant

MedStar Community Clinical Research Center (MCCRC) has randomized and enrolled their 150th D2d participant at the University Town Center location. The Vitamin D and Type 2 Diabetes (D2d) Study is a nationwide, multi-site study, designed to determine whether high-dose vitamin D supplementation is safe and effective in delaying the onset of type 2 diabetes in people at risk. Additionally, the investigators look to gain a better understanding of how vitamin D affects glucose metabolism.

The D2d study is funded by the National Institutes of Health and is taking place in 22 sites across the United States. Since beginning enrollment screening in October 2013, the staff of MCCRC have screened 402 patients. By enrolling the 150th randomized patient, they have reached their study goal for enrollment. The D2d investigators hope to enroll approximately 2,400 patients across the country.

The 150th participant, pictured here with Veronica Rodriguez, clinical research coordinator, and Vanita Aroda, MD, MedStar Health Research Institute principal investigator, is the brother of Jean Flack, clinical trial manager for Oncology Research in Baltimore. It is very meaningful that our own MedStar Health Research Institute family is supportive of the research process, making personal referrals for study consideration. Dr. Aroda personally thanked the participant for his willingness to pose for this picture, to which he replied, "No problem—I'm part of the team now."



The D2d study is also being conducted at the Good Health Center at MedStar Good Samaritan Hospital in Baltimore, Maryland, with Jean Park, MD, and Adline Ghazi, MD, as co-investigators. MedStar Good Samaritan staff began enrolling participants in 2014 and is over 70 percent of the way to their goal. **MedStar Health is a strong contributor to D2d, with enrollments that account for over 11 percent of all enrolled participants in this trial.**

Craig H. Neilsen Grant Awarded to Improve Detection of Urinary Tract Infections among Spinal Cord Injury Patients

Suzanne Groah, MD, MSPH, has been awarded a \$500,000 grant by the Craig H. Neilsen Foundation to support screening for urinary tract infections (UTIs) among patients with spinal cord injuries at MedStar National Rehabilitation Network.



**Suzanne Groah,
MD, MSPH**

“Urinary tract infection is the most common bacterial infection seen in the outpatient setting and the most common healthcare-associated infection, making it a major worldwide public health problem,” said Dr. Groah. In addition, spinal cord injury patients are at high risk for recurrent UTI, which is known to cause significant pain and discomfort. Mobility limitations, however, often create barriers to these patients receiving comprehensive care.

The study, “Development of a Urinary Symptom Questionnaire for People with Neuropathic Bladder,” will develop a questionnaire for individuals being treated for bladder dysfunction due to spinal cord injury to assist them in self-assessments of their health. **The process of creating the questionnaire is centered on working with patients with spinal cord injuries, focusing on utilizing their feedback to develop usable tools for others through focus groups and interviews.** Focus groups will help develop the questionnaire, which will be validated and assessed by a large, diverse, national sample of people living with spinal cord injury.

The goal is that other patients will be able to use the tool to self-assess whether their symptoms may be related to a UTI.

“When the study team surveyed people with neuropathic bladder due to spinal cord injury and spina bifida, we found that UTI is a problem for more than 80 percent of people,” Dr. Groah said.

By creating this tool, Dr. Groah’s research team will have an enhanced diagnostic approach to UTIs within this population that will be useful in future research, clinical care, patient education, and patient and clinical decision-making.

Firefighters' Burn and Surgical Laboratory Supports Development Skin Regeneration Technologies

As part of a multicenter clinical research study, the Firefighters' Burn and Surgical Laboratory at MedStar Washington Hospital Center is helping to test the effectiveness of an investigational device called ReCell® by Avita Medical that enables clinicians to harvest skin cells from small sections of a patient's own healthy donor skin, yielding a potential treatment for skin regeneration in a burn injury area up to 80 times the size of the piece of the healthy skin. This product aims to improve upon traditional skin grafting and meshing techniques by providing coverage to a larger area and achieving better long-term scar outcomes.

In addition to this clinical trial, Avita Medical and MedStar Health have agreed that MedStar will conduct further research with this product.

"We've taken on a series of preclinical studies for Avita that are aimed at focusing on various aspects of this device and looking at next-generation augmentation of their technology," said Lauren Moffatt, PhD, director of the Burn Research Laboratory.

The research team also has plans for studies involving lasers, Dr. Moffatt said. "Lasers are being used a lot for scar treatment and skin pigment abnormalities, but the literature on how and why they are effective and under what conditions is limited. It's another area we want to help pioneer in order to provide new, targeted therapies to burn patients."

Jeffrey Shupp, MD, director of the Burn Research Program and co-founder of the burn research laboratory, said, **"Adding to and expanding the research portfolio of the Burn Center has really completed the multidisciplinary team we have here. We're focused on ground-up innovation, thinking differently and finding revolutionary ways to treat our patients."**



MedStar-Georgetown Surgical Outcomes Research Center Launches Program to Support Residents

MedStar Health Research Institute and MedStar Health Academic Affairs, in conjunction with the MedStar-Georgetown Surgical Outcomes Research Center, have officially launched their first joint program to support residents' interest in conducting research.

The new MedStar Surgical Resident Research Program is designed to encourage MedStar Health surgical residents to pursue careers focused on clinical, translational and medical education research in academic surgery by providing faculty mentoring and structure and bio-statistical and study design support from MedStar Health Research Institute's Biostatistics and Bioinformatics department.

Recipients of the year-long research award are Filipe Carvalho, MD; Chris Devulapalli, MD; Conor Hynes, MD; and Michael Sosin, MD.

Residents applied to this new program by submitting research proposals for review by the newly formed MedStar Surgical Resident Research Program Council co-chaired by Shimae Fitzgibbons, MD; Jeffrey Shupp, MD; and Waddah Al-Refaie, MD.

"As a novel program, this represents a pilot effort and, pending successful completion and review of program performance, may serve as a model for future expansion across MedStar Surgery," said Dr. Al-Refaie, John S. Dillon chair and chief of Surgical Oncology at MedStar Georgetown University Hospital and surgeon-in-chief of the Georgetown Lombardi Comprehensive Cancer Center.



Dr. Sosin, a third-year general surgery resident, was selected to research benefits of nipple-sparing mastectomy. Dr. Sosin said, "I applied to this program because it offers a unique opportunity of supporting resident-driven research that can be translated to optimization of patient care at the bedside and surgical decision making in the treatment of breast cancer."

Dr. Carvalho is a second-year urology resident selected to research a pre-surgical medication alternative to chemotherapy for patients with bladder cancer. Dr. Devulapalli was selected to investigate incisional hernias following major abdominal cancer operations. Dr. Hynes will examine the role of a type of stem cell in patients with diabetes mellitus, a condition that affects the body's ability to use energy from food.

"This is a wonderful opportunity for residents to see a research project through to completion with the help of the very best in the business," said Thomas J. Watson, MD, regional chief of MedStar Washington Integrated Surgery Service at MedStar Georgetown.

MedStar Health Services Researcher Awarded Grant to Study Payment Reform in Emergency Departments

Jessica E. Galarraga, MD, MPH, attending physician, MedStar Emergency Physicians, and clinical instructor, Georgetown University School of Medicine, has been awarded a \$100,000 Emergency Medicine Foundation Health Policy Research Scholar Grant.

Dr. Galarraga will be working on her project, "An Evaluation of a Payment Reform Experiment: The Effects of Global Budgets on Emergency Department Admissions and Associated Healthcare Costs," at MedStar Health and the Georgetown University School of Medicine. This grant is in addition to the New Investigator Grant that she received from MedStar Health Research Institute, as announced in June 2016.

"The state of Maryland has embarked on a payment reform experiment which aligns the financial incentives of hospitals with the incentives of population health to keep patients healthy and out of the hospital setting in an effort to control the trends in healthcare spending," said Dr. Galarraga. "This all-payer, global budget revenue (GBR) model incentivizes hospitals to minimize hospital admissions per given year and become cost-efficient in the care of admitted patients. If the new financing structure introduced by the GBR program is successful at reducing hospitalization rates, the leading source of national health expenditures, then this bold payment reform model in Maryland may become the precedent for addressing the healthcare cost dilemma for the rest of the country."

She hopes that her "research will introduce a foundation of understanding for emergency department (ED) providers on how the GBR model impacts ED care and may uncover the potential need for improved outpatient resources to balance quality patient care in the ED with the financial incentives of a GBR model."



Researchers Publish Study on Shoulder Replacement Materials

A study by Shannon R. Carpenter, Ivan Urits, and Anand M. Murthi, MD, Department of Orthopaedic Surgery, MedStar Union Memorial Hospital, titled "Porous metals and alternate bearing surfaces in shoulder arthroplasty," was published in *Current Reviews in Musculoskeletal Medicine*. In this study, the authors examined the long-term effects of innovative materials used in shoulder replacements.

Of the complications suffered by patients who undergo shoulder arthroplasty, 24 percent are caused by glenoid loosening, which may be caused by the implant designs. This study focused on innovative materials used in the creation of new prostheses. Currently, prostheses are primarily made of a combination of metals and polyethylene (plastic) components. Carpenter et al. found that the prosthesis design needs to be conducive to growth to increase the body's acceptance of the materials and thus increase longevity in the patient.

The team determined that using porous materials, such as porous tantalum or titanium, may increase the longevity of the prosthesis in patients. One effect of this new technology is the allowance for possible biological ingrowth into the porous material. These materials may provide increased duration of fixation compared with previous implant designs. The study examined the use of two types of porous materials, but because limited literature is available on the options, more study is required before either option can be endorsed.

Studies have shown that in both knee and hip replacements, modifications to the materials used in the creation of the prosthesis can extend the life of the prosthesis. **Increases in the life of the prosthesis affect patient outcomes, as a higher-quality or modified prosthesis will work better with the body and decrease the need for future surgery to repair or replace the joint.**



Current Reviews in Musculoskeletal Medicine, 2016.
DOI: 10.1007/s12178-016-9319-x

MedStar-Georgetown Publication Informs Stance on Medicare Hospital Readmissions Reduction Program in the Affordable Care Act

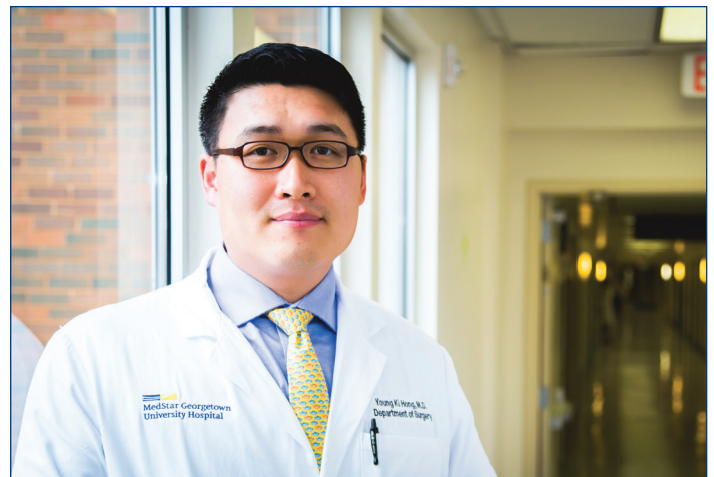
In addition to placing first at an American College of Surgeons (ACS) chapter meeting, Young K. Hong, MD, also helped to inform the stance of the ACS in relation to the Affordable Care Act. In presenting his team's research on minority hospital readmissions at a Washington, D.C./Virginia chapter meeting, Dr. Hong was awarded first place in the Commission on Cancer's resident competition for the presentation on "Minority-Serving Hospitals and Cancer Surgery Readmissions: A Reason for Concern". The research was published in the *Journal of the American College of Surgeons*.

The study evaluated 110,857 adult patient cases by using the California Inpatient Database. The cases evaluated were patients who had one of eight possible cancer surgeries. Dr. Hong and colleagues **found that one-fifth of all major cancer operations were performed at minority serving hospitals, and these procedures had a nearly 20 percent higher re-admission rate than hospitals serving other populations.** Minority-serving hospitals were defined in the study as being in the top quartile of hospitals serving Black or Hispanic patients.

Following the publication of this research, ACS released a press release regarding their position on Medicare Hospital Readmissions Reduction Program as part of the Affordable Care Act. In 2015, ACS submitted comments on behalf of their members, placing their support behind government policies that are based on clinical data over those that are based on claims-based data.

"Patient conditions and hospital infrastructure make vulnerable hospitals prone to higher readmissions from the outset. Policymakers need to be aware of the drivers that lead to higher readmissions at these hospitals so payment penalties do not push financially strained hospitals into further hardship," said Dr. Hong.

Dr. Hong is a resident in the Department of Surgery at MedStar Georgetown University Hospital. He is a staff member at the MedStar-Georgetown Surgical Outcomes Research Center.



MedStar Diabetes Study Finds Long-Term Effects of Traditional Treatment

The Journal of Clinical Endocrinology & Metabolism recently published a study authored by Vanita Aroda, MD, on the effects of metformin on vitamin B12 in patients with diabetes. In this article, titled "Long-term Metformin Use and Vitamin B12 Deficiency in the Diabetes Prevention Program Outcomes Study," Dr. Aroda and colleagues assessed the risk of B12 deficiency in patients enrolled in "The Diabetes Prevention Program (DPP)/DPP Outcomes Study (DPPOS)," which is funded in part by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health.

The DPP/DPPOS study represents one of the largest and longest studies of metformin treatment for people at high risk for diabetes, being conducted at 27 centers across the country. No previous literature exists on vitamin B12 status in those taking metformin. The DPPOS was recently funded for another five years, extending the lifespan of this research.

Smaller studies have suggested "an association between metformin and B12 deficiency," but the DPP/DPPOS study allows for ongoing research. While metformin is considered one of the safest and effective medications for treatment of type 2 diabetes, "interval screening for B12 deficiency should be considered for patients receiving this medication," says Dr. Aroda.



Dr. Aroda also presented on the results of the SUSTAIN 4 trial, at American Association of Clinical Endocrinologists 25th Annual Scientific and Clinical Congress. SUSTAIN 4 was a randomized, open-label, multicenter, multinational 30-week trial to investigate the safety and effectiveness of semaglutide, administered once-weekly, versus once-daily insulin glargine (U100/mL). "Type 2 diabetes is a complex disease and many patients on insulin are still uncontrolled," said Dr. Aroda. "The results of SUSTAIN 4 are encouraging, as once-weekly semaglutide demonstrated superior glycemic control compared to insulin glargine U100 in people that generally had a relatively long duration of type 2 diabetes."

MedStar Health Researcher Leads Study on Standardization of Aorta Measurements and Imaging

Federico M. Asch, MD, from the MedStar Cardiovascular Research Network and MedStar Health Research Institute, has published a study on the importance of creating a unified protocol for aortic measurements.



Federico M. Asch, MD

The study, "The Need for Standardized Methods for Measuring the Aorta: Multimodality Core Lab Experience From the GenTAC Registry," utilized the National Registry of Genetically Triggered Thoracic Aortic Aneurysms and Cardiovascular Conditions to understand the current limitations and lack of consistency in the methods used to perform aortic measurements, a key marker of risk for lethal complications, such as aneurysms and rupture.

Published by the *Journal of the American College of Cardiology: Cardiovascular Imaging*, the study used data from six national leading centers focused on the management of aortic diseases related to genetic conditions. In patients with aortic disease, imaging of the thoracic aorta allows for physicians to look for life-threatening complications and to determine timing of surgical intervention. Currently, there is no standardized protocol for this imaging and the resulting measurements.

In this study, 965 paired imaging studies from 930 patients were examined. The initial aortic measurements were provided by the enrolling clinical centers, following their local protocols. These "clinical" measurements were compared with those performed at a centralized laboratory, the MedStar Health Research Institute Cardiovascular Core Laboratory, using a standardized protocol for all images. **The study found significant variations in the protocols used at each clinical center and for different imaging modalities, resulting in significant differences in the aortic size measured.**

Importantly, these differences were resolved by using the standardized protocol implemented in the Core Lab. Dr. Asch and his co-authors (from MedStar Health and other institutions nationwide) concluded that a standardized protocol for imaging acquisition and measurement would better serve the clinical needs of patients susceptible to aortic events.

MedStar Health Research Team Publishes Study Results on Thyroid Cancer Treatment

The Endocrine Section at MedStar Washington Hospital Center has published an article in the *European Journal of Endocrinology*. In this article, "Phase 2 clinical trial of sunitinib as adjunctive treatment in patients with advanced differentiated thyroid cancer," the authors evaluate the efficacy and safety of sunitinib for patients with advanced differentiated thyroid cancer (DTC). The study was led by MedStar Washington Hospital Center investigators Kenneth D. Burman, MD, and Leonard Wartofsky, MD, with statistical support from Mihriye Mete, PhD, manager, and Sameer Desale, biostatistician, both of the MedStar Health Research Institute Department of Biostatistics and Bioinformatics.

In this trial, sunitinib exhibited significant anti-tumor activity in patients with advanced DTC.

This conclusion was based on tracking progression-free survival rates, of which the overall median progression-free survival was 241 days.

A new class of drugs, Tyrosine Kinase Inhibitors (TKI), represents an emerging therapy for progressive DTC. Sunitinib is an oral, small-molecule, multi-targeted TKI, which has already been approved by the U.S. Food and Drug Administration (FDA) for some other types of cancer.

In this nonrandomized, open-label, phase 2 clinical trial, 23 patients were evaluated with periodic imaging, laboratory tests, and physical examinations to track progression of the cancer. All participants had disease that had progressed despite having previously received large doses of radioactive iodine treatment.

The adverse events profile of sunitinib was similar to that of other FDA-approved TKI for DTC, and included diarrhea, fatigue, skin reactions on hands and feet, nausea, musculoskeletal pain, high blood pressure and decreases in blood cell counts. The authors concluded that sunitinib is relatively well tolerated and that further clinical investigation is warranted for the use of sunitinib as treatment for DTC.



European Journal of Endocrinology, 2016.
DOI: 10.1530/EJE-15-0930.

NIH Funds MedStar Health Program “Diabetes to Go” to Educate from the Bedside

MedStar Health Investigator, Michelle Magee, MD, has been awarded a National Institutes of Health (NIH) grant to study an implementation science study to assess the feasibility of having nurses integrate the “Diabetes to Go” education program into the workflow of hospital nursing to improve self-care and outcomes.

Dr. Magee, director of the MedStar Diabetes Institute at MedStar Washington Hospital Center, piloted “Diabetes to Go” as a MedStar Health Research Institute study that involved 125 people hospitalized with uncontrolled type 2 diabetes. Results showed that providing focused diabetes education in the hospital improved medication-taking behaviors after discharge and showed a trend for fewer Emergency department readmissions.

“What we found is that people want the education,” Dr. Magee said. “We mistakenly assume that people received this information at some point. In reality, not knowing how to manage type 2 diabetes is the issue for a lot of people. If we can use the opportunity offered by a hospital stay to teach essentials of diabetes self-care, we will be providing an important service.”

The “Diabetes to Go Inpatient” program is unique in that it merges multidisciplinary expertise in implementation science, nursing and specialized diabetes education. Dr. Magee and the MedStar Diabetes Institute team will collaborate with Kelly Smith, PhD, scientific director for MedStar Health Quality and Safety Research; Joan Bardsley, RN, CDE, MBA, assistant vice president for MedStar Health Research Institute; and Patricia McCartney, RN, PhD, director of Nursing Research, MedStar Washington Hospital Center, to conduct this research.

“Our work will inform how we can develop workable and efficient processes for our frontline staff to allow them to effectively engage with our patients to improve diabetes survival,” Dr. Smith said. **“When the research we do becomes an improved process in our hospitals and benefits our patients, that is bringing together the best of academics and real-world medicine.”**



MedStar Health and Georgetown Announce New Clinical Trial Management System

MedStar Health is pleased to announce a new collaboration with Forte Research Systems, a leading provider of clinical research software solutions. Through this collaboration, MedStar and its academic partner, Georgetown University, will implement Forte's clinical trial management system (CTMS) software solution, OnCore®.

Stephen R.T. Evans, MD, executive vice president, Medical Affairs and chief medical officer, MedStar Health, and Edward Healton, MD, MPH, executive vice president for health sciences and executive dean of the School of Medicine, Georgetown University, announced this newest development earlier this month in support of our investigators and clinical research teams.

"Georgetown University and MedStar Health are continuing to build on our synergistic partnership by strengthening our clinical research infrastructure to advance the health of our community. We are excited to embark on this partnership with Forte, a market leader in clinical research management software," Dr. Evans said.

The implementation of a single CTMS across both institutions will provide a unified infrastructure for clinical research. Specifically, the clinical research management module in the OnCore® Enterprise Research system will provide MedStar Health Research Institute investigators and teams with centralized management of protocols and research participants.



"OnCore will be a wonderful tool for our researchers, supporting them as they design and execute clinical trials to discover cures for a wide range of prevalent diseases and disorders," Dr. Healton said. "I'm so pleased to be collaborating with our clinical partner, MedStar Health, in this exciting endeavor."

The OnCore® CTMS suite will be implemented in MedStar's cardiology and oncology departments as pilot systems this year and will be integrated into all MedStar Health Research Institute departments after the pilot has been fully vetted.

MedStar Health Researchers Publish Novel Study on Cardiac Function in Women with Breast Cancer

Ana Barac, MD, PhD, staff cardiologist and director of MedStar Heart and Vascular Institute's Cardio-oncology program and Filipa Lynce, MD, breast oncologist with MedStar Georgetown University Hospital recently published a study in the *Breast Cancer Research and Treatment Journal*. In the study, "Cardiac function in *BRCA1/2* mutation carriers with history of breast cancer treated with anthracyclines", **Drs. Barac and Lynce found that women who are being treated with anthracycline for breast cancer do not have a higher risk of cardiac events if they carry the *BRCA1/2* gene mutation.**

The motivation for this research was data that demonstrated how mice with deletions of the *BRCA1/2* gene (a simulation of gene mutation that occurs in some women with breast cancer) were more susceptible to heart failure and death when treated with doxorubicine, an anthracycline class drug often used to treat breast cancer. The authors hypothesized that women who carry the *BRCA1/2* gene mutation and who have been treated for breast cancer with anthracyclines may be at higher cardiac risk compared to women who do not have the *BRCA1/2* gene mutation.

The study utilized 81 participants who had been treated in similar fashions with an anthracycline for breast cancer, with 39 of those participants showing mutation in the *BRCA1/2* gene and the remaining 42 participants without the gene mutation. The study participants were young and with low prevalence of cardiovascular risk factors and no evidence of hypertension.



The results demonstrated no significant differences in either left ventricular ejection fraction or myocardial strain between the two groups. Importantly, in this population of normotensive, primarily young breast cancer survivors, very few patients had evidence of decreased myocardial function that was not associated with *BRCA1/2* mutation status. The authors indicate that their findings, while requiring confirmation, indicate that there is no increase in cardiac risk with the use of standard-doses of anthracyclines in treatment of *BRCA1/2* mutation carriers with early stage breast cancer.

MedStar Health Researchers Publish Highly Cited Thyroid Paper in the *New England Journal of Medicine*

Kenneth D. Burman, MD, and Leonard Wartofsky, MD, have published a clinical practice article in the *New England Journal of Medicine* on the management of thyroid nodules.

In the article, the authors discuss this commonly encountered clinical problem, review the clinical guidelines, including those of the American Thyroid Association, and provide recommendations and an algorithm for evaluation of thyroid nodules. Slides of ultrasonographic images of thyroid nodules and thyroid fine-needle aspiration specimens are included.

Palpable thyroid nodules are common, with some patients having multiple nodules. Ultrasonography of the thyroid is more sensitive than palpation and detects thyroid nodules in many patients without suspected thyroid disease. The frequency of nodules increases with age. Only about eight to 16 percent of thyroid nodules are cancerous.

Risk factors for malignancy include a history of differentiated thyroid cancer in an immediate family member, experiencing external-beam radiation or exposure to ionizing radiation as a child or teen, prior diagnosis of thyroid cancer and male gender. Nodules that are benign tend to remain relatively stable in size. Nodules that are firm or immobile are more likely to be cancerous than those that are soft or mobile. A blood test to measure thyroid hormone levels should be routinely performed in patients with a thyroid nodule.



Kenneth D. Burman, MD



Leonard Wartofsky, MD

Nodule size, clinical context, and characteristics seen upon ultrasound are used to guide the decision to perform a fine-needle aspiration biopsy for further testing. **The authors recommend that in the absence of growth or suspicious clinical or radiologic findings, patients with thyroid nodules with benign findings upon fine-needle aspiration can then be managed by observation**, while those with nodules that show malignancy or suspicion of malignancy should be referred for surgery.

New England Journal of Medicine, 2015.
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MedStar Health Awarded Second AHRQ ACTION III Network Contract to Improve Patient Safety

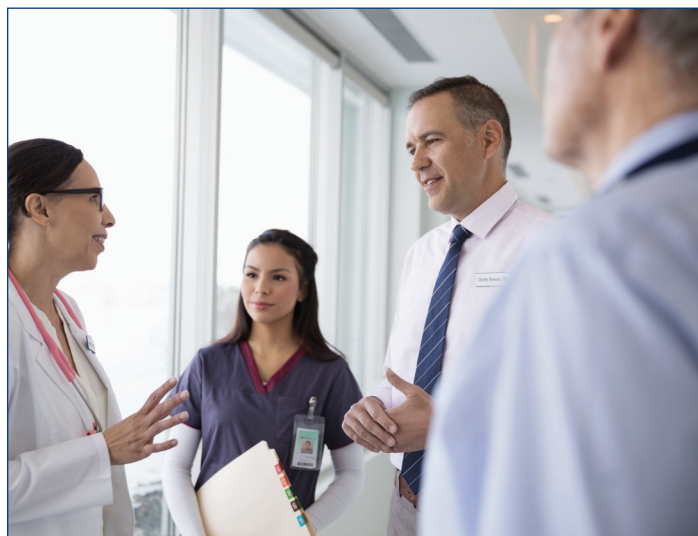
A team of MedStar Health researchers has been awarded a 38-month contract from the federal Agency for Healthcare Research and Quality (AHRQ) to design, develop, test and disseminate a guide for improving patient safety in primary care settings by engaging patients and families in their care. The award is through AHRQ's ACTION III (Accelerating Change and Transformation in Organizations and Networks) research network.

Research suggests that while there have been significant advances in patient and family involvement in hospital settings, the role of patient and family engagement in primary care settings has lagged behind. **The MedStar ACTION III team will build a robust, scalable and influential guide for patients and families in the primary care setting.** MedStar's experienced investigators, Kelly Smith, PhD, and Christine Goeschel, ScD, MPA, MPS, RN, FAAN, and patient and family investigator Martin Hatlie, JD, have collaborated extensively for more than a decade on initiatives that engage patients and families in improving healthcare safety.

This ACTION III project incorporates the strengths of a diverse research team; network partners, including CVS Health, Prince George's County Health Department, the Clinical Directors Network, Georgetown University and Consumers Advancing Patient Safety; and dissemination partners Iowa Healthcare Collaborative and Telligen Inc.

"MedStar Health is dedicated to bringing the community voice into our quality and safety initiatives through the efforts of Christine Goeschel, Kelly Smith and Martin Hatlie. We look forward to collaborating with the ACTION III Network to extend this critical work even further into the growing ambulatory care setting," says David Mayer, MD, vice president of Quality and Safety, MedStar Health.

MedStar Health Research Institute continues to be among the top 20 percent of U.S. institutions receiving funds from the National Institutes of Health and other federal agencies.



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**MedStar Health
Research Institute**

6525 Belcrest Rd.
Suite 700
Hyattsville, MD 20782
301-560-7300 **PHONE**
research@medstar.net **EMAIL**