

In The Research BUSINESS

Volume VI, Issue 1

February 2012

In This Issue...

A Chat with...
Dr. Adrian Goldszmidt

Meet... Marianne Reed

Research Around The
World...

What's New... In Research?

What Else is New...
In Research?

Recently Approved IRB
Studies!

A Chat With... Dr. Adrian Goldszmidt

Adrian J. Goldszmidt, M.D., is chief of the Department of Neurology at Sinai Hospital. Dr. Goldszmidt also heads the Stroke Center and Headache Program for the Sandra and Malcolm Berman Brain & Spine Institute.

Dr. Goldszmidt received his medical degree from the Harvard Medical School and completed his residency in neurology at the Harvard Longwood Neurology Training Program in Boston. Following his residency, Dr. Goldszmidt was a fellow at the New England Medical Center and Spaulding Rehabilitation Hospital, where he pursued his interest in stroke. He is the co-author of "Stroke Essentials" a guide for neurologists.



According to Dr. Goldszmidt 15% of all stroke victims die from the effects of their stroke. Less than 50% of stroke victims survive stroke without disability or death. The Department of Neurology uses both acute and preventive measures for treatment of patients who have suffered a stroke and those at risk of possible stroke. Acute measures reduce death and disabilities in people who have experienced stroke. Preventive measures target those at risk and reduce the chances of suffering a stroke. Those at risk of stroke are pre-diabetic and/or insulin resistant patients. The Department of Neurology participates in a number of National Institute of Neurological Disorders and Stroke research studies, including POINT, ALIAS and IRIS. POINT is an acute stroke trial whereas ALIAS and IRIS are two preventive stroke studies, and are summarized below.

Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) Trial (Acute/Short-Term Study; 90 Day Treatment)

Dr. Goldszmidt explained that after patients have a transient ischemic attack (TIA) or minor ischemic stroke there is a higher risk of having a stroke or heart attack, especially immediately afterwards. There are antiplatelet drugs, including aspirin and clopidogrel (*aka* Plavix) that can reduce your risks of having other medical conditions develop after a transient ischemic attack (TIA) or minor ischemic stroke. Antiplatelet drugs work by keeping platelets (white blood cell fragments



**Sinai Hospital of Baltimore,
Department of Research**
2401 West Belvedere Avenue
Schapiro Building, Suite 203
Baltimore, Maryland 21215-5271

A Chat With...

DR. ADRIAN GOLDSZMIDT

needed for normal blood clotting) from sticking together. This helps to maintain adequate blood flow to the heart and brain, reduces the likelihood of inappropriate clot formation, and provides protection against a future heart attack or stroke.

In this study low-dose aspirin and clopidogrel are combined as a treatment. This is being done to see if this combination is more effective than aspirin alone in reducing the risk of stroke and heart attack after a TIA or minor ischemic stroke. This is a randomized study which means that subjects are randomly assigned to either one group that is treated with low dose aspirin and clopidogrel or another group that is treated with low-dose aspirin and a placebo (a pill that contains no medicine). Prior studies have tested the combination of clopidogrel and aspirin, and the results suggest that when taken together these medications increase protection from major stroke and heart attack. Clopidogrel is already approved by the Food and Drug Administration (FDA) to prevent heart attack and stroke. The FDA is allowing the use of clopidogrel in this study to see if it is safe and effective in combination with aspirin immediately after TIA or minor ischemic stroke.

Albumin in Acute Ischemic Stroke (ALIAS) Trial (Acute/Short-Term Treatment)

According to Dr. Goldszmidt the purpose of this study is to determine if high-dose, intravenous human serum albumin is an effective treatment for stroke. Human serum albumin is a natural protein already in clinical use for a variety of indications. The use of human serum albumin is currently not a standard treatment for stroke, and therefore is considered an experimental treatment. Human serum albumin has been shown in pre-clinical animal studies to reduce the size of a stroke-induced infarction (amount of tissue death) in the brain and improves neurological function after a stroke. Initial studies indicate that human serum albumin decreases or eliminates brain swelling, and may reduce or prevent the brain damage resulting from a stroke in humans.

Insulin Resistance Intervention after Stroke Trial (IRIS) (Long-Term Treatment)

The purpose of this study is to test the effectiveness of pioglitazone for preventing future strokes and heart attacks among persons with a recent stroke or TIA. Dr. Goldszmidt explained that pioglitazone is a medication that improves the way insulin functions in the body. Although pioglitazone is approved by the FDA to treat people with diabetes, it is not currently approved for prevention of stroke and heart attacks. Scientists believe that pioglitazone, by treating insulin resistance (a physiological condition where insulin becomes less effective at lowering blood sugars), may prevent stroke and heart attack. Recent clinical studies in diabetic patients have shown that patients who receive pioglitazone had fewer heart attacks, strokes or deaths compared to patients treated with other medications or a placebo. The current study will test if pioglitazone has a similar benefit in patients with insulin resistance who have had a stroke or TIA. This study will also evaluate the effectiveness of pioglitazone for preventing diabetes.

If you would like more information on Dr. Goldszmidt and the Neurology team at Sinai, please visit their website at: http://www.lifebridgehealth.org/Sinai/DepartmentofNeurology1.aspx?cpsys_redirect=404.

If you would like more information on the POINT, ALIAS or IRIS studies, please contact Alan Orpia at: 410-601-0960.

Meet... Marianne Reed



Meet Marianne “Mari” Reed! Mari is the newest addition to the Department of Research. The native of Southern New Jersey graduated from the University of Delaware and obtained her Master’s Degree from Boston College.

Mari brings over 40 years of nursing experience to the Department’s Research Coordinator Program. Prior to becoming a member of the LifeBridge family, she was a research nurse at the Maryland Psychiatric Research Center (MPRC). Mari’s interest in research stemmed from her exposure to clinical research in a number of her past mental health settings, and her desire to help others in medical settings, as well.

Mari currently resides in Maryland with Bruce, her husband of nearly 38 years. Mari and Bruce have two grown sons, Zach and David. They still miss their 12 year old Golden Retriever who they lost in 2005. In her spare time, Mari enjoys baking bread, needlepoint, kayaking, hiking, travel and music. According to Mari, her favorite thing about working here at LifeBridge are the people!

RESEARCH AROUND THE WORLD...

Gene therapy can protect against HIV

Gene therapy is an approach most commonly used to treat various chronic genetic diseases, such as cystic fibrosis, but this therapy may soon prove practical for use in disease prevention. In research recently published in *Nature*, scientists at the California Institute of Technology reported that a single injection, which inserted DNA for an HIV-neutralizing antibody into the muscle cells of live mice, completely inhibited HIV transmission in this animal model.

Read more of this article at: <http://www.nature.com/news/gene-therapy-can-protect-against-hiv-1.9516>

Cancer-Fighting Cells Get Boost From Viagra

A new study involving mice suggests that Viagra may provide more than a wake-up to a man's sex life – it may help the body's immune system to fight cancer.

Scientists in Germany found that mice genetically engineered to develop melanoma, the deadliest form of skin cancer, lived longer when given Viagra (sildenafil citrate) in their drinking water. In fact, they lived twice as long as untreated mice. It appears that sildenafil turns-off tumor suppressor cells that inhibit the immune system’s T lymphocytes (a type of white blood cell) that assists in killing cancer cells.

Read more at: <http://www.foxnews.com/health/2011/11/28/cancer-fighting-cells-get-boost-from-viagra/#ixzz1k22DKWmj>

WHAT'S NEW...

In Research?

The Grants Administration Office is Open for Research!

- Are you passionate about a clinical research project that you feel would be ideal for an NIH grant, but felt that the application process would be overwhelming?
- Would you like to know which foundations fund research in your field?
- Has a colleague at another institution asked you to be a co-investigator on a grant application and you don't know how to start the paperwork?

If questions like this keep you awake at night, take heart! The *Grants Administration Office* can help!

Our team can assist with both proposal AND budget development, gather required documentation and approvals, and submit and update all electronic submissions! As part of the LifeBridge Health Development Department, we are the only office authorized to submit grant proposals for private foundation, city, state, and federal grant funding. Led by the Director of Grants Administration, Lindsay Beane, DrPH, who herself has received NIH research funding, our team includes Robin Kroft, PhD, Research Grants Manager, who brings many years' experience running a research foundation to her efforts in helping members of the LBH community pursue grants; Helen Solomon, CPA, our Post-Award Grants Manager who is very adept at helping to formulate research budgets, including projecting the cost of clinical activities and percent of personnel effort; and Grants Coordinator, Anna Slesinski, who is our resident expert on each new grant opportunity.

Please contact us to discuss your grant proposal! The earlier you reach out to us, the better so that we can make sure you are following the right steps, avoid unnecessary frustration, and stay on track in meeting submission deadlines! Contact Dr. Kroft at (410) 601-4440, or rkroft@lifebridgehealth.org.

Speaking of help...

Have you been wondering where to start in getting your research project off the ground? Do you need an Institutional Review Board (IRB) or Administrative Review Board (ARB) Application? Want help filling-out an IRB or ARB application form? Wondering when the next submission deadlines are for those IRB & ARB applications you've been working on? Need to know the fees charged for IRB review? Don't know what information is required by law that must appear in that consent form you've been writing? Would you like to know if your proposed research project requires full board review or qualifies for expedited review? Well, your not alone! Help really is just a phone call away at (410) 601-9021, or drop by the Research Office in Schapiro, Suit 201. Although we can't entice you with *Wellness points*, try killing "two-birds-with-one-stone" by *running* to the research office whenever you have an IRB or ARB question that requires an answer NOW.

WHAT ELSE IS NEW...

In Research?

There's a "We Do Research Too" Contest Co-Winner!!!

Another winner? Really? Really! Well, again it's not *really* like winning, it's more like a public plea for forgiveness accompanied by a consolation prize (doesn't everyone just love consolation prizes?). Anyway, many months after Akiva Shmidman was unceremoniously announced as the "winner" of this contest in the last issue of *In the Research Business*, we discovered that another submission from Janice Lamb fell through a proverbial crack, and it recently resurfaced! After eating a very large piece of humble pie, a contest judge (who wishes to remain anonymous) declared Janice an official "co-winner" of the "We Do Research Too" contest. Unfortunately, Janice no longer works at Sinai, but if she happens to be in the neighborhood, she should come on down and pick-up her prize... 5 LB Bucks!



We Do Research, TOO! Sinai Hospital's Women & Children Services



Latest Researchers:

Catherine Haut, RN, DNP, C.P.N.P.,
C.C.R.N.



Candy Rouse, RNC, MSN, CNS-BC



Lynn Harris, RN, MSN



Recently Approved

IRB STUDIES!

Evaluation of Neonatal APD, a Simple Noninvasive Diagnostic/Monitoring Device for Measuring Pulmonary Resistance in Newborn Infants.

Investigator: Melinda Elliott and Nahid Rostami

The purpose of this study is to evaluate the ability of the APD (Airflow Perturbation Device), a simple noninvasive diagnostic/monitoring device for estimating pulmonary resistance in newborn infants in the neonatal intensive care unit, to monitor respiratory resistance in healthy term infants and in stable preterm infants with and without chronic lung disease, and to establish normative values using this device.

A Randomized Open-Label Trial of Caspofungin versus Fluconazole to Prevent Invasive Fungal Infections in Children Undergoing Chemotherapy for Acute Myeloid Leukemia (AML) (COG ACCL0933)

Investigators: Joseph Wiley, Jason Fixler, Kristen Britton, Yoram Unguru, Stephanie Entrup, and Revonda Mosher

To determine if using Caspofungin (also called Cancidas®) will be better than the current standard antifungal drug fluconazole at preventing invasive fungal infections when given to people with AML after receiving chemotherapy treatment.

A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group, Withdrawal Study to Evaluate the Safety and Efficacy of Delayed-Release Rabeprazole in 1 to 11 Month Old Pediatric Subjects with Symptomatic/Erosive Gastroesophageal Reflux Disease

Investigators: David Tuchman, Kalpana Murthy, Jennifer Benfield, Ritu Walia, and Christina Shuja

To evaluate the use of delayed-release rabeprazole in the treatment of GERD (Gastroesophageal Reflux Disease) in infants up to 11 months old. Delayed-release rabeprazole is in a class of drugs called proton pump inhibitors (PPIs). PPIs are commonly used to treat GERD in children older than 1 year, as well as adolescents and adults. Infants from the ages of 1 to 11 months old that have been diagnosed with GERD will be eligible to participate in this study.

USEFUL LINKS

Department of Research
Homepage
www.lifebridgehealth.org/research/body.cfm?pid=6053

A service of the NIH
www.ClinicalTrials.gov

US Food & Drug Administration
www.fda.gov

National Institutes of Health
www.nih.gov



Department of Research

Director of Research

Arthur N. Freed, PhD
afreed@lifebridgehealth.org
(410) 601-8742

Research Manager

Patty Lohinski, CIM
plohinsk@lifebridgehealth.org
(410) 601-9272

Research Coordinator Program

Alan Orpia, BSN, RN
aorpia@lifebridgehealth.org
(410) 601-0960

Sharmaine McAadoo

smcadoo@lifebridgehealth.org
(410) 601-8461

MaryLou Mullen, RN

mmullen@lifebridgehealth.org
(410) 601-8609

Marianne Reed, BSN, RN

mreed@lifebridgehealth.org
410-601-5559

Mower Central Research Laboratory

Sean O'Hearn, PhD
sohearn@lifebridgehealth.org
(410) 601-6237

Animal Care Facility

Andrea Kellert
akellert@lifebridgehealth.org
(410) 601-5526

Newsletter Editor

Jacquetta Robinson
jlrobins@lifebridgehealth.org
(410) 601-9021