MEDSTAR HEALTH RESEARCH

Highlights

2015

MedStar Health
Research Institute

MedStar Health Research Institute to Oversee Walt Whitman High School Sports-Related Concussion Study

Walt Whitman High School recently announced that the school is partnering with the MedStar Health Research Institute and a Bethesda neurotechnology firm, BrainScope, to conduct a research study that's designed to improve the recognition and diagnosis of sports-related concussions among student-athletes.

The study will test a new hand-held, noninvasive electroencephalogram (EEG) device developed by BrainScope that can quickly assess concussions and other traumatic brain injuries. MedStar Health researchers will recruit 50 varsity student-athletes to participate in the yearlong study. MedStar Sports Medicine physicians and concussion specialists, Elizabeth Delasobera, MD, and Kori Hudson, MD, will oversee the study, along with Andrew Lincoln, ScD, MS, director of the Sports Medicine Research Center for the MedStar Health Research Institute.

The study will follow participating student-athletes who meet specific criteria to see if they sustain a traumatic brain injury while playing a school sport. Those who are injured will undergo a standard screening protocol and be tested with the BrainScope handheld device within 24 hours and then undergo an magnetic resonance imaging (MRI) within 72 hours.

The MedStar Health Research Institute has been conducting similar research studies and outreach programs, including a concussion care and training program in collaboration with Children's National Medical Center, several head impact exposure studies looking at youth and collegiate lacrosse players as well as a national injury surveillance study examining the incidence of concussion in youth lacrosse players.

December 2015

MedStar Health Research Institute Renews Successful NIH Stroke Program at MedStar Washington Hospital Center

The MedStar Health Research Institute has recently been approved for continued funding within a five-year contract award for the NIH Stroke program at MedStar Washington Hospital Center.

In 2003, the Research Institute was first awarded a contract to serve as one of two clinical sites for research conducted by the NIH Stroke Program. The overall program is designed to study the use of magnetic resonance imaging (MRI) in the clinical evaluation of acute stroke and traumatic brain injury patients and to develop acute stroke therapies.

As part of the NIH Stroke Program, the Hospital Center's Comprehensive Stroke Center will continue to provide support and clinical services, including patient identification and referral; MRI and computed tomography (CT) support for imaging of prospective patients for referral and research participation; vascular neurology physician services; nurse coordinator services; emergency preparation and blinding of study drugs by a hospital pharmacist; chemistry and hematological laboratory tests required by the NIH team research protocols and NIH Stroke Care Pathway; general radiological services; neurosurgical and neuroradiological services; interventional radiology services; and neurointensive care and monitoring.

This contract award continuation is a reflection of the continued successful collaboration between the Hospital Center and the NIH Stroke program. Many acute stroke patients admitted to the Hospital Center are referred to the NIH Stroke team for evaluation and assessment for acute treatment and clinical trial eligibility. The Hospital Center's Comprehensive Stroke Center is led by Medical Director Amie Hsia, MD, a board-certified vascular neurologist. It is the first and only Joint Commission-certified Comprehensive Stroke Center in the Washington region and one of only approximately 85 hospitals nationwide.

A key element of the initial award was the placement of an NIH-supported 3T MRI scanner in close proximately to the emergency room. Medstar Washington Hospital Center has had uninterrupted NIH funding since that first contract was awarded more than 10 years ago.

MedStar to Design, Develop and Test Guide for Improving Patient Safety—Award is Second Contract from AHRQ ACTION III Network

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, pilot, 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 advancements in hospital-based patient and family involvement in patient safety, the role of patient and family engagement in primary care-based settings lags behind.

The project incorporates the strengths of a diverse research team and leverages network partners, including CVS Health, Prince George's County Health Department, the Clinical Directors Network (CDN) practice-based research network, Georgetown University, 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.

The team, assembled by MedStar ACTION III project leads, 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.

November 2015

A Celebration: 20 Years of the Women's Health Initiative Study

The Women's Health Initiative was established by the National Institutes of Health (NIH) in 1991 to address the most common causes of death, disability and impaired quality of life in postmenopausal women. It included randomized controlled trials of hormone therapy, low-fat diet and calcium/vitamin D supplementation to address cardiovascular disease, cancer and osteoporosis, as well as an observational study.

MedStar Health Research Institute's group enrolled nearly 4,000 women in three years, including the highest number of African American women per site to the study (57 percent of participants). The trials and observational study have produced 1173 papers as of September 2015.

The Women's Health Initiative enrolled more than 160,000 postmenopausal women at 40 clinical centers, making it the largest U.S. prevention study of its kind. MedStar Health Research Institute has been a part of the study for 20 years and has helped make significant strides toward women's health.

A presentation of the study took place on Tuesday, Oct. 13, and featured Dr. Barbara V. Howard, former Research Institute president and Women's Health Initiative principal investigator at MedStar Health Research Institute. Dr. Howard gave an informative overview of the study and results to a full room, in which you could feel the warmth, pride and engagement of those involved in the initiative. Geraldine Boggs, program manager for Women's Health Initiative, who will be retiring after 20 years and who was a vital contributor to this study and to the Research Institute, also was recognized at the presentation.

Amy Loveland, program manager, who worked with the study more recently, recalled a time when her mother had told her about a doctor's appointment in Michigan in which she had discussed with her doctor the results of Women's Health Initiative and what they meant for her.

"I knew if the news of the study made its way to a small town doctor in Michigan, I was doing something meaningful."

October 2015

MedStar Human Factors Study Examines Usability of Electronic Health Records

A study by the MedStar Health Human Factors Team (a division of MedStar Institute for Innovation), led by Raj Ratwani, PhD, senior Human Factors Research scientist and scientific director, was recently published in the Journal of the American Medical Association (JAMA) and is quickly garnering national attention, including testimony to the Senate Committee.

The study examined usability of electronic health records for physicians. The findings showed that vendors of electronic health record systems often fail to meet federal compliance rules and guidelines for user-centered design, with 30 percent of electronic health record vendors not attesting to a user-centered design process. The result may be an electronic health record with poor usability, with can lead to user frustration and safety risks for patients.

A certification requirement from the U.S. Dept. of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) says that to develop a certified electronic health record, vendors are required to employ a user-centered design. This process places the cognitive and information needs of the user at the forefront of software development and requires formal usability testing on eight different electronic health record capabilities to ensure the product meets its performance objectives.

Vendors must then provide written results of their usability tests to an ONC-authorized third-party. The ONC guidelines stipulate that at least 15 representative end user participants be included in the usability testing. This study analyzed these reports to determine whether usability certification requirements and testing standards were met.

Of the 50 reports that were reviewed, more than 60 percent did not meet the threshold of testing their systems with 15 users. The lack of adherence to usability testing may play a large role in contributing to the poor usability experienced by clinicians.

This work was highlighted in several media outlets including *Modern Healthcare, Healthcare IT News, Politco 1, Health Data Manamagent,* and *Medical Xpress*.

Dr. Ratwani, along with Terry Fairbanks, MD, MS; Zachary Hettinger, MD, MS; Alan Fong, MS, and the Human Factors team have received an Agency for Healthcare Research and Quality (AHRQ) RO1 award to develop and implement guidelines to improve health information technology usability.

October 2015

New England Journal publication on HCV/HIV Treatment Study

MedStar Health Research Institute Investigator Dawn Fishbein, MD, attending physician, Infectious Diseases at MedStar Washington Hospital Center, recently coauthored an article published in The New England Journal of Medicine on the results of a Phase III trial of a new treatment regimen for patients infected with both human immunodeficiency virus (HIV) and hepatitis C virus (HCV). This treatment regimen has significantly reduced the time it takes to cure HCV without interfering with the HIV antiretroviral therapy. Dr. Fishbein, with the support of the Research Institute's HCV team (Alex Geboy, program manager), was the Research Institute PI for this multisite trial that was designed to study use of combined daclatasvir and sofosbuvir (HCV inhibitors) for patients with HCV/HIV co-infection.

The combination of daclatasvir and sofosbuvir was highly effective when given for 12 weeks in patients with HCV genotypes 1-4. Over 90 percent of the patients were cured of HCV.

Liver disease is a leading cause of death among patients with HIV infection and co-infection with HIV appears to accelerate the course of HCV-associated liver disease. This open-label study, sponsored by Bristol-Myers Squibb, involved 151 patients who had not been previously treated for HCV and 52 previously treated patients, all of whom were co-infected with HIV Type 1. Previously, untreated patients were randomly assigned to receive either eight or twelve weeks of daclatasvir at a standard dosage of 60 mg daily (with dosage adjustment for concomitant antiretroviral medications) plus 400 mg of sofosbuvir daily. Previously treated patients were assigned to undergo 12 weeks of therapy. The primary end point was a sustained virologic response upon completion of the therapy.

Patients had HCV genotypes one through four. Fourteen percent had compensated cirrhosis, and 98 percent were receiving HIV antiretroviral therapy. The most common adverse events were fatigue, nausea and headache. No participants discontinued the study drugs because of adverse events, and HIV-1 suppression was not compromised in the participants.

October 2015

MedStar Health Research Institute Awards Summer Mental Health Research Scholarship

The MedStar Health Research Institute, in conjunction with the Georgetown University Medical School, is in the third year of awarding a summer research internship, supported by the Pines-Kleinman Mental Health Fund. The recipient of this year's award is Jeremy Chaikind, a rising second-year medical student who will focus on factors that predict success or failure in treatment for substance use disorders and addiction, under the direction of Risa Fishman, MD, and Bruno Anthony, PhD.

The Pines-Kleinman Mental Health fund was established in 2007 with donations from Wayne Pines, a director and former chairman of the board of the Research Institute, Carol Kleinman, MD, JD, a practicing psychiatrist in Chevy Chase, Maryland, and their family and friends. The intent of the fund is to support a summer research internship in the field of mental and behavioral health. The annual prize is awarded to someone who has demonstrated service excellence, "patient first" activities, innovation, inter-hospital collaboration, and/or leadership in the field of mental health research.

The summer research internship is designed for rising second-year medical students at Georgetown University Medical School who will work with an experienced investigator to gain greater understanding and experience in research. The intern will take part in a research project that will contribute to a better understanding or treatment of mental health and, ultimately, lead to advancing health care through research.

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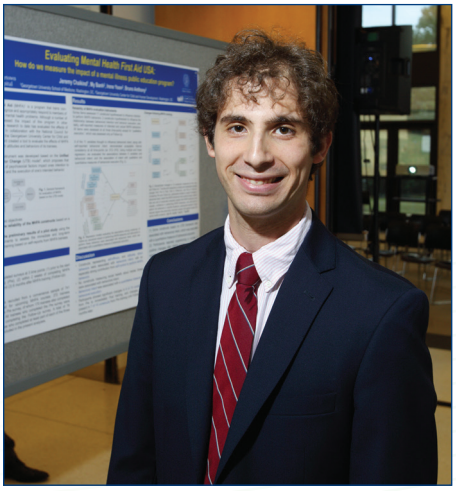


October 2015

SAFEHeart study featured in *U.S.News and World Report* on Herceptin's Link to Heart Failure

MedStar Investigators, Dr. Sandra Swain and Dr. Ana Barac were profiled in an October issue of *U.S.News & World Report* for their SAFEHeart trial in Washington, D.C., Swain, a cancer specialist at MedStar Washington Hospital Center, and Barac, a cardiologist with MedStar Heart & Vascular Institute, launched SAFEHeart to see whether women with mild heart failure can continue to take Herceptin and Perjeta, another designer antibody that works in a similar way.

The article profiles Nanci Young who was diagnosed with breast cancer in 1991. She had been battling the disease for nearly 25 years and for eight years, Herceptin changed her life. Young flourished. Then, in 2010, her heart began to fail.

"You need a heart," her doctors told her, and took her off the drug.

Within three years, the cancer roared back with a vengeance, in her spine, lymph node and chest. After caring for her successfully for more than two decades, her local doctors conceded defeat. But they didn't quit. They referred her to Dr. Sandra Swain and Dr. Ana Barac and the SAFEHeart trial in Washington, D.C.

So far, Nanci Young's heart is holding up nicely, says Dr. Maria Raquel Nunes, also of Georgetown University and MedStar Washington Hospital Center, where Young, 61, receives treatment. If there's no change, she can continue taking Herceptin even after the trial is over.

Every three weeks, Young travels to the oncology clinic where she is given infusions of Herceptin and Perjeta, with a half an hour in between. Each session lasts three and a half hours. The worst side effect, she says, is a temporary rash with a burning sensation so overpowering that she has tried everything to stop it. Only ice seems to help.

A rash, Young says, is a small price to pay for survival.

"Think about this folks; it's life and death here," she says, adding: "Every third Friday there's no place on earth I'd rather be."

Author: Steve Sternberg
U.S.News & World Report
Oct. 20, 2015

After caring for her successfully for more than two decades, her local doctors conceded defeat. But they didn't quit. They referred her to Dr. Sandra Swain and Dr. Ana Barac and the SAFEHeart trial in Washington, D.C.

Nerve Mapping for Minimally Invasive Flatfoot Reconstruction: The Safe Zone Project

Neural structures in medial displacement calcaneal osteotomy: a cadaveric and radiographic investigation is a study led by Paul G. Talusan, MD; Ezequiel Cata, MD; Eric W. Tan, MD; Brent G. Parks, MSc; and Gregory P. Guyton, MD, of the MedStar Union Memorial Orthopeadics Team was accepted for publication by *Foot and Ankle International*, the journal of the American Orthopaedic Foot & Ankle Society.

Orthopaedic surgeons cut the calcaneus (heel bone) as part of surgical reconstruction to correct flatfoot. Traditionally this is performed using a 4-centimeter incision and a saw. While this surgery has a relatively low incidence of complications, such as nerve damage and wound infections, these complications are problematic when they occur. The nerves at risk give sensation to the foot and innervate the muscles in the foot.

Minimally invasive techniques have emerged with the hope that they will lower the incidence of soft tissue complications in surgery to restore the arch. With minimally invasive techniques and smaller incisions, orthopaedic surgeons rely on the use of X-rays during the procedure to decide where to cut the heel bone. X-rays; however, do not show the location of the nerves. This study mapped the location of the nerves around the heel bone and their relationship to landmarks found on intraoperative X-rays.

Drs. Talusan and Tan are foot and ankle fellows in the Department of Orthopaedic Surgery, MedStar Union Memorial Hospital. During the study, Dr. Cata was a visiting foot and ankle research fellow in Orthopaedic Surgery department. Mr. Parks is the director of the biomechanics and STAT laboratories at MedStar Union Memorial Hospital, and Dr. Guyton is an attending physician in the foot and ankle service, also at MedStar Union Memorial Hospital.

So far, only a few surgeons in the U.S. are performing this heel operation using minimally invasive techniques. As this surgery gains popularity with foot and ankle surgeons, this publication will serve as a guide for surgeons so that they can cut the heel bone without damaging the nerves around the heel and foot.

August 2015

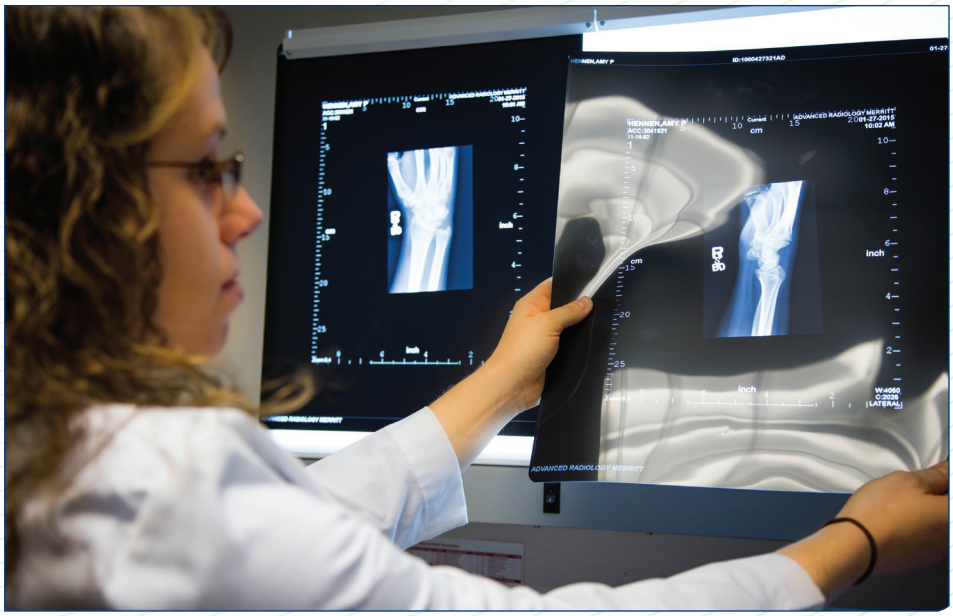
Eleven-Year Multicenter Rheumatoid Arthritis Study Published

The Silicone Arthroplasty in Rheumatoid Arthritis (SARA) study was a prospective, multicenter, NIH-sponsored study led by Kevin Chung, MD, University of Michigan Departments of Plastic and Orthopaedic Surgery, in collaboration with Frank Burke, FRCS, Pulvertaft Hand Centre, Derby, UK, and E.F. Shaw Wilgis, MD, Curtis National Hand Center, MedStar Union Memorial Hospital.

The Curtis National Hand Center is the nation's preeminent leader in the repair and rehabilitation of injuries and other disabling conditions of the hand and upper extremities. The Curtis National Hand Center was designated by the U.S. Congress as the only National Center for the Treatment and Rehabilitation of the Hand and Upper Extremities.

This study resulted in at least five American Society for Surgery of the Hand podium presentations and 12 journal articles with Dr. Wilgis as a senior co-investigator. The articles were first published starting in 2006; the final paper was published in April 2015.

From 2004 to 2008, the study enrolled 169 rheumatoid arthritis patients with severe deformities of the metacarpophalangeal joints. Cases were equally distributed between surgical and nonsurgical treatment. The study represents the largest prospective case series comparing surgical treatment (silicone metacarpophalangeal arthroplasty) with nonsurgical treatment, and it had a seven-year follow-up period.



Dr. Wilgis is chief emeritus and former director of the Curtis National Hand Center, former MedStar Health and MedStar Health Research Institute chairman of the Board, and a pioneer of the International Federation of Societies for Surgery of the Hand. He recently retired as director of Research of the Curtis National Hand Center.

July 2015

MedStar Health Teaching Scholar Examines Whether Facial Plastic Surgery Affects Likeability

A MedStar Georgetown University Hospital study published in JAMA Facial Plastic Surgery, led by former MedStar Teaching Scholar Michael J. Reilly, MD, Department of Otolaryngology-Head and Neck Surgery, with the help of Stephen J. Fernandez, MPH, MedStar Health Research Institute Department of Biostatistics and Bioinformatics, studied whether facial plastic surgery affects perceived attractiveness, femininity, and personality.

The study was a retrospective evaluation of preoperative and postoperative photographs of 30 white female patients who underwent facial rejuvenation surgery between Jan. 1, 2009, and Dec. 31, 2013. Procedures included rhytidectcomy (facelift), upper blepharoplasty (eyelid surgery), lower blepharoplasty, eyebrow lift, neck lift, and/or chin implant. The 60 photographs (30 preoperative and 30 postoperative) of these patients were split into six groups, each with five preoperative and five postoperative photographs. The same patient's preoperative and postoperative photographs were not included in any single group to avoid recall bias. At least 24 individuals rated each photograph for six personality traits (aggressiveness, extroversion, likeability, trustworthiness, risk seeking, and social skills), as well as for attractiveness and femininity. The raters were blinded as to the intent of the study.

There is no doubt that facial rejuvenation surgery changes how patients are perceived by others, but this is the first study in the surgical literature to more deeply explore these potential changes. Dr. Reilly and his team have additional studies underway to help answer remaining questions about how differing surgical procedures may affect perception of character traits, how this may differ based on gender, and how this understanding can be applied to each individual patient.

Scores for perceived femininity, social skills, attractiveness, and likeability showed statistically significant improvements when considering all facial rejuvenation procedures together. When the analysis was performed on a procedure-specific basis, facelift and lower blepharoplasty were the two procedures to show statistically significant changes in ratings.

The results of this study has been covered in numerous media outlets such as, *Today Show, Fox News, Today, Time, Washington Post,* and *Cosmopolitan*.

June 2015

New England Journal of Medicine: Protocolized Care for Early Septic Shock (ProCESS) Trial

The NIH-sponsored ProCESS trial, recently published in *The New England Journal of Medicine*, evaluated protocol-based care for early septic shock. The study itself started in 2007 and ended in 2011 and was logistically challenging because physicians and r esearch coordinators needed to be on call Monday through Friday from 7 a.m. to 7 p.m. The investigators worked with Hank Rappaport, MD, MedStar Institute for Innovation, who designed a system to notify investigators electronically if a patient was found to have a lactate level of greater than four.

Although MedStar Washington Hospital Center didn't join the trial until 2010, it had the fifth highest enrollment rate out of 30 sites.

Ron Migues, Scientific Center administrative director, was the research coordinator for this study, which Munish Goyal, MD, the director of Emergency Intensive Care in the Department of Emergency Medicine at MedStar Washington Hospital Center (site principal investigator), said contributed to the success of the study.

"It helps when a knowledgeable, sincere, personable professional is available to answer the patient's questions thoroughly," Dr. Goyal said. "If our investigators can't answer questions in a calm, reassuring manner, the patient is less likely to consent."

One of the subinvestigators, Dr. Carolyn Phillips, volunteered to take calls regularly and donated numerous hours of her time to help carry out the study protocols.

Associations of Postoperative Wound Dehiscence: A Cohort Study Using Pooled Electronic Health Records Data from Explorys

A recently published study in Wound Repair and Regeneration, co-authored by three MedStar Health Research Institute biostatisticians along with other researchers, studied pooled electronic health records data from Explorys.

In this study, Victoria Shanmugam, MD, MRCP, chair of rheumatology and associate professor of medicine at George Washington University, and Research Institute biostatisticians Stephen Fernandez, Mihriye Mete and Nawar Shara, examined the Agency for Healthcare Research and Quality (AHRQ) patient safety indicators. Patient safety indicators were developed to provide information regarding hospital complications and adverse events following surgeries, procedures and childbirth. Patient safety indicators are used not only as a measure of hospital complications, but also as a starting point to develop strategies to reduce preventable errors.

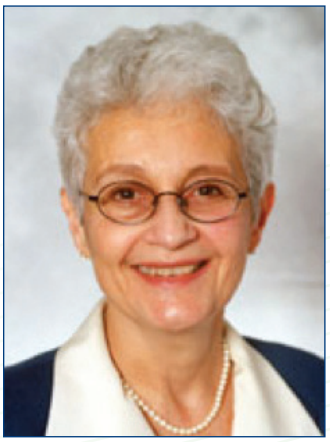
Using the Explorys platform, 25,636 eligible patients were identified who had undergone abdominopelvic surgery in the MedStar Health system between Jan. 1, 2008, and Dec. 31, 2012. Of these cases, 786 had post-operative wound dehiscence.

This study illustrates how platforms that leverage large multicenter healthcare networks (e.g., Explorys) enable investigations, such as this one, to explore the relationships between clinical co-morbidities, medication exposures and positive and negative clinical outcomes in large populations. Utilizing the MedStar Health system and Explorys, the study team was able to hypothesize that PSI-14 would be associated with measurable patient-related co-morbidities. A secondary investigation examined the relationship between PS-14 and exposure to various medication classes.

For the past few years, MedStar Health Research Institute's Department of Biostatistics and Bioinformatics has been using the Explorys secure software platform to conduct studies using "Big Data." Explorys allows healthcare systems to aggregate, analyze and manage the four V's of Big Data—high-volume, high-velocity, high-variety, and high-veracity—the kind of data that are too large and expensive to load into traditional information technology systems.

WATCH Study Examines Hypertension and Type 2 Diabetes Prevalence

Two articles resulting from the Western Alaska Tribal Collaborative for Health (WATCH) study have been published recently, one in the Journal of Clinical Hypertension and one in Diabetes Research and Clinical Practice. The WATCH study is a collaboration involving MedStar Health Research Institute; the Georgetown-Howard Universities Center for Clinical and Translational Sciences, the University of Alaska Fairbanks, the Alaska Native Tribal Health Consortium, Anchorage, and several others. MedStar Health investigators on this research were Barbara V. Howard, PhD, senior scientist, and Jason G. Umans, MD, PhD, scientific director of the Biomarker, Biorepository and Biochemistry Laboratory at MedStar Health Research Institute.



In "Prevalence of Hypertension and Associated Risk Factors in Western Alaska Native People," by Stacey Jolly et al., the prevalence of hypertension and prehypertension was determined overall, by sex, age and region in the WATCH cohort. The investigators examined known risk factors, including age, body mass index/obesity, smoking status, lipids, and diabetes. In addition, the investigators assessed the proportion of participants who were aware of having hypertension, and among those for whom records were available of treatment for high blood pressure. The proportion who had met their blood pressure targets was assessed.

In "Cardiometabolic Correlates of Low Type 2 Diabetes Incidence in Western Alaska Native People," by Kathryn Koller et al., the prevalence and incidence of type 2 diabetes in western Alaska Natives were examined and associated cardiometabolic risk factors were analyzed. State registry data for this population had indicated an increase of 300 percent in diabetes in some western Alaska regions.

"This consortium has allowed the creation of a dataset large enough to obtain reliable data on western Alaska Native peoples, a group that is distinct from other Alaska Natives," Dr. Howard said. "This population is unique in having high rates of cardiovascular disease despite the low rates of diabetes. The results from analyses of this dataset should help to improve medical care to this underserved population."

April 2015

MedStar Selected as a Research Partner by the Agency for Healthcare Research and Quality

MedStar Health has been selected by the federal Agency for Healthcare Research and Quality to participate in its ACTION III (Accelerating Change and Transformation in Organizations and Networks) research network.

MedStar is one of just 13 healthcare organizations to win the five-year award. As a participant in this network, MedStar is now eligible to become a direct contractor with the federal government to undertake research focused on one or more of Agency for Healthcare Research and Quality's priorities:

- Improve the quality of health care and care delivery
- Make health care safer
- Increase accessibility
- Improve health care affordability, efficiency and cost transparency

"Through this network, we will leverage MedStar's breadth and depth as a healthcare provider, our experience and our commitment to collaborate, in pursuit of better health outcomes," said Neil J. Weissman, MD, president of MedStar Health Research Institute.

In responding to the highly competitive bid process, MedStar organized its own network that includes 22 partners from outside the health system, including universities, foundations, a health department, hospital association, patient safety organizations, and a startup incubator.

This award aligns well with MedStar Health's 2020 goal to be a distributive care delivery network and have a robust research program that provides a better, safer quality of care—and Health Services Research is the perfect mechanism to meet that goal.

An article on this partnership appeared in the *Washington Business Journal*

MedStar is already engaged in Agency for Healthcare Research and Quality's ACTION II network, through a partnership with the Healthcare Research and Educational Trust, in a project called CANDOR (Communications and Optimal Resolution). CANDOR involves developing and testing an educational toolkit to help hospitals respond to, defuse and quickly resolve potential patient harm situations.

April 2015

New York Times Covered: Lowering Diabetes Risk in Women with Gestational Diabetes

According to a study published in the *Endocrine Society's Journal of Clinical Endocrinology & Metabolism*, women with a history of gestational diabetes face a heightened risk of developing type 2 diabetes for years after giving birth, but intensive lifestyle intervention or a medication regimen can have a protective effect in this population.

The Diabetes Prevention Program Outcomes Study (DPPOS), led by Vanita Aroda, MD, scientific director of the MedStar Community Clinical Research Center (MCCRC), studied 350 women with a history of gestational diabetes, comparing them with 1,416 women with previous live births but no history of gestational diabetes.

The researchers found that women with a history of gestational diabetes had a 48 percent higher risk of developing type 2 diabetes over the 10-year study compared with women who had not had gestational diabetes. Metformin reduced the long-term risk of diabetes by 40 percent, while the lifestyle program lowered risk by 35 percent. Among the women who had never had gestational diabetes, the drug was not effective, but the lifestyle program was effective in significantly reducing the risk for type 2 diabetes.

"Medical and lifestyle interventions were remarkably effective at slowing the progression of type 2 diabetes in this at-risk population in both the short and long term," Dr. Aroda said.

The study was covered by the New York Times here: Well.Blogs.NYTimes.com/2015/03/02/Lowering-Diabetes-Risk-After-Pregnancy/?_r=3.

MedStar Research Team Wins Award from the Endocrine Society

A recent study on the use of Sunitinib®, a tyrosine kinase inhibitor, as an adjunctive treatment for patients with advanced differentiated thyroid cancer has been selected as one of the Endocrine Society's outstanding studies in the young investigator category at their annual meeting.

The study was a Phase II clinical trial led by principal investigator, Kenneth D. Burman, MD, director of the Endocrine Section at MedStar Washington Hospital Center with the assistance of Athanasios Bikas, MD. Other contributors rounding out the research team included Mihriye Mete, Sameer Desale, Priya Kundra, Jason Wexler, Leonard Wartofsky, Lynette Wray, Brandon Clark, and Cristina Barett. As a Phase II study, the drug is given to a larger group of people with the intended disease to see if it is effective and to further evaluate its safety. Because Sunitinib was studied as an adjunctive treatment, this treatment was tried in patients whose thyroid cancer continued to progress after application of first line treatments (in the case of differentiated thyroid cancer, the first line treatment is surgery and radioactive iodine therapy).

March 2015

Groundbreaking New England Journal of Medicine Breast Cancer Study Led by MedStar Washington Cancer Institute Investigator

Treatment combining chemotherapy with two drugs, Perjeta® and Herceptin®, lengthens survival of patients with HER2-positive metastatic breast cancer by an average of nearly 16 months, according to a study led by Sandra M. Swain, MD, medical director, Washington Cancer Institute at MedStar Washington Hospital Center. The results from the CLEOPATRA study were published in late February in the *New England Journal of Medicine*.

"We've never seen results like this before in HER2-positive metastatic breast cancer," said Dr. Swain. "This unprecedented data gives patients with an aggressive disease hope to live a longer, better life."

The CLEOPATRA trial, conducted around the world from 2008 to 2010, studied 808 patients with previously untreated HER2-positive breast cancer that was metastatic, meaning it had spread to other parts of their body. Patients lived around 16 months longer if treated with a combination of the drug Perjeta with Herceptin and chemotherapy, compared to those treated with Herceptin-only plus chemotherapy.

The CLEOPATRA trial was a Phase III, randomized, double-blind, placebo-controlled study, which means neither the patients nor the researchers know who is getting a placebo and who is getting the treatment. The study was designed by senior academic authors and representatives of the sponsors, Roche and Genentech.

Waiting List Trends for Combined Liver and Intestine Transplants May Reflect Improved Care of Infants and Children with Intestinal Failure

Investigators, including those at MedStar Georgetown University Hospital and MedStar Health Research Institute, discovered a drop in the number of infants who need liver-intestine transplants and believe that improved care of infants with intestinal failure has led to the reduction of referrals for transplants.

Their study found a decrease in the number of liver-intestine transplants needed for infants since 2006.

Lead investigator Khalid M. Khan, MD, of MedStar Georgetown University Hospital, along with Sameer Desale and Mihriye Mete, PhD, of MedStar Health Research Institute's Department of Biostatistics and Bioinformatics, studied the United Network for Organ Sharing (UNOS) database for trends in the intestinal transplant waiting list from 1993 to 2012, examining listings for isolated intestinal transplant versus liver-intestine transplant. Their study found a decrease in the number of liver-intestine transplants needed for infants since 2006.

Dr. Khan said, "We looked at the national transplant registry to study waitlists for intestine transplants and noted that the number of small children being referred for transplants has gradually gone down ([infants are] historically the largest group for such transplants), while the number of adults on the waitlist has continued to increase." He added, "This implies that overall, the care of children with intestine failure has improved."

January 2015

MedStar Awarded Pioneer Research Award as a Learning Healthcare System

The American Association of Medical Colleges awarded one of the five Pioneer Awards for 2014 to MedStar Health Research Institute Investigator Kelly M. Smith, PhD, scientific director of Quality and Safety Research. This award is part of the American Association of Medical Colleges' Learning Health Systems Research program.

The Pioneer Research Awards recognize innovations and collaborations among medical education, care delivery, research, and diversity and inclusion. The awards recognize institutions that have implemented or wish to enhance the capacity of innovative, system-wide processes that improve opportunities for research.

Dr. Smith's study evaluates the relationship between a patient and a provider in the wake of preventable harm or medical error. Few organizations have adopted an open and honest approach to communicating with patients and families after preventable harm events, leading to continued abandonment and isolation, thus perpetuating the medical-legal crisis and limiting the opportunity for organizational learning.

The award will foster ongoing efforts in support of MedStar Health's High Reliability Organization journey to enhance transparency, patient engagement and patient safety event reporting and catalyze health services and implementation research throughout the health system.

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January 2015

National Center for Human Factors in Healthcare Awarded Robert Wood Johnson Foundation Grant

Researchers at the National Center for Human Factors in Healthcare, part of the MedStar Institute for Innovation, were awarded an 18-month grant by the Robert Wood Johnson Foundation. This project, titled "Leveraging the Informal Social Networks that Exist in Healthcare Settings to Improve Patient Safety," is led by Sarah E. Henrickson Parker, PhD, research scientist, National Center for Human Factors in Healthcare. The team also includes National Center's Ella Franklin, RN, BSN, CCRN; Raj Ratwani, PhD; and Allan Fong, MS; as well as collaborators from Georgetown University, MedStar Washington Hospital Center and Children's National Medical Center.

Despite extended training efforts and focus from hospitals, patient safety remains a major concern for hospitals (17.1 Billion Annual Cost of Measurable Medical Errors), as well as for patients and their families, with recent estimates suggesting that care remains unsafe. This project proposes a new way to examine safety culture. Using principles of social psychology, innovation diffusion and implementation science, this project will examine and use the informal social networks that already exist in healthcare settings to improve patient safety. This type of social approach to identifying informal networks of influence and targeting the informal leaders is unique in health care.

The grant will support the development and pilot testing of the Social Integration of Goals and Network Allocations (SIGNALS) process to refocus staff attention on patient safety and improving patient outcomes. SIGNALS is a three-step process that is designed to be portable and easy to implement in any hospital. While engaging all members of a hospital unit, the SIGNALS process works to identify members who are particularly influential and may be able to rapidly disseminate innovative practices throughout their networks.

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