SWEDISH CENTER FOR RESEARCH AND INNOVATION

SPECIAL POINTS OF INTEREST:

- Swedish Awarded Major NIH Grant for Brain Disorders Research
- Swedish Participates in CorPath PRECISE Clinical Trial
- President Obama Honors Dr. Michelle Williams

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SCRI Newsletter

SWEDISH CENTER FOR RESEARCH AND INNOVATION

Summer 2012

Director's Corner

Jennifer Hansberry, RN BSN, — Administrative Director of Research

Swedish has a long history of participation in the research community. From the days when research was a specified element of our mission statement to now, when it is a thread that weaves through all of our systems. Working in a private, nonprofit setting, Swedish personnel see that their first priority is always the health and well-being of each person they serve. They are clinicians first, researchers second. Focusing their research on improving the lives of their patients now and in the future ensures that these priorities are in alignment and enhances both.

Research encourages and rewards invention, innovation, and intellectual risk-taking; it is a way to give something back and make a difference, even when traditional medical options are limited. Through research, our patients gain access to promising new treatments that would otherwise not be available to them. Swedish acquires access to new technologies often at a reduced cost, regional and international recognition, philanthropic support, and the best clinicians who thrive in a stimulating environment that nurtures their growth and interests.

The role of the Swedish Center for Research and Innovation (SCRI) is to provide the infrastructure that enables this all to happen. Unlike less centralized models, our framework allows us to fully capture the true costs of research and proactively address compliance risks. In today's financial environment there is competition over resources and research suffers behind clinically-driven priorities, putting the research, patient, and organization at risk if research activities are not conducted accordingly. For example, a dedicated research nurse or coordinator teaming with the clinical side maximizes patient safety and throughput, and compliance with the protocol from a research-trained professional ensures data integrity and regulatory compliance. Through this centralized mechanism, we support the core research functions of study coordination, financial oversight, risk management, pre and post award federal grant administration, feasibility and ethics review, clinical trial tracking and billing integration, regulatory compliance, and investigator development and training. By relying heavily on our expertise and over-

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Exploring solutions to health-care problems

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sight, our model ensures smooth integration of research projects with regulatory requirements in a clinical environment.

With the implementation of Epic (electronic medical records software), the interest in research at Swedish from both within the hospital and throughout the community has grown. Such an environment is rich with opportunity for internal research as well as cooperative projects. However, electronic medical records create risks to patient privacy that do not exist with paper records. SCRI provides the both the gateway and the platform for interagency cooperation on access to our patients and data for research purposes, ensuring patient rights are protected.

Over the years, Swedish has become known for our first-in-man research work in cardiovascular (mitral valve repair, carotid stenting, stem cell therapy for heart failure, chronic angina, and critical limb ischemia), oncology (administration of the GC33 drug in liver cancer), neurology, and many other clinical areas. Our research will continue to bring patients to Swedish and our partner organizations in order to have access to cutting edge treatment.

For all those reasons, the team at SCRI is dedicated to providing a full spectrum of support to an evolving research environment in our organization. We publicly congratulate our researchers for all their successes and look forward to our continued partnership. It's an exciting time for research at Swedish! Thank you and best wishes to all.

A Word from our CSO

Mark Reisman, MD, FACC — Chief Scientific Officer

The role of research at Swedish has been supported by the hospital for many years, providing recognition of its importance to our patients, our physicians, and our community. Research has several connotations when heard by a patient; often it implies something "experimental" or not fully tested, and frequently causes anxiety in the patient. It also may raise the question—why would Swedish, which is not a university or research institute, embark on the path of research? The answer for many of the physicians and physician investigators is simple - to be certain that as many possible health care options are made available to our patients. The caregivers at Swedish would like to have the ability to offer patients all relevant and investigational therapies, so that patients have confidence in the knowledge that when they come to one of our hospitals, they need not go any further for treatment.

The Swedish Center for Research and Innovation is involved in more than 600 clinical trials, many of which are drug therapies and medical devices. One of the important advantages of conducting research is the ability to attract top notch physicians. Many of our excellent physicians are also researchers. We are also fortunate to have many investigators who are at the forefront of their fields; in some cases, these physicians are not only investigators, but educators for other physicians. Providing a platform that embraces those research activities clearly is attractive for these physicians to want to work at Swedish.

Much of our research could not be conducted without the gracious support of our donors. Often, the competitiveness of proposals for large, federally-funded grant programs

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(A Word from our CSO—continued from page 2)

is predicated on showing proof of concept through smaller pilot projects. These pilot projects demonstrate the ability of the researcher to succeed in conducting the study on a limited scale with anticipated results. Donor gifts even support fellows and other training programs, which allow SCRI to teach tomorrow's up and coming investigators about the importance of research in providing the best possible care to our patients. Other urgent needs for philanthropic funds consist of supporting efforts to analyze data and documenting study results in publications and presentations for dissemination to the community at large. Donor support is what makes this work possible.

We are all proud to work in a climate of excellent clinical care that is fueled by the curiosity of what drugs or technologies of the future will give our patients the best outcomes. In future newsletters, I will be outlining some of the great advances and innovations that are currently being worked on at our center.

Community Benefit Contribution of Research

Swedish directly contributes to the welfare of the community through its research activities. Under SCRI in 2011, research touched the lives of more than 13,000 individuals, either through direct patient participation in clinical trials, research analysis of clinical care, or the generosity of our patients in donating tissues to find treatments and cures for multitudes of medical conditions. The recognized value of these research endeavors contributed more than $11 million dollars worth of services and care to Swedish's community benefit statistics. Much of this work was funded by philanthropy, federal grants, and the generous support of the organization. Without this support, much of the research we do would not be possible, thereby negatively impacting our patients, our physicians, and our community.

Research Divisional Community Statistics	
New Studies Opened	95
Total Studies Conducted	732
New Participant Enrollments	1,020
Total Research Patients Served	13,052
Community Benefit Contributions	$11,460,210
Therapeutic Areas Served	26*
All figures for year ending Dec. 31, 2011	

*includes but not limited to: Cancer (Breast, Lung, Ovarian, Prostate, Urologic), Cardiovascular, Chronic Depression, Headache, HIV, Leukemia, Lymphoma, Multiple Myeloma, Neuroscience (Epilepsy, Multiple Sclerosis, Spine, Stroke, Brain Tumor), Nursing, Oncology (Colorectal, Pancreatic, Radiation), Organ Transplant, Pain Management, Pediatrics, Perinatal, Rheumatology

Heart and Vascular Research, A System-Wide Approach

Tracie Granger — Manager, Heart and Vascular Research; interim Manager, Neuroscience Research

The Heart & Vascular and Sleep Medicine Research department at Swedish Medical Center continues to provide cutting edge medical treatment for patients. We have over 70 ongoing clinical trials and roughly 750 subjects on trial across 9 programs. From minimally invasive methods to repair the mitral valve to autologous stem cell therapy, the department brings new technologies and therapies to daily clinical patient care.

Ongoing studies include adjunct pharmacotherapy for heart and vascular disease, new device-based therapy for structural heart disease, cell-based therapy for cardiovascular, and new advancements in peripheral intervention including therapy for patients with critical limb ischemia.

The Heart & Vascular and Sleep Medicine Research department also supports research endeavors of vascular surgery, electrophysiology, cardiac surgery and sleep medicine. Examples of ongoing studies in those areas include researching the potential impact storage age has on red blood cells used in transfusions, new treatment options for atrial fibrillation, development of new vascular grafting technology and treating patients with sleep apnea.

The Heart & Vascular and Sleep Medicine Research department continues to be committed to providing excellent, contemporary care options to patients at Swedish Medical Center.

Accomplishments

In 2010 the Heart and Vascular research program received a 1 million dollar philanthropic gift to expand our program of clinical research and research-related training activities. The Rising Stars Clinical Research, Quality and Innovation Program was established from this funding. Three interventional research fellows were onboarded in 2011 as the first milestone of this program. Since then multiple investigator initiated trials have been supported under this program.

Over the past eight years Dr. Mark Reisman has developed the department's percutaneous valve program at Swedish. Swedish was one of five hospitals to participate in the original Cardiovascular Valve Repair System (CVRS) study which provides patients, suffering from mitral valve regurgitation, a minimally invasive option to repairing the mitral valve.

Dr. Mark Reisman is also a regional leader in minimally invasive methods to replace the aortic valve. As a co-PI on the Partner trial Dr. Reisman has brought a cutting edge transcatheter aortic valve replacement (TAVR) program to Swedish. Swedish is on target to be one of the few training sites across the country for TAVR.

Under the oversight of Dr. Paul Huang the Heart and Vascular research department has developed a comprehensive cell-based therapy program. The objective of the program is to participate in clinical trials that research new ways cell-based therapies can improve a patient's clinical outcome. Current trials include autogolous stem cell trials for patients who have suffered a severe heart attack or stroke, are suffering form chronic myocardial ischemia or have critical limb ischemia.

Last year our Sleep Medicine group embarked on their first clinical trial since returning to Swedish. The study is looking at the safety and effectiveness of a new stimulation therapy for patients with moderate to severe obstructive sleep apnea (OSA). We are excited to continue maturing the sleep medicine research program in years to come.

Over 40 peer reviewed articles in areas of cardiology, electrophysiology, peripheral vascular disease and cardiac surgery since 2010.

Swedish Participates in CorPath PRECISE Clinical Trial

Swedish First on West Coast to Perform Robotic-Assisted Coronary Angioplasty by Participating in CorPath PRECISE Trial

Swedish Heart & Vascular Institute-affiliated interventional cardiologists recently completed their first robotic-assisted coronary angioplasty (the catheter-based balloon treatment to help treat a narrowed or blocked artery) as part of the CorPath PRECISE clinical trial. The sponsored clinical trial is evaluating the safety and effectiveness of the CorPath200 System in delivering and manipulating coronary guide wires and stents in percutaneous coronary interventions (PCI) procedures. Swedish is one of only seven hospitals in the world – and the only one on the West Coast – evaluating this new investigational technology.

Coronary artery disease (CAD) is the most common form of heart disease and the leading cause of death in America. The most common treatment for CAD is a PCI procedure, commonly known as angioplasty. Traditionally, PCI procedures are performed by an interventional cardiologist in a catheterization laboratory (cath lab). The physician visualizes the coronary arteries by utilizing X-ray angiography (real-time X-ray). Miniature equipment (as small as 1/14,000 of an inch in diameter) is advanced through blockages within the coronary arteries.

"An aging baby boomer population at increased risk for CAD has driven the demand for innovative, new technologies in the cath lab. However, since I started my career, the way we perform the procedure really has not changed," said Mark Reisman, M.D., interventional cardiologist and principal investigator of the CorPath PRECISE Trial at Swedish. "It is exciting to perform a procedure with robotic precision from the CorPath's control cockpit."

"I was able to easily and safely manipulate the guide wire and stent with precise millimeter-by-millimeter adjustments," added Dr. Reisman. "I was able to completely focus on the patient's physiology and anatomy with excellent visualization of the arteries. Implanting a stent while wearing heavy radiation protection is hopefully a thing of the past."

Today, a traditional PCI procedure exposes the interventional cardiologist to constant radiation exposure. An interventional cardiologist's daily exposure to radiation and the physical stresses inherent in the cath lab can lead to occupational health risks — including orthopedic problems, cataracts, cancer and fatigue according to recent data published in Catheterization and Cardiovascular Intervention journal.

The CorPath 200 System provides precise, robotic-assisted placement of coronary guide wires, angioplasty balloons and stents from an ergonomically optimized interventional cockpit. The operator is protected from radiation exposure in a lead-shielded cockpit. The comfortable seated position provides enhanced visualization of the angiography screens, while reducing fatigue and minimizing head, neck and back pain.

"We are excited to begin the CorPath PRECISE trial," said Dr. Reisman. "We believe that improving precision of PCI procedures and the ergonomic conditions of the cath lab will ultimately improve patient care. Vascular robotics at Swedish emphasizes our continuous commitment to delivering state-of-the-art technology to our patients and clinical community."

The trial is a prospective, single-arm, multi-center, non-randomized research study, which will enroll up to 175 patients at medical centers across the country. Swedish is one of only seven centers in the United States – and the only one on the West Coast – participating in the trial.

Read more: http://www.swedish.org/About/Swedish-News/Swedish-Participates-in-CorPath-PRECISE-Trial-and-#ixzz1hOQDcXmm

The Ben and Catherine Ivy Center for Advanced Brain Tumor Treatment

Parvinder Hothi, PhD —Research Scientist

The Ben and Catherine Ivy Center for Advanced Brain Tumor Treatment (Ivy Research Center) is a CLIA (Clinical Laboratory Improvement Amendments) certified research laboratory dedicated to the treatment of malignant brain tumors at the Swedish Neuroscience Institute (SNI). The center collaborates with the nation's leading cancer researchers and partners with biotech companies to explore promising new brain cancer treatments. Patients diagnosed with Glioblastoma Multiforme (GBM), the most aggressive primary brain tumor in adults, have an average survival time of only 12-14 months. Not many treatments have been FDA approved for GBM over the last 25 years, and those that are currently in clinical use have not significantly improved survival rates. Numerous research efforts are underway at the Ivy Research Center to enable the development of more effective targeted therapies.

GBM is a highly heterogeneous disease, meaning that each tumor is unique. As such, the development of personalized patient therapies depends on an improved understanding of the molecular differences in brain tumors. Malignant brain tumors resected at SNI are analyzed using next-generation sequencing technology, enabling scientists to analyze the genetic makeup of each patient's tumor. Additionally, the Ivy Glioblastoma Atlas Project (Ivy GAP), a major research initiative focusing on mapping the gene activity in brain tumors, was launched in 2009. The four-year project is a partnership between the Allen Brain Institute (a recognized leader in research of localized gene expression in the brain), the Ivy Center, and the Ben and Catherine Ivy Foundation. Each tumor is comprehensively characterized with whole genomic analysis, high-throughput *in situ hybridization*, and clinical data correlations. When complete, the atlas will be a freely accessible web-based resource available to medical and scientific communities around the world.

With the hope to extend remission and median survival in brain tumor patients, scientists at the Ivy Center are targeting tumor stem cells; the presumed cause of tumor recurrence. This cell population has been shown to be resistant to current standard therapy, either because of distinct biophysical and genetic properties, or to migration outside of the treatment field. Stem cells are isolated (Figure 1) for high-throughput screens of diverse chemical libraries (50,000+ compounds), to identify new agents with the potential to prevent tumor recurrence by inhibiting stem cell growth. Furthermore, patient-derived xenografts (PDX) are routinely developed from tumor tissue as part of the Jackson Laboratories Cancer Consortium, providing patient-specific animal models for testing drug activity, interactions, and side effects *in vivo*. A key feature of this approach is the optimization of methodologies for agents to be identified and tested within a clinically-relevant time frame (3-6 months) to allow for subsequent patient-specific clinical trials. The Ivy Center is also actively pursuing an immunotherapy program, aimed at stimulating the patient's own immune system to recognize and fight against the tumor. Combining the information gathered from these studies will allow physicians and researchers to correlate tumor differences with treatment response for each patient. This will directly influence the design of each patient's treatment plan, enabling the development of more effective personalized therapies. The long-term goal is to establish clinical trials to prolong patient survival and ultimately find a cure for brain cancer. Greg Foltz, MD, is director of the Ivy Research Center.

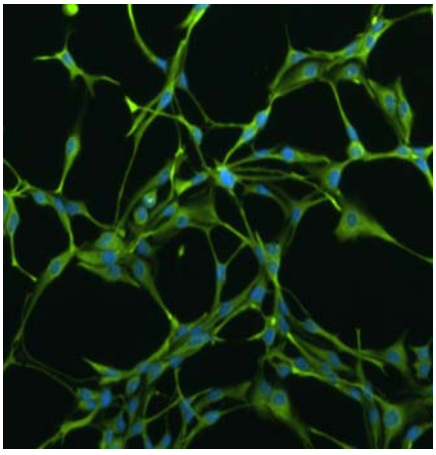

Figure 1. Patient-derived brain tumor stem cells (BTSCs). Cultures fulfill the accepted criteria for BTSCs, namely self-renewal, multipotency, and tumor-initiating ability *in vivo*. BTSCs are shown stained with the neural stem cell marker nestin (green) and the nuclear counterstain DAPI (blue).

Neuroscience Research, A Multi-Faceted Endeavor

Tracie Granger — Manager, Heart and Vascular Research; interim Manager, Neuroscience Research

Research at Swedish Neuroscience Institute (SNI) in 2011 includes 88 active investigations across 9 programs and is supported by more than $3.4 million dollars in annual funding. Sixty-seven of these studies are sponsored by pharmaceutical and medical device companies, 7 are investigator-initiated, and 21 are funded by federal agencies or other non-profit foundations. Over the past three years we developed a solid, financially sustainable research program, doubling the number of research projects and the number of participating patients, from 300 to 800. Participating in studies is important for each of these patients, as they are typically not well-served by existing standards of care and seek out those centers that offer access to investigational therapies. Milestones from the last year include:

- Publishing 16 journal articles, four book chapters, and eight conference abstracts in the areas of brain cancer, multiple sclerosis, stroke, spine surgery, cognitive enhancement, neuroendocrinology and cerebrovascular disease.
- Establishment of a psychiatric research program at SNI to offer deep-brain stimulation to our patients with major depression and obsessive-compulsive disorder. Psychiatry is a new specialty area for SNI and is a testament to the strength of our physicians and research team that we were selected to participate in this cutting-edge study.
- Development and approval for the very first oral medication for multiple sclerosis, Gilenya. This therapy has revolutionized the treatment of MS and our patients were some of the very first worldwide to receive this drug by participating in our clinical trials.
- SNI attained national prominence as the sole non-university member of the NeuroNEXT consortium, a national clinical trials network that will offer access to early stage clinical trials for patients with neurological disorders. This award from the National Institute of Neurological Disorders and Stroke is definitive recognition that SNI has established a well-oiled research program capable of competing at the national level.

Swedish Awarded Major NIH Grant for Brain Disorders Research

John Henson, M.D.

Swedish Neuroscience Institute (SNI) has been selected by the National Institutes of Health as the Pacific Northwest member of a national consortium of 25 neuroscience centers that will conduct clinical research studies on a variety of brain-related diseases. SNI received a seven-year, $2.2 million grant from the National Institute of Neurological Disease and Stroke (NINDS), part of the National Institutes of Health (NIH), through a competitive selection process. The NeuroNEXT program at Swedish Neuroscience Institute will be led by Associate Chief Medical Director and Director of Neurology, John W. Henson, M.D., F.A.A.N.

"The strength of our clinical programs and investment in research infrastructure in the neurosciences made SNI a strong candidate for this center designation," said Dr. Henson. He noted that the major challenge for the NeuroNEXT consortium will be to translate discoveries about neurological diseases into improvements in health, while pushing the frontiers

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(NIH Grant—continued from page 7)
of basic research forward. Many serious neurological disorders will become more common as the U.S. population ages.

"Our research program is focused on discoveries that can be directly applied to patient care," said Dan Rizzuto, former Manager of Neuroscience Research at SNI. "Everything we do is geared toward solving some problem or improving the quality of life for those who have a complex neurological disease. Participation in the NeuroNEXT consortium is a natural addition to our existing efforts."

"NeuroNEXT will expand the capability to test the most promising new therapies for a wide range of neurological disorders affecting children and adults," said Elizabeth McNeil, M.D., the NIH/NINDS program director who will oversee the program. "Through 25 clinical sites across the U.S., as well as a clinical- and a data-coordinating center, NIH will provide the expertise and infrastructure needed to rapidly assess treatment options as they become available from both academic and industry investigators."

Marc Mayberg, M.D., Chief Medical Director at SNI said, "I believe SNI was selected because of its broad areas of specialization, the track record of quality research by SNI investigators, and the high volume of patients with neurological and neurosurgical disorders treated at Swedish Neuroscience Institute."

According to NIH, the first study will investigate a rare but devastating condition in pediatric patients called spinal muscular atrophy. The NeuroNEXT consortium hopes to identify biomarkers that improve diagnostic testing, track disease progression, and permit assessment of the effectiveness of new therapies. Identifying biomarkers for spinal muscular atrophy is an example of translational research, as the study is not testing a new therapy per se, but is expected to support the development of new therapies in the future. Due to the rare nature of spinal muscular atrophy, having a nation-wide consortium of 25 regional centers will be very important for enrolling sufficient numbers of patients into the trial. SNI will work closely with neurologists throughout the WWAMI (Washington, Wyoming, Alaska, Montana and Idaho) region and with disease-specific community organizations, such as the Muscular Dystrophy Association, to raise awareness of the NeuroNEXT trials and help identify appropriate study participants.

Cancer Research, A System of Inter-Disciplinary Approaches

Patra Grevstad, RN — Manager, Oncology Research

The Swedish Cancer Institute Research Program was started in the mid 1970's when Dr. Saul Rivkin initiated participation in the Southwest Oncology Group, an NCI sponsored clinical trials program. SCI research has grown and diversified significantly since the 1970's and focuses on bringing new, innovative cancer treatments to patients. The program develops affiliations and collaborations with other investigators, institutions, and pharmaceutical and biotech companies locally, nationally, and internationally. By gaining access to new agents, cutting edge technology and innovative studies, additional treatment options other than standard of care are available to patients. Having an active research program provides physicians with the opportunity to develop new ideas, share knowledge and participate internationally in a highly stimulating scientific environment in the fight against cancer.

The SCI has over 100 clinical trials available from commercial and federal sponsors, including trials developed by SCI physicians. Efforts are aimed at testing new approaches in prevention of cancer, find-

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(Cancer Research—continued from page 8)

ing new methods of early detection, and discovering new and more effective drugs and treatment combinations. The SCI has participate din hundreds of trials that have helped bring new drugs to the market that are now used as standard of care therapy; some of these drugs include: Taxol, Carboplatin, VP-16, Herceptin, oxaliplatin, Avastin, Tarceva, Gleevec, and Zometa. Research also includes developing image guided targeted radiation therapy options, and improving the quality of life for people with cancer. Trials include chemotherapy, immunotherapy, vaccine therapy, radiation and surgical therapeutic approaches.

A History Full of Successes

In its 40 years of existence, there have been many successes from the research program at the SCI:

- SCI is in Year 36 of NCI grant funding in support of Swedish as the central office for the Southwest Oncology Group (SWOG). Our collaborations with FHCRC, UW, & GHC make us the largest SWOG clinical trials site in the country.
- In 2001 a partnership with Seattle Radiology was developed to conduct the Early Lung Cancer Action Project (I-ELCAP), under the direction of Ralph Aye, MD. The study evaluates the effectiveness of low dose CT scanning in the early detection of lung cancer.
- The SWOG SELECT study was in operation for 10 years and coordinated by Gary Goodman, MD. It was a prostate cancer prevention trial evaluating the effectiveness of Vitamin E, and Selenium. The SCI was the 4th largest site in the country, enrolling 1,000 men and our premier site was known country wide for excellent work, even being featured in a national training video.
- SCI physicians partner with industry and local and regional cancer centers, which have recently included companies such as Accuray for a study using Cyberknife for prostate cancer, Aptium Oncology Gastrointestinal Cancer Consortium, and Elekta.
- The SCI has a well established relationship with FHCRC under the guidance of Dave Beatty, MD, and a partnership with the UW School of Nursing for 20 years, recently under guidance of Drs. Patricia Dawson and John Wynn.

Cyberknife robotic-assisted radiosurgery system

- SCI's SWOG Affiliate Program, has 24 sites across Washington, Alaska, and Oregon in regional cancer centers. These programs receive access to over 50 NCI sponsored studies and many partner with Swedish for IRB services.
- The Breast Cancer Research Registry is a very unique program that is dedicated to outcomes management for treatment of breast cancer. It is a data base that houses over 11,000 breast cancer cases, adding over 800 new cases annually. The registry contains detailed information that is evaluated by physicians and is utilized for quality outcome initiatives.
- In 2011 the SWOG Affiliate Program welcomed three new Affiliate members; Island Hospital in Anacortes; United General in Sedro Woolley; and, Highline Hospital in Burien. We welcome participation from these institutions and look forward to rewarding relationships in the future.
- 2011 also saw the fruition of many years' work with the launch of the Society of Thoracic Surgeons (STS) Registry, a national database enabling the Thoracic Surgical Program to collect detailed patient data and benchmark treatment outcomes against national data.
- The last twelve months also brought about the SCI's selection as the only site in Washington State for the I SPY Trial. This very important national study, "Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis 2", will help learn if adding investigational drugs with standard chemotherapy will improve the treatment of breast cancer. The goal is to try and personalize treatment for breast cancer patients in the future.
- On the horizon in 2012 is the initiation of research support at the Issaquah SCI and Puget Sound Cancer Center in Edmonds. Activities and planning are actively being conducted to provide physicians access to clinical trials for their patients. We look forward to working with our new partners!

Mammography-Detected Breast Cancer in 40-49 Year-olds Has Better Prognosis

Based on a study of nearly 2,000 breast-cancer patients, researchers at the Swedish Cancer Institute say that, in women between the ages of 40 and 49, breast cancers detected by mammography have a better prognosis. The study appears in the March issue of *Radiology*.

"In our study, women aged 40 to 49 whose breast cancer was detected by mammography were easier to treat and had less recurring disease and mortality, because their cancer was found at an earlier stage," Henry Kaplan, M.D., medical oncologist with Swedish Cancer Institute (SCI).

Judith A. Malmgren, Ph.D., president of HealthStat Consulting, Inc., and a team of researchers – which included Dr. Kaplan and SCI-affiliated breast-imaging specialist Jay Parikh, M.D. – reviewed breast-cancer patient data from a dedicated registry at the Swedish Cancer Institute's community cancer center. The researchers analyzed data on 1,977 breast-cancer patients between the ages of 40 and 49 who were treated between 1990 and 2008. The researchers looked at method of diagnosis (detected by mammography, patient or physician), stage at diagnosis (0-IV, confirmed by biopsy), treatment, and annual follow-up information, including recurrence of disease.

"Our goal was to assess the differences between mammography and non-mammography detected breast cancer, to determine whether earlier detection confers a treatment and morbidity advantage because the disease is found at an earlier stage," said Dr. Kaplan.

The data analysis revealed a significant increase in the percentage of mammography-detected breast cancer over the 18-year period: from 28 percent in 1990 to 58 percent in 2008. Over the same period, patient- and physician-detected breast cancer declined from 73 percent of all cases in 1990 to 42 percent in 2008.

"The shift toward more mammography-detected breast cancer cases was accompanied by a shift toward diagnosis at an earlier stage of disease that required less treatment," said Dr. Parikh.

Over the 18-year period, the number of breast cancers diagnosed at Stage 0 increased by 66 percent, while the number of Stage-III breast cancers decreased by 66 percent. The majority of Stage-0 cancer cases were ductal carcinoma in situ (DCIS), a non-invasive cancer that is confined to a milk duct. The treatment of DCIS remains controversial, because not all experts agree that it is potentially life threatening.

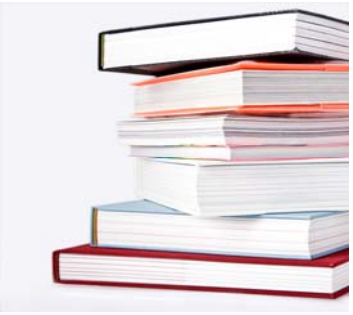
Dr. Malmgren said another key finding of the study was the extent of treatment patients received. Compared with women whose cancer was self-detected or discovered by a physician, patients whose cancer was detected using mammography were more likely to have breast-conserving treatment and less likely to have chemotherapy. Specifically, they were more likely to undergo lumpectomy (67 percent versus 48 percent), less likely to undergo modified radical mastectomy (25 percent versus 47 percent), and less likely to die of breast cancer (4 percent versus 11 percent).

"The benefits of breast cancer treatment are accompanied by significant harms," said Dr. Kaplan. "Chemotherapy may have long-lasting toxic effects on a woman's body, and mastectomy and reconstructive surgery are difficult and expensive operations that can have a significant effect on body image."

"The objective of screening is to detect disease at an earlier, more treatable stage, which — based on our review — mammography accomplishes," said Dr. Parikh.

Read more: http://www.swedish.org/About/Swedish-News/Mammography-Detected-Breast-Cancer-in-40-49-Year-o#ixzz1oN1d0NGS

PUBLICATIONS



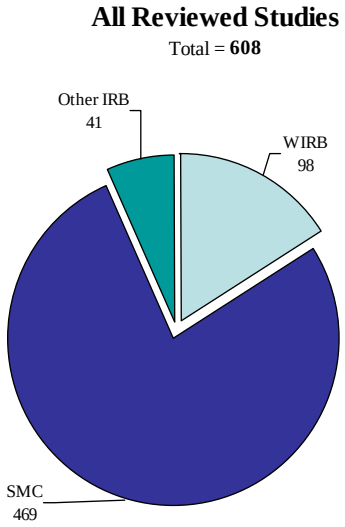
Swedish's Office of Research Administration has created a Master List of Investigator Publications in an effort to recognize and promote the immense contributions of our investigators to the medical community. The list is retrieved from PubMed on a semi-annual basis and is comprised of peer-reviewed journal, chapter, and book submissions; poster presentations or speaking engagements are not included. In this first collection of works, 343 publications from 63 investigators spanning 18 specialties were collected. It is our hope that more and more investigators will submit their written works for inclusion in this impressive listing. The current document can be found on the Research Center webpage under *Research Publications.* To submit your publication, please contact us at Research.Center@swedish.org

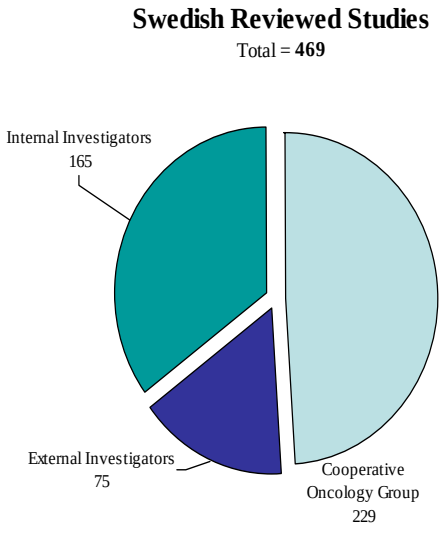
Institutional Review Office, Protecting Patient's Rights, Safety, and Welfare

Estela Hamblen — Manager, Institutional Review Office

Swedish has an internal IRB which supports all research endeavors conducted by Swedish investigators and with researchers who partner with Swedish. The Swedish IRB meets once a month and consists of IRB members within the institution and many community members. The IRB office consists of 6 FTEs available to assist researchers with questions on research applications and with the IRB process.

In 2011 the Swedish IRB office supported just over 600 studies. Of those studies, 469 were reviewed by the Swedish IRB. These reviews consisted of internal researchers and external researcher affiliated with Swedish.





The IRB has an electronic review process, IRIS. This system can be accessed 24 hours a day from any computer with internet access. It requires a user ID and password. If you are interested in conducting research, please call the IRB office at 206-215-2536 for assistance. The 2012 IRB meetings have been published and can be found on our website. We look forward to assisting you in your research endeavors.

SCRI Partners with Local Business to Support Cancer Awareness

The Swedish Center for Research and Innovation has partnered with Woodcraft of Seattle to raise funds for cancer research by selling Cancer Awareness pens. Each Awareness pen was individually handcrafted by volunteers who have been personally affected by cancer. These caring friends and family members generously donated their time in an effort to celebrate the commitment of researchers in finding a cure for a disease that has impacted so many lives.

Woodcraft of Seattle graciously donated all materials to help raise money in support of cancer research. These pens can be purchased at the Swedish Cancer Institute Resource Center on the First Hill campus. All proceeds from the sale of these pens go directly toward finding new ways to prevent and treat cancer at the Swedish Cancer Institute. To learn more about these pens and donating to research at Swedish, please contact SCRI at (206) 215-3100.

Clinical Trials Unit, A Consortium of Researchers

Heather Algren, RN, BSN — Manager, Clinical Trials Unit

The Clinical Trials Unit (CTU) at Swedish provides the opportunity for people throughout the Puget Sound region to gain access to cutting edge medical care and life-saving treatments by participating in clinical trials. Initiated in 1999, the Swedish Research Program developed the CTU with a consortium of leading clinicians and researchers in the Seattle community. Thirteen physicians, along with 12 nurses, research coordinators, and support staff conduct over 75 clinical trials a year, using offices throughout Swedish for all trial coordination efforts.

The mission of the CTU is to improve the health and wellbeing of our patients. We believe having access to new medications and contributing to the development of new treatments is an essential part of medical care. With the support of Swedish, the Swedish Foundation, and donors, the physicians participating in the CTU have provided new treatments and hope to patients in our community, many whom have very few treatment options. The CTU investigators are highly sought after clinicians leading drug development efforts nationally and internationally. Their expertise includes research in diverse clinical conditions such as, headache, rheumatoid arthritis, psoriatic arthritis, HIV, kidney transplant, central precocious puberty, and pain.

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The Clinical Trials Unit also provides the infrastructure for physicians within our community to partner and conduct research at Swedish. Currently, there are strong collaborations with researchers in private practice, Minor and James, Group Health, the University of Washington and Seattle Children's Hospital. Bringing academic research to the bedside and uniting clinicians will lead to the best possible solutions to complex clinical problems such as chronic depression or preterm labor.

Accomplishments in 2011

Based on studies conducted at Swedish under the guidance of Drs. Bill Marks and Lisa Florence, and data collected from other transplant centers over the past 6 years, the FDA approved the new drug Nulojix for the prevention of organ rejection following kidney transplant. This is the first new class of drugs developed for transplant since the 1990's.

Swedish partnered with the Global Alliance to Prevent Prematurity and Stillbirth and began enrolling pregnant women to help with this international initiative. As a regional leader in births, Swedish is partnering with Seattle Children's Hospital and other centers across the globe to develop a tissue and data repository to aid researchers in understanding and addressing the tragedy of preterm birth and stillbirth.

Under the direction of Jeff Cary, MD, Swedish opened and enrolled the first patients in a new trial of an inhaled antibiotic for bronchiectasis. This chronic and debilitating condition requires frequent use of antibiotics which can have many complications for patients. Inhaled antibiotics have been investigated for years, with limited success. This study plans to use new technology to deliver antibiotics directly to the lungs in an aerosolized form thereby offering hope for this new treatment method.

Staff Spotlight

Courtney Miller, MS CRCP, is our Grant and Contract Analyst in the Office of Research Administration. She has held the position since October of 2010. Her role focuses on the Neuroscience and Oncology research departments, where she is responsible for study set-ups, contract review and negotiation, and analysis of Budget & Billing Matrices.

Courtney takes pride in her mastery of contract negotiation, and is proficient in negotiation of subcontracts, Material Transfer Agreements, Data Use Agreements, Clinical Trial Agreements, Master Agreements and Federal Subawards.

In addition to her vast contractual knowledge, Courtney has over 15 years experience in biomedical research. She has worked as a research assistant, Nuclear Magnetic Resonance Specialist, and also performed analytical work. She has experience with bench research, clinical research, and pharmaceutical manufacturing quality control.

Courtney earned her Bachelors at University of Alabama-Birmingham and her Masters Jacksonville State University. In her free time, she enjoys spending time with her partner Jonny and their 3 Great Danes Hazzard, Suki, and Ishtar.

Courtney can be reached at (206) 215-1452 or via email at Courtney.Miller@swedish.org

Center for Perinatal Studies

At the Center for Perinatal Studies (CPS), researchers are engaged in a series of clinical and population-based research projects seeking to increase knowledge concerning the causes and mechanisms of adverse pregnancy outcomes. In several new and on-going projects supported by various funding sources, CPS investigators are conducting ground breaking studies with potentially significant contributions to maternal and child health.

The Migraine, Platelet Activation and Preeclampsia study (NIH-funded) entered its third year, continuing with the success of previous large cohort studies conducted at CPS, including the Omega study. Investigators are conducting multi-disciplinary studies to investigate causes of preterm birth as it relates to vitamin D (CDC-funded), microRNAs (MOD-funded), and partner abuse and mood & anxiety disorders (NIH-funded). In the last year, CPS researchers began an innovative case crossover study of triggers of Abruptio Placentae with support from the NIH. Based on a unique collaborative model with an industry, investigators are working on a project to develop a flexible information visualization and analysis software for biomedical research, particularly –omics research. This research will have significant impact in the current setting of exploding research using –omics tools.

In the past year, work at the Center was profiled in several publications in high impact journals including the American Journal of Obstetrics and Gynecology, Diabetes Care and Epidemiology. Team members presented their work at several key venues promoting their research findings on etiological, clinical and diagnostic research of pregnancy complications. The recognitions received included the Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring (Dr. Michelle Williams). The year was also marked by the commencement of a close working collaboration with Harvard University initiated by a move of the former CPS Co-director (Dr. Michelle Williams) to the position of Chair of the Department of Epidemiology at Harvard School of Public Health. Since this transition, CPS research team has maintained same standard of excellence under the leadership of Dr. Daniel Enquobahrie and Dr. Naya Frederick.

President Obama Honors Dr. Michelle Williams

U.S. President Barack Obama has selected Dr. Michelle Williams as one of the nation's top science, mathematics, and engineering mentors. Dr. Williams is co-director and principal investigator at the Center for Perinatal Studies at Swedish, the largest, most comprehensive non-profit health provider in the greater Seattle area. Dr. Williams is one of 11 individuals and four organizations chosen to receive the prestigious Presidential Award for Excellence in Science, Mathematics and Engineering Mentoring. These mentors met with President Obama in the Oval office and received their awards at a special White House ceremony on January 27, 2011.

The Presidential honor is awarded by the White House annually to individuals or organizations in recognition of the crucial role that mentoring plays in the academic and personal development of students studying science or engineering—particularly those who belong to groups that are underrepresented in those fields. By offering their expertise and encour-

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agement, mentors help prepare the next generation of scientists and engineers while ensuring that tomorrow's innovators reflect the full diversity of the United States.

Candidates for the Presidential Mentoring Awards are nominated by colleagues, administrators and students in their home institutions. The mentoring can involve students at any grade level from elementary through graduate school. In addition to being honored at the White House, recipients receive awards of $10,000 to advance their mentoring efforts.

"Dr. Williams is a true asset to our community. She has gone above her normal day job to ensure that our Puget Sound region remains on the forefront of top tier science and engineering," said Mark Reisman, M.D., Swedish's Chief Scientific Officer. "We are really honored to have Dr. Williams as part of our Swedish team and congratulate her on this incredible award."

Dr. Williams' Center for Perinatal Studies is a multidisciplinary research program involving clinical scholars, basic scientists and epidemiologists. Her research program focuses on integrating genomic sciences and epidemiological research methods to identify risk factors, diagnostic markers, treatments, and prevention targets for disorders that contribute to maternal and infant mortality. Dr. Williams, her collaborators and her cadre of pre- and post-doctoral fellows actively study cohorts of pregnant women as they work to understand the determinants of preterm delivery, preeclampsia, gestational diabetes, and placental abruption. Her research laboratory at Swedish is working to identify unique gene expression patterns that may be used to predict which pregnant women will go on to develop hypertension in late pregnancy or deliver prematurely.

Read more: http://www.swedish.org/About/Swedish-News/U-S--President-Obama-Honors-Dr--Michelle-Williams#ixzz1hlyGOUWV

PHILANTHROPY FUELS INNOVATION

The clinical research program at Swedish is dedicated to ensuring that Swedish remains a leader in the development and early adoption of important new medical therapies and devices. This commitment to innovation helps our patients rest-assured that their physicians have access to the best tools and treatment options available to diagnose and improve their conditions. Philanthropy makes this possible.

In today's environment, the declining availability of federal grant funding for research and reduced hospital reimbursement rates make it increasingly difficult to invest in research. As a nonprofit hospital, Swedish depends on generous gifts from the community to close the gap. Philanthropy leverages Swedish resources to fund important investments such as:

- Patient participation in clinical trials
- Fellowships for emerging physician-researchers
- Cutting-edge lab space and equipment
- Scientist and support staff salaries
- Materials and supplies

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Opportunities are available to support the research initiatives of Swedish physicians advancing clinical research in almost every area of care, from cardiovascular medicine to pediatrics. To learn how your gift can make a difference, please contact:

Swedish Medical Foundation 206.386.2738 | www.swedishfoundation.org

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http://www.swedish.org/For-Health-Professionals/Research#axzz1iQauqrGg

EVENTS CALENDAR

July

SummeRun & Walk—7/22

September

Brain Cancer Walk—9/22

Research Investigator Forum

October

Swedish Luncheon—10/9

BioMedical Research Day—10/22

November

Life Sciences Research Weekend

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