

GEISINGER Research Connections



June 2011

Linking the Research Community

Obesity Research Effort Highlights Geisinger's Part of NIH-funded Obesity Center

Geisinger has partnered with the University of Maryland and other sites to form the Mid-Atlantic Nutrition Obesity Research Center (NORC), which is a 5-year, \$2 million project funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NORC's mission is to fund research examining the effect of nutrition on the risk for chronic diseases and explore effective treatments and prevention strategies. The NORC currently focuses on the genetics of obesity, diabetes, cardiovascular disease, and osteoporosis; molecular and cellular research, particularly on adipose tissue; and translational research on the effects of weight loss and exercise on metabolic risk factors, particularly in minority and urban populations.

Geisinger's involvement with the NORC stemmed from successful earlier collaborations between Christopher D. Still, DO, the Director of Geisinger's Obesity Institute and Medical Director of the Center for Nutrition and Weight

Management; Glenn S. Gerhard, MD, the Director of the Geisinger Clinic Genomics Core and Staff Scientist at the Weis Center for Research; and Alan R. Shuldiner, MD, the Director of the University of Maryland School of Medicine's Mid-Atlantic NORC. Dr. Shuldiner identified several synergies between the obesity research being undertaken by Geisinger and the University of Maryland and invited Geisinger's participation in NORC-funded research.

The Mid-Atlantic NORC has four cores, with site directors at both Geisinger and University of Maryland. At Geisinger, Dr. Still serves as Director of the Clinical and Translational Research Core; George Argyropoulos, PhD, a molecular biologist at the Weis Center for Research, serves as Director of the Adipose Biology and Basic Mechanisms Core; H. Lester Kirchner, PhD, senior biostatistician, is the Director of the Biostatistics and Medical Informatics Subcore; and Dr.

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Partnering Key to Improving Health Care While Cutting Costs

The Keystone Beacon Community is a network of hospitals, nursing homes, doctors, nurses, and other health care professionals working together to give patients in central Pennsylvania the best, most convenient care, while reducing costs.

The Keystone Beacon Community project extends the medical home case management model, already in use at

Geisinger, to non-Geisinger facilities, focusing on patients who are recent surgical discharges as well as those with chronic obstructive pulmonary disease and congestive heart failure. In time, the initiative will extend wellness activities to area residents.

Keystone Beacon Community care managers work inside the four

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Geisinger, Temple Test Progesterone as Neuroprotection After Traumatic Brain Injury

Geisinger is participating in a trial sponsored by the National Institutes of Health (NIH) that may finally identify an effective therapy to reduce neurocognitive damage following traumatic brain injury (TBI).

A long list of once-promising neuroprotective agents has been tested before and failed to show sufficient efficacy or safety to move forward, but progesterone, the focus of the present study, did well in an earlier Phase II study in which a mortality benefit was suggested. Dubbed the ProTECT study, this double-blind, multicenter, Phase III trial, which is scheduled to enroll more than 1,100 patients nationwide, is designed to be definitive. Shelly D. Timmons, MD, PhD, Director of Neurotrauma for the Geisinger Health System, has assumed the responsibilities of principal investigator for the study from Steven A. Toms, MD, Director of Neurosurgery at Geisinger, who ushered the ProTECT protocol through the community consultation requirements for this type of study.

"There are abundant experimental data suggesting that neuronal death can be attenuated after injury, but the clinical trials have been disappointing. If the results of this study are positive, we may have an opportunity to prevent disability or even save lives,

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Geisinger Implementing Data-Sharing Software Critical to Cancer Research

Geisinger Health System has joined a coalition of cancer centers, National Cancer Institute (NCI) Community Cancer Centers Program (NCCCP) sites, and federal and academic research institutions in an ambitious effort to foster collaboration in cancer research and to accelerate the discovery of new methods for the detection, diagnosis, treatment, and prevention of cancer.

The purpose of the initiative, which is called the cancer Biomedical Informatics Grid (caBIG®) and is funded by the NCI, is to create a collaborative research and therapeutic community with an infrastructure for data sharing and analysis. Geisinger's bioinformatics specialists, led by Gerardus Tromp, PhD, a scientist at the Weis Center for Research, are working on the implementation of software that will be crucial for sharing data, caBIG's key feature. The challenge is to put the data in a consistent format so that terms and specifications are precisely understood and completely accessible.

"The problem with sharing data is that terminology is often institution-specific or even study-specific. These very different sets of definitions prevent different institutions or study groups from pulling different sets of data together and building on the work of others. It is a huge and difficult problem. Our task is to implement software that can allow data, such as complex lab data, to be more readily integrated and analyzed," Dr. Tromp explained.

For example, genetic microarrays are likely to offer critical information about the fundamental mechanisms of cancer, but the data generated by microarrays

Joint Research Initiatives Offer Many Benefits

Extending the scope and range of Geisinger's research through collaborations with external organizations is a central focus of Geisinger Health System's research strategic plan.

For instance, participation in the HMO Research Network, a collaboration of 17 integrated health care organizations, is an excellent example of the value that a true collaboration can yield. Together the members have developed common resources, including the Virtual Data Warehouse (VDW), a system of parallel databases set up identically at each participating site, and have secured funding for several initiatives, including the Cancer Research Network, the Cardiovascular Research Network, and Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network, among others.

As the articles in this issue demonstrate, collaborations—whether with academic medical centers, research institutions, or local or regional medical centers—provide great value.

For instance, participating in the ProTECT study reflects the strength of Geisinger's neurosurgery program. It is one of three studies being conducted in collaboration with Temple University School of Medicine. Likewise, there are currently two projects being conducted with the University of Maryland.

These examples show successful synergistic relationships that are exemplars of the overall research strategic plan. As noted by Judith Argon, Chief Administrative Officer of Research, collaborations between institutions provide many benefits, including the ability to leverage relationships that expand the existing reach of Geisinger's science and available resources. Collaborations serve to focus the attention of national medical organizations on Geisinger's capabilities and showcase the benefits of teaming with Geisinger. These partnerships also capture valuable research dollars, energize the research effort with new revenue and ideas, and optimize the use of the core facility.

may be influenced by a large number of variables, including cancer stage, treatment exposure, or the age of the patient. Large data sets help control for the heterogeneity of microarray data and still sustain statistical significance for the answers to complex questions. Accurate integration of these data is a daunting task, but it is fundamental for harnessing the power of a large data set.

"Originally, we became involved when we received the NCCCP award

that required Geisinger to be caBIG-compliant," said Dr. Tromp. Geisinger's role has become central to the initiative, however, now that it is working with caBIG to integrate data across institutions. This work is still in its pilot stages. Versions of the software tools are being tested in a protected environment before being released for larger application, but this pioneering work will likely be fundamental to the success of caBIG, which is destined to be a major resource for cancer research.

Brent Williams, PhD, Focuses on Optimizing Cardiac Imaging

Brent Williams, PhD, came to Geisinger in September as a Research Investigator I at the Center for Health Research.

Dr. Williams has a master's degree in statistics from Pennsylvania State University, a doctorate in epidemiology from the University of Buffalo, and six years as a biostatistician at Mayo Clinic, as well as significant research experience in cardiac imaging research. At the University of Buffalo, his research focused on positron emission tomography and single-



Brent Williams, PhD

photon emission computed tomography (SPECT).

Dr. Williams will extend this research on optimizing cardiac imaging in clinical practice at Geisinger, which employs several cardiac imaging techniques at high volumes, including echocardiography, computed tomography angiography, and SPECT. Each imaging technique offers a unique visualization of pathology. "You start with a somewhat homogeneous group of patients with a clinical indication for one of these three tests," Dr. Williams said. "The question is: Does one of these tests improve 'worst outcomes' better than the others?"

Those worst outcomes, he explained, are cardiac-related death, nonfatal heart

attack, and the need for an invasive procedure such as a stent placement or bypass surgery.

"Ultimately, what the physician sees from these tests guides care, setting the patient along a unique trajectory of additional testing and therapy. What was the total collective course of action that each test provoked? This research is therefore really about the most efficient use of resources while minimizing poor outcomes."

Dr. Williams hopes that his research in cardiac imaging, still in the planning stages, will ultimately contribute to changes in provider behavior, improvements in care, and a reduction in costs.

Partnering Key to Improving Health Care

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participating hospitals and then help patients transition out of the hospital, following up within 24 to 48 hours of discharge to ensure patients have obtained prescribed medications or have scheduled and attended follow-up appointments.

The Keystone Beacon Community is funded with support from the Department of Health and Human Services' Office of the National Coordinator for Health Information Technology, and is one of just 17 areas in the United States chosen to beta test novel health care programs.

The source of funding underscores the fact that health information technology (IT) is important to this endeavor. "The goal is to utilize technology to connect everyone in central Pennsylvania to allow health information to be shared

with participating health care providers," explained Jim Younkin, Director of IT at Geisinger and Administrator of the Keystone Beacon Community. He also is the Director of the Keystone Health Information Exchange (KeyHIE®), which is the regional health IT element that allows the collaboration that is so essential to the Keystone Beacon Community.

IT-enabled care coordination is designed to serve patients as they navigate through various health care venues, which may include the hospital, emergency room, a nursing home, and a specialist's care. KeyHIE is the engine that keeps all patient medical information in one place and readily available when and where it is needed. It provides information to care managers, providers, and patients, all in a manner that maintains data security.

Although KeyHIE is an important element in the collaborative efforts of the Keystone Beacon Community, it also is itself an example of collaboration. With funding from the Agency of Healthcare Research and Quality, Geisinger developed KeyHIE with participation from two community hospitals; today, 21 health care organizations are involved at some level in KeyHIE.

"When we developed the proposal for the Beacon Community we envisioned KeyHIE as a tool that would allow care managers to oversee care more efficiently," Mr. Younkin explained.

The Keystone Beacon Community, which is a three-year program, is now beginning its second year. Success will be measured by determining whether and how much readmission rates and emergency room visits have been reduced.

NIH-funded Obesity Center

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Gerhard is the Director of the Molecular Genetics and Nutrigenomics Core. Dr. Gerhard is also Geisinger's overall Principal Investigator of the Mid-Atlantic NORC.

"In just the first year of funding the NORC has supported a variety of collaborations between Geisinger and several institutions, including New York University, Yale University, Boston University, the Translational Genomics Research Institute (TGen) in Arizona, Temple University, University of Maryland, and others," Dr. Gerhard explained. "These are usually individual investigators who are interested in collaborating on nutrition and obesity research, with whom we analyze samples or data."

"The genomics core is pursuing a variety of projects," Dr. Gerhard said, "ranging from analyzing the DNA of different genes associated with weight loss after bariatric surgery to fatty liver disease and type 2 diabetes. We are also collecting stool samples for microbiome sequencing to investigate whether the different types of bacteria that are located in the intestine may change following bariatric surgery."

"Geisinger's advanced electronic health records, coupled with extensive biobanks of liver, blood, serum, urine, DNA, subcutaneous and visceral fat, stomach, small intestine, and stool samples are all vital to furthering the Mid-Atlantic NORC's funded research projects," Dr. Gerhard said. Geisinger also has a largely white population that tends to remain in the area, allowing for long-term follow-up, which is fundamental for obesity research. Samples are obtained through the Clinical and Translational Research Core, headed by Dr. Still, who noted that, "The objectives of the Core are to translate and transform patient-oriented preventive and mechanism-based clinical nutrition as well as metabolic research in

obesity from the bedside to the bench and back to the bedside for translation into community medical practice."

"The NORC also funds pilot projects and provides seed money," Dr. Gerhard added. "And education is a part of NORC funding, which sponsors a summer student training program that includes a small scientific conference for the students."

"There are several benefits to this collaboration," Dr. Argyropoulos said. "First, we are collaborating with some of the best scientists and clinicians in the world at the University of Maryland. Second, this collaboration will certainly help us get publications into top peer-reviewed journals. And third, there are reciprocal informational benefits through which research knowledge is shared, to everyone's benefit." Geisinger's electronic health records system allows instantly accessible, always anonymous patient information, and includes a substantial obese cohort. Samples are readily available.

Dr. Argyropoulos' particular expertise is in adipose biology. "We look at the adipose tissue as being more like an organ than a tissue, because adipose secretes a lot of important metabolic hormones and plays a vital role in the way the body metabolizes food, expends energy and regulates brain signals to eat, sleep, etc." One question among many that the NORC programs are studying is the effect of bariatric surgery on adipose tissue. With several studies now confirming that diabetes can cease following bariatric surgery, the question arises about the procedure's effect on adipose tissue. "There is some evidence that the hormones in adipose tissue do change after bariatric surgery, but there has been no long-term study yet. We also don't yet know how the hormones from adipose tissue differ in people who have responded well to bariatric surgery compared to those who did not, but if we did we could use

that information as a diagnostic criterion for recommending surgery."

Biostatistical expertise is fundamental to the study of complex, multifactorial health issues like obesity. The Geisinger Obesity Institute and Geisinger's Biostatistics & Research Data Core are employing their integrated clinical research efforts to assist the NORC's mission. Dr. Kirchner explained that the NORC's Biostatistics and Medical Informatics subcore is tasked with the storage, review, and analysis of data accumulated through NORC research.

"We are a perfect partner for this initiative because we already have much of the template for collecting, storing, and analyzing longitudinal clinical data generated from an electronic health record, but being part of the NORC collaboration with the University of Maryland is going to allow us to further the Obesity Institute's efforts," Dr. Kirchner explained.

Dr. Kirchner said that the collaboration would allow both Geisinger and the University of Maryland to leverage their strengths to attain research goals that would be difficult to achieve separately. For instance, one ongoing project is assembling weight loss data following gastric bypass surgery and analyzing its relationship to the resolution of comorbidities associated with obesity, such as hypertension and diabetes. This Geisinger collaboration brings complex statistical modeling and clinical expertise together, and by so doing elucidates the influence of variables in far greater detail.

"Our strengths in biostatistics can provide fundamental support to all phases of this research, from the framing of an idea for a research project to designing how the data might be collected, stored, and evaluated to address the question," Dr. Kirchner said.

Geisinger, Temple Test

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a particularly important potential in the relatively young individuals who are common casualties," reported Dr. Timmons.

A substantial benefit from progesterone, a hormone that is naturally present in the body in small amounts, would have enormous public health implications. Mannitol, the only current pharmacologic therapy for TBI, reduces swelling but is not directly neuroprotective. A therapy to prevent neuronal cell loss to limit or avoid disability is an urgent unmet need.

The trial is unusual in that patients may be enrolled without their consent, a result of the nature of the disabilities in the patients themselves and the level

of effectiveness of the hormone when administered quickly after injury. The FDA, under special rules called "Exception from Informed Consent," permits research without patient approval if the patient is in a life-threatening situation and possible therapies are either unproven or unsatisfactory, when it is impossible to obtain formal consent from the patient or legal guardian because of time constraints, and if the therapy provided in the study may directly benefit the patient.

The Geisinger site was characterized by Dr. Timmons as a spoke from a hub located at Temple University School of Medicine in Philadelphia, one of several such participating academic medical centers that are members of the NIH-supported Neurological Emergencies

Treatment Trials network. This is one of a growing number of studies in which Temple has chosen Geisinger as a collaborating institution. For the ProTECT trial, Geisinger is an appropriate participant because it maintains the type of rapid-response trauma center essential to test the hypothesis. Candidates for the study must be randomized to progesterone or placebo and treated within four hours of injury.

"We have been disappointed before, but there are good theoretical reasons as well as some clinical data to suggest that progesterone will offer a clinically meaningful degree of neuroprotection. It is an important trial and we are excited to be participating," Dr. Timmons said.

Staff Publications

These publications feature Geisinger employees as authors, with publication dates from November 2010 through April 2011. Publications with a Geisinger employee as the sole author have no special markings. When the publication is jointly authored by a Geisinger employee and employees of other institutions, the Geisinger employee's name is bolded or appears with an asterisk. The listings below follow National Library of Medicine format and were compiled using Ref Works.

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Staff Publications

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Recent External Awards

This list includes new awards and competitive renewals from external agencies and Geisinger's Clinical Research Fund from November 2010 through April 2011. To protect sponsors' confidential information, we omit dollar amounts for clinical trials and industry-sponsored agreements and some clinical trial listings. If an award is inadvertently overlooked, please forward the information to Shauna Seger (smsseger@geisinger.edu) for inclusion in the next issue.

Peter Berger, MD

Cardiology

Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF)
Ortho-McNeil
\$728,000

Peter Berger, MD

Cardiology

QT90 Flex Tnl, TnT, CKMB & Myo assays-
Clinical Sensitivity/Specificity (DC-041842)
Radiometer
\$251,827

Peter Berger, MD

Center for Clinical Studies

Effect of Statins and Modifiable Risk Factors on Stroke Outcome in Atrial Fibrillation
Boston University
\$125,654

James Blankenship, MD

Cardiology

CHAMPION PHOENIX: A Clinical
Trial Comparing Cangrelor to Clopidogrel

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Recent External Awards

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Standard of Care Therapy in Subjects Who Require Percutaneous Coronary Intervention
The Medicines Company

Paul Bourbeau, PhD

Laboratory Medicine

Resin AR Bottle Biomerieux: BACT/ALERT RESIN BOTTLE (AR,NR,PR)

Biomerieux

John Cardella, MD

Radiology

Multi-State Consortium Proposal for Medicare Imaging Demonstration

Brigham and Women's Hospital/CMS

\$879,526

Charlotte Collins, MD

Psychiatry

Bariatric Surgery Patients' Journeys: Impact on Psychosocial and Mental Health

ACR

\$2,052

Amir Dehdashti, MD

Neurosurgery

The Involvement of the Notch Pathway and its Regulators in the Pathobiology of Brain Arteriovenous Malformations

Leslie Munzer Neurological Institute of Long Island

\$30,000

James Elmore, MD

Vascular Disease

Carotid Stenting for High Surgical-Risk Patients: Evaluating Outcomes Through the Collection of Clinical Evidence

Abbott

\$106,800

Glenn Gerhard, MD

Bucknell University and Geisinger Health System Biomedical Innovation and Device Institute (BIDI)

Bucknell University

\$78,884

Glenn Gerhard, MD

Weis Center for Research

Genetic Determinants of Weight Loss and Resolution of Co-Morbidities

NIH

\$2,585,710

Glenn Gerhard, MD

Weis Center for Research

Mid-Atlantic Nutrition Obesity Research Center

University of Maryland

\$761,735

Edward Gorak, DO

Oncology

Connect CLL: The Chronic Lymphocytic Leukemia

Celgene Corporation

\$226,500

Edward Gorak, DO

Oncology

CONNECT MM Celgene: Connect MM the Multiple Myeloma Registry

Celgene Corporation

G. Dean Harter, MD

Orthopaedics

Prospective Multicenter Open Label Study of the Encore Reverse Shoulder Prosthesis

DJO Surgical

\$115,320

Sandra Hill-Felberg, PhD

Weis Center for Research

TNF Receptors and Gene Expression

ACR

\$5,000

John Hodgson, MD

Cardiology

Prospective Multicenter Imaging Study for Evaluation of Chest Pain (Promise Trial)

Duke Clinical Research Institute/NIH

\$250,000

Jay Jones, PhD

Cardiology

AQT90 Flex Tnl, TnT, CKMB & Myo assays-Reference Interval

Radiometer

\$58,038

Paul Simonelli, MD

Thoracic Medicine

Prospective Randomized Placebo-Controlled

Trial of Simvastatin in the Prevention of COPD Exacerbations

Temple University/NIH

\$62,800

Kimberly Skelding, MD

Cardiology

ALERTS (AngelMed for Early Recognition and Treatment of STEMI) Study

Contract approved and signed 11/15/2010

Angel Medical Systems

Kimberly Skelding, MD

Cardiology

Medtronic CoreValue US Pivotal Test

Medtronic, Inc.

Azadeh Stark, PhD

Center for Health Research

Formative Research to Prepare to Assess

Patient-Centered Communication in Cancer Care

Kaiser Permanente/NIH

\$9,966

Steven Steinhubl, MD

Cardiology

HMO Research Network Cardiovascular Research Network: Administrative Supplement

Kaiser Permanente/AHRQ

\$48,506

Walter Stewart, PhD

Center for Health Research

A Randomized Trial of Behavioral Economic Interventions to Reduce CVD Risk

University of Pennsylvania

\$748,253

Walter Stewart, PhD

Center for Health Research

Alpha Clinic (EProjects)

Geisinger Clinic

\$82,000

Walter Stewart, PhD

Center for Health Research

Scalable Partnering Network For CER: Across Lifespan, Conditions, And Settings (Span)

Kaiser Permanente/AHRQ

\$88,973