PROFILE 2009

NIH CLINICAL CENTER
DIRECTOR'S ANNUAL REPORT

There's No Other Hospital Like It

U. S. Department of Health and Human Services • National Institutes of Health

CONTENTS

PROFILE 2009

Message from the Director **1**

Recent Clinical Center Achievements **3**

Advancing Clinical Research **4**

Patient Activity and Support **18**

Organizational Improvement/Teamwork **26**

Training the Next Generation **31**

Noteworthy **40**

Organization and Governance **46**

EXPANDING OPPORTUNITIES

In 2009, the NIH Clinical Center will face numerous challenges and opportunities. A new Presidential administration will mean new priorities for our country, and the Clinical Center must be prepared to respond quickly and thoughtfully. Another major challenge will be to address continuing resource constraints. Several years of essentially flat budgets have strained our ability to achieve an optimal level of clinical research support activity

A thorough review of the Clinical Center is planned for 2009. It will be conducted by a new group mandated by Congress, the Scientific Management Review Board. This review will be part of the Board's overall examination of NIH. The goal is to provide recommendations for enhancing the agency's mission. Aligned with this review will be our continuing careful assessment of the needs of our institute colleagues so that the most appropriate, highest quality clinical research and patient care resources are in place.

The Clinical Center will continue to define and play key roles in clinical research worldwide in 2009. Numerous collaborations are opening doors to remarkable new opportunities. Through partnerships with the Clinical and Translational Science Awards network and other external groups, we are able to offer clinical research training resources, informatics tools, and a unique research environment to support new areas of research. We will be working with the Uniformed Services University of the Health Sciences and the Department of Defense to find new ways to diagnose and treat traumatic brain injury and post-traumatic stress in both military and civilian populations. More than a thousand potential patients have sought to participate in the NIH's new Undiagnosed Diseases Program, a collaboration with the National Human Genome Research Institute and the NIH Office of Rare Diseases. The program, which is expected to continue to grow, is a tangible reminder that our hospital truly is a "house of hope."

The Clinical Center team—which includes patients, our partners in discovery—enables medical discovery and advancement every day. Our hospital's successes are possible because of their combined dedication and commitment to excellence.

John I. Gallin, MD
Director, NIH Clinical Center

VISION As America's research hospital, we will lead the global effort in training today's investigators and discovering tomorrow's cures.

MISSION To provide a versatile clinical research environment enabling the NIH mission to improve human health by:

- Investigating the pathogenesis and natural history of disease
- Developing state-of-the-art diagnostic, preventive, and therapeutic interventions
- Training the next generation of clinical researchers
- Ensuring that clinical research is safe, efficient, and ethical.

There's No Other Hospital Like It

RECENT CLINICAL CENTER ACHIEVEMENTS

IN 2008 WE:

Established new partnerships and expanded existing ones. For example,

- Through collaborations with the Clinical and Translational Science Awards network, the Clinical Center will serve as a hub for clinical research training, provide leadership in defining the role of clinical research nursing, and develop and share informatics tools that support clinical research.
- Under a new $70 million initiative with Uniformed Services University of the Health Sciences and the Department of Defense, the Clinical Center will play a key role in clinical research studies on traumatic brain injury and post-traumatic stress disorder, investigations that will involve both members of the military and civilians.

Offered renewed hope to patients seeking answers through the Undiagnosed Diseases Program.

Provided new opportunities for training in clinical research worldwide. A modified version of the Clinical Center's course "Introduction to the Principles and Practice of Clinical Research" was offered in Beijing, the first time an adaptation has been presented live outside NIH.

Advanced the Data Transformation Initiative, a project that enables the Clinical Center to define and share operational data in ways that can be benchmarked with other hospitals. The initiative is the first step in moving the organization's management data from an activity-based costing model to a hospital industry standard.

Continued to enhance and broaden informatics resources to support clinical research and patient care, including CRIS, the Clinical Research Information System; BTRIS, the Biomedical Translational Research Information System; and ProtoType, an automated protocol writing tool.

Continued to meet the challenge of tight resources by asking staff to do more with less and carry out the Clinical Center mission while containing costs.

Sought opportunities to be eco-friendly, which in the Nutrition Department has led to changes that are environmentally friendly and help keep costs down.

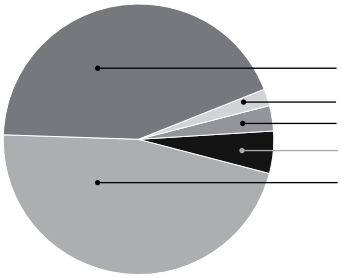
Improved communications with referring physicians in response to a survey of more than 3,000 physicians nationally.

Expanded volunteerism by creating a patient ambassador program, which provides special support to patients while helping to reduce costs.

PROTOCOLS BY RESEARCH TYPE

(ONSITE INTRAMURAL PROTOCOLS, FISCAL YEAR 2008)

Total active protocols: 1,449

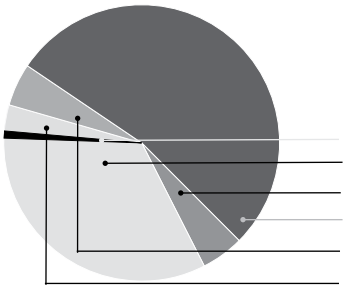


Clinical trials:	632	(44%)
Training:	28	(2%)
Sample data analysis:	59	(4%)
Screening:	72	(5%)
Natural history (disease pathogenesis):	646	(45%)

(12 protocols are pharmaco-dynamics/kinetics studies.)

Breakdown of clinical trials

Total clinical trials: 632



Phase 0:	9	(1%)
Phase I:	209	(33%)
Phase I-2:	30	(5%)
Phase 2:	332	(53%)
Phase 3:	35	(5%)
Phase 4	17	(3%)

Clinical studies are medical research studies (or protocols) in which human volunteers participate. *Clinical trials* are studies developing or investigating new treatments and medications for diseases and conditions. *Natural history studies* investigate normal human biology and the development of a particular disease. *Screening studies* determine if individuals may be suitable candidates for inclusion in a particular study. *Training studies* provide an opportunity for staff physicians and other health-care professionals to follow particular types of patients.

Clinical trials phases

Phase 0: An initial first-in-human study (20-30 participants) under an exploratory IND (investigational new drug) for early identification of biologic and molecular markers in new clinical agents. There is very little agent exposure with no therapeutic or diagnostic intent.

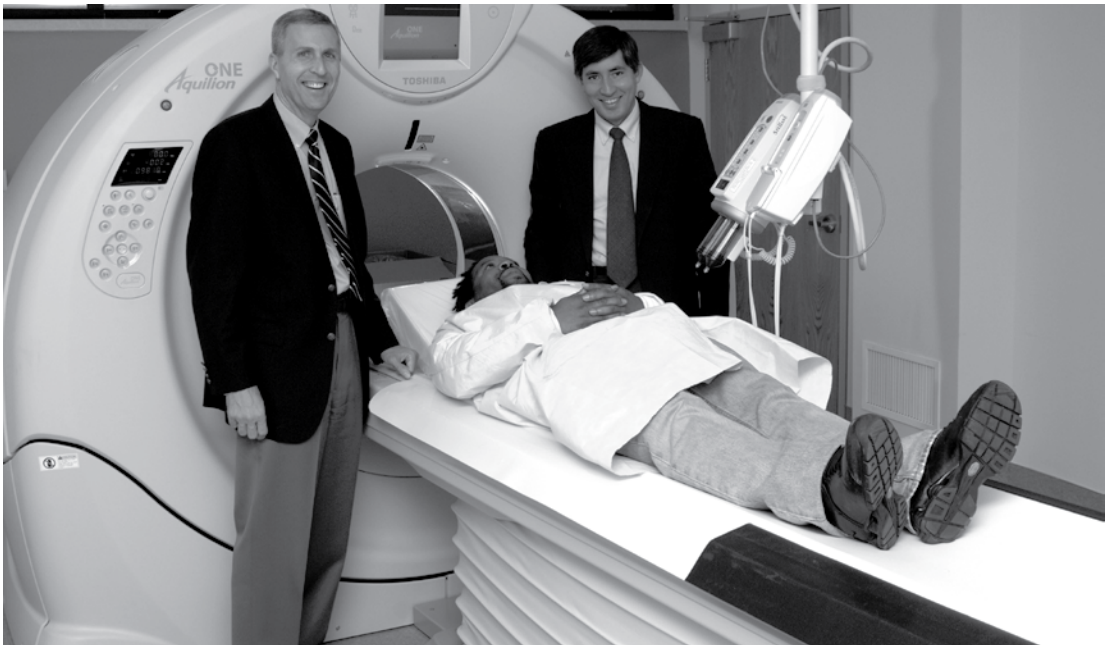
Phase I: Researchers test a new drug or treatment for the first time in a small group of people (20–80) to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II: The study drug or treatment is given to a larger group of people (100–300) to see if it is effective and to further evaluate its safety.

Phase III: The study drug or treatment is given to large groups of people (3,000 or more) to confirm its effectiveness, monitor side effects, compare it with commonly used treatments, and collect information that will ensure safe usage.

Phase IV: These studies are done after the drug or treatment has been marketed. Researchers continue to collect information about the effect of the drug or treatment in various populations and to determine any side effects from long-term use.

CC PARTNERS WITH NHLBI ON A POWERFUL NEW CT SCANNER



Dr. David Bluemke (left), director of Radiology and Imaging Sciences at the Clinical Center, and Dr. Andrew Arai (right), senior investigator with the National Heart, Lung, and Blood Institute, demonstrate the new CT scanner with Gregory Henderson, CT scan technician. The machine came to the CC through an NHLBI-CC partnership.

Stronger, faster, better—the new breed of computed tomography (CT) scanner captures the image of an entire organ in only one rotation. In a partnership with NHLBI, Radiology and Imaging Sciences at the Clinical Center installed one such machine in August.

"We plan to expand this type of collaboration with institutes to broaden the imaging capability and expertise offered at the Clinical Center," said Dr. John I. Gallin, CC director.

The newest CT scanner captures images in milliseconds, reducing patients' radiation exposure and diagnosis time. "Instead of standard X-ray films of the abdomen or chest in a fraction of a second, we now can get a full 3-D CT scan that contains much more information for the patients and their physicians in 0.2 seconds," said Dr. David Bluemke, director of Radiology and Imaging Sciences. Older technology pieces together multiple scans to give doctors and researchers a three-dimensional image.

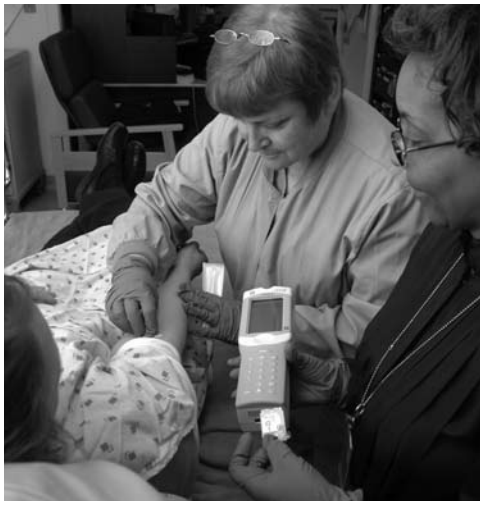
This new technology delivers remarkably detailed pictures of the inside of the body.

To capture the entire heart cycle, older scanners used helical, or spiral, methods, which required a large amount of overlap in rotations resulting in high radiation exposure, according to Dr. Andrew Arai, an NHLBI senior investigator. "By getting the whole heart in a single rotation, radiation exposure to the patient decreases significantly," he said.

The new CT scanner also lends itself to new applications such as perfusion imaging. The injection of X-ray contrast material that circulates in the bloodstream can show if the heart muscle is receiving adequate blood supply under stress or rest conditions. The first studies using the new machine will focus on low-radiation dose cardiac exams, with later NHLBI trials using the scanner to study coronary artery disease and myocardial perfusion.

The quick and comprehensive output of the scan will reduce the need for multiple tests and invasive procedures, which cuts diagnosis time from hours or days to minutes. "I have great confidence that in the future all CT scanning will be done this way," said Bluemke.

POINT-OF-CARE TESTING BRINGS FAST RESULTS



Nurses Marti Shepherd and Betty Patterson from the Department of Anesthesiology and Surgical Services demonstrate the use of the bedside point-of-care testing device.

Accurate patient information collected efficiently is the goal of any point-of-care testing program. The Clinical Center took a giant step forward to broader adoption of such a program in 2008 when the Department of Clinical Research Informatics worked with the Department of Anesthesiology and Surgical Services and the Department of Laboratory Medicine to deploy a Central Data Station, a machine to upload point-of-care testing results into the Clinical Research Information System and Laboratory Information System.

Anesthesiology and surgical services staff use a handheld device at the patient's bedside to measure blood gases, electrolytes, and glucose levels. This and other point-of-care testing instruments calculate results on the spot. There is no need to send a patient's samples back to a lab. "Within two minutes you have your results, as opposed to waiting perhaps 15-20 minutes for the main lab results," said Marti Shepherd, nurse anesthetist and point-of-care testing coordinator for the department.

Results are fed directly into the Central Data Station. Eliminating manual entries means fewer opportunities for transcription errors or misplaced paper forms. The immediacy of the dock and load system frees nurses for more patient care. With phase one now complete, the Department of Clinical Research Informatics plans to implement other point-of-care testing projects for nursing and other patient care services.

Dr. Jim Cimino shows Vien Vanderhoof of NICHD how to access and navigate BTRIS, the Biomedical Translational Research Information System.

Cimino Shares BTRIS Vision At CC Forum

"The problem we're trying to solve is access to research data," Dr. Jim Cimino said during a 2008 introduction of the Biomedical Translational Research Information System (BTRIS). "BTRIS is intended to provide researchers with easy access to clinical data derived from multiple sources, including the clinical information systems at the Clinical Center, for their on-going trials," said Cimino, chief of the Laboratory for Informatics Development and BTRIS project director. He notes that the system also allows investigators to search across data sets to answer new questions and shape fresh ideas for future studies. Principal investigators volunteered data from 29 protocols involving 8,000 patients to test the new system.

In a demo of BTRIS at a town hall meeting in September, Cimino walked attendees through the steps to reach lab results, medicine dosage, and other information of interest to researchers. Without the newly developed technology, one had to download each patient's data from the Clinical Research Information System. "To do this manually would take you quite a bit of time," Cimino said.

NIHers had the opportunity to work in a BTRIS demonstration environment through during the fall. "In that time, the BTRIS team received many positive reviews and recommendations that will feed into the development of BTRIS 1.0, due out in July 2009," said Cimino.

CC, NIAID VACCINE RESEARCH CENTER LAUNCH MOBILE CLINIC TO TAKE RESEARCH, EDUCATION MESSAGES TO THE STREETS

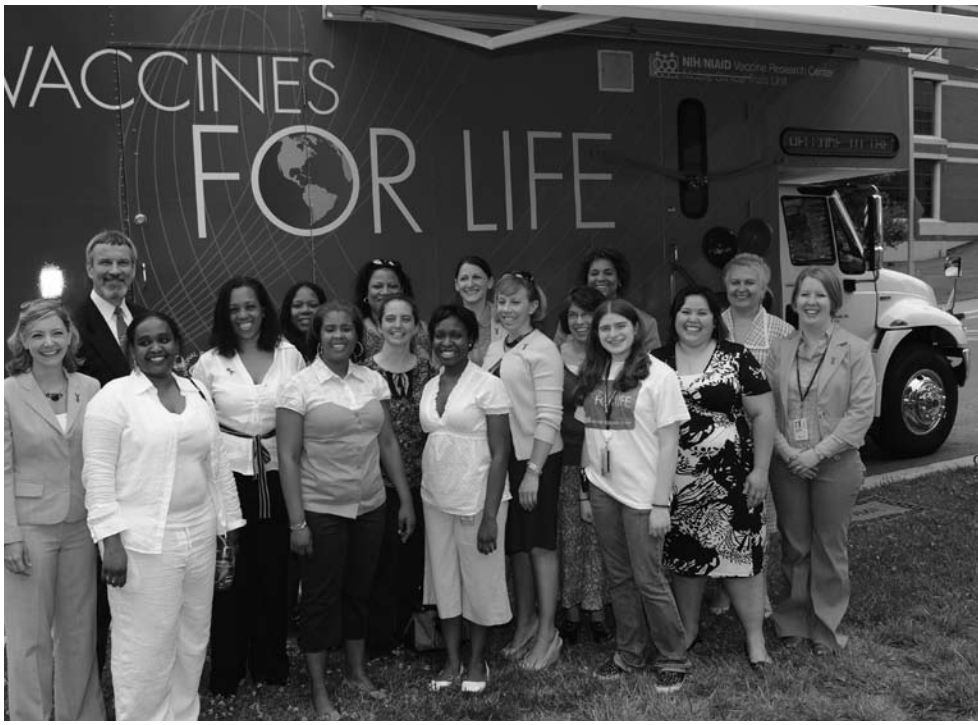
A new resource aimed at increasing community involvement and clinical research education in the region was introduced in 2008. It's a mobile clinic, an extension of NIAID's Vaccine Research Center's vaccine clinic at the Clinical Center.

According to Dr. Barney Graham, NIAID senior investigator and chief of the clinical trials core and the viral pathogenesis laboratory, the clinic team will use the mobile unit to raise awareness about HIV vaccines, enhance the capacity for enrolling healthy adults into outpatient studies, and make participation in clinical trials more convenient. "These volunteers are typically employed, busy people, and we hope the mobile clinic will make enrollment in trials more convenient and at the same time extend the visibility of NIH and the Clinical Center," he said.

VRC staff plan to take the clinic anywhere they are currently involved in HIV/AIDS and other infectious disease outreach, including neighborhoods in Baltimore, Frederick, and the District. They will continue to work with HIV/AIDS organizations, city health departments, churches, college campuses, and outreach event organizers, but in an expanded capacity.

In his welcoming remarks, CC Director Dr. John I. Gallin noted the recent attention to mobile health facilities in providing care to rural and underserved areas within the US and abroad. "This is an exciting experiment in how to reach out to new volunteers. We hope it will bring more participation to all clinical research activities, as well as attention to NIH, NIAID, and the Clinical Center," Gallin said.

In his remarks, Dr. H. Clifford Lane, deputy director for clinical research and special projects at NIAID, outlined the history of the VRC, which opened in 2000 to spearhead vaccine research from basic to applied science. The VRC has developed and implemented 20 protocols, of which 10 are complete, he said. The VRC's work has included not only HIV/AIDS, but also established and emerging viral infections such as Ebola, Marburg, H5 influenza, West Nile, severe acute respiratory syndrome (SARS), and smallpox.



"The VRC is a genuine national asset that contributes to the health of the nation and the world," Lane said. "It's wonderful to see this new outreach to the DC-area, which is one of the places in the US that is hardest hit by HIV. There's such a great need for prevention, and this mobile clinic will reach out to the community outside the NIH gate to bring in new volunteers."

All smiles in front of a mobile clinic from NIAID's Vaccine Research Center (VRC) and the Clinical Center, VRC Clinical Trials Core Chief Dr. Barney Graham (second from left) and Deputy Chief Dr. Julie Martin (far left) join VRC nurses and administrators during the clinic's launch on June 6.

Vaccine Evaluation Clinic

The Clinical Center provided clinical research support in developing NIAID's new Vaccine Evaluation Clinic on 5NE-S. Ribbon cutting was held Dec. 1, 2008, World AIDS Day. The patient-care unit includes state-of-the-science infrastructure for the safe conduct of clinical research protocols involving new vaccines and vaccine technologies that require high-level containment. Clinic staff will include (from left) Olga Vasilenko, clinical data manager, nurse Kathryn Zephir, Dr. Nilu Desai, and Sara Hubka, nurse practitioner.

Merel Kozlosky, director of the NIH dietetic internship and supervisory metabolic dietitian, welcomed attendees to the 2008 Nutrition Research Day March 18.

NUTRITION RESEARCH DAY SHARES NEW TERRITORY EXPLORED BY CLINICAL RESEARCH DIETITIANS

Nutrition Research Day 2008 drew participants from across the country in a week-long CC-NCI nutrition and cancer prevention research practicum. Representing all levels of training, from undergraduate to PhD, attendees learned about the role of clinical research dietitians at the CC and a sampling of nutrition-related protocols. Nutrition as a field is also increasingly involved in the cutting-edge territory of biomedical informatics, which Dr. James Cimino, chief of the Laboratory for Informatics Development, defined in his presentation as the art and science of organizing knowledge of human health and disease and making it useful for problem solving. Madeline Michael, chief of clinical nutrition services in the Nutrition Department, described the CC's experience transforming practice from paper to electronic health records and designing nutrition documentation for research. Dr. Amy Subar, a nutritionist with NCI, shared how her team developed an automated, self-administered 24-hour dietary recall system. By answering a series of questions about what they ate, patients created a food list of what they consumed the day before that—with further probing about food preparation, additions, and portion size—leading to the assignment of a standard USDA food code that is used to calculate a total nutrient and food group intake for the reporting day.

A SPECIALTY: CLINICAL RESEARCH NURSING

Clinical research nursing (CRN) is nursing practice with a specialty focus on clinical research and the care of clinical research participants. It includes care provided to research participants in addition to activities that support protocol implementation, data collection, and human subject protection. Despite nursing involvement in clinical research for decades, the CRN practice domain is not well defined or documented. Expansion of the national and international clinical research enterprise requires investigators, health policy makers, regulators and clinical research sponsors to understand the important role that clinical research nurses play in assuring patient safety, integrity of protocol data, and ongoing informed consent, all within the context of effective and appropriate clinical care. Nursing at the Clinical Center has undertaken a multi-year project to describe and define the CRN domain of practice and lead the way in establishing CRN as a recognized specialty practice area.

In 2008, the first set of validation activities was conducted. These activities focused on a role analysis of the practice demonstrated by the more than 900 clinical research nurses at the Clinical Center. A critical review and synthesis of themes from available literature and practice documents was conducted. Structured interviews were conducted with CC nurse managers and clinical staff representing inpatient units, outpatient clinics and day hospitals, along with research nurses from five institutes and centers within the NIH intramural program. All were asked to define both the formal position roles and the informal roles and activities for nurses in their respective areas. Interview data analysis revealed two separate role clusters within the CRN domain of practice—the Clinical Research Nurse and the Research Nurse Coordinator. Five proposed dimensions (distinctive categories of activities) emerged: clinical practice, study management, human subjects protection, contributing to the science, and care coordination and continuity. Clinical Research Nurses had most activities clustered within the dimensions of clinical practice and care coordination. Research Nurse Coordinator role descriptors included the dimensions of study management, human subject protection, and care coordination.

The validation process continued with a review of the literature, research-management degree and certificate-granting programs, certification tests from research organizations, and NIH clinical research nurse position descriptions. The goal was to identify and code specific activities within the two CRN roles.

The final step of the validation process is currently under way to achieve consensus on the activities and dimensions within the CRN Domain of Practice. A survey was developed and has been distributed to an expert panel of nurses who actively provide or supervise clinical research care and Clinical and Translational Science Awards, General Clinical Research Centers (GCRC), and NIH. Future projects will include role profile studies to compare clinical research nursing roles in different practice settings.

Indian Health Service

Nursing and Patient Care Services and the Indian Health Service (IHS) have collaborated with the National Alaska Native American Indian Nurses Association (NANAINA) since 2006 to begin training staff at IHS clinical facilities to conduct research and evidence-based practice projects. In May 2008, a workshop was held for IHS nurses throughout a five-state area at the Northern Navajo Medical Center in Shiprock, New Mexico. A research development meeting in Bethesda followed in July. These workshops resulted in evidence-based project development including 2008 NANAINA Summit podium and poster presentations by IHS nurses from New Mexico, North Dakota, and Oklahoma. An additional $40,000 grant by the National Center of Minority Health and Health Disparities was awarded to further support interagency collaboration with the Indian Health Service.

2008 BENCH-TO-BEDSIDE AWARDS

The NIH Clinical Center created the Bench-to-Bedside awards program in 1999 to speed translation of promising laboratory discoveries into new medical treatments by encouraging collaborations among basic scientists and clinical investigators. Since 2006, the program has been open to research teams made up of intramural and extramural partners. Awardees for 2008 are listed below.

GENERAL CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NCI NIAID Ludwig Institute for Cancer Research Weill Medical College, Cornell	Targeting cancer-testis gene expression for lung cancer therapy	D. Schrump, MD, NCI; V. Lobanenkov, PhD, NIAID; L. Old, MD, Ludwig Institute for Cancer Research; and N. Altorki, MD, Weill Med College, Cornell
NINR University of Maryland	Molecular mechanisms of glial cell modulation of chemotherapy-induced painful peripheral neuropathy	X. Wang, MD, PhD, NINR; S. Dorsey, RN, PhD, and C. Renn, RN, PhD, U of MD

AIDS CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NCI University of California, San Diego	New strategies to decrease and eradicate HIV-1 reservoirs	F. Maldarelli, MD, PhD, NCI; E. Reid, MD, UCSD
NICHD Case Western Reserve	HIV-1 suppression by Acyclovir in patients coinfected with human herpes viruses from basic mechanism to clinical application	L. Margolis, PhD, NICHD; M. Lederman, MD, Case Western
NIAID NHLBI, Children's National Medical Center NCI	Non-invasive cardiac 3T MRI for evaluation of premature coronary artery disease and myocardial dysfunction in adolescents and young adults with HIV acquired in infancy and childhood	C. Hadigan, MD, MPH, NIAID; A. Gharib, MD, NHLBI; R. Cross, MD, MS and S. Clauss, MD, CNMC

AIDS/MINORITY HEALTH CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NIAID Johns Hopkins University Uganda (Makere Medical School, Mulago Hospital)	Hepatitis B and HIV co-infection in Uganda	T. Quinn, MD; S. Reynolds, MD, NIAID, Uganda; and L. Stabinski, MD, MPH, NIAID; C. Thio, MD and G. Kirk, MD, MPH, PhD, JHU
NCI FDA University of Washington	Development and evaluation of a nanoparticle-based HIV-1 p24 antigen assay for monitoring therapy in resource limited settings	F. Maldarelli, MD, PhD, NCI; I. Hewlett, PhD, FDA; L. Frenkel, MD, U of WA

MINORITY HEALTH & HEALTH DISPARITIES CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NIDDK University of Michigan	Toward molecular-marker based management of diabetic nephropathy in Pima Indians	R. Nelson, MD, PhD, NIDDK; M. Kretzler, MD, U MI

RARE DISEASES CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NHGRI University of South Carolina University of Texas-MD Anderson	Predicting the response to treatment using gene mutation profiling in metastatic melanoma patients	Y. Samuels, PhD, NHGRI; P. Buckhaults, PhD, U of SC; P. Hwu, MD, U of TX-MD Anderson
NHLBI NIH Clinical Center	Graft-Versus-Host Disease: novel cellular therapy using selective thawing of umbilical cord blood to obtain an aliquot for ex-vivo natural killer cell expansion and infusion following allogeneic hematopoietic stem cell transplantation	R. Childs, MD, NHLBI; S. Vasu, MD, CC
NIH Clinical Center NHLBI INOVA Fairfax Hospital	Evaluation of the platelet transcriptome expression profile in pulmonary arterial hypertension	R.F. Machado, MD, NHLBI; N. Raghavachari, PhD, CC; S. Nathan, MD, INOVA
NHLBI Harvard Temple University NIH Clinical Center	Characterization of Jak/Stat activation in patients with monosomy 7 and the development of targeted therapy for patients using a Jak2 inhibitor	E. Sloand, MD and N. Young, MD, NHLBI; J. Groopman, MD, Harvard
NHLBI Imperial College, London	Development of immunotherapeutic strategies to overcome tolerance in leukemia	A. J. Barrett, MD, NHLBI; K. Rezvani, MD, PhD, Imperial College School of Med
NIAID NCI	Recombinant human IL-& (CYT107) as immunomodulatory therapy for idiopathic CD4 lymphopenia: a phase I/IIA open-label pilot study	J. Brenchley, PhD and I. Sereti, MD, MHS, NIAID

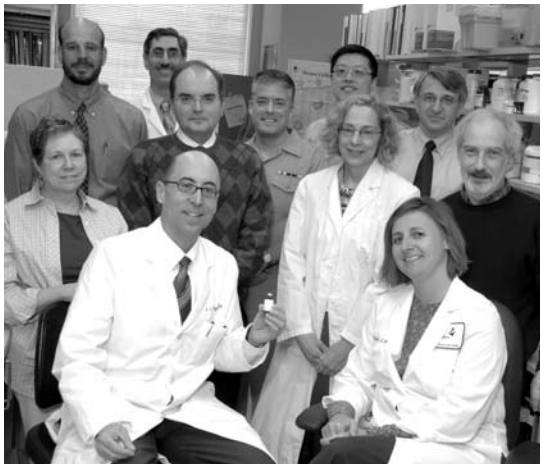
WOMEN'S HEALTH CATEGORY

TEAMS	PROJECTS	PRINCIPAL INVESTIGATORS
NHLBI NCI	Immunogenicity of quadrivalent human papilloma virus vaccine (HPV Types 6, 11, 16, 18) in recipients of reduced intensity hematologic stem cell transplantation (HSCT)	A. Chenoy, MD, NHLBI; P. Stratton, MD, NICHD; L. Pinto, MD and L. Wood, MD, NCI
NICHD NIDDK Sackler School of Med, Tel Aviv, Israel	Histaminergic pathways and energy intake in obese women	J. Yanovski, MD, PhD, L. Yanoff, MD, and C. Cropp, PharmD, NICHD

BENCH-TO-BEDSIDE AWARDS PROGRAM

More than 400 investigators have collaborated in 135 projects since the NIH Clinical Center's Bench-to-Bedside awards program was begun in 1999. Funding has totaled about $24 million. Here is a look at some of the research advances this program has generated.

B2B SPOTLIGHT | NOVEL CANCER VACCINE



In front are NCI's Dr. Alan Wayne and Dr. Crystal Mackall. In back (from left) are Dr. Elaine Jaffe, NCI; Dr. Terry Fry, NCI; Dr. Rodger Kurlander, CC; Dr. David Stroncek, CC; Kelly Richards, NCI; Hua Zhang, NCI; Dr. Mary Alice Stetler-Stevenson, NCI; Dr. Ronald Gress, NCI; and Dr. Mark Raffeld, NCI.

Bench-to-Bedside awards in 2003 and 2005 have led to the introduction of a new cancer vaccine developed from the blood cells of healthy donors. Acute lymphoblastic leukemia (ALL) is the most common childhood cancer. Statistics show that for 20 percent of pediatric patients with ALL, and half of the adults who are diagnosed with the disease, the final result will be death.

One way doctors have treated ALL is to perform an allogenic stem cell transplant (SCT). In a best case scenario, SCT results in what's called a "graft-versus-leukemia (GVL)" effect, whereby the immune system from the donor cells wipes out residual cancer, and becomes part of the cure. But this effect is not as strong in ALL as it has been shown to be in other cancers of the blood.

Dr. Alan Wayne is the clinical director and head of the hematologic diseases section at the NCI's Pediatric Oncology Branch and Center for Cancer Research. He is also the principal investigator for a clinical trial designed to develop a new vaccine strategy to enhance the GVL effect after SCT for the treatment of ALL and other blood cancers.

In this Phase 1/2 pilot trial, the goal is to develop a novel cancer vaccine that will treat children and adults with blood cancers that have either recurred or persisted despite a previous SCT. This is one of the first attempts in human subjects to use cells taken from healthy stem cell transplant donors to develop cancer vaccines. Previously, a patient's own blood, bone marrow, or tissue was used in vaccine development.

A typical method of treating patients with relapsing leukemia following a SCT is to infuse lymphocytes from a healthy donor into the patient. In some types of leukemia, this procedure leads to an 80 percent cure rate. Not so in ALL where the cure rate is less than 10 percent. One reason for this, researchers speculate, is that the ALL cells aren't as "visible" to the lymphocytes.

To make these cells more easily seen, researchers have created a vaccine from specialized cells called dendritic cells, which present proteins to the lymphocytes and direct their attack. These dendritic cells are cultured and matured *in vitro* by the Clinical Center's Department of Transfusion Medicine Cell Processing Section.

Patients in this trial receive two small vaccine injections from the cultured donor cells every other week. Then, once each month, they receive standard donor lymphocyte infusions. This happens over a three-month period with outpatient visits to the Clinical Center's Day Hospital. The first patient received the investigational vaccine last spring. Wayne, and his colleagues hope to test the vaccine in 12 individuals before moving on to the next phase of the study.

"We are excited about all of this expertise and multiple technological advances converging on a clinical need: better therapies for individuals whose cancer relapses after a stem cell transplant," Wayne said.

The current trial is designed to test the safety and effectiveness of the vaccine. However, Wayne said he could see a day when the vaccine could be given as a way to prevent cancer relapse as part of the initial transplant procedure.

"It's always a race between the disease and the treatment," Wayne said. "The less disease patients have at the start of the race, the better off they are."

B2B SPOTLIGHT | INTRACTABLE PAIN

Messengers with good news to deliver can count on a warm reception. Bearing bad news? Your watchword should be the cliché, "Don't kill the messenger."

But what if *killing the messengers*—in this case, pain-responsive neurons in the sensory ganglia—can be proven as a practical way to manage intractable pain?

That's the central question in research being done by Dr. Michael Iadarola, chief of the Neurobiology and Pain Therapeutic Section at the National Institute of Dental and Craniofacial Research, and Dr. Andrew Mannes in the NIH Clinical Center's Department of Anesthesia and Surgical Services.

Iadarola's team is about to launch a Phase I clinical trial of a new pain-relieving drug called resiniferatoxin (RTX). He called the drug a single-shot dose of analgesic that lasts forever. "We call it a 'fire and forget' missile," he said. The target neurons in the sensory ganglia connect the body to the spinal cord, and interrupting this one specific class of pain sensing neurons will eliminate the connection and eliminate some, but not all, types of pain.

This research was funded, in part, by a B2B award Iadarola received from the NIH Clinical Center in 2001, and the clinical trial is the culmination of a long journey both for the drug and the doctor. The experimental drug comes from Morocco where it is isolated from latex of the plant *Euphorbia resinifera*. The latex from this cactus-like plant has been used for topical pain relief, as well as for other medicinal uses, for thousands of years.

RTX has a molecular structure similar to capsaicin, the active ingredient in hot peppers. Like capsaicin, RTX binds to the same pain receptor in a neuron, but 500 to 1,000 times more tightly. Capsaicin causes an ion channel called TRPV1 in the sensory neuron to open briefly allowing a small amount of calcium and sodium ions to flow into the cell. That generates the burning sensation one associates with eating a hot pepper. RTX, however, holds the channel open for a much longer period, flooding the cell with enough calcium to kill it. Within an hour, most neurons with a TRPV1 channel are compromised or dead. They do not grow back.

From left are Brian Bates, NIDCR; Dr. Andrew Mannes, CC; Dr. Michael Iadarola, NIDCR; Dr. Kendall Mitchell, NIDCR; Ruth Yaskovich, NIDCR; and Jason Keller, NIDCR.

Not all neurons have TRPV1 channels, and RTX doesn't affect the ones that don't. These TRPV1-positive neurons are contained in the dorsal root ganglion. Their nerve endings are in the skin where they respond to sensations of moderate heat and in the internal organs where they seem to be the main messengers of pain from cancer and inflammation.

Iadarola credited the B2B award for getting the ball rolling in the translational direction of this research. "First off, it got us started thinking about, and actually doing something about, taking laboratory findings and bringing them into clinical practice," he said. "Not that we didn't want to do this, but we had a basic science laboratory and we had no mechanism to take findings from live-cell imaging with a microscope and translating that into a clinical protocol. Getting the B2B award is what got us started on what has been a long road."

The B2B award funded some of the early research that extended the lives of family pets at the University of Pennsylvania Medical School. These dogs suffered from painful conditions that made them candidates for euthanasia. "These animals were enrolled into the protocol, they were treated

BENCH 2 BEDSIDE

with RTX and it was like magic," Iadarola said. "They went home pretty much pain free, and the pain control lasted the duration of their lives. One treatment led to almost complete pain control. Most of the dogs came off their concurrent medications, like NSAIDS or opiates."

Iadarola said the efficacy of the drug's effect on the dogs and lack of side effects were very strong incentives to move into the next phase of the clinical journey: testing RTX on humans suffering from intractable pain. This transition occurred with the help of the Division of Pharmacotherapies and Medical Consequences of Drug Abuse of NIDA who were experts in the development of treatments for addictive drugs. First, the research team needed a clinical grade drug. "That was a very long adventure," Iadarola explained. But after a few false starts, Iadarola said they have enough of the experimental medication to use in studies for several years. He said having the B2B funds was very helpful in this step as well.

Iadarola noted that his team is just about to kick off the clinical trial with their first patient. Dr. Mannes, a long-term collaborator and anesthesiologist, is the person who will inject the RTX. They hope to enroll as many as 24 into the study. Injection of the RTX into the cerebral spinal fluid space around the spinal cord is tricky business because the patient is placed under general anesthesia for 60 to 90 minutes while the drug does its work, killing off the pain neurons in the spinal cord. If the treatment is successful, the patient should no longer have to rely on high doses of morphine or other opioids to control pain.

"We hope this is the beginning of a much bigger program for pain control," Iadarola said. "This is a very versatile agent and approach. We can use this not only in people with end stage cancer, but hopefully in a lot of other specific pain conditions if we can demonstrate both safety and efficacy. Safety is one of the key components here, and we're very cognizant of that."

B2B SPOTLIGHT | SMITH-MAGENIS SYNDROME

Front row (from left) are Hanna Hildenbrand, CC Rehabilitation Medicine; Ann Smith, NHGRI; and CAPT Michaele Smith, CC Rehabilitation Medicine. In back are Rebecca Morse, NHGRI; Dr. Maryland Pao, NIMH; Beth Solomon, CC Rehabilitation Medicine; Dr. Wallace Duncan, NIMH; and Dr. Marjan Huizing, NHGRI.

Smith-Magenis Syndrome (SMS). It's not a household-name disease. In fact, many times it's mistaken for something else entirely, like Down Syndrome. Other times, it's missed completely.

Thanks to the B2B awards program, a team of dedicated researchers is working to not only increase awareness of the syndrome, but to find new and better ways to treat it.

Leading the team is Dr. Ann C. M. Smith. She's the "Smith" in Smith-Magenis Syndrome. Working at Children's Hospital in Denver as a genetic counselor in 1981, she saw her first two patients within six months of each other. Both infants had failure to thrive; defects of the heart and palate; developmental delay; a typical facial appearance; short stature with small hands and feet; low muscle tone; and motor delays, among other signs. They were identified to have a small missing piece from the short arm of chromosome 17, called "deletion 17p11.2". She described and presented these cases at a 1982 meeting of the American Society of Human Genetics and began collaborating with Dr. Ellen Magenis, a cytogeneticist at Oregon Health & Sciences University (who gave the condition the second half of its moniker). They published a paper together in 1986 identifying the first nine individuals with deletion 17p11.2, expanding the now-trademark characteristics to include middle ear problems, hoarse voice, ocular abnormalities, sleep disturbances, and neurobehavioral features, such as hyperactivity and autistic-like repetitive behaviors.

Smith is now a senior genetic counselor on contract with NHGRI, having recently retired from the medical faculty at Georgetown University Medical School. The research team she leads has received two B2B awards, the first in 1999.

"That award went, in part, to establish the multidisciplinary research team at NIH, which allowed us to focus on research efforts to understand the clinical and molecular manifestations of SMS," she said. It resulted in a natural history protocol and

allowed her to convene a SMS research roundtable with the parent's support group *PRISMS* to bring together experts and researchers in the field. The natural history protocol, Smith said, yielded several publications and the description of new findings, including the validation of early expressive speech delays caused by underlying physiological issues related to low muscle tone, decreased tongue strength and movement, laryngeal and palatal abnormalities, poor suck reflex, and difficulties transitioning to solid foods. This initial B2B award also funded a pediatric nasal endoscope used to visualize the palate and vocal cord function.
The sleep disturbance that occurs in the syndrome is chronic and seen across all ages. "A lot of parents thought their children were sleeping very well as infants," Smith said. "We've identified the sleeping disturbance as young as nine months of age. They were so quiet, they weren't alerting their parents. They weren't crying."

The initial protocol also showed that many of the kids with SMS have short stature. "We're collecting growth data to generate specific growth curves," Smith explained. Other findings of the initial natural history protocol showed that SMS patients tend toward obesity during adolescence and have lowered immunoglobulins, and hypercholesterolemia (elevated total cholesterol, triglycerides, and/or LDL cholesterol).

"One of genes in this region (of the chromosome deletion) is involved in cholesterol management. A second gene is involved in IgA deficiency. So it's interesting because these children only have one copy of these genes," Smith explained.

The natural history protocol also defined an earlier onset of sensory neural hearing loss, which can occur shortly after age 10, and increased frequency of hyperacusis, which is a condition described as an over-sensitivity to certain frequency ranges of sound.

The research team got a second B2B award in 2004, which Smith said was being used to assemble an approach to what she called "the novel inverted melatonin circadian rhythm" found in SMS patients. Where most of us produce the sleep hormone melatonin at night, people with SMS produce it during the day. Where light suppresses the formation of the hormone in most folks, it doesn't in SMS patients. People with SMS experience chronic sleep disturbances with frequent nighttime and early morning awakenings compounded by daytime sleepiness.

Smith said the second B2B award was used to fund a new Phase I treatment trial. It paid for several medical devices, such as digital thermometers, and Actiwatches—which are wristwatch-like accelerometers used to measure an SMS patient's activity-rest cycle in the home setting and give the researchers a good idea of the patient's sleep pattern. Actigraphy is less invasive than standard EEG sleep studies (the gold standard) and provides a continuous estimate of sleep based on wrist motion for a prolonged period. The objective information about the dynamics of home sleep in the context of behavioral and developmental changes was critical to the design of the phase 1 sleep treatment trial that began in 2008 at NIH.

The second B2B award also funded the purchase of bright light boxes and creation of a melatonin tablet used for the treatment study. "Melatonin isn't regulated by the FDA. You can buy it at health food stores," Smith said. "But for NIH, we wanted a purer form of melatonin with a time delayed release. So the Clinical Center's Pharmacy Department developed a coated tablet."

Patients with SMS began enrolling in the protocol in April 2008, along with healthy adults who tested the safety, and efficacy of the melatonin tablet.

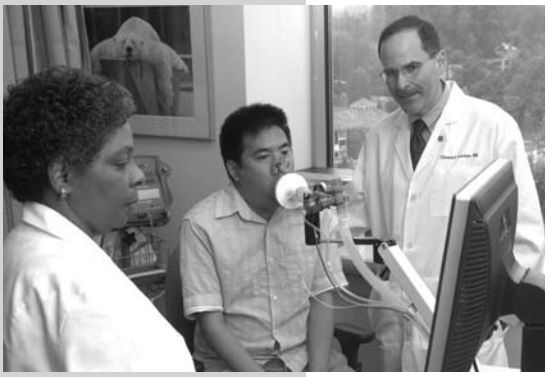
The official statistics on SMS suggest that one out of every 25,000 children is born with SMS. Smith thinks that number is too low—more like one out of every 15,000. She said that with improved molecular genetic techniques for examining chromosomes when health-care providers see a child with speech and motor developmental delays, they may be able to diagnose more children who might have gone unrecognized. Smith said many SMS patients are not identified until school age when the sleep, and behavioral issues are readily apparent. The oldest was identified at age 65.

Smith looks at herself as something of a "team captain." "I've got some stellar researchers who, before they met this syndrome, didn't know a thing about it," she said. "Now, probably, they have more experience than anyone else in the world with the syndrome, having seen more individuals."

She is excited by the prospect of new discovery in the Phase I trial, funded by the latest B2B award. "I think this population can actually offer us a better understanding of something that is so unusual—this inverted circadian rhythm of melatonin," she said. "That biologic conundrum to me is the piece that, if we can understand it, will open a new understanding of this syndrome."

"We've identified the sleeping disturbance as young as nine months of age. They were so quiet, they weren't alerting their parents. They weren't crying."

—Dr. Ann C.M. Smith



NHLBI's Dr. Stewart Levine, technician Clara Jolly, and patient and fellow Jonathan Lam demonstrate the pulmonary function tests that trial participants will receive to monitor the progress of their asthma.

Protocol tests type 2 diabetes medication to treat severe asthma

Two Japanese patients with type 2 diabetes and asthma sparked the idea. They started taking pioglitazone hydrochloride (HCI), a medication used to treat type 2 diabetes, and noticed that their asthma also improved.

Coincidence? There is no published data in humans on the topic, so it's impossible to know until research can move beyond anecdotal evidence. Dr. Stewart Levine, principal investigator with NHLBI's Pulmonary and Vascular Critical Care Medicine Branch, launched one of the first randomized, placebo controlled, double-blind pilot clinical trials in patients with allergic asthma to find out whether pioglitazone HCI (Actos) is effective for treating patients with asthma who do not respond to standard therapy.

Pioglitazone belongs to a class of medications called thiazolidinediones, which have been shown to have anti inflammatory effects. These medications have been used to improve asthma in preclinical studies, so there is compelling evidence that this approach might be useful for asthmatic patients.

According to Levine, 22 million people in the US have asthma, and approximately 10 percent of those patients have severe cases. The mild to moderate treatments don't work for them, so Levine's goal is to find new treatments for people with moderate to severe asthma. Often already using inhalers, these patients' next options would be oral corticosteroids or injectable anti-IgE therapy. Levine hopes that about 50 asthma patients between 18 and 75 years of age who have had asthma for at least one year and whose symptoms are not well controlled with current treatments will choose to enroll in his study.

The study has three phases. First, candidates are screened with blood and urine tests, breathing tests, an allergy skin test, chest X-ray, electrocardiogram, and echocardiogram. Participants are given a device to measure and record lung function and asthma symptoms at home for four weeks before starting the study medication. Lung function is also measured at clinic visits before and after inhaling a bronchodilator medicine and participants are admitted to the hospital for fiberoptic bronchoscopy and lavage—a test to examine the lung's airways. In phase two, participants are randomly selected to receive either pioglitazone or placebo, a look-alike pill with no active ingredient, once a day for 10 weeks. They return to the clinic after two weeks to repeat the tests done in the first phase and to monitor any reactions to the study drug or placebo. If there are no problems, the amount of medication is increased and they return for follow-up evaluations every two weeks for eight weeks. Pulmonary function tests and bronchoscopy and lavage are repeated after 10 weeks on medication.

In the last phase, patients return for follow up one month after stopping the medication or placebo to monitor their asthma. Because pioglitazone is an already FDA-approved medication commonly prescribed for type 2 diabetes, about seven million people have already taken it. According to Levine, the main side effects are weight gain, edema, and anemia. Long-term use of this class of medication has been associated with worsening heart failure in diabetic patients who use insulin, as well as bone fractures, so patients will be monitored with bone density assessments.

If the results from Levine's pilot study look promising, he hopes to open it up in a few years to patients with severe asthma at multiple locations. According to Levine, there is an important unmet need for the development of new treatment options for patients with severe asthma. "If pioglitazone or other medications could be shown to be effective for the treatment of severe asthma, this would represent a wonderful new option for these patients."

Promising pilot study by CC researchers treats deep vein thrombosis

Clinical Center researchers have developed and published a novel treatment for blood clots in the legs that appears to be safe and effective, according to their pilot study.

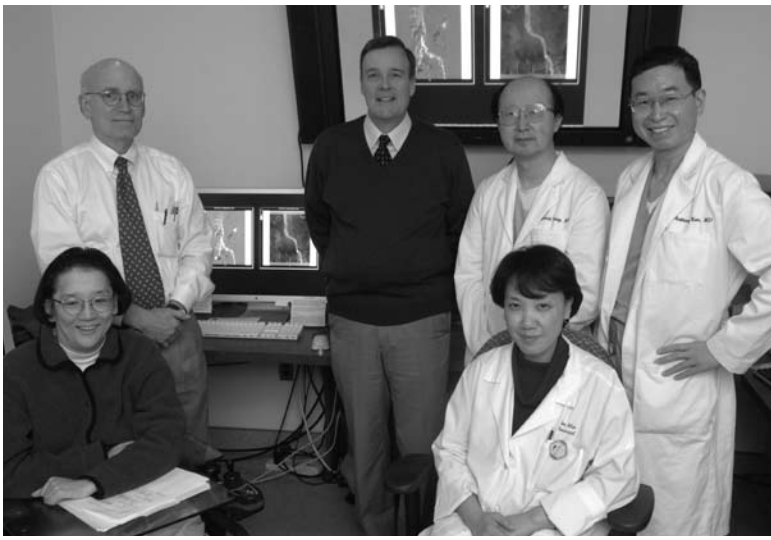
Deep vein thrombosis (DVT) is a common but serious health problem that happens when a blood clot, or thrombus, forms in the deep veins, particularly in the lower leg or thigh. Complications occur when the clot breaks off and travels to the lungs, resulting in pulmonary embolism, a potentially fatal condition. Lack of movement is a risk factor for DVT, which is why long-distance airline passengers and patients who recently had surgery or were hospitalized often hear about the condition.

Most patients with DVT are treated with medications to thin the blood and compression stockings. However, studies have shown that one-third of these patients will suffer from post-thrombotic syndrome, characterized by pain, swelling, or changes in skin color. Another third are likely to have another clot or pulmonary embolism within five years of their initial DVT.

Clot-dissolving therapies could potentially protect against these occurrences, but can pose a bleeding risk. Therefore, lead author Dr. Richard Chang, chief of the interventional radiology section in Radiology and Imaging Sciences, sought to develop a safe, effective, and affordable clot-dissolving treatment regimen for DVT.

For the pilot study, the researchers injected or "laced" the clots of 20 acute DVT patients with alteplase, a clot dissolving agent. Alteplase binds to the clot, so the procedure does not require continuous infusion of the drug, as do other clot-dissolving therapies. With this treatment, after lacing one vein segment with alteplase, the interventional radiologist can immediately direct catheters to treat other vein segments to ensure that the entire clot has been adequately treated. The patients also received blood thinners.

The new treatment restored blood flow throughout the deep venous system in 16 (80 percent) of the 20 patients during therapy with complete resolution of symptoms in 18 patients (90 percent) after six months of treatment with blood thinners. Alteplase left the patients' circulatory system within two hours of treatment, reducing the risk of subsequent bleeding. "This treatment regimen is able to clear blood clots rapidly and safely, restoring blood flow in the veins of the lower leg, and the results are durable," said Chang.

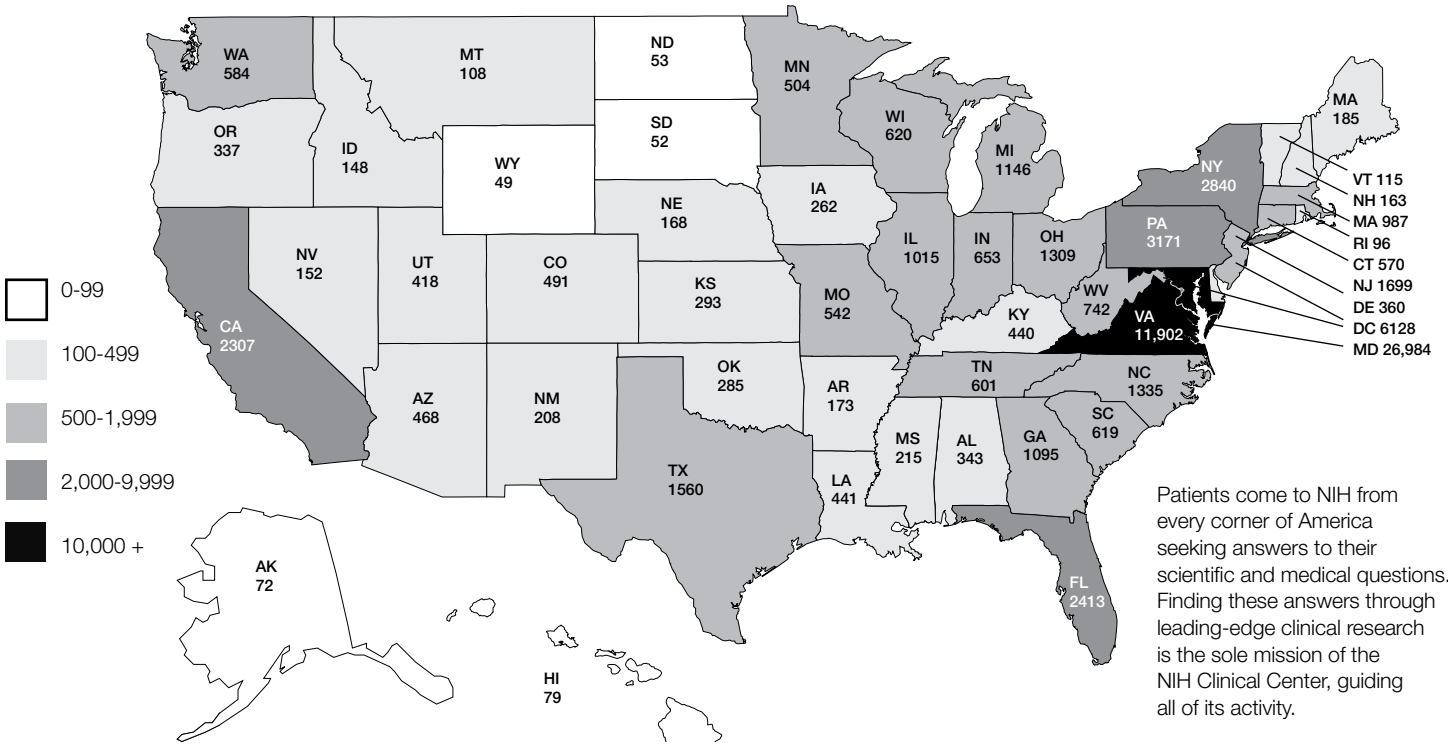


Researchers who collaborated on the project stand in front of scans showing (from left) a pilot study participant's veins before and after the alteplase treatment. (Back row, from left): Drs. McDonald Horne, Richard Cannon, Richard Chang, and Anthony Kam. (Front row, from left): Drs. Clara Chen, and Edie Mao. Not pictured: Thomas Shawker. Cannon is NHLBI clinical director.

There were no cases of clinically important pulmonary embolism or serious bleeding during the treatment, and no cases of post-thrombotic syndrome or recurrent clotting during the more than three years that the researchers followed the patients. "With this therapy, pain and swelling resolve rapidly, and, in most cases, the patient is able to resume all normal activity within a week," said the study's co-author, Dr. McDonald Horne from the hematology section of Department of Laboratory Medicine.

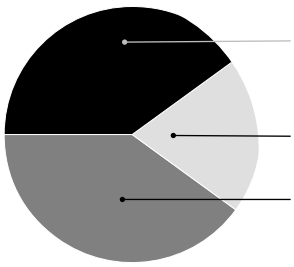
The CC researchers' paper, "Deep Vein Thrombosis of the Lower Extremity: Direct Intraclot Injection of Alteplase Once Daily with Systemic Anticoagulation—Results of a Pilot Study," appeared in the February 2008 issue of *Radiology,* a monthly scientific journal devoted to clinical radiology and allied sciences. The authors caution that larger clinical trials are required to further support the efficacy of the treatment.

HOME STATES OF ALL ACTIVE CLINICAL CENTER PATIENTS



Patients come to NIH from every corner of America seeking answers to their scientific and medical questions. Finding these answers through leading-edge clinical research is the sole mission of the NIH Clinical Center, guiding all of its activity.

WORKFORCE DISTRIBUTION



Nursing & patient care/support services 41%

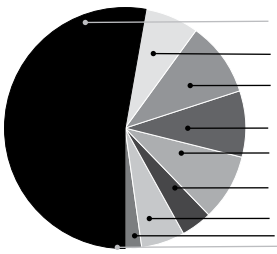
Administrative & operations 17%

Clinical departments & imaging sciences departments 42%

The Clinical Center has a staff of approximately 2,000.

FY 2008 BUDGET BY MAJOR CATEGORY

351.9 MILLION



Salaries and benefits 53%

NIH assessments 7%

Drugs 10%

Contracts (labor) 9%

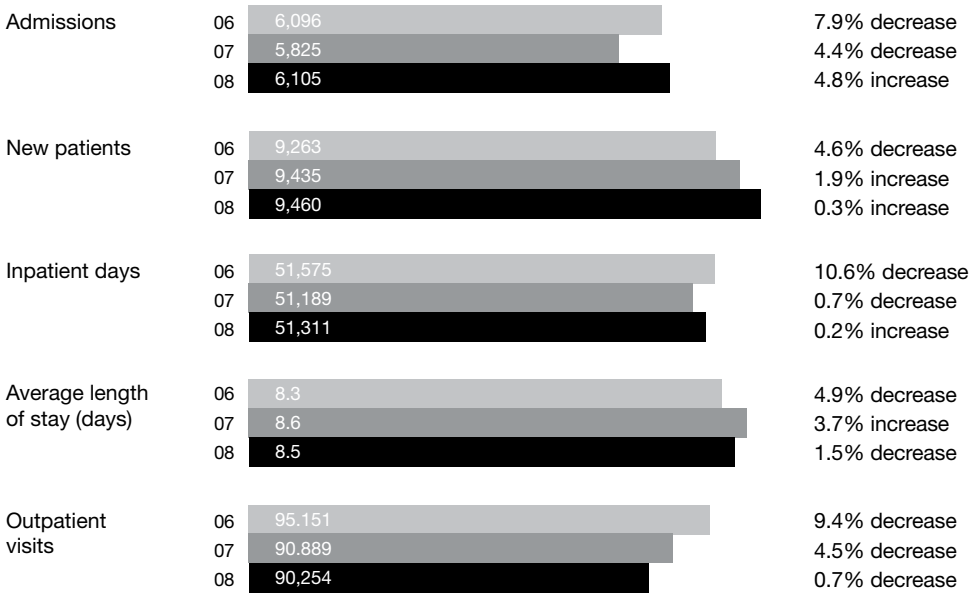
Contracts (non-labor) 9%

Equipment 4%

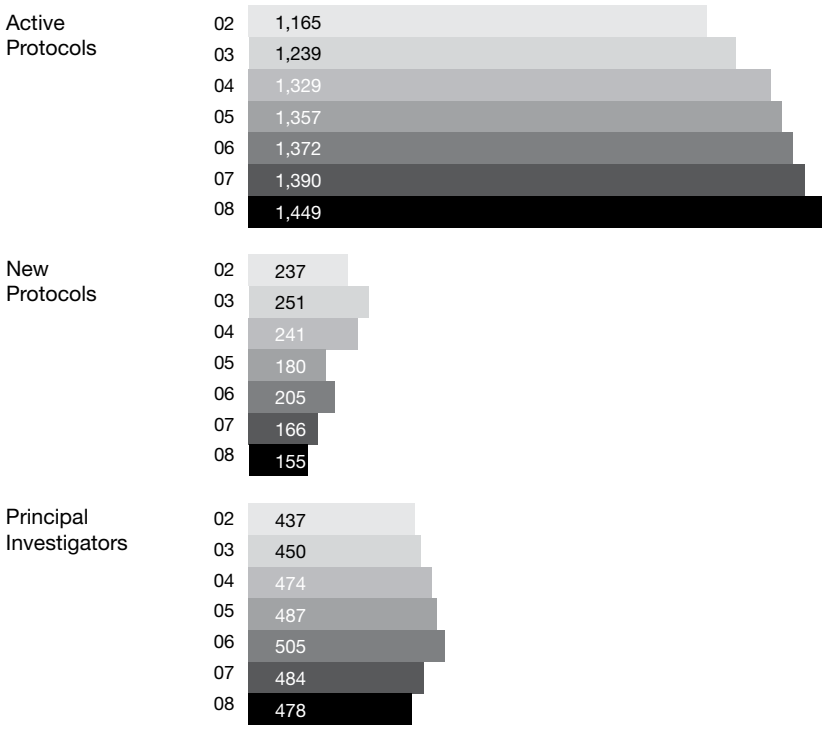
Supplies 6%

All other 2%

PATIENT ACTIVITY



ONSITE CLINCAL ACTIVITY FOR 2002–2008



TRANS-NIH UNDIAGNOSED DISEASES PROGRAM TO HELP NAME PATIENTS' PUZZLING CONDITIONS

In May 2008, NIH introduced a new clinical research program that will aim to provide answers to patients with mysterious conditions that have long eluded diagnosis. Called the Undiagnosed Diseases Program, the trans-NIH initiative will focus on the most puzzling medical cases referred to the Clinical Center by physicians across the nation. "A small number of patients suffer from symptoms that do not correspond to known conditions, making their care and treatment extraordinarily difficult. However, the history of biomedical research has taught us that careful study of baffling cases can provide new insights into the mechanisms of disease—both rare and common," said former NIH Director Dr. Elias A. Zerhouni, who made a point during his six-year tenure at NIH of encouraging trans-NIH initiatives. "The goal of NIH's Undiagnosed Diseases Program is two-pronged: to improve disease management for individual patients and to advance medical knowledge in general."

The new program was the culmination of efforts by Dr. William A. Gahl, NHGRI clinical director; Dr. John I. Gallin, director of the NIH Clinical Center; and Dr. Stephen Groft, director of the NIH Office of Rare Diseases. "The NIH Clinical Center, the nation's clinical research hospital, provides an extraordinary environment for excellence in both patient care and collaborative clinical investigation," said Gallin. "This new program will capitalize on a rich set of skills already at the Clinical Center to help patients with unusual medical conditions. These patients often partner with us in clinical research to identify new diseases or new treatment."

To evaluate each patient enrolled in the new program, NIH will enlist the expertise of more than 25 of its senior attending physicians, whose specialties include endocrinology, immunology, oncology, dermatology, dentistry, cardiology, and genetics. Gahl, who is an expert on rare genetic diseases, directs the new program.

"We have developed a stringent referral process to ensure this program deals with those cases that have truly confounded medical experts," Gahl said.

Dr. William Gahl (from left), clinical director of the National Human Genome Research Institute; Dr. John I. Gallin, director of the Clinical Center; Amanda Young, a special representative from the patient community; and Dr. Stephen Groft, director of the Office of Rare Diseases, at the launch of the Undiagnosed Diseases Program.

"We will be very selective when it comes to patient eligibility. Our focus is strictly on conditions that have not been diagnosed."

An undiagnosed disease is what brought Amanda Young and her family to the Clinical Center in 1990. Years of intensive testing led to a diagnosis of an IRAK-4 deficiency. An extremely rare genetic mutation affects her body's ability to create a protein needed to fight bacteria, leaving her vulnerable to life-threatening infections. The oldest of only about 20 patients known to have the deficiency, Mandy seems to have put the worst behind her. Entering a career in motivational speaking, Mandy is positive about her future. She looks forward to visiting her Clinical Center "family," including Gallin—her doctor—and she's ecstatic that the Undiagnosed Diseases Program will be in place to help others like her.

"This new program will be more than a place for families to come for help," Mandy said. "It will be their place to come for hope."

To be considered for the program, a patient must be referred by a physician and provide all medical records and diagnostic test results requested by NIH. Patients, as many as 100 a year, who meet the program's criteria will then be asked to undergo additional evaluation during a visit to the Clinical Center that may take up to a week.

During the program's first five months, more than 1,200 inquires were received from potential participants and the team screened 400 charts. About 40 cases were accepted in 2008.

Two nurse practitioners manage logistics for the new program, which will use existing facilities and staff already at the NIH Clinical Center, NHGRI, and ORD. Funding for the program includes $280,000 per year from the ORD.

In organizing the Undiagnosed Diseases Program, NIH reached out to patient advocacy groups that often serve as a source of information and support for people struggling with mysterious ailments. "We hope to build upon our strong working relationships with many patient advocacy groups. These organizations provide a crucial link in our nation's efforts to improve human health through biomedical research," said Groft. "We hope that this new partnership of NIH researchers, advocacy groups and patients will give hope for many Americans who now face troubling medical symptoms with no clear diagnosis."

"This new program will be more than a place for families to come for help. It will be their place to come for hope."

—-Amanda (Mandy) Young

Clinical Center launches patient ambassador volunteer program

Denise Ford (at left), chief of hospitality services and patient ambassador program coordinator, and Courtney Duncan (at right), director of volunteer services and patient ambassador program co-coordinator, stand with one of the first groups of patient ambassadors at their orientation.

White coats are nothing new in the Clinical Center's halls, but burgundy ones are. Proudly showing the colors are the 65 volunteers with the Patient Ambassador Program, launched Oct. 1, 2008. The program will help lower the cost of the messenger and escort contract by extracting duties that volunteers can perform. Initial savings totaled about $150,000 and more are expected. The program also helps strengthen community relations and foster inclusion and diversity A task force led by Denise Ford, CC Hospitality Services, and Courtney Duncan, CC Volunteer Services, devised a plan to recruit and train the team. Volunteers include staff scientists, retirees, high school students, and the disabled. Patient ambassadors handling patient transport in Radiology and Imaging Sciences and the Department of Anesthesia and Surgical Services, medical record transport, and wheelchair management. Volunteers are asked to commit a minimum of four hours of service a week for one year.

Phlebotomy supervisor Veronica Washington checks in CC patient Ronald Stokes.

New phlebotomy system helps alleviate wait times for patients, staff

The Department of Laboratory Medicine's phlebotomy service's new electronic queuing and wait-time display system is helping minimize wait times for patients while preserving patient confidentiality. It's been so effective, wait times have been cut in half.

Selecting the new system was the culmination of staff efforts to find ways to improve the patient experience in phlebotomy. The CC Pharmacy Department also uses an electronic queuing system. Veronica Washington, phlebotomy supervisor, proposed the idea for an electronic system. She saw how long waits frustrated patients because patients had no way of tracking where they were in the queue for service or understanding why others who arrived later were seen first.

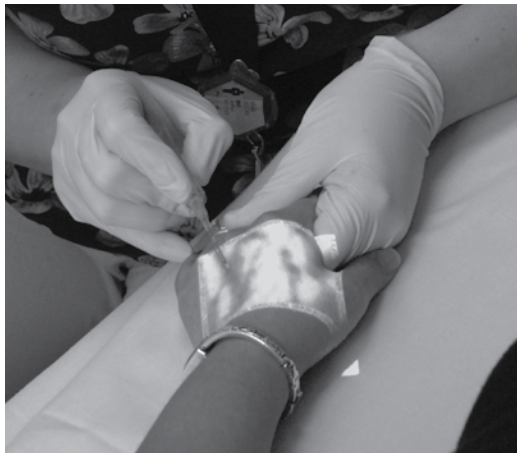
Also, the team wanted to be able to immediately identify cases where phlebotomy orders were not yet available in CRIS (the Clinical Research Information System) so that staff could proactively obtain the orders—averting a common reason for patient waits.

Under the service's new system, staff greet arriving patients, confirm orders for blood work, and give each patient a numbered ticket. Patients use the ticket number, which is displayed on an electronic screen, to track their place in line.

Ronald Stokes, who has visited the CC as a patient for 23 years, said after his first experience with the new system, "I didn't think the wait time was very long in phlebotomy before, but this made things even faster. Veronica and her staff are wonderful. They always have a smile and take care of any problems that come up. They make it pleasant to come here even though you're coming because of an illness."

The phlebotomy staff are evaluating patient feedback on the new system. The next step will be to add electronic kiosks, which will allow patients to enter their names and collect their tickets.

NEW VEIN ACCESS TECHNOLOGY INCREASES PATIENT COMFORT



3 SW-N nurse Mara Vecchio demonstrates how the new vein finder illuminates patient veins.

Many Clinical Center patients young and old alike dread the needlesticks involved in starting an IV or other lines. Some patients consider venipuncture to be one of the most painful and frequently performed invasive procedures. The CC's Vascular Access Device Service (VAD), a collaboration between the Critical Care Medicine and Nursing Departments, continuously evaluates new technologies that will improve venipuncture care for patients and recently adopted a novel technology to ease the placement of venous catheters. Debbie Gutierrez, nurse manager for the VAD team, said that many CC patients' veins are difficult to find on the first try because of the types of rare conditions they have or the medications they take.

For several years, VAD has used ultrasound imaging to more easily determine the difference between a vein, which looks like a round dark circle that squishes easily, from an artery, which looks like a pulsating circle that doesn't change shape from the pressure of the ultrasound probe. Watching the ultrasound screen, the nurse can identify a vein, line up the dots on the ultrasound probe with the vein, and observe the needle, which shows up as a bright white speck, penetrating the vein. "This allows us to reach the vein on the first try every time," Gutierrez said.

When VAD began ultrasound placements, they would perform fewer than 60 per month. Now they are doing about 300 monthly.

For economy and efficiency without compromising patient comfort, VAD adopted a new method of visualizing veins that uses a special light to provide a map of where the veins are located in the extremities. Using a combination of green infrared light and projection technologies, the viewer locates subcutaneous veins and projects their location onto the skin's surface in real-time. This makes the process of inserting needles and catheters more efficient and comfortable for both CC patients and nurses. needle sticks." Dr. Anthony Suffredini, senior investigator in critical care medicine, said that the VAD team is "doing an outstanding job and hope that by using these new technologies that they will make an excellent vascular access service even better with the new approaches."

RECYCLED READS—R&R FOR CC PATIENTS

Gently read magazines are in demand. Recycling them is helping brighten the day for Clinical Center patients. Magazines covering a variety of interests are a great resource to help patients pass the time while at the CC for appointments. It's easy to make the drop. Red-roofed collection bins are located in the elevator lobbies of the P2 and P3 parking garages and outside the patient library on the 7th floor of the Hatfield Building. Patient library and Red Cross volunteers collect and sort the magazines, make sure address labels are removed, and distribute them at least weekly to waiting areas in clinics, radiology, and phlebotomy.

HOPE FLOWS FROM ONE PATIENT TO ANOTHER IN ART TILE PROJECT

Megan Robb (left), a board certified art therapist, and Natalie Haynes, certified recreation therapist—both within the Rehabilitation Medicine Department's Recreation Therapy Section—help patient Danielle Harriott and her mom, Cassandra Christopher, create tiles for the project that remind them of their home in Kingston, Jamaica. They painted the green-blue color of the ocean, the white sandy beaches, and their country's flag.

A treasure chest of frustration. A lone goldfish swimming in a bowl. The word "hope" stretched across a sunrise.

These are just a few of the themes of masonite tiles decorated by Clinical Center patients as part of a project called "The Art of Healing." It was conducted by the Rehabilitation Medicine Department's Recreation Therapy Section. More than 100 tiles have been collected so far—all filled with images and phrases that capture the personal symbols of patient experiences at the CC.

Patients saw the process as a way to make a statement about their experience of illness, have their voices heard, and give a thing of beauty back to the CC community.

Many tiles were made during a weekly drop-in clinic. Megan Robb, a board certified art therapist at the CC, and Natalie Haynes, a certified recreation therapist, traveled to patient units so that patients who must remain in bed, connected to medical devices, or in isolation had a chance to participate. Their works of art will be displayed in a flowing wall installation at the CC. Family members, caregivers, and staff helped patients create their tiles.

"It's a good visual reminder for staff that receiving care here can be a simultaneously fearful and hopeful experience, where our patients may alternate between feeling powerful and vulnerable as they progress through their journey," Robb said.

A MUSICAL THANK YOU

Clinical Center patient Heidi Peck, now a high school senior in Mountain Home, Idaho, has played the flute since she was in fifth grade. But doctors thought at one time that she might not play again.

Heidi has a type of kidney and liver disease that results in underdeveloped lungs in some patients. When Heidi's mother, Debi, researched her daughter's disease, she found the NIH protocol Heidi is currently enrolled in and contacted the doctors involved.

It was Heidi's mom who thought of a concert as a way to thank CC staff. "She's an inspiration to all of us that, no matter what's going on, you can still do what you love," said NHGRI nurse Joy Bryant. Winner of several music performance competitions and college scholarships, Heidi is still deciding on a college, but plans to major in music performance. She is in her third year playing with the Treasure Valley Youth Symphony, part of the Boise Philharmonic.

Heidi Peck

SIBLINGS ARE SUPER

The Clinical Center Pediatric Clinic, NCI's Pediatric Oncology Branch, and the Children's Inn hosted a sibling day on July 15, 2008, to recognize and honor siblings aged 7 to15 of NIH pediatric patients.

Brothers and sisters of children enrolled in NCI, NIAID, NICHD, NHLBI, and NIMH protocols participated.

The group experienced the Department of Laboratory Medicine's "Fantastic Voyage" demonstrations and a tour of the Department of Rehabilitation Medicine's Biomechanics Laboratory. In therapeutic recreation activities, the kids shared their expertise as super siblings in the form of a newspaper advice column and made worry boxes to express what they might be experiencing as their patient sibling receives care.

At the end of the day, each sibling received a medal and a laminated certificate declaring them a "super sibling." At the award ceremony, one boy said, "This is the best day of my entire life."

CC medical technologist Teresa Genson Bauch demonstrates to (from left) Lindsey Hancock, Shaquille Jones, Jolly Rop, and Emilie Hancock the importance of hand washing, as event organizer Dr. Lori Weiner peeks in to see what the kids are learning.

SPECIAL VISITORS AT THE SAFRA FAMILY LODGE

The Edmond J. Safra Family Lodge welcomed a pair of famous visitors on December 13: Marvin Hamlisch, Oscar, Grammy, Tony, Emmy, and Pulitzer Prize-winning composer; and Santa. Since 2005, Hamlisch has performed at the Lodge during the holidays to bring cheer to the residents. He was joined this year by a vocalist, harpist, and violinist from the National Symphony Orchestra.

EMERGENCY DRILL PROVIDES A LEARNING EXERCISE, CHANCE TO PRACTICE

Bad weather hits the Bethesda area. Clinical Center staff, patients, and family members can't get to—or leave—Building 10. The roof of the Edmond J. Safra Family Lodge collapses and guests need to be moved to the Clinical Center. This was the scenario that CC staff members played out in February during an emergency drill to test the activation of the code yellow emergency management plan.

The drill was also the first test of a new mass notification system that uses automated phone calls and emails to provide open and immediate contact for staff during a disaster or emergency.

The drill is one of the ways the Clinical Center stays prepared to respond to emergency events in accordance with the Joint Commission's six critical functions for emergency management: communications, resources and assets, safety and security, staff responsibilities, utility management, and clinical and support operations.

Laura Lee, special assistant to the deputy director for clinical care, said a key objective of the drill that was extremely successful was practicing communication within departments through emails and phone trees.

All CC departments played a critical role in testing their internal communication processes, assessing staffing needs, assessing supply levels, and food and shelter needs.

The CC activated its central command center to coordinate hospital-wide logistics and communications during February's disaster drill. Staff also manned a nursing command center (below) to coordinate patient capacity and available beds, distribute staffing assignments for the accessible labor pool, and monitor public safety.

NUTRITION DEPARTMENT EFFORTS SEEK ECOLOGICAL, ECONOMIC SAVINGS

David Folio, chief of the Nutrition Department at the Clinical Center, is among the nation's hospital food service managers looking for more eco-friendly ways to carry out essential operations. Their goal is to help create a healthier environment in their health care communities.

The CC Nutrition Department collaborates with Maryland Hospitals for a Healthy Environment (MD H2E), part of the University of Maryland's School of Nursing. MD H2E is working with the national campaign for healthy food in health care through Health Care Without Harm, an international coalition of organizations whose mission is to transform the health-care sector so that it is ecologically sustainable without compromising patient safety or care.

Folio's approach is to question every practice within the department and ask if it could be better in terms of saving money and helping the environment. "The Nutrition Department's budget remains flat, but food costs keep going up. The way we have been able to come in under budget for the past four years is to find ways to reduce costs. Sometimes making environmentally friendly changes can also save money," he said. However, before adopting each proposal, Folio evaluates it to make sure it is a sound business decision, in addition to being green.

He's also gradually reducing the department's carbon footprint by purchasing smaller, more energy-efficient pieces of food service equipment as older machines need to be replaced and technology improves.

Most foods on patient room service menus are cooked to order. The department's new high-speed oven combines convection, microwave, and infrared cooking technology to prepare individual servings 10 times faster while using less energy and preserving nutrients and taste. The new oven is not the only eco-friendly food service equipment change. Plastic air-strip curtains hang over all walk-in refrigerator and freezer doors to lower the amount of energy used and the CC electric bill. Used fryer oil is collected and recycled into biofuel. A cardboard compactor minimizes waste volume. The dish room pulper reduces 10 trash cans of food waste into one.

"It takes time to research products, analyze the business decision, and pressure distributors to offer eco-friendly products. It's a continuous process of learning, questioning, and considering new ideas—wondering all the while what's best for the CC mission, our patients, and the planet," Folio said.

Food service workers Alekos Polyzos (above) and Crystal Cavin break down breakfast trays for the dish room pulper. The team dumps food and paper items into the water flowing over the conveyor belt, which moves it forward, and stacks the dishes into a machine that washes, rinses, dries them. The pulper gurgles and thumps as it extracts the liquid from the items and chops them into tiny pieces. Lionel Coriolan (left) cooks a pizza in one minute with the Nutrition Department's new high-speed oven.

GOING GREEN…WHAT IT MEANS

Item	Annual Cost Savings	Environmental impact	Patient impact
New milk vendor	$6,500	Packaged in paper, not plastic, containers	Recombinant bovine growth hormone-free
Room service program	Cost-neutral. Food costs go down, but labor costs go up	Reduces food waste as patients order only what they want	Meets patient requests on demand
Soup broth purchased as a base, rather than cans	$3,800	4,370 fewer cans used per year	No difference for patients
Re-useable cup	$15,000	125,000 fewer disposable cups used	Cup is a nicer product for patients
Rechargeable batteries for staff pagers	$400 within three years after the cost of batteries and charger	144 fewer batteries used per year	No difference for patients

(from left, standing): Latiff Yacoob, Donald Bryant, George Kennedy, Dr. David Henderson, Roger Rizer, Ronald Jones, Nathan Grey, and Angela Michelin. (from left, seated): Fikirte Gebremichael, Belaynesh Bekele, Abeba Syefu, Sonia Vaquiz, and Teresa Guevara. HFCD team members not pictured: Teresa Scheler, Larry Williams, Maria Bommarito, Florencia Zaldivar, Annette Poindexter, Teresa Fuentes, and Selina Gyimah

HOUSEKEEPING STAFF NAMED CC PATIENT SAFETY CHAMPIONS

The Housekeeping and Fabric Care Department (HFCD) received the CC's fourth Patient Safety Champion Award, which is given annually to individuals or teams demonstrating a sustained commitment to a safe patient environment.

From May to November 2007, the Clinical Center experienced an outbreak of *Acinetobacter baumannii*. Managing an outbreak with such an organism requires a coordinated team approach. In addition to aggressive medical and nursing care, special attention to the patient care environment is essential. In response to this challenge, the housekeeping team received additional training, applied innovative cleaning practices far more stringent than typical in a patient-care unit, and maintained a positive attitude. Their efforts sanitized every single item in affected patient rooms with one thorough cleaning. HFCD built quality assurance checks into the process before repeating cleaning tasks and followed up with a second quality assurance check.

HFCD Chief Rob Mekelburg said the intensive cleaning, combined with the communication and education efforts from the entire patient-care team, were instrumental in eliminating the organism at the CC. "We're proud of our housekeeping team and their important role in containing this organism, as well as their ongoing, overall contribution to the patient-care team," Mekelburg said.

When notifying HFCD of their award, Henderson thanked the team on behalf of CC patients for their efforts. "*Acinetobacter baumannii* often infects the sickest, weakest patients who are least able to fight off an infection—often those in the ICU. The HFCD team had to come up with ideas beyond conventional strategies to quickly solve this patient-care issue. This involved a lot of extra work and training," Henderson said, noting that the CC has not identified a single isolate since early December 2007 and developed a strategy in case of a recurrence.

CC VOLUNTEERS FIND BRIDGE TO MEDICINE

Dr. Cynthia Guime-Gonzalez (left) and Vanessa Flores.

Experiences for many Clinical Center volunteers offer both personal and professional enrichment. For Dr. Cynthia Guime-Gonzalez and Vanessa Flores, who both began as volunteer Spanish language interpreters, their work here has helped pave paths to becoming physicians and establishing medical practices.

Guime-Gonzalez began volunteering here in 1998 during vacations to visit relatives in Bethesda. She earned her medical degree in Panama in 2008 and has returned to the U.S. for a residency. Originally from Ecuador, Flores was a summer research student with the NHLBI's vascular medicine branch for three years and interned in the Social Work Department's volunteer office in 2004. A medical research career has long been Flores' goal. "Coming to NIH gave me that perspective and also raised my awareness about public health issues. I want to collaborate with research institutions and be a part of the evolution of improving medicine."

Flores is in the NIH Undergraduate Scholarship Program, which offers competitive scholarships to students from disadvantaged backgrounds who are committed to biomedical, behavioral, and social science health-related research careers. She will return to NIH to serve one year of full-time employment for each year of scholarship tuition she receives to attend a combined MD and master's program in clinical research at the University of Pittsburgh's School of Medicine.

Because the CC is a special hospital, with patients coming here to participate in research, the personalities of the staff are also special, according to Guime-Gonzalez. "They're friendlier, not rushed, and they take the time to explain things. They understand that most of the information about a disease comes from the patient, so people here listen to what patients say and feel so they can provide the best treatment. I really admire the NIH staff at all levels. It feels like a big family here."

OUT AND ABOUT

Clinical Center staff led and participated in a variety of walks and runs in 2008. In May, it was the first ever Take a Hike Day (top right). About 2,000 NIHers participated in this 3-mile non-competitive walk and fun run. The NIH Office of Management—in partnership with the Office of Research Services, Division of Amenities and Transportation Services, and the NIH Clinical Center—coordinated the event, which was held in conjunction with the 2008 National President's Challenge and the HealthierFeds initiative. In June, about 40 NIH colleagues participated as Team NIH at the 2008 Komen National Race for the Cure to fight breast cancer. Despite the heat and humidity, Team NIH was the first team to cross the finish line (bottom right).

In October, about 100 NIH staff gathered for a 1.5 mile wellness walk to celebrate National Physical Therapy Month. When done on an employee's lunch break, the walk plotted for the Physical Therapy Month event would be an easy way to fit in exercise, said physical therapist Bart Drinkard, CC Department of Rehabilitation Medicine.

NEW COURSE IN THE ESSENTIALS OF SUPERVISING OFFERED

Though a testament to one's abilities, a promotion to supervisor role from individual performer can be a challenge. To support a successful transition, the CC Office of Organizational Development has implemented Supervisory Essentials, a training program with strategies to effectively transition.

"In an effort to support their success and to provide a strong foundation on which to advance into positions of increasing responsibility, it is essential that we provide supervisors with the necessary tools to do their jobs," said Maureen Gormley, the CC's chief operating officer.

The program is designed for new and current CC supervisors, soon-to-be supervisors, and team leaders. Attendees will learn how to use influence and delegate, as well as how to apply motivational principles to assess employee needs, build upon strengths, and recognize and reward performance. The course provides basic knowledge on how to work effectively with human resource and administrative officer colleagues.

The CC Executive Committee has endorsed the supervisor training a required course beginning in 2009.

WEEK CELEBRATES SCIENCE, PRACTICE OF CLINICAL RESEARCH NURSING

Dr. Donna Berry, vice chair for research and the Myrene C. McAninch term professor in nursing at the University of Washington's School of Nursing, opened the week of celebration with her keynote address.

Each year, the Clinical Center honors the more than 1,000 nurses who are committed to fulfilling the unique needs of the agency's public health mission with a week-long celebration sponsored by Nursing and Patient Care Services. The CC interpretation of the American Nurses Association's 2008 theme, "Nurses Making a Difference Everyday," emphasized the broad impact that nurses, especially those involved in clinical research, have on how patients receive health-care treatment. The CC observance was May 5-9.

Dr. Patricia A. Grady, director of the National Institute of Nursing Research (NINR) and one of the speakers at the week's opening ceremony, reflected on "how exciting and complicated it is to be a clinical research nurse at the CC—one of the most important places in the world because it's where ideas are developed and tested, a place where you know you're making a difference all across the country and the world."

Dr. Donna Berry, vice chair for research and the Myrene C. McAninch term professor in nursing at the University of Washington's School of Nursing, opened the celebration with her keynote address, "Patient-Centered Technologies—Making a Difference in Patient Care."

According to Berry, an opportunity exists to begin moving patient-clinician interactions to times and places that are more convenient to patients. For example, Berry and her team developed electronic questionnaires that could be answered at home through the Web or in clinic waiting rooms with a laptop to shift when and where intake interviews occur. The idea, developed by nurses, offers a way to enhance the process of intake. During the week-long event, staff were able to visit the 1SE patio for an interactive nurse education fair with stations highlighting topics including CRN 2010, the Public Health Service, nutrition, shared governance, and ideas for broadening professional development.

On May 7, Dr. Margaret Bevans and Sandra Mitchell, both of the CC Nursing Department, presented CC Grand Rounds on issues related to hematopoietic stem cell transplants. At the opening ceremony, CC Director Dr. John I. Gallin called this lecture a "landmark" Grand Rounds because it marked the first time in the series that CC nurse scientists presented their research conducted at the CC. "The nurses make this place so special and make it work on a daily basis," Gallin said.

The specialty practice of CRN was the theme of the presentations at the closing ceremony. Dr. Clare Hastings, chief of Nursing and Patient Care Services, said that other nurses involved in clinical research around the country and across the world were waiting for someone to clearly define the CRN role. "The CC leads the US in developing the specialty practice model for CRN, so it's appropriate for us to define CRN roles and contributions and develop and disseminate practice documentation, standards, and management tools," she said.

According to Hastings, the long-term outcomes for the CC's CRN 2010 initiative include:

- Defining the practice domain;
- Establishing practice standards;
- Determining core competencies;
- Developing content for the certification process; and
- Creating tools to assist CRNs in specialty practice development and documentation.

3NW received the 2008 "Best Collegial Practices" Patient Care Area Award. From left are Tanjanell Simon; Caroline Stewart; OP8 team members Amy Nelson, Liz Formentini, Rose McConnell, Jakki Plummer, Barbara Corey, Margie Lloyd, Jean Hammer, Sten Witzel, France Sundt, Brent Bonfiglio, and Gregg Roby; and Dr. Clare Hastings.

COURSE ON CLINICAL RESEARCH PRESENTED IN CHINA

Clinician-scientists and biostatisticians from the National Institutes of Health were instructors in a modified version of the Clinical Center's course "Introduction to the Principles and Practice of Clinical Research" to Beijing in November 2008.

This is the first time an adaptation of the course, offered at the Clinical Center annually since 1995, has been presented live outside the NIH in Bethesda. "More than 7,500 participants have enrolled in this course since its inception and it has been videoconferenced to 29 locations in the US and to seven countries," noted Dr. John I. Gallin, director of the Clinical Center and course leader along with Dr. Frederick P. Ognibene. "We are honored our colleagues in China offered this opportunity to broaden education and training in the conduct of clinical and translational medical research."

The course taught in China covered clinical research design, ethics, methodology, and data analysis. "Better health and health care for the future depend on successful and productive clinical research today," said Gallin. "Medical research involving human subjects must be safe, ethical, and efficient. This course provides a strong foundation in these basics."

The NIH Clinical Center has been invited back to provide more training in China in 2009 and is exploring partnerships to take the training to Russia and sub-Saharan Africa. "The goal of this program is to help countries become self-sufficient in providing their own training in clinical research," Gallin said.

Live lectures included: "Clinical Research Project Design and Guidelines," presented by Dr. Laura Lee Johnson, NIH National Center for Complementary and Alternative Medicine; "Institutional Review Boards and Integrity in Research," Dr. Jerry A. Menikoff, director, Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services; "Clinical Case Studies and Meta-Analysis," Dr. Charles Natanson, Critical Care Medicine Department, NIH Clinical Center; "Clinical Research Methodology," Dr. Dennis O. Dixon, National Institute of Allergy and Infectious Diseases; and "Ethical Principles and Bioethical Questions," Dr. Reidar Lie, Bioethics Department, NIH Clinical Center.

ROTATION SWAP SERVES NIH TRAINEES AND FDA REVIEWERS

Before each drug, vaccine or treatment device can be distributed for public use, it must be proven safe and effective. A new rotation lets clinical researchers, including trainees, to learn the regulatory process first-hand at the Food & Drug Administration (FDA). It also accommodates FDA investigators and trainees who would like to learn about Clinical Research at the Clinical Center.
The FDA Clinical Pharmacology Rotation, led by Dr. Juan Lertora, from the Office of Clinical Research Training and Medical Education and director of the Clinical Center's Clinical Pharmacology Program, is open to all clinical research trainees and other interested personnel. Since the CC specializes in translational research, fellows from various programs could use the skills taught in this rotation, Lertora said.

Participants will learn about guidelines on therapeutic area-specific drug development and how to prepare an Investigational New Drug (IND) application. In the FDA Center for Drug Evaluation and Research (CDER), participants will review pre-clinical and clinical data on investigational drugs, take part in specialized therapeutic team meetings and meetings with sponsors, and contribute to an IND 30-day safety review. Trainees sign a confidentiality agreement because of the proprietary nature of the information discussed at the meetings they may attend.

"Scientist exchange is a novel and critical way to give scientists both at NIH and FDA an opportunity to leave their routine and pursue independent, but related, knowledge of clinical pharmacology,

drug development and clinical medicine," said Dr. Lawrence Lesko, director of FDA CDER's Office of Clinical Pharmacology and Biopharmaceutics. Lertora described the program to the Clinical Fellows Committee in July. "This type of rotation in a high-powered governmental agency that has a primary role in drug development, evaluation, and approval is exactly the kind of experience that sets an NIH clinical fellowship apart from all other programs in the country," said Dr. Brian Porter, the committee's co-chair. "I am unaware of any other training program that could offer such a flexible, unfettered learning experience with a major federal agency partner, such as this."

CTSA SCHOLARS VISIT

The Clinical Center is anxious to embrace new Clinical and Translational Science Award (CTSA) partnerships. That's the message 18 CTSA scholars and program administrators heard from Dr. John I. Gallin, CC director, during a spring 2008 visit. They represented Emory University, Johns Hopkins University, the Mayo Clinic College of Medicine, Rockefeller University, University of Pittsburgh, and Washington University, six of the 38 academic health centers in 24 states that are part of a national consortium aimed at transforming how clinical and translational research is conducted at academic health centers across the country.

In 2012, when the program is fully implemented, approximately 60 CTSAs will be connected with an annual budget of $500 million.

Gallin told the visitors that new CC-CTSA partnerships would complement research that is done intramurally and extramurally. "Our hope is that partnerships among intramural and extramural investigators will enrich both investigators' research programs," he said.

A major opportunity for collaborations is through the Bench-to-Bedside program created by the Clinical Center in 1999 to speed translation of promising laboratory discoveries into new medical treatments by encouraging collaborations among basic scientists and clinical investigators. The program has been open to research teams made up of intramural and extramural partners since 2006. Informatics tools developed at the Clinical Center also offer specialized resources in support of clinical research. One is ProtoType, a Web-based clinical protocol writing tool that provides investigators with a standard protocol structure, online help, and templates of suggested language. Investigators use it to put ideas for new protocols into the proper format to satisfy regulations and facilitate review.

Gallin also shared with the group the vision for BTRIS—the Biomedical Translational Research Information System now in development. Investigators can use to help identify promising new

Alex Razzook, a project engineer in the CC Rehabilitation Medicine Department's Physical Disabilities Branch, gives the CTSA scholars an overview of the clinical movement analysis lab. It's a unique resource using cutting-edge imaging technology to map human muscle movement while patients walk or run so that therapists can help patients learn how to move better. It also gives researchers investigating stroke, Parkinson's disease, and brittle bone disease insights into how their patients move.

avenues for research and foster data-sharing across NIH institutes and with extramural collaborators. "We're building this data repository so that it will be compatible with the CTSA sites' repositories. We envision that one day we will have a national clinical research data repository," Gallin said "The opportunity to tour the CC first hand and meet outstanding leaders in the research community provided considerable excitement for each of the clinical research scholars. They identified important new resources at the NIH for support of their respective innovative multidisciplinary clinical research programs," said Joan M. Lakoski, associate vice chancellor for academic career development at University of Pittsburgh Health Sciences and CTSA program committee chair.

PROGRAM AIMS TO PREPARE NEXT WAVE OF IMAGING SCIENTISTS

A new competitive research-training program aims to recruit radiologists and nuclear medicine physicians to the NIH to participate in translational research. A partnership between the National Institute of Biomedical Imaging and Bioengineering (NIBIB) and Radiology and Imaging Sciences at the Clinical Center, the Imaging Sciences Training Program (ISTP) will prepare participants to move forward in their careers through exposure to hypothesis-driven research.

"The goal is to train them with necessary skills and techniques to carry out hypothesis-driven research, to present findings at scientific meetings, write an IRB-approved protocol, and compete for grants," said Dr. Joseph Frank, director of the ISTP. He cited computer-assisted diagnosis, radiofrequency ablation of tumors, cellular imaging, and DNA repair as potential areas for interest for ISTP applicants. Fellows could be placed in Radiology and Imaging Sciences or with other investigators, depending on availability.

All enrolled in the ISTP will receive didactic training in biostatistics, grant writing courses, and instruction on writing a scientific paper are also part of the training, a one-to-two-year fellowship. The ISTP will accept recent medical-school graduates as well as those who have completed their residency or fellowship for the program's six slots.

"With Dr. Frank's leadership and in partnership with NIBIB, the ISTP will become the premier program nationally to provide translational research training for the clinician scientist involved in advanced imaging programs," said Dr. David Bluemke, director of the CC's Radiology and Imaging Sciences.

DR. RICHARD CHILDS NAMED 2008 DISTINGUISHED CLINICAL TEACHER

Dr. Richard Childs, senior clinical investigator in NHLBI's Hematology Branch and a commander in the US Public Health Service, received the 2008 Distinguished Clinical Teacher's Award. The recipient is a mentor, chosen by NIH clinical fellows, who guides professional growth by helping trainees identify and develop skills and talents, set and achieve goals, anticipate roadblocks, and overcome obstacles.

Chairperson of this year's selection committee of fellows, Dr. Jennifer Heimall from NIAID, presented Childs with the award, given annually since 1985. Heimall read from her peers' comments regarding their chosen mentor:

- "He is absolutely the best teacher I have ever had the pleasure of working with."
- "Under his tutelage, I have been motivated to strive for and achieve exceptionally high standards in both patient care and research. He is an excellent role model."

"I am thrilled and absolutely honored to win this award," Childs said. "It is humbling to be nominated by members of the fellows committee, particularly when one considers there are so many outstanding physicians dedicated to teaching some of the brightest and most creative research-oriented fellows in training." As recipient of the award, Childs will deliver the annual John Laws Decker Memorial Lecture June 10, 2009.

Dr. Jennifer Heimall, chairperson of this year's fellows committee, presented the 2008 Distinguished Clinical Teacher's Award to Dr. Richard Childs.

ROLE REVERSAL FOR NINDS FELLOW, CRTP ALUM

Dr. Michael Dimyan (left), a neuro-rehabilitation fellow with NINDS' Human Cortical Physiology Section of the Medical Neurology Branch and CRTP participant Erick Tarula, currently a fourth-year medical student.

"See one, do one, teach one." A motto within medicine expressing the obligation to teach those a step behind, it's the goal of the Clinical Research Training Program (CRTP) that places research-minded medical and dental students in mentored clinical or translational research projects in a field matching their personal interests and goals. Eight years ago Dr. Michael Dimyan, now a neuro-rehabilitation fellow with the human cortical physiology section in the NINDS, participated in CRTP. He returned to NIH in 2006 and from 2007-2008 mentored CRTP fellow Erick Tarula, who is currently a fourth-year medical student from Charles Drew University of Medicine and Science.

"For medical students training at other hospitals, there is usually little exposure to fellows, who primarily teach senior residents," noted Dimyan. "This program is different. Medical students work with fellows at a time when fellows really begin to define themselves career-wise. Observing the fellows—who themselves are learning new techniques, navigating unwritten rules, and demonstrating that instead of an instruction booklet there are multiple paths to reach your goals—helps medical students clarify their understanding of themselves, what they want, and how they want to get it."

Dimyan credits his return to NIH to the positive experience he had as a medical student in the CRTP. He describes the year as extremely inspiring and influential. So much so that after leaving NIH, he kept in touch with both mentors Dr. Mark Hallett, chief of the NINDS human motor control section, and Dr. Takashi Hanakawa, currently a professor of cortical function disorders at the National Center of Neurology and Psychiatry in Tokyo. Dimyan's project during his 2000-2001 CRTP academic year focused on imaging brain activity during motor planning, imagery, and movement.

Also influential was Hallett's ability to bridge the gap between being a scientist and a clinician. "He is a rare person in still being an outstanding clinician and an amazing scientist as well. There are

very few people who can do both," he said. "Observing subtle aspects of behavior and movement, which are the products of the nervous system, is what makes a great neurological diagnostician. Then as a clinical researcher, the challenge is to use those observations to address what might be a subtle, yet scientifically critical question," Dimyan said. CRTP demonstrated a way for Dimyan to mix the clinical and scientific aspects of neuroscience, which helped shape him and his career.

Tarula also benefited from the program's emphasis on mentoring around both clinical research skills and professional development. Dimyan and Tarula worked together in Dr. Leonardo Cohen's laboratory studying brain functioning through electromagnetic stimulation. Tarula's CRTP project focused on the cerebellum's role in motor learning using transcranial magnetic stimulation.

"Michael really took me under his wing, showed me the ropes, and helped me develop my own project. He has helped mature both my clinical and scientific skills, things I need to become a successful clinician-scientist," Tarula said.

Tarula is already continuing the medical community's tradition of mentoring. He worked with students at his former high school and spoke at the 2008 National Network of Latin American Medical Students conference, encouraging others to go into clinical research.

As a mentor, Dimyan encouraged Tarula to be confident in the work that he has put into his CRTP project and to project that confidence to his interactions with medical colleagues and patients. "Your patients depend on you to be confident, especially in neurology where you see a lot of bad disease that robs memories, personality, and a lot of what makes you human."

OFFICE OF CLINICAL RESEARCH TRAINING AND MEDICAL EDUCATION

The Clinical Center programs to train the next generation of clinical researchers continue to expand. Established in 2003, the Office of Clinical Research Training and Medical Education offers three courses (Introduction to the Principles and Practice of Clinical Research, Principles of Clinical Pharmacology, and the required Clinical Research Training for principal investigators) and manages the NIH-Duke program in clinical research leading to a Master of Health Sciences in Clinical Research degree, Clinical Center Grand Rounds, the NIH Clinical Research Training Program (CRTP) for medical and dental students, the 16 approved Accreditation Council for Graduate Medical Education (ACGME) residencies and fellowships at the NIH, the Annual Clinical Fellows' Orientation and other educational and training programs. More than 30,000 students worldwide have participated in the full range of CC clinical research educational programs; including its web-based training.

In 2008/2009, there are 952 enrollees (547 from 21 remote sites) in the Introduction to the Principles and Practice of Clinical Research course and 537 enrollees (200 from 13 remote sites) for the Principles of Clinical Pharmacology course.

SIXTH ANNUAL CIST FORUM ENGAGES AND INSPIRES STUDENTS

Students attending the annual Clinical Investigator Student Trainees Forum were able to tap into advice from successful clinician-scientists during networking sessions, with the students branching out to networking lunches grouped by research interests. The session on pulmonary critical care attracted 30 students.

Mention of a changing political landscape drew cheers from the 321 medical and dental students representing 78 schools gathered at NIH for the Sixth Annual Clinical Investigator Student Trainees (CIST) Forum in November.

Dr. Michael M. Gottesman, NIH deputy director for intramural research, acknowledged the enormity of the upcoming transition—a new US president, HHS secretary, and NIH director. "Despite all of the changes, NIH and the federal government are very strongly dedicated to the idea of training research scientists who can really pick up on the thread of improving public health in this country," Gottesman said in welcoming the attendees.

Dr. John I. Gallin, Clinical Center director, echoed the sentiment. "To see all the young people in the room representing the future of research science, I feel very excited and hopeful of change."

The students, who represent the next generation of clinician-scientists, met November 6 and 7 for lectures and panels comprised of leading researchers speaking on recent changes in medical research methods and technologies as well as the range of career options for clinical researchers, a tour of the Clinical Center's newest labs and patient care and research units, and networking opportunities with peers and potential mentors.

Student participants included Howard Hughes Medical Institute (HHMI)-NIH research scholars and HHMI medical fellows; Doris Duke Charitable Foundation clinical research fellows; students sponsored by National Center for Research Resources/Clinical and Translational Science Awards (NCRR/CTSA) programs; NIH Clinical Research Training Program fellows; Sarnoff Cardiovascular Research Foundation fellows; Applied Epidemiology Fellowship participants at the Centers for Disease Control and Prevention; Fogarty International Clinical Research Scholars;

and the NIH MD/PhD Partnership Training Program fellows.

A highlight was a presentation illustrating the importance of mentoring in students' training in clinical research, "Mentoring Teams in Clinical Research: Project in Tugela Ferry, South Africa, on Multi-Drug Resistance in Tuberculosis." Dr. Gerald H. Friedland, professor of medicine, epidemiology, and public health at Yale University School of Medicine, is the study's lead investigator. Joining him on the panel were four of his protégées at various stages in their training.

"The work done by members of the Friedland team is an excellent example of how senior clinicians nurture and enrich their students' educational experiences," noted Dr. Frederick P. Ognibene, director of the Office of Clinical Research Training and Medical Education at the Clinical Center.

A series of lectures entitled "Translation from the Bench to the Bedside: Innovations in Imaging Sciences," was moderated by Gallin and a panel about "The Importance of Mentoring in the Development of Careers in Clinical and Translational Research," was led by Ognibene.

Speakers for the imaging lectures were Dr. N. Reed Dunnick, Fred Jenner Hodges Professor and chair, Department of Radiology, University of Michigan, "Better Living Through Imaging;" Dr. Ronald M. Summers, chief of the Clinical Image Processing Service, CC Radiology and Imaging Sciences, "Virtual Bronchoscopy and Virtual Colonoscopy;" and Dr. David A. Bluemke, director, CC Radiology and Imaging Sciences, "Insights Using MRI and CT in Evaluating Cardiovascular Disease."

Participating in the panel discussion on mentoring were Dr. Peggy C. Nopoulos, professor of psychiatry, pediatrics, and neuroscience and director of the Iowa Doris Duke Clinical Research Fellowship Program and of the Psychiatric Iowa Neuroimaging Consortium University of Iowa Carver College of Medicine; Dr. Lars F. Berglund, professor of medicine, associate dean of clinical and translational research, and program director, Clinical and Translational Science Center, University of California Davis School of Medicine; and Dr. Timothy G. Buchman, Edison Professor of Surgery, professor of anesthesiology and of medicine, Washington University School of Medicine. In the presentation, Buchman noted, "There are only two things you own: your integrity and your passion. Guard them and grow them."

Attendees were able to tap into advice from successful clinician-scientists during networking sessions, with the students branching out to networking lunches grouped by research interests. The session on pulmonary critical care attracted 30 students. "You really need to pick something you love—that will make you happy," urged Dr. Stewart Levine, chief of NHLBI's Asthma and Lung Inflammation Section and acting chief, Pulmonary and Vascular Medicine Branch.

The forum included tours of the Clinical Center. "I don't think many of us had seen such a large hospital devoted to clinical research," said Parham Khalili, a NCRR/CTSA-sponsored student at the University of Chicago Pritzker School of Medicine. Emily Williams, a HHMI fellow at the University of Pennsylvania School of Medicine, noted peer connections as her biggest takeaway from the meeting. "It's so intriguing to hear about their research and what the different medical schools are like," she said.

"You really need to pick something to love–that will make you happy."

—Dr. Stewart Levine

FELLOWS RECOUNT AFRICAN RESEARCH EXPERIENCES AT CIST FORUM

Palav Babaria (left) and Michelle Scott tell of their time spent addressing multi-drug resistant tuberculosis in South Africa.

For a student engrossed in research, the lab can begin to feel like a home away from home. For Doris Duke Charitable Foundation Clinical Research Fellows Michelle Scott and Palav Babaria, stationed in South Africa in 2007 and 2008, it was more than a feeling.

The two spent the year in Tugela Ferry in the province of KwaZulu-Natal working on two studies aimed at fighting the drug-resistant tuberculosis (TB) epidemic in the area. The leading infectious disease cause of death in the world, TB accounts for 30-40 percent of the annual morbidity in HIV patients.

The students and their mentors—Dr. Neel R. Gandhi and Dr. Gerald H. Friedland—presented a panel discussion describing their experiences during the CIST forum. Gandhi is assistant professor in the Departments of Medicine and Epidemiology & Population Health at Albert Einstein College of Medicine. Friedland is professor of medicine, epidemiology, and public health at Yale University School of Medicine.

While drug-sensitive TB is very responsive to treatment, South Africans and their neighbors suffer from stronger strains of the disease. Multi-drug-resistant TB (MDR TB) is not cured by two of the most popular TB drugs, isoniazid and rifampicin. The second-line drugs used on MDR TB are less effective and exponentially more expensive, require longer therapy, and create risk for more adverse reactions, Gandhi said. Extensively drug resistant TB (XDR TB) sufferers have limited options, as isoniazid, rifampicin, and the second-line drugs do not treat the disease.

Fellows Scott, attending Harvard Medical School, and Babaria, attending Yale School of Medicine, worked to characterize and bring treatment to patients in KwaZulu-Natal, home to a large HIV-infected population. The MODS (microscopic-observation drug-susceptibility) study implemented a recent faster, cheaper way first developed in Peru to diagnose and characterize TB. Previously tested only in low-HIV prevalent settings, MODS was tested in South Africa for its sensitivity and specificity on dual HIV-TB patients.

The other study, the Community-Based MDR TB Study, tested the effectiveness of bringing care to into patients' homes. Tugela Ferry, an area roughly the size of Manhattan, had one hospital and one tar road. "We believe that an alternative treatment—one that would bring the treatment to the patients instead of the patient to the treatment—would work," Gandhi said. A nurse visited the home on weekdays to administer a treatment vaccine, supplemented by monthly visits to a clinic to repeat sputum and drug-susceptibility tests.

More than the physical and technical obstacles of administering medical care in a developing country, the mental and social challenges wore on the fellows. "I don't think there was a single day in Tugela Ferry that I didn't see someone die," Babaria said. While tragic, such casualties steeled her commitment even more to the research she and her team worked on. Babaria noted that it helped to e-mail her mentor or voice her concerns during their weekly scheduled phone calls. "That was really great to have someone invested in the research, but invested in us as people, too," said Scott.

"Mentoring is the soul of our profession," said Friedland. "The traditions and the skills and the culture of what we do are passed down." He emphasized the responsibility of mentorship: "A mentor must convey the excitement."

Another hurdle Scott and Babaria faced was the skepticism of the locals they were there to serve. The South Africans were wary of them as foreigners, wondering what they wanted from them, they said. In time, though, the research team earned the trust of the people they wanted to care for. Before their fellowship ended, Scott and Babaria became mentors of a sort to the caregivers in Tugela Ferry. "We didn't want things to fall apart when we left," Scott said.

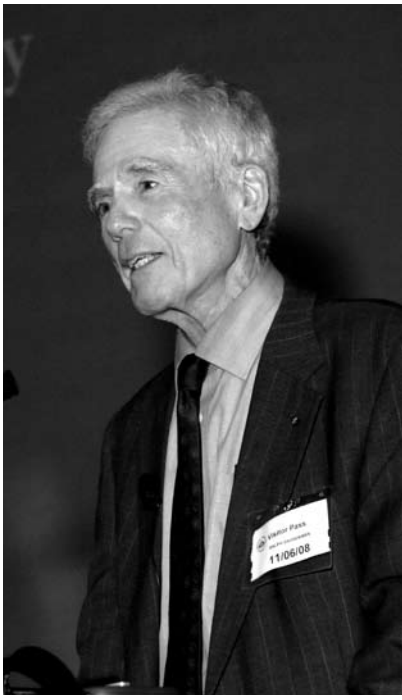
Far from falling apart, the work the fellows began is thriving. "I can proudly tell you that both projects are enrolling patients and we are seeing promising results," Gandhi told the CIST Forum crowd.

Babaria has returned to KwaZulu-Natal since her fellowship ended and is impressed with the growth in the project and technology. Scott plans to carve out some time soon to return also.

2008 CIST KEYNOTER

Delivering the 2008 CIST keynote address was Dr. Ralph Snyderman, chancellor emeritus of Duke University and James B. Duke Professor of Medicine at the Duke University School of Medicine. He spoke on the historical impact of science on medical research and the transition seen today toward personalized medicine. "When you're in the forest, it's hard to look at it from the outside in, but I hope you see how dynamic your profession is and how it is teetering on a really big change. You can be a part of that." he said.

Snyderman named the tools trainees should employ to succeed: persistence, curiosity, passion, and creativity. He warned the students, though, not to give too much weight to predetermined milestones such as grants or awards. "What it's really all about is the value of your self-worth," Snyderman said. "The real thing is having that insatiable curiosity of yours satisfied by your own mind."



GRAND ROUNDS IN JAMA

NIH investigators presenting at NIH Clinical Center Grand Rounds have been invited to submit manuscripts based on their presentations to the *Journal of the American Medical Association* (JAMA). The manuscripts are featured as "Grand Rounds at the National Institutes of Health—Clinicians Corner." Rounds presentations have for the past two years focused on clinically relevant topics from a bench-to-bedside perspective, said coordinator Dr. Frederick P. Ognibene, who directs the Office of Clinical Research Training and Medical Education. In 2008, manuscripts accepted included: "Evolution of Novel Small-Molecule Therapeutics Targeting Sickle Cell Vasculopathy" and "Pulmonary Hypertension: An Increasingly Recognized Complication of Hereditary Hemolytic Anemias and HIV Infection." Others are currently being considered.

Chief operating officer earns presidential rank award

For her exceptional service to the American people, Maureen Gormley, the Clinical Center's chief operating officer (COO), has been awarded a Presidential Rank of Meritorious Executive. The annual award is presented to members of the Senior Executive Service (SES) for sustained accomplishments. Nominated by their agency heads, reviewed by citizen panels, and designated by the president, candidates are evaluated on results-oriented leadership; balance of the needs and perspectives of clients, stakeholders, and employees; and relentless commitment to public service.

"This award is a singular honor for Maureen and the Clinical Center," said Dr. John I. Gallin, CC director. "It honors her commitment to our mission and her sincere dedication to her work." Gormley has served as the CC's COO since 1999, joining NIH in 1987 as an administrative fellow in the CC Office of the Director. Between those posts she was special assistant to the CC director and chief of Administrative Management and Planning. Gormley earned a bachelor of science in nursing from the Boston College School of Nursing and a master of public health degree from the Yale University School of Medicine. Gormley serves as executive secretary to the NIH Advisory Board for Clinical Research and led the activation effort for the 234-bed Mark O. Hatfield Clinical Research Center.

Clinical Center greets new director of radiology

Dr. David Bluemke has been named the Clinical Center's director of Radiology and Imaging Sciences. He also has been awarded tenured scientist status at NIH.

In announcing the appointment, Dr. John I. Gallin, CC director, said, "Dr. Bluemke's breadth of experience and expertise will be an extraordinary asset to NIH's imaging sciences programs."

Bluemke, who holds joint appointments at NHLBI and NIDDK, had been clinical director of the MRI division at Johns Hopkins and professor of radiology and medicine at the Johns Hopkins University School of Medicine.

Bluemke, an American Heart Association fellow, conducts research on cardiovascular disease and its complications and seeks to better understand how subclinical disease can be detected with newly developed imaging technologies, described, and tracked over time.

His group at Johns Hopkins was the first to describe the use of myocardial delayed enhancement in arrhythmogenic right ventricular dysplasia (ARVD). He is the world-recognized imaging expert in this extraordinarily difficult-to-diagnose condition and was the principal investigator of the MRI reading center for the US ARVD multicenter trial. His group was also one of the first to demonstrate a method for multi-station MR angiography for peripheral vascular disease and to use MRI for direct intravascular, ultra-high resolution evaluation of atherosclerotic plaque in humans. His expertise in imaging also includes oncologic disease and the evaluation of cancer with MRI.

He was a lead author on four multicenter clinical trials evaluating the use of novel contrast for MRI for oncologic applications, the largest multi-study of MRI in the evaluation of breast cancer, and a multi-center trial in cardiovascular disease. He is currently studying cardiovascular disease with MRI

in the Epidemiology of Diabetes Interventions and Complications trial involving more than 1,000 type 1 diabetic patients and the Multi-Ethnic Study of Atherosclerosis study of 6,800 individuals.

To date, Dr. Bluemke has authored more than 260 peer-reviewed publications and 27 book chapters and monographs. He sits on the editorial boards of several journals: *Radiology,* the *Journal of Computed Axial Tomography, Journal of Magnetic Resonance Imaging, Applied Radiology,* and the *International Journal of Cardiovascular Imaging.*

He is a member of the board of trustees for the International Society of Magnetic Resonance in Medicine (ISMRM), board member of the North American Society of Cardiovascular Imaging, current chair of the American College of Radiology (ACR) Cardiac Accreditation Committee, past program chair of the ISMRM Cardiac MR Study Group, and has been appointed to the AHA Council on Radiology and Intervention, the ACR Committee on Standards for Body MRI, and for Standards and Accreditation for Body and Neuroradiology Magnetic Resonance.

His most recent awards include an outstanding teacher award from ISMRM in cardiovascular imaging, the *Journal of the American College of Cardiology* elite reviewer award, two Executive Council awards and a silver medal from the American Roentgen Ray Society, and Cum Laude and contrast agent awards from the Society of Computed Body Tomography and Magnetic Resonance. In 2007 he was named among the top 10 radiologists by Medical Imaging and among America's Best Doctors by Castle Connolly Medical Ltd.

He earned his medical degree at the University of Chicago's Pritzker School of Medicine as part of the medical-scientist training program and his PhD from the University of Chicago's Department of Biophysics and Theoretical Biology, where he studied the evaluation of three-dimensional macromolecules using advanced computer modeling techniques. He holds an undergraduate degree in chemical engineering from the University of Wisconsin-Madison and a master's in business from Johns Hopkins University. He was a fellow in cross-sectional imaging in diagnostic radiology at Johns Hopkins School of Medicine and completed residency training at the Johns Hopkins Hospital.

New CFO joins CC director's staff

Maria Joyce is the Clinical Center's new Chief Financial Officer (CFO).

Joyce is a CPA in the state of Maryland and holds a master's in business administration from Johns Hopkins University and an undergraduate degree from Shepherd University. Before coming to the CC, she was the director of the Division of Financial Operations at the Program Support Center within the Office of the HHS Secretary, where she was responsible for accounting operations, financial reporting, financial systems, debt management, and travel management. She also served as the director of NIH's Office of Business Systems and Finance in the Office of Research Services (ORS), where she was the CFO and CIO for ORS and the Office of Research Facilities.

Her federal government tenure also includes time at the Federal Deposit Insurance Corporation, where she worked in accounting policy, internal auditing, and enterprise financial systems development. She spent 10 years in the private sector, at MCI and Marriott's corporate headquarters, performing accounting, finance, and project management functions.

Since 2003 Joyce has been a member of the NIH Federal Credit Union's Board of Directors, where she is also the treasurer. She is also a member of the credit union's assets and liabilities management committee and the information technology committee.

Her awards include a 2004 NIH award for design and implementation of a best practices approach for lease planning and analysis, a 2003 GSA achievement award for real property innovation and honorable mention for best innovative practice, a 2003 NIH award for outstanding financial leadership responding to security needs, and a 2003 NIH award for organizational "delayering."

CC employees honored with NIH Director's Awards
Four Clinical Center employees received 2008 NIH Director's Awards.

Clockwise from top left: Michael Alexander, hospitality services coordinator, accepts his award for creating a welcoming environment from NIH director Dr. Elias Zerhouni (right); Dr. Bradford Wood and Dr. Elizabeth Jones, Radiology and Imaging Sciences, received awards for leading the CC imaging program during a time of change and transition; and Joseph Hendery, chief of credentialing services, was honored for providing high quality credentialing and privileging support.

DeChristoforo named pharmacy chief
Robert DeChristoforo has been named chief of the CC Pharmacy Department. A Pharmacy Department employee for 28 years—14 of those as chief of the clinical pharmacy section and two periods as acting department chief—DeChristoforo helped his teams provide "unparalleled clinical and developmental pharmaceutical support to investigators and patients alike," said Dr. John I. Gallin, CC director.

DeChristoforo received a Bachelor of Pharmacy degree from the Massachusetts College of Pharmacy and a Master of Science in Pharmacology from Northeastern University in Boston. He completed an American Society of Health-System Pharmacists-accredited hospital pharmacy residency at the US Public Health Service Hospital in San Francisco.

He is a Fellow of the American Society of Health-System Pharmacists and throughout his career has been an active contributor at the local and national levels to ASHP activities. He is a two-time recipient of the CC Director's Award, and also received a partnering award from the National Institute for Occupational Safety and Health for his work with the National Occupational Research Agenda.

Retired CC nurse reaches a Valentine's Day milestone

Last Februrary, Rosa Lee Powell (with flowers) became the first African-American woman to make 100 whole blood donations to the NIH blood bank at the Clinical Center. Department of Transfusion Medicine staff helping mark the occasion are (from left) Margaret Dodson, donor resources specialist; Dr. Susan Leitman, director of blood services; and Jackie Brown, donor resources specialist. A mental health nurse at NIH for more than 15 years, Powell began donating blood when she heard that the blood bank particularly needed donations from individuals with her blood type. She then learned that as an African American, her blood donations could benefit Clinical Center patients with sickle cell disease.

According to Leitman, the best transfusion match for an African-American patient with sickle cell disease usually comes from an African-American donor. Sometimes sickle cell patients are unable to proceed with life-saving marrow transplants because of an insufficient supply of blood from African-American donors. One in six African Americans may be a match for a specific patient. "Sickle cell patients are often young and need the blood. It extends their life," Powell said.

Transfusion Medicine laboratory dedicated to Charley Carter

The Clinical Center's Department of Transfusion Medicine (DTM) dedicated the Charles S. Carter Cellular Therapy Laboratory within their Cell Processing Section in June 2008.

Carter, who died in 2006, co-founded the cell processing laboratory and worked as a biologist, technologist, and supervisor in DTM for 24 years. The words engraved on his plaque describe Carter as "a wizard in the laboratory with an uncanny ability to grow cells in culture and a special affinity for medical instrumentation. His career was marked by energetic, innovative practical thinking," as well as devotion to CC patients.

"A lab is more than just the walls, benches, and equipment within it. A lab is also the people who work there and their spirit," said Klein. "Even those working in this lab today who never knew Charley are imbued with his spirit of creativity."

In a 2006 tribute to Carter published in *Cytotherapy,* former DTM section head Dr. Elizabeth Read, who worked with Carter to develop methods for radiolabeling cells for in vivo cell trafficking studies, described how his career "was inextricably linked with the development of modern cellular engineering." His career at NIH started as a summer volunteer in what is now the National Institute of Dental and Craniofacial Research.

He was hired as a technician in Dr. Joost Oppenheim's lab, where he spent three years learning basic research. "The experience nurtured his passion for immunology and cell biology, and gave him a mature understanding of scientific investigation that imbued his future work," Read noted. DTM hired him as a lab technician in 1982. According to Read, Carter was "recognized early on as one of the most skilled and innovative developmental technologists in our field" and would develop new procedures rather than rely on those previously used by a colleague.

Carter had a special genius for devising novel methods for preparing cellular therapies for

Several members of the Carter family attended the dedication, including Carter's widow Laura, a medical technologist in FDA's Laboratory of Cellular Hematology, and his daughter Kate. With them is Department of Transfusion Medicine Chief Dr. Harvey Klein.

clinical trials. He was a key figure in a small team of scientists who prepared the first gene-corrected cells to treat a child with severe combined immunodeficiency syndrome. Media coverage of the event included a November 1991 *U.S. News and World Report* cover of him standing in the lab pipetting cells.

His work was critical to the progress of numerous other intramural cell therapy programs, such as gene marking and gene therapy trials with investigators from several ICs. That same decade, Carter worked with NCI and NHLBI to develop new procedures for depletion of T cells from allogeneic bone marrow and peripheral blood stem cells to prevent graft versus host disease.

Other NIH cell therapy programs, many of which are still ongoing, that Carter's work benefited include dendritic cell tumor vaccines for cancer immunotherapy, iron labeling of cells for diagnostic imaging, and culture-expansion of natural killer cells. Current CPS Chief Dr. David Stroncek said that he and his staff hope to "keep up Charley's good work as we move forward in the laboratory." In his lifetime, Carter authored or co-authored more than 75 publications on investigative methods for cell collection, ex vivo processing and preservation, and characterization and testing of cell therapy products. He received both the Clinical Center Director's Award and the NIH Director's Award.

Carter's mentoring and training of a generation of scientists from around the world in good laboratory practice as applied to research biologics inspired an award of its own. DTM medical technologist Jean Gildner presented the first CPS Technologist of the Year award to Peter Chen. Dedicated to Carter's memory, the awardee is selected by their peers for their qualities in leadership, mentorship, and "Charley-ship"—which they defined as the willingness to smile, get to know others, and remember even in the worst moments the importance of the work at hand. According to Gildner, it was in Carter's capacity as a supervisor that he influenced his colleagues the most. Klein also shared emails and phone calls he'd received to mark the occasion from Carter's former colleagues, fellows, and friends around the globe—one coming from as far away as Norway.

In the words of Jo Lynn Procter, supervisor of operations for the section, it was "a special day to be with those who knew, worked with, and loved Charley." Well-wishers stretched down the long hallway and around the corners near the laboratory, which was built in an area that used to be part of the roof of the old building before the need for such a lab existed at NIH.

NIH recognizes Lasker recipients

Members of the NIH intramural research community who have received a prestigious Albert Lasker Medical Research Award are recognized in a new exhibit on the first floor of the Clinical Center. It's in the hallway east of the clinic elevators. Since 1945, Lasker awards have recognized the contributions of scientists, physicians, and public servants who have made major advances in the understanding, diagnosis, treatment, cure, and prevention of human disease. Seventy-five Lasker Award recipients have gone on to win a Nobel Prize.

The Lasker awards are administered by the Albert and Mary Lasker Foundation. Mary Woodard Lasker (1901–1994) was a champion of medical research. She and her husband, pioneer advertising executive Albert Davis Lasker (1880–1952), established a legacy of philanthropy and public support of important causes. Mrs. Lasker, recognized for her singular contribution to the growth of the National Institutes of Health, once said: "If you think research is expensive, try disease!"

Staffers complete integrative medicine fellowship

Two Clinical Center employees completed the prestigious two-year Bravewell Associate Fellowship Program in Integrative Medicine in 2008

They were Dr. Gwenyth Wallen, chief of the research and practice development service, Nursing and Patient Care Services, and Dr. Jay Shah, senior staff physiatrist, Rehabilitation Medicine Department.

The comprehensive program, offered through the University of Arizona Medical School's Program in Integrative Medicine, includes 1,000 hours of instruction in biologically based therapies (phytochemicals, supplements, and botanicals), mind-body therapies (breath-work, progressive muscle relaxation, and meditation), manual medicine (massage therapy, osteopathy), and spirituality and energy medicine (qigong, reiki), among others. Various whole system therapies are also presented, including homeopathy, traditional Chinese medicine, and Ayurvedic medicine. Fellows complete three residential weeks in Tucson. Curriculum presented via the Internet—videos, e-mails, and online discussions—allowed fellows to participate from across the nation.

In addition to these studies, the Bravewell Collaborative also provided Shah and Wallen with the opportunity to complete clinical rotations at one of the eight leading clinical centers comprising the Bravewell Clinical Network.

The Bravewell Collaborative is a community of philanthropists dedicated to advancing integrative medicine through the funding of research initiatives and collaboration with like-minded physicians and organizations. It emphasizes healing that focuses on the entire person—body, spirit, mind, and community.

Wallen is the first clinical nurse scientist fellow to complete the program. She currently studies the health behaviors of Hispanics and African-Americans with rheumatic diseases, including their use of complementary and alternative treatments. She is also conducting a randomized, controlled clinical trial exploring the use of hypnosis as a pain and symptom management strategy for the treatment of sickle-cell disease patients. In her clinical rotation at The Penny George Institute for Health and Healing at Abbott Northwestern Hospital, Minneapolis, Wallen attended inpatient rounds and shared her current and future research plans with the interdisciplinary integrative health team. Feedback she received included the suggestion for a renewed focus on the relationship between an individual's susceptibility to hypnosis and biomarkers such as nitric oxide and Vitamin D levels.

"The fellowship has been great for me both personally and professionally because it honed my knowledge and skills in integrative medicine, but, also, I've been able to share my research and just the idea of doing this kind of research," Wallen said.

Shah echoed the sentiment, noting that complementary and alternative approaches too often rely on anecdotal evidence. "This is an excellent program because it emphasizes the importance of scientific evidence-based integrative approaches wherever possible," said Shah. He also enjoyed the opportunity to present his research and to encourage research among his peers.

The Bravewell Fellowship, together with his clinical rotation at the University of California, San Francisco's Osher Center for Integrative Medicine, reaffirmed for Shah the importance of integrating the bio-psycho-social aspects of health care with modern science to provide optimal patient care.

Shah and his colleagues are studying the biochemical milieu of myofascial trigger points—discreet, palpable, hyperirritable nodules in taut bands of skeletal muscle. He commonly treats myofascial pain with "dry needling," a form of mechanical myofascial release with the goals of reducing abnormal muscle contractures, relieving pain, and restoring range of motion and function. Although he uses acupuncture needles, Shah emphasizes that dry needling is quite different from traditional acupuncture—a practice from ancient China based on the flow of energy through acupuncture meridians. He teaches dry needling and other treatment techniques through Harvard Medical School's "Structural Acupuncture for Physicians" course.

ADVISORY BOARD FOR CLINICAL RESEARCH NATIONAL INSTITUTES OF HEALTH (2008–2009)

Governance

The NIH Advisory Board for Clinical Research oversees the Clinical Center's resources, planning, and operations. The Board also advises on NIH's overall intramural program, including priority setting, the integration and implementation of research programs of the individual institutes and centers, and overall strategic planning for the intramural program.

Comprised of NIH clinical and scientific leaders and outside experts in management of health care and clinical research, the Board advises the NIH deputy director for intramural research and the Clinical Center director and reports to the NIH director.

CHAIR: Edward J. Benz, MD
President and Chief Executive Officer
Dana Farber Cancer Institute

VICE-CHAIR: Ronald G. Evens, MD
Senior Executive Officer
BJC HealthCare

Duane F. Alexander, MD
Director
National Institute of Child Health and Human Development

Barbara M. Alving, MD
Director
National Center for Research Resources

Elizabeth B. Concordia, BA, MAS
Executive Vice President
University of Pittsburgh Medical Center
President
Hospital and Community Services Division

Robert M. Dickler
Independent Consultant

Maria C. Freire, PhD
President, The Lasker Foundation

Donald Ganem, MD
Investigator
Howard Hughes Medical Institute
Professor of Microbiology and Medicine
University of California San Francisco

Thomas R. Insel, MD
Director
National Institute of Mental Health

Daniel L. Kastner, MD, PhD
Clinical Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Michael J. Klag, MD, MPH
Dean
Johns Hopkins Bloomberg School of Public Health

Crystal Mackall, MD
Chief, Pediatric Oncology Branch
Head, Immunology Section
National Cancer Institute

Peter Markell
Vice President of Finance
Partners HealthCare System, Inc.

Henry F. McFarland, MD
Chief
Neuroimmunology Branch
National Institute of Neurological Disorders and Stroke

Olufunmilayo (Funmi) Olopade, MD
Walter L. Palmer Distinguished Service Professor of Medicine and Human Genetics
Director
Center for Clinical Cancer Genetics
University of Chicago

Monica Skarulis, MD
Chief
Clinical Endocrine Section
National Institute of Diabetes and Digestive and Kidney Diseases

Neal S. Young, M.D
Chief
Clinical Hematology Branch
National Heart, Lung, and Blood Institute

Ex Officio Members
John I. Gallin, MD
Director
Clinical Center
National Institutes of Health

H. Clifford Lane, MD
Chair
Medical Executive Committee
Clinical Director
National Institute of Allergy and Infectious Diseases

Michael M. Gottesman, MD
Deputy Director for Intramural Research
National Institutes of Health

Executive Secretary
Maureen E. Gormley, RN, MPH
Chief Operating Officer
Clinical Center
National Institutes of Health

Senior Staff Support
Richard G. Wyatt, MD
Executive Director
Office of Intramural Research
National Institutes of Health

MEDICAL EXECUTIVE COMMITTEE MEMBERS (2009)

NIH Clinical Center

The Medical Executive Committee is made up of clinical directors of the NIH intramural clinical research programs and other senior medical and administrative staff.

H. Clifford Lane, MD
(Chair) National Institute of Allergy and Infectious Diseases

William A. Gahl, MD, PhD
(Vice Chair)
National Human Genome Research Institute

James E. Balow, MD
National Institute of Diabetes and Digestive and Kidney Diseases

Richard O. Cannon, III, MD
National Heart, Lung, and Blood Institute

Carlo Contoreggi, MD
National Institute on Drug Abuse

Raymond A. Dionne, DDS, PhD
National Institute of Nursing Research

Demetrio Domingo, DDS, MS
National Institute of Dental and Craniofacial Research

William B. Ershler, MD
National Institute on Aging

Frederick L. Ferris, III, MD
National Eye Institute

Mary Kay Floeter, MD
National Institute of Neurological Disorders and Stroke

Clare E. Hastings, PhD, RN, FAAN
NIH Clinical Center

Markus Heilig, MD, PhD
National Institute on Alcohol Abuse and Alcoholism

Lee Helman, MD
National Cancer Institute

David K. Henderson, MD
NIH Clinical Center

Stephen G. Kaler, MD, MPH
National Institute of Child Health and Human Development

Daniel L. Kastner, MD, PhD
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Henry Masur, MD
NIH Clinical Center

Deborah P. Merke, MD, MS
NIH Clinical Center

Robert Nussenblatt, MD
National Center for Complementary and Alternative Medicine

Maryland Pao, MD
National Institute of Mental Health

Brian Porter, MD, PhD, MPH
National Institute of Allergy and Infectious Diseases

Steven A. Rosenberg, MD
National Cancer Institute

Carter Van Waes, MD, PhD
National Institute on Deafness and Other Communication Disorders

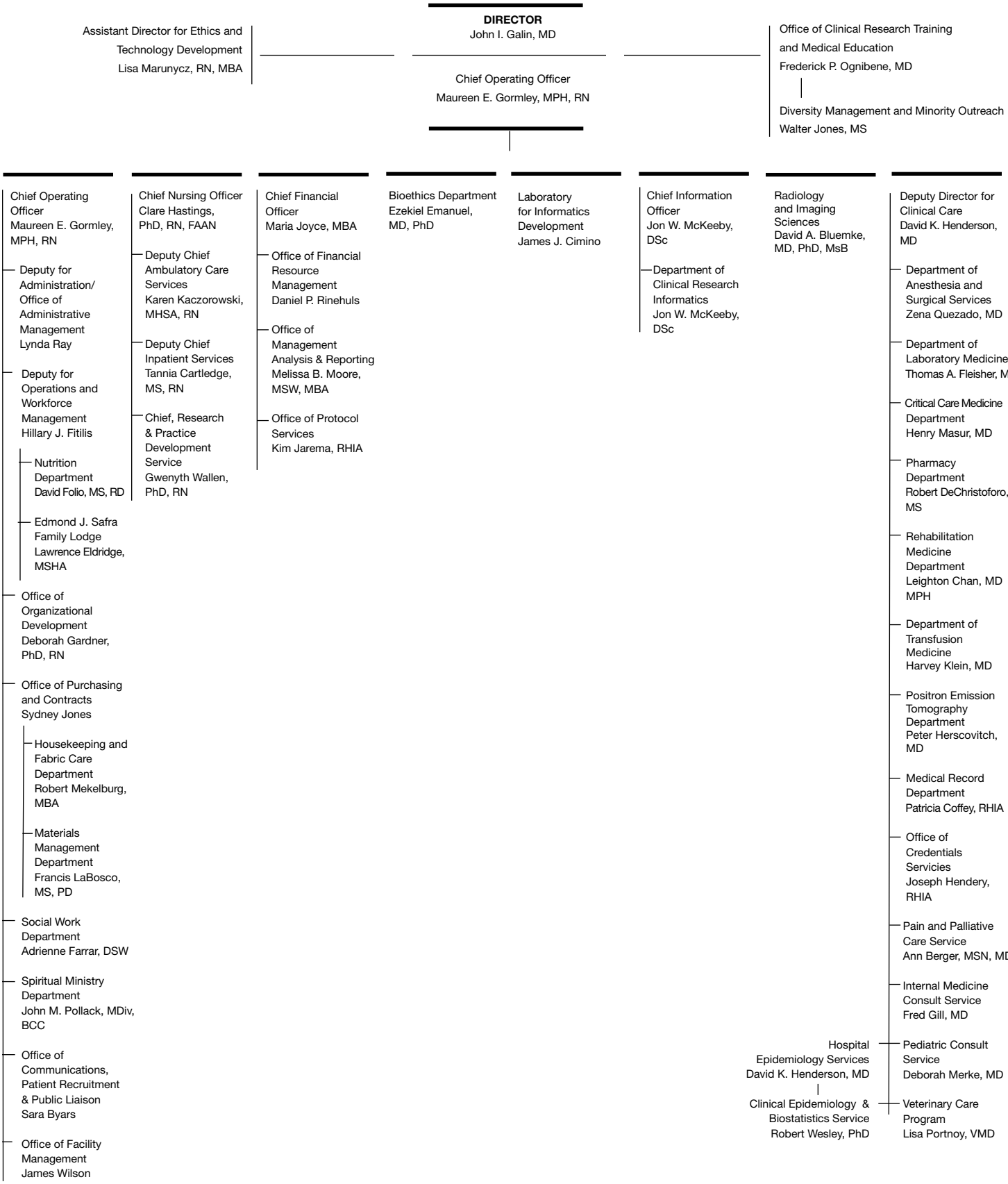
Darryl C. Zeldin, MD
National Institute of Environmental Health Sciences

Ex Officio Members
John I. Gallin, MD
NIH Clinical Center

Patricia A. Kvochak, JD
Deputy NIH Legal Advisor

Richard G. Wyatt, MD
Office of Intramural Research, NIH

Laura M. Lee, RN
NIH Clinical Center


DIRECTOR
John I. Galin, MD
Assistant Director for Ethics and Technology Development
Lisa Marunycz, RN, MBA
Chief Operating Officer
Maureen E. Gormley, MPH, RN
Office of Clinical Research Training and Medical Education
Frederick P. Ognibene, MD
Diversity Management and Minority Outreach
Walter Jones, MS
Chief Operating Officer
Maureen E. Gormley, MPH, RN
Deputy for Administration/ Office of Administrative Management
Lynda Ray
Deputy for Operations and Workforce Management
Hillary J. Fitilis
Nutrition Department
David Folio, MS, RD
Edmond J. Safra Family Lodge
Lawrence Eldridge, MSHA
Office of Organizational Development
Deborah Gardner, PhD, RN
Office of Purchasing and Contracts
Sydney Jones
Housekeeping and Fabric Care Department
Robert Mekelburg, MBA
Materials Management Department
Francis LaBosco, MS, PD
Social Work Department
Adrienne Farrar, DSW
Spiritual Ministry Department
John M. Pollack, MDiv, BCC
Office of Communications, Patient Recruitment & Public Liaison
Sara Byars
Office of Facility Management
James Wilson
Chief Nursing Officer
Clare Hastings, PhD, RN, FAAN
Deputy Chief Ambulatory Care Services
Karen Kaczorowski, MHSA, RN
Deputy Chief Inpatient Services
Tannia Cartledge, MS, RN
Chief, Research & Practice Development Service
Gwenyth Wallen, PhD, RN
Chief Financial Officer
Maria Joyce, MBA
Office of Financial Resource Management
Daniel P. Rinehuls
Office of Management Analysis & Reporting
Melissa B. Moore, MSW, MBA
Office of Protocol Services
Kim Jarema, RHIA
Bioethics Department
Ezekiel Emanuel, MD, PhD
Laboratory for Informatics Development
James J. Cimino
Chief Information Officer
Jon W. McKeeby, DSc
Department of Clinical Research Informatics
Jon W. McKeeby, DSc
Radiology and Imaging Sciences
David A. Bluemke, MD, PhD, MsB
Hospital Epidemiology Services
David K. Henderson, MD
Clinical Epidemiology & Biostatistics Service
Robert Wesley, PhD
Deputy Director for Clinical Care
David K. Henderson, MD
Department of Anesthesia and Surgical Services
Zena Quezado, MD
Department of Laboratory Medicine
Thomas A. Fleisher, MD
Critical Care Medicine Department
Henry Masur, MD
Pharmacy Department
Robert DeChristoforo, MS
Rehabilitation Medicine Department
Leighton Chan, MD MPH
Department of Transfusion Medicine
Harvey Klein, MD
Positron Emission Tomography Department
Peter Herscovitch, MD
Medical Record Department
Patricia Coffey, RHIA
Office of Credentials Servicies
Joseph Hendery, RHIA
Pain and Palliative Care Service
Ann Berger, MSN, MD
Internal Medicine Consult Service
Fred Gill, MD
Pediatric Consult Service
Deborah Merke, MD
Veterinary Care Program
Lisa Portnoy, VMD

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute (NCI)
National Eye Institute (NEI)
National Heart, Lung, and Blood Institute (NHLBI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Library of Medicine (NLM)

Center for Information Technology (CIT)
Center for Scientific Review (CSR)
John E. Fogarty International Center (FIC)
National Center for Complementary and Alternative Medicine (NCCAM)
National Center for Minority Health and Health Disparities (NCMHD)
National Center for Research Resources (NCRR)
NIH Clinical Center (CC)

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
National Institutes of Health
NIH Clinical Center
clinicalcenter.nih.gov

NIH Publication Number 09-7382
January 2009