NIH CLINICAL CENTER DIRECTOR’S ANNUAL REPORT

2014

60 Years Discovering Tomorrow’s Cures

There’s No Other Hospital Like It
Cover Images (left to right)

NIH Medical Research Scholars Program Fellow (2013-2014) in the laboratory. Clinical Center staff, photographer.


NIH Clinical Center building north entrance. Thomas Arledge, photographer.

President Harry S. Truman helped place the cornerstone for the original Clinical Center building on June 22, 1951. NIH Office of History. Photographer unknown.

Researcher looking through microscope, National Cancer Institute. Rhoda Baer, photographer.

Background is stock image of Deoxyribonucleic acid (DNA).

Right: Microscopic view of Aspergillus fumigatus, which can cause lung infections in humans, is being studied at the NIH Clinical Center. Department of Laboratory Medicine.
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Greetings! The National Institutes of Health (NIH) has been at the forefront of many of the most important discoveries in biomedical research. These advances have saved the lives of people in every corner of the United States and all around the globe.

Composed of 27 Institutes and Centers, NIH provides leadership and funding to support research at more than 2,500 universities, medical schools, non-profit institutions, and small businesses. In addition, intramural scientists conduct research on NIH’s own campus in Bethesda, Maryland.

At the heart of this effort is the NIH Clinical Center, which is the world’s largest hospital completely dedicated to clinical research. Throughout this report, you will learn about the Clinical Center’s impressive history of achievement over the past 60 years. These accomplishments range from early breakthroughs in cancer research, to treatments for rare diseases, to novel use of genomics to tackle emerging bacterial infections.

Much of this pioneering work could only have happened at the Clinical Center. Nowhere else on earth will you find such an amazing array of scientific minds, such a heroic legion of patient volunteers, and such a dedicated cadre of support staff, all working together to realize NIH’s common vision of turning research discoveries into lasting improvements in human health.

So, along with my colleague, Clinical Center Director John I. Gallin, I urge you to take a few minutes to learn more about this wonderful place we call the NIH Clinical Center. Appreciate the great things it has done in the past, see the hard work it is doing today, and look forward to where all of this might take us tomorrow!

Francis S. Collins, MD, PhD
Director
National Institutes of Health
60 Years Discovering Tomorrow’s Cures

Sixty years ago, the NIH Clinical Center opened its doors to exploring the possibilities of medical advances that would impact the world. Today, we celebrate numerous achievements that together our researchers, staff, and patients have made along the way.

At the dedication of the National Institutes of Health and its grounds in 1940 President Franklin D. Roosevelt said, “We cannot be a strong nation unless we are a healthy nation.” Thirteen years later, the Clinical Center admitted its first patient, and through the years we have honored this sentiment, prevailing as a driving force behind many of the nation’s greatest achievements in public health.

Throughout this report we share our progress in medical research: progress that is changing lives today and promising better outcomes tomorrow. A special 60th anniversary section highlights a few prominent discoveries that are having an impact in the United States and abroad. These include achievements in cancer, heart disease, and AIDS research; improvements for a safer blood supply; and novel uses of gene therapy.

While it is far too difficult to recognize the countless contributions made by our world-class researchers through the years, we attempt to provide a glimpse within these pages, and invite you to learn more at our 60th anniversary website http://www.cc.nih.gov/about/news/annivers60.shtml

Despite the budgetary challenges we have faced during the past year due to sequestration, which have impacted our ability to conduct clinical research, we have persevered. We are continuing to work across scientific disciplines to tackle major public health problems and we are building new data repositories to encourage data sharing.

As we strengthen our focus on patient-centered care, we are introducing new technologies to improve patients’ access to their medical records from any location; to enhance online social interactions within and outside the Clinical Center; and to increase patient safety through point-of-care clinical interventions.

Our patients remain at the forefront of our purpose. The medical crises they face may be rare or common: many of them are overwhelming and daunting. However, despite the challenges they face, they remain hopeful for medical cures, if not for themselves then for those who follow closely behind. In these pages, we share two patient experiences of hope and courage.

We are encouraged by our historical progress, inspired by our patients’ faith and perseverance, and fueled by the unfailing dedication and commitment of our researchers, health care professionals, and administrative staff to forge ahead, imagining new possibilities for the next generation.

John I. Gallin, MD
Director
NIH Clinical Center
OUR VISION
As America’s research hospital, we will lead the global effort in training today’s investigators and discovering tomorrow’s cures.

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

- investigating the pathogenesis of disease;
- conducting first-in-human clinical trials with an emphasis on rare diseases and diseases of high public health impact;
- developing state-of-the-art diagnostic, preventive, and therapeutic interventions;
- training the current and next generations of clinical researchers; and,
- ensuring that clinical research is ethical, efficient, and of high scientific quality.
The road to building “the nation’s research hospital” began long before the first patients were admitted. In 1940, President Franklin D. Roosevelt dedicated the buildings and grounds of NIH, and in 1951, President Harry S. Truman laid the cornerstone for the NIH Clinical Center. Finally, in July of 1953, our doors were opened to the first patients. Sixty years later, thousands of lives have been saved and improved through the hard work and dedicated effort of staff working with researchers from across NIH. This section highlights just some of the many scientific milestones achieved, and medical advances made at the Clinical Center. The work of discovering tomorrow’s cures is our ongoing endeavor, leading us toward undreamed-of possibilities for the future.

“We cannot be a strong nation unless we are a healthy nation.” — President Franklin D. Roosevelt, 1940

1953
The first patient admitted to the Clinical Center.

1956
First use of chemotherapy to cure a solid tumor (for gestational choriocarcinoma).

1958
Childhood acute leukemia cured by combination chemotherapy.

1965
The Australia antigen, later known as hepatitis B, discovered.

1967
Fluoride gels used to treat cavities as an infectious disease.
60 Years of Clinical Center Achievements Impacting Public Health

**1950s: Chemotherapy treats cancer with broad-scale success**

The federal government established intensive pre-clinical and clinical chemotherapy testing programs at the Clinical Center during the 1950s, hoping to expand the promise of single drugs that had already shown short-term effectiveness in cancer patients. Success came with the combination of two anti-leukemic drugs, which improved patient outcomes compared with treatment using conventional single agents. High-dose, repetitive dosing with methotrexate to treat choriocarcinoma—a rare cancer of the placenta related to pregnancy—led to the first sustained remissions and cases of cure for human cancer. Other dramatic results came from combination chemotherapy, resulting in long term remission and eventually cure of childhood leukemia and then a four-drug combination used to treat patients with advanced Hodgkin disease. Because of these studies, the focus of cancer treatment shifted to chemotherapy.

**1960s: Blood lipids established as biomarkers for heart disease**

Researchers at the National Heart, Lung, and Blood Institute who studied lipoproteins in the human circulatory system helped define the normal metabolic functions of these proteins throughout the body. In 1965, these researchers established a new system for classifying diseases that involve high levels of lipoprotein in the blood, and their system was adopted as an international standard for identifying increased risk of heart disease.

Ongoing research with lipoproteins, metabolism, and genetics had widespread effects on public health policy and clinical practice. It changed dietary recommendations for fat and cholesterol; led to standard tests that are used even today to assess a person’s cardiovascular health based on levels of lipoproteins, such as HDL and LDL, in the blood; and pointed the way to cholesterol-lowering drugs that can help mitigate the genetic lifestyle risk factors for cardiovascular disease.

**1970s: Hepatitis B test makes blood supply safer**

The source of hepatitis B infections remained elusive until NIH researchers identified an unusual antigen in blood collected from an Australian aborigine. This antigen was later identified as the surface protein of the hepatitis B virus (HBV), and it became the basis for the first donor screening test for this infectious agent. A test was necessary because the vast majority of persons who were found to be chronic carriers of HBV showed no clinical signs of harboring the infection.

Within a few years, Clinical Center researchers developed a double-antibody technique for radioimmunoassay of the hepatitis B antigen that was thousands of times more sensitive than earlier tests, and it was practical enough for widespread screening of blood donors. This test and others virtually eliminated the spread of hepatitis B infection due to tainted blood transfusions.

**1980s: Diagnostics and treatments developed for HIV infection**

Following reports of unusual pneumonia outbreaks and cancer clusters in California and New York, researchers at the National Cancer Institute (NCI) suggested that the root cause of these deadly illnesses could be a retrovirus in the human T-cell leukemia virus.

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**1969**
Lithium, a mood-stabilizing drug, is used to treat depression and mania in bipolar disorder.

**1970**
Combination chemotherapy used to treat advanced Hodgkin disease.

**1971**
A hepatitis-associated antigen, or hepatitis B, blood test developed, and subsequently used to make blood transfusions safer.

**1983**
Combined therapy of cyclophosphamide and alternate-day prednisone to treat Wegener’s granulomatosis.

**1985**
A diagnostic test for AIDS developed.
family. With collaborators at the American Red Cross, the Veterans Affairs Medical Center in New York, and several biotech companies in Maryland, they developed an adequately sensitive test for virus particles in the blood and published their results with it in 1985. Their test enabled the first widespread screening for HIV-1 infection.

Simultaneously, NCI researchers at the Clinical Center began testing compounds that interfere with HIV-1 replication, hoping to treat individuals infected with the virus. They found good results with three compounds that had never before been used in humans, publishing their findings with zidovudine (AZT) in 1985, and with didanosine and zalcitabine in 1986. These three drugs became the first drugs for treating HIV-1 infection and AIDS.

1990s: Gene therapy cures disease in humans

NIH researchers tested the first successful gene therapy at the Clinical Center with two young girls who were born with a deadly disease caused by a single-gene defect on chromosome 20 that made it impossible for them to produce an enzyme called adenosine deaminase (ADA). ADA is particularly important for the survival of lymphocytes, immune system cells that help fight off infections.

The researchers used blood samples from the girls to isolate T lymphocytes. They then exposed these lymphocytes to a retrovirus that inserted a functional copy of the ADA gene into the cells, and the cells were grown in the laboratory for about two weeks before being given back to the girls. After nearly two years with repeated cycles of this treatment, the girls showed normal immune system function, as well as improved growth and overall health. They returned to elementary school, and the NIH researchers published their results in 1995, two years after the girls received their last treatment on the trial.

2000s: Adoptive immunotherapy treats metastatic cancer

National Cancer Institute researchers working at the Clinical Center showed for the first time that T lymphocytes could be genetically engineered outside of the human body to recognize cancer markers and attack cancer cells once they were put back into the original patients, an approach that is called adoptive immunotherapy.

They used the approach with 34 patients who had advanced cancer that resisted standard treatments, and whose tumors expressed a protein called NY-ESO-1. The researchers isolated and exposed the participants' T lymphocytes to a retrovirus that genetically enhanced their ability to recognize NY-ESO-1 on cancer cells. They then cultivated the enhanced lymphocytes to high amounts in the laboratory and gave them back to the original patients.

After nearly two years, 10 of 19 patients who had metastatic melanoma saw their tumors shrink with the treatment, and four people had complete responses in which their tumors disappeared. Ten of 15 patients who had metastatic synovial sarcoma also showed a partial response to the treatment. There were no unexpected side effects to the treatment.

1987 First anti-retroviral drug, zidovudine (AZT), for treatment of AIDS approved by the Food and Drug Administration.

1990 First gene therapy in a child with adenosine deaminase deficiency.

1995 Hydroxyurea as first treatment for patients with sickle cell anemia.

Intensive immunosuppression therapy to treat severe acquired aplastic anemia.

2005 Mark O. Hatfield Clinical Research Center opened.

A vaccine used to prevent shingles shown to be effective.

2006 Rapid-onset antidepressants are used to treat patients with treatment-resistant major depression.
MOMENTS IN TIME

Dr. Roy Hertz (left) admits the Clinical Center's first patient, Charles Meredith, in 1953.

An aerial shot of the NIH campus before the Clinical Center was built. Construction began in 1948 on Building 10 (the NIH Clinical Center).

In the 1950s and early 1960s, many operations at the Clinical Center involved cancer, cardiac, and neurosurgical procedures. Pictured here is an operating room from the early days of the Clinical Center.

Today in the Interventional Radiology lab, image guidance and minimally invasive approaches have revolutionized the management of many common diseases.

Visit www.cc.nih.gov/about/news/annivers60.shtml

Directors of the NIH Clinical Center

John I. Gallin
1994-Present

John L. Decker
1983-1990

Mortimer B. Lipsett
1976-1982

Robert S. Gordon, Jr.
1974-1975

Thomas C. Chalmers
1970-1973

Donald W. Patrick
1954-1956

John A. Trautman
1951-1954

Jack Masur
1948-1951, 1956-1969

2009
Allogeneic stem-cell transplant reverses sickle cell anemia.

2011
Clinical Center receives the Lasker–Bloomberg Public Service Award.

2012

2013

NIH announces a new grant mechanism that opens collaborations between intramural and extramural investigators.
Recent NIH Clinical Center Achievements

In 2013, The Clinical Center:

**Clinical Research**

- Opened doors of the Clinical Center to extramural investigators through a new NIH grant mechanism which will enable the Clinical Center to be a conduit of team-based, cross-disciplinary science using our state-of-the-art biomedical resources and unique patient population.

- Recognized by the Partnership for Public Service for earning the Samuel J. Heyman Service to America Medals top award “Federal Employee of the Year” for novel use of whole genome sequencing of multi-drug resistant bacterium to trace the etiology of an infection.

- Developed advanced imaging techniques to improve diagnosis of obstetric brachial plexus palsy, a common birth-related injury, and to provide low-dose computed tomographic (CT) scans as an alternative to magnetic resonance imaging (MRI) for diagnosis of heart disease.

**Patient Care and Safety**

- Introduced new technologies, including
  - Online patient portal, providing patients access to their medical records from any location
  - Smart TVs, giving patients finger-touch access to email, social media, TV shows
  - Bar coding, assuring accurate matching between clinical interventions and patients

- Expanded collaborations with NIH institutes to enhance the overall patient experience, including pre-registration to simplify the admissions process, on-campus access and amenities, and other logistics related to clinical study participation at the Clinical Center.

**Training and Workforce Development**

- Held first NIH Clinical Fellows Day fostering networking, career guidance, scientific publishing, and grant applications and patient safety in clinical research.

- Received continued full accreditation for 12 years by the Accreditation Council for Graduate Medical Education for 18 graduate medical education programs on the NIH campus in collaboration with nine NIH Institutes and Centers.

- Established the Veterans Incentive Program, offering veteran corpsmen and medics the opportunity for training in a unique setting while pursuing a nursing degree.
Patients come to NIH from every corner of America seeking answers to their medical questions. Finding these answers through leading-edge clinical research is the sole mission of the NIH Clinical Center.

2013 Workforce Distribution
The Clinical Center has a staff of approximately 2,000.

Nursing & patient care/support services 43.5%
Administration & operations 15.8%
Clinical departments & imaging sciences departments 40.7%

2013 Budget by Major Category
$397.6 MILLION

Salaries and benefits 54%
All other* 11%
NIH assessments 7%
Supplies 7%
Drugs 9%
Equipment 4%
Contract (labor) 8%

* All other: Contracts (non-labor), travel, maintenance agreements, training, etc.
### Patient Activity 2011–2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
<th>Change from Prior Year</th>
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</thead>
<tbody>
<tr>
<td>Admissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>6,082</td>
<td>+ 1%</td>
</tr>
<tr>
<td>2012</td>
<td>5,916</td>
<td>−2.8%</td>
</tr>
<tr>
<td>2013</td>
<td>5,887</td>
<td>−0.5%</td>
</tr>
<tr>
<td>New patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>10,696</td>
<td>+ 6%</td>
</tr>
<tr>
<td>2012</td>
<td>10,694</td>
<td>−0.01%</td>
</tr>
<tr>
<td>2013</td>
<td>10,196</td>
<td>−4.8%</td>
</tr>
<tr>
<td>Inpatient days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>56,594</td>
<td>+ 0.2%</td>
</tr>
<tr>
<td>2012</td>
<td>54,971</td>
<td>−2.9%</td>
</tr>
<tr>
<td>2013</td>
<td>51,418</td>
<td>−7%</td>
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<tr>
<td>Average length of stay (days)</td>
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<tr>
<td>2011</td>
<td>9.2</td>
<td>−2%</td>
</tr>
<tr>
<td>2012</td>
<td>9.3</td>
<td>+1%</td>
</tr>
<tr>
<td>2013</td>
<td>8.9</td>
<td>−4%</td>
</tr>
<tr>
<td>Outpatient visits¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>101,942</td>
<td>+ 6%</td>
</tr>
<tr>
<td>2012</td>
<td>102,169</td>
<td>+ 0.2%</td>
</tr>
<tr>
<td>2013</td>
<td>102,115</td>
<td>− 0.01%</td>
</tr>
</tbody>
</table>

¹ Note: Data updates for 2011/2012 are due to a system modification performed on outpatient census in January 2013. The result of this modification more accurately aligns the historical outpatient census.

### Clinical Research Activity 2009–2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Active Protocols</th>
<th>New Protocols</th>
<th>Principal Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,451</td>
<td>162</td>
<td>480</td>
</tr>
<tr>
<td>2010</td>
<td>1,443</td>
<td>158</td>
<td>474</td>
</tr>
<tr>
<td>2011</td>
<td>1,513</td>
<td>207</td>
<td>489</td>
</tr>
<tr>
<td>2012</td>
<td>1,530</td>
<td>167</td>
<td>482</td>
</tr>
<tr>
<td>2013</td>
<td>1,570</td>
<td>162</td>
<td>499</td>
</tr>
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</table>
Leaders Get a Close-up View of the Nation’s Research Hospital

The Clinical Center provides a very clear picture of how important clinical research initiatives across the government are delivering new treatments, better diagnoses, and a more patient-centered experience to real patients in real time. This year, in the midst of budget debates and federal sequestration, that view was particularly valuable to members of Congress and President Barack H. Obama’s administration. The Clinical Center hosted a number of such visitors during the year.

HHS Secretary Kathleen Sebelius visited August 1 to tour the Clinical Center and talk with NIH leadership. After these visits, she hosted a town hall meeting in Masur Auditorium to answer questions from the audience, express admiration for the work she had witnessed, and confirmed the President’s support for NIH and the biomedical research enterprise.

In February, with the deadline for sequestration looming, Sen. Barbara Mikulski (D-MD) and Sen. Benjamin Cardin (D-MD) visited the Clinical Center to show their support for biomedical research at NIH.
A nine-member, bipartisan delegation led by House Majority Leader Rep. Eric Cantor (R-VA) visited on May 9. They toured the National Cancer Institute’s Laboratory of Molecular Biology of Lymphoid Malignancies, where Dr. Louis Staudt, deputy chief of the Clinical Center Metabolism Branch, explained current clinical trials for patients who have lymphoma, and members of his lab demonstrated the effect these new drugs can have on cancer cells grown in the lab.

On June 17, Senate Majority Leader Harry Reid (D-NV) visited the Clinical Center to meet with NIH Director Dr. Francis S. Collins, Clinical Center Director Dr. John I. Gallin, and several institute directors. The next day Sen. Reid took to the Senate floor to emphasize the value of investing in NIH research.

Clinical Center Director Dr. John I. Gallin (right) leads tour of the Clinical Center with NIH Director Dr. Francis S. Collins (4th from right) for a Congressional delegation led by House Majority Leader Eric Cantor (R-VA) on May 9. Shown from left Rep. Andy Harris (R-MD), Rep. Ted Yoho (R-FL), Rep. Tim Murphy (R-PA), Majority Leader Cantor, Rep. Earl Blumenauer (D-OR), Rep. Eliot Engel (D-NY), Dr. Collins, Rep. Michael Burgess (R-TX), and Rep. Renee Ellmers (R-NC).

Bill Gates, Microsoft Chairman and co-chair of the Bill and Melinda Gates Foundation, reviewed progress made improving people’s health around the world and outlined the challenges remaining to improving global health in his talk for the David E. Barmes Global Health Lecture on December 2 in the Clinical Center’s Masur Auditorium.
Sickle Cell Patient Receives Lifesaving Care at the Clinical Center

Sickle cell disease (SCD) is the most common inherited blood disease in the United States. It is caused by a mutation in the oxygen-carrying molecule hemoglobin. The “sickle” shaped red blood cells tend to clump in the circulation and have a short life span, which leads to anemia, weakness, pain, slow wound healing, strokes, renal and cardiopulmonary damage, and ultimately premature death.

People with sickle cell disease take many medications to manage their complications, while efforts are ongoing to cure the disease. Their prognosis is improving thanks to better management.

Tyese Womack is a patient who enrolled in a study by the National Heart, Lung and Blood Institute (NHLBI) on the natural history of SCD ten years ago. She suffers from chronic pain, stroke, and a bone infection arising from a chronic leg ulcer. Because the wound would not heal, her local doctors recommended an amputation. Thankfully, after a series of surgical procedures, transfusions, a year of intravenous antibiotics, diligent wound care, and participation in a trial for leg ulcers, under the constant guidance and supervision of the NHLBI SCD team, her wound healed successfully after 17 years.

“The main reason things have gone so well for me is because I’ve been coming to NIH,” she says. “It’s a privilege. I know a lot of people who would be grateful to be taken care of the way I’ve been cared for at the Clinical Center.”

Pediatric Patient Inspired to Study Diseases at the Clinical Center

When 9-year-old Jada Mahoney came to the Clinical Center, she suffered from persistent sinus congestion, difficult breathing, rashes, and weight loss. She’d been to dozens of doctors at home, but none of them were able to diagnose the cause of her symptoms.

Fortunately, Dr. Amy Klion, chief of the Eosinophil Pathology Unit at the National Institute of Allergy and Infectious Diseases, recognized that Jada had hypereosinophilic syndrome, a rare disease marked by high numbers of certain white blood cells that normally fight infections. Dr. Klion made the diagnosis early enough to spare Jada permanent organ damage from the disease.

Now Jada comes to the Clinical Center every six months to have blood drawn for a clinical trial. One day she hopes to join the staff at the hospital as an infectious disease doctor. “I think what Dr. Klion does is really wonderful. I want to help other people, like she helped me,” she says.

In the meantime, she co-founded the CureHES blog with another hypereosinophilic syndrome patient, hoping to share helpful information about the disease with other patients and families who are affected by it. Visit her blog at http://www.curehes.org/
Sounds of the National Symphony Orchestra Resonate Throughout the Clinical Center

Clinical Center staff, patients, and their families were invited to the Clinical Center atrium Sept. 11 to listen to the world famous National Symphony Orchestra. Co-presented by the Foundation for Advanced Education in the Sciences and the Clinical Center, Assistant Conductor Ankush Kumar Bahl directed works by Prokofiev, Rossini, Barber, and Mozart.

“We are delighted and honored that the National Symphony Orchestra chose the NIH Clinical Center to launch its ‘Sound Health’ initiative,” said Clinical Center Director Dr. John I. Gallin. “Our patients and their families, who come from all over the nation and the globe, can enjoy this unique experience as they partner with us to achieve vital advances in science and health, while receiving outstanding care.”

The new “Sound Health” initiative is designed to serve hospitals and other health-related venues. In December, a Brass Quintet performed holiday music, and additional orchestral concerts as well as smaller ensembles will continue throughout 2014. The National Symphony Orchestra visit to the NIH campus also included a performance by Viva Violins, an ensemble of violinists, followed by an “Instrument Petting Zoo,” held at the NIH Children’s Inn.

Young Philanthropists Prove That Every Little Bit Counts

Just outside the Beltway, about five miles southwest of NIH, the Student Government Association at Carderock Springs Elementary School organized a school-wide fundraising competition that they call the Penny Wars.

They organized the school into competitive teams, with children from all classrooms bringing in spare change and doing the calculations. (Pennies added points to each team’s score, while silver coins and bills subtracted from them.)

The students gathered pennies from generous siblings and neighbors, the bottom of the washing machine, and under-the-couch cushions. Astonishingly, they managed to raise $5,214.50 in this competition.

They selected as beneficiary the Clinical Center’s Patient Emergency Fund, a program operated through the Social Work Department that provides periodic limited emergency financial assistance to selected patients and family members at the Clinical Center.

“If people could only see the outpouring of energy and commitment that went into this,” said Matthew Ghaman, the fifth grade teacher who advises student government at Carderock Springs Elementary School. “It was awesome.”
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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Phase 1:</td>
<td>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.</td>
</tr>
<tr>
<td>Phase 2:</td>
<td>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.</td>
</tr>
<tr>
<td>Phase 3:</td>
<td>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.</td>
</tr>
<tr>
<td>Phase 4:</td>
<td>These studies are undertaken 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.</td>
</tr>
</tbody>
</table>
NIH Clinical Center Opens Collaborations with Academia, Industry

The Clinical Center is expanding upon its collaborative research with new projects under the newly launched NIH grant program, “Opportunities for Collaborative Research at the NIH Clinical Center”. Through these new three-year awards, scientists from institutions across the United States will collaborate with government scientists in our unique hospital setting.

With access to Clinical Center resources and infrastructure, outside scientists will be able to test promising laboratory discoveries using emerging technologies and tools, a range of biomedical specimens including those for rare diseases, and other research resources to help advance disease diagnosis, treatment and prevention.

In its first competitive cycle, twelve NIH institutes and Centers are participating in the grant initiative. Among the varied research topics were molecular imaging for prostate cancer and a clinical trial of a vaccine to prevent malaria.

“We are very excited about opening the doors of the Clinical Center to our extramural colleagues who will bring additional cutting-edge research projects and new partnerships that will enrich our ongoing efforts translating scientific discovery into tomorrow’s cures,” said NIH Clinical Center Director Dr. John I. Gallin.

For the most up-to-date information visit: http://go.usa.gov/Zb8C

Improving the Safety of Blood Transfusions

Under a microscope, you’ll notice something odd about blood that has been stored outside the human body for more than a few days: the cells no longer look round and they may have little needles, or spicules, emerging from their surface. “Over time,” says Dr. Harvey Klein, chief of the Clinical Center’s Department of Transfusion Medicine, “the cells begin to look worse and worse.”

Researchers suspected that these changes might mean that the old blood was less effective than fresh blood. But they didn’t have the data to be sure, until Dr. Klein teamed with Dr. Charles Natanson, a senior investigator in the Critical Care Medicine Department. Together, they gathered data using a canine pneumonia model to test blood that had been stored for different amounts of time.

The researchers found that when sick dogs received older blood, they suffered lung damage and died more frequently than when the blood was fresh. However, if the blood was “washed” to remove iron and hemoglobin that may have leaked from old blood cells, then the dogs fared better. Surprisingly, if the dogs received fresh blood that had been washed, they fared worse than if the blood was unwashed.

It’s too soon to expect major changes in U.S. blood banking because of these results, they say. However, “These data could have a big impact on what’s happening in hospitals around the country, particularly in blood transfusions for patients who have pneumonia or are at risk for infections,” says Dr. Natanson.

“The paradigm for blood storage and transfusions is shifting,” adds Dr. Klein, “from figuring out how we can store blood longer to concentrating on how we can maintain the quality of the blood that we have.”


Above: Dr. Harvey Klein, Chief, Department of Transfusion Medicine, Clinical Center.

Left: NIH Blood Bank staff with donor.
New Low-Dose CT Method Works for Diagnosing Heart Disease

When heart disease is diagnosed early, doctors can prescribe medications and lifestyle changes that may save a person's life. Cardiac MRI is one tool that helps them make these diagnoses, revealing signs of thickened or scarred heart tissue, as well as problems with filling and emptying blood when the heart contracts. Unfortunately, cardiac MRI is not widely performed, and some patients can’t receive it because of other health concerns.

Researchers led by Dr. David Bluemke, director of Radiology and Imaging Sciences at the Clinical Center and Dr. Marcelo Nacif, research fellow, tested whether low-dose computed tomography (CT) could be used effectively in these patients, instead. They developed a low-dose CT method to measure a heart-disease marker—the fluid volume between muscle cells of the heart, or the “extracellular volume” fraction—that increases when there is abnormal fibrosis or scarring in the heart.

Patients with known heart failure had the new CT test, and it showed excellent agreement with the previously developed MRI marker of fibrosis. This new low-dose CT method may lead to better diagnosis of heart disease in hospitals and clinics that already use CT to evaluate the coronary arteries for signs of disease.

More information:

Using Temperature to Boost Metabolism and Fight Obesity in Adults

Babies chill easily because they have a large skin surface relative to their body size. Thankfully, they're born with a special type of fatty tissue that is loaded with mitochondria, the tiny engines that burn sugar and generate heat inside of cells.

This warming tissue—which is called brown adipose, or brown fat—was assumed to disappear during childhood. However, researchers recently learned that some adults still have it in pockets of the neck, the upper chest, and other areas of the body. Now scientists from the National Institute of Diabetes and Digestive and Kidney Diseases at NIH are working with the Clinical Center’s Clinical Nutrition Service to test how ambient room temperature can activate brown fat to help people burn energy.

Last year, they completed a study that showed a small reduction in ambient temperature (from 75°F to 68°F) can activate brown fat in adults and stimulate their metabolism.

Their next step is to enroll patients in a four-month study in the Clinical Center’s Metabolic Research Unit, where the participants will live in temperature-controlled hospital rooms to observe the long-term effects of a mild reduction in ambient temperature on their metabolism. Diet will be closely controlled with the help of a special metabolic kitchen that measures by weight precisely how much food each person eats, and the participants will spend two days at the end of each month in special high-tech hospital rooms where oxygen and carbon dioxide sensors will measure how many calories they burn.

With this unique setup, the researchers can assess each person’s metabolic response to temperature changes that are experienced in everyday life.


Participants in the brown-fat study eat a typical American diet that includes foods such as salmon, rice, green beans, fruit cocktail, juice, and chocolate chip cookies, similar to the foods that are pictured above. A scale, which is shown behind the tray, weighs the food before each meal and weighs it again after the meal to figure out exactly how much energy each person eats. In this way, the researchers can control the diet as a variable and isolate the effect of room temperature on the participants’ metabolism.
**3D Cinematic MRI Reveals New Details for Common Birth Injury**

Last year, members of the Clinical Center Rehabilitation Medicine Department gathered the clearest-ever dynamic pictures of muscles and bones in the shoulders of children who have obstetric brachial plexus palsy, the second most common birth-related injury in newborns.

When an expectant mother has a small pelvic outlet or if her baby is large, the baby’s shoulders may get stuck during delivery. This can lead to stretching and possible damage to the nerves of the baby’s brachial plexus, which travel from the neck to the arm to control movement and sensation in the shoulder, elbow, and hand.

Most children affected will get better as their nerves re-grow and re-supply the weak muscles. But others are left with significant weakness, loss of feeling, bone deformity, and functional disabilities that can last for months or even be permanent.

“Imagine not being able to lift a fork to your mouth or to get your arm in the sleeve of a shirt, or if your ability to play or participate in sports is limited,” says Dr. Katharine Alter, a pediatrician who helped lead the study. She treats many children with this injury each year, and she notes that physical therapy and surgery can help them regain function.

In an effort to provide clinicians with better information about the nature of functional disabilities in these children, Dr. Alter teamed with biomechanical engineer Dr. Frances Gavelli, who has developed a 3D cinematic MRI technique for studying obstetric brachial plexus palsy.

The current project focuses on defining the three-dimensional changes in bone shape and losses to muscle volume following the injury. Their next step is to measure how the affected muscles and joints move, to demonstrate patterns of injury and developmental disability. Pediatricians, physical therapists, and surgeons will be able to use this information as reference while treating children with obstetric brachial plexus palsy at hospitals outside of NIH.


**Protein Extraction Speeds Up Identification of Disease-Causing Molds**

Some microscopic organisms can be identified accurately and inexpensively by figuring out their protein composition. When the Clinical Center acquired a new type of tool that performs this analysis, a mass spectrometer called MALDI-TOF MS, “It completely revolutionized the way that we do clinical microbiology,” says Dr. Anna Lau, a fellow in the Department of Laboratory Medicine.

The MALDI-TOF MS works beautifully for rapidly identifying bacteria and yeasts. But for molds—which can cause infections of the skin, fingernails, lungs, sinuses, and tissue lining the central nervous system—technical complications posed a major challenge until last year, when Dr. Lau developed a new way to extract proteins directly from mold grown on solid media and a new comprehensive database that can be shared with other laboratories worldwide.

Since then, Dr. Lau and other team members have identified mold samples shipped to NIH from microbiology laboratories across the globe, usually in less than an hour, which is a significant improvement, given that it can take experts up to two weeks to identify molds using traditional techniques. In the process, they have expanded the NIH database to become the most accurate and sensitive one available for identifying molds by protein.

“The beauty of this is that we’re able to share the information in our mold database with other laboratories, so that we can help accurately identify bugs early and improve patient care,” says Dr. Lau. “Early and accurate identification makes a huge difference in terms of patient management and helping to direct antifungal treatment.”

In the 1980s, an early sign of the AIDS epidemic was the spike in lung infections with *Pneumocystis*, a family of microbes that can cause pneumonia in immunosuppressed people. Medications that control HIV have made these pneumonias far less common today. But recent outbreaks in Europe, as well as in Japan and Australia, have shown that certain groups, such as organ transplant recipients, are still vulnerable to *Pneumocystis* infection. And signs that some strains of *Pneumocystis* have begun to develop resistance to current medications only add to the concern.

Fortunately, researchers in the Clinical Center’s Critical Care Medicine Department are among a handful of labs worldwide that have continued to study *Pneumocystis* for more than three decades, undeterred by the fact that because it will not grow outside of a host—it must be collected directly from an animal or person who has the infection—*Pneumocystis* is a very difficult organism to work with.

Last year, their collaboration with experts at the Broad Institute in Boston and Leidos Biomedical Research, Inc., formerly SAIC-Frederick, in Maryland, led to sequencing of the genome of *Pneumocystis murina*. They made the data available with free access online, hoping to hasten related research at other institutions, and they’ve begun working on the sequence of other *Pneumocystis* species, with the hope that what they learn about the genetic code of these closely related organisms will lead to new medications that treat or prevent infection.

“This was an important step. Where it will lead us, time will tell,” says Dr. Joseph Kovacs, a senior investigator in the Critical Care Medicine Department. “Knowing as much as we can about these pathogens is an investment in the future.”


**Pneumocystis Genome May Point the Way to New Drugs for Pneumonia**

**Task Force Helps Scientists Navigate FDA Application Process**

To facilitate important regulatory review before new drugs are tested in people, the Food and Drug Administration’s Center for Drug Evaluation and Research and members of the Clinical Center staff formed a task force in 2012 that identified necessary and helpful information for clinical researchers.

An important product of the task force included developing a course focused on Investigational New Drug (IND) applications. Held in December 2013 at the Clinical Center, the course educated Clinical Center staff on relevant FDA regulations and the process of preparing and submitting an IND application. The course featured presentations by Clinical Center and FDA experts, as well as discussions of best practices in this very important area of clinical research.

The task force also pulled together a new FDA website, which was launched in November 2013. This online “IND tool chest” will provide FDA regulatory information related to IND applications in a user-friendly way. It will also guide clinical and translational investigators on ways to interact with the FDA at all stages of the IND process, ensuring that all the required pre-clinical IND-enabling information is provided to FDA early, in anticipation of a first-in-human clinical trial.

For more information: [http://go.usa.gov/ZWMh](http://go.usa.gov/ZWMh)
Online Self-Assessment Gives a Better Picture of Work Ability

Nearly three million people contact the Social Security Administration for work disability claims each year. And when they do—whether because of an injury, cancer treatment, or other illness—they begin a process that involves multiple doctor assessments and extensive paperwork.

“A person who applies for this assistance is usually on their last legs, financially,” says Dr. Leighton Chan, chief of the Clinical Center Rehabilitation Medicine Department. “And while they’re waiting for a decision, the person is usually not able to work. So it’s a tough situation and we’re looking at ways to improve the process for everyone who is involved.”

At the request of the Social Security Administration, and working with experts at the Boston University Health and Disability Research Institute, his team developed and tested a comprehensive online questionnaire that can be used with the existing disability claims program to provide a clear picture of someone’s work ability, including their feelings of self-efficacy, their behavior control, their social interaction, and their emotions and mood. “No one else has done this before now,” Dr. Chan says, noting that previous patient questionnaires were paper-based and merely voluntary.

He hopes the new tool can be used early in the disability claims process, perhaps even at the point of initial assessment. And because the questions are grouped according to four areas of ability (see image below), “We can help doctors, therapists, and claims evaluators see someone’s major deficits at a glance, so that they can set that person on the right path for assistance early,” Dr. Chan says. “This will be good for the individual, and it also makes good economic sense.”

More information:

Using Genes to Diagnose Immune Disorders

Primary immune deficiencies are caused by mistakes in genes that are supposed to build critical parts of the immune system. Similarly, genetic defects can lead to autoinflammatory diseases in which fevers develop without cause. Because these diseases are so rare, and because the immune system is so incredibly complex, doctors often struggle to figure out the correct diagnosis based on symptoms alone. Patients can languish for years as a result, suffering repeated medical tests and ineffective treatments.

Fortunately, researchers have now identified more than 200 genes that are strongly associated with primary immune deficiency and autoinflammatory disease. Working with staff from the National Institute of Allergy and Infectious Diseases last year, members of the Clinical Center’s Department of Laboratory Medicine Immunology Service developed a procedure for high-throughput, next-generation sequencing to analyze 172 of these genes quickly and at minimal cost.

“What this means for individual patients is that doctors can figure out which genes are mutated, and in many cases, they can provide specific medications that treat the problem,” says Dr. Sergio Rosenzweig, chief of the Immunology Service, who helped lead the project. “For example, someone who lacks functional receptors for interleukin 12, which is an important signal for immune response to mycobacterial infection, can be given interferon gamma to help close the loop and restore normal immune responses. In addition, sequencing the genes of patients who have unusual symptoms for these diseases can help us define new clinical phenotypes for known genetic disorders.”

He notes that because these diseases are so rare, “You need a place like the Clinical Center, which has the resources to invest in this research. And what we learn can be used in the general population.”

More information:

Spider graphs, like the one to the left, can help evaluators to see a disability claimant’s major deficits at a glance. This graph simulates the picture of self-efficacy, mood and emotions, behavioral control, and social interactions in an individual who has depression, panic attacks, and low-back pain, indicated by the lines marked with circles. The abilities of an average, healthy person are shown by the lines marked with squares.
Adaptation: How the Clinical Center is Using Genetics to Maintain Infection Control

Darwin described the tendency of organisms to change slightly between generations, with some changes bringing a survival advantage under adverse conditions. He had no idea, however, that the source of that variation is an enormous, shifty molecule we call DNA. Last year, it was this knowledge, as well as the ability to analyze multiple DNA sequences with unprecedented speed, that helped researchers at the Clinical Center and the National Human Genome Research Institute (NHGRI) meet the challenge of bacteria that have evolved to survival antibiotics.

A patient who was known to be a carrier of carbapenem-resistant Klebsiella pneumoniae (CRKP) came to the Clinical Center in the summer of 2011. Klebsiella bacteria usually live harmlessly in the intestinal tracts of healthy people, but antibiotic-resistant strains can be deadly if they get into the bloodstream of someone who has a weakened immune system. Members of the hospital staff were aware that the new patient was a CRKP carrier, and they followed standard protocols to prevent spread to other patients. Nonetheless, in August 2011, additional cases of CRKP infection and colonization developed among other patients despite these infection control measures.

Dr. David Henderson, who is the Clinical Center’s deputy director for clinical care and associate director for hospital epidemiology and quality improvement, and Dr. Tara Palmore, the Clinical Center’s deputy hospital epidemiologist, instituted rigorous surveillance culturing and patient isolation protocols to contain antibiotic-resistant bacteria that arrived at the hospital. And, according to Dr. Segre, a program called PanPCR that was developed for the Clinical Center has been shared directly with hospitals outside of NIH to help them track antibiotic-resistant bacteria that are detected on their own turf. “It designs PCR primers to distinguish closely related strains of hospital pathogens, such as multi-drug resistant Acinetobacter baumannii or vancomycin-resistant Enterococcus,” she explains, noting a related publication in the March 2013 Journal of Clinical Microbiology.

NIH teams are also working closely with other federal agencies, including the U.S. Department of Agriculture, the Food and Drug Administration, and the Centers for Disease Control and Prevention, which manages national surveillance of antibiotic resistance. “CDC is now working to build on this experience to bring advanced molecular techniques to bear on the problem of antimicrobial resistance in health care,” says Dr. Arjun Srinivasan, associate director for Healthcare Associated Infection Prevention Programs at the CDC.

The CRKP genetic sequence may reveal unique proteins in the bacteria that can be targeted with new antibiotics, as well as ways to bring down the bacteria’s defenses so that traditional antibiotics will continue to work. Researchers across NIH are looking for those possibilities now. However, until new treatments are available, “Prevention is of paramount importance,” says Dr. Palmore. “Especially when you’re talking about hospitals like the Clinical Center, where the patients are extraordinarily vulnerable.”

Family Studies Lead to Targeted Treatments for Different Kidney Cancers

World-class experts from across NIH collaborate through the Clinical Center to improve our understanding of human diseases, particularly rare diseases and those that have a high public-health impact. An excellent example of this can be found in a trans-NIH research project led by National Cancer Institute’s Urologic Oncology Branch Chief Dr. Marston Linehan, which is revealing the true nature of kidney cancer and pointing the way toward better treatments for people who have the disease.

Sixty-five thousand people in the United States will be diagnosed with kidney cancer in 2013. When this disease is treated early, before it grows beyond the kidney, 91 percent of patients survive for at least five years. However, more than one-third of people don’t realize that they have it until after the cancer has already begun to spread, at which point the two-year survival drops to 19 percent.

Furthermore, 25 percent of kidney cancer patients are diagnosed with non-clear cell cancers (named according to how they appear under a microscope) that have been historically immune to most cancer drugs and can be difficult to manage with surgery alone.

Dr. Linehan assembled a team that includes 135 people from nine different NIH Institutes and Centers to study how kidney cancer develops and look for the genetic basis of the disease. They set up a genetic cancer program to evaluate the family members of kidney cancer patients who came to the Clinical Center, screening nearly 1,000 families and more than 1,800 patients.

Working with these families as their primary research model for more than two decades, the researchers have studied five subtypes of heritable non-clear cell kidney cancer, each involving genetic mutations that alter how tumor cells sense oxygen, iron, nutrients, or energy. The most notable of these mutations shift the tumors away from using mitochondria to produce energy and toward a less-efficient metabolic process called aerobic glycolysis.

“Many cancers are characterized by aerobic glycolysis,” notes Dr. Linehan. “Our genetically defined model of this metabolic shift is notable because of the fact that we’ve studied the families and we know the genes.”

He notes that scientists at NIH and around the world are now working with cell lines that were developed from patients at the Clinical Center, looking for ways to target the metabolic basis of cancer. Already, their research has provided the foundation for the development of seven FDA-approved targeted drugs for advanced kidney cancer. And with the roadmap provided by the Human Genome Project and the Cancer Genome Atlas, Dr. Linehan expects that the pace of discovery will only get faster.

“We’ve learned so much from the brave patients and families who have come to the Clinical Center for treatment and allowed us to manage them long-term,” Dr. Linehan says. “Their relationship with us has been invaluable. We couldn’t have done this work without having those patients as our primary research model, and we could not have done this work anywhere else in the world.”

Clinical and Translational Course for PhD Students

This year, 27 students from 16 institutions across the United States as well as abroad came to the Clinical Center to participate in this innovative new course, designed to encourage young basic scientists to learn more about potential careers in clinical and translational research. “The students took full advantage of the opportunity to interact with NIH scientists, while also going through a formal curriculum that introduces them to the ethical and scientific principles guiding research in human subjects,” said Dr. Juan Lertora, Clinical Center director of clinical pharmacology. George Fercana, a bioengineering doctoral student at Clemson University, was featured in his campus newspaper. “It taught me how to design robust studies and critically analyze the outcomes and implications of existing studies,” Fercana said.

Virginia Commonwealth University students receive certificates at the conclusion of the Clinical and Translational Course for PhD students.

From left to right: Dr. Frederick P. Ognibene, deputy director for Educational Affairs and Strategic Initiatives and director, Office of Clinical Research Training and Medical Education; Virginia Commonwealth University Students Melissa Powell, Monique Brown, Laura O’Brien, Morse Faria, Justine Abais, Justin Brookes, Niti Vanee, and Dr. Juan Lertora, course faculty leader and director of Clinical Pharmacology, NIH Clinical Center.

Graduate Medical Education Accreditation

The NIH Clinical Center serves as a training site for 52 residency and fellowship training programs on the NIH campus. In fiscal year 2013, these programs provided both clinical and research training to a total of 278 physicians and dentists (spanning the continuum from bench to bedside). The Clinical Center, which is fully accredited as an institutional sponsor of graduate medical education by the Accreditation Council for Graduate Medical Education (ACGME), sponsors 18 graduate medical education training programs on the NIH campus in collaboration with nine different NIH Institutes. In fiscal year 2013, with the administrative support of the Clinical Center’s Office of Clinical Research Training and Medical Education, all 18 of these programs remained in substantial compliance with ACGME accreditation standards, and each program remained individually accredited by the ACGME to provide clinical education and research training leading to specialty or subspecialty certification by the American Board of Medical Specialties.
The first annual NIH Clinical Fellows Day, held Oct. 25, was organized with the support of the Office of Clinical Research Training and Medical Education and the Foundation for Advanced Education in the Sciences. This event brought more than 130 clinical fellows from across NIH together with each other, as well as with senior NIH physician-scientists and NIH leaders. A full day of panel discussions, presentations and breakout sessions provided clinical fellows with the opportunity to get to know each other while also gaining access to valuable career advice; information about publishing scientific manuscripts; grant and fellowship opportunities; and patient safety and quality improvement, among other topics.

NIH–Duke Program in Clinical Research

The NIH–Duke Program in Clinical Research, established in 1998, was one of the nation’s first training programs in clinical research. This collaboration between the NIH Clinical Center and the Duke University School of Medicine provides health professionals at the NIH with formalized academic training in the quantitative and methodological principles of clinical research via videoconferencing and on-site classes taught by adjunct faculty. Since its creation, this program has served 210 students from a cross-section of Institutes and Centers; 88 have earned a Master of Health Sciences in Clinical Research while continuing their work at NIH. The program is a mutually beneficial collaboration that has remained robust in recent years, despite a concerning budgetary climate. In 2013, a new classroom for this long-distance learning program was relocated into the new Foundation for Advanced Education in the Sciences (FAES) Academic Center as part of a Clinical Center–FAES partnership.
Collaboration Leads to Enhanced Admissions Process

The Admissions Redesign Team was launched to improve the Clinical Center’s admissions process in response to patient feedback that instructions were inconsistent and often confusing.

Process improvement efforts to date include: implementation of a pre-registration phone call to reduce time spent at admissions; improved external Bldg. 10 signage; increased hours at the patient entrance on campus; and additional booths in admissions for expanded capacity during peak admissions periods.

In order to improve these processes, the Clinical Center has partnered with patients and Institute clinical research coordinators. This team has developed a new Patient Information Sheet to provide information about getting to the NIH, entering campus, security, and campus amenities. Also, a standardized welcome letter has been developed for new patients.

The Clinical Center has also worked closely with the Medical Executive Committee to identify lead points of contact for each Institute responsible for patient communications. With their support, the Clinical Center now maintains an extensive email distribution group of patient communication contacts so that improvements and issues related to patient travel, insurance, scheduling, and campus access can be shared and addressed broadly and quickly with the appropriate audience.

Barcoding Technology Protects Clinical Center Patients

A new point-of-care barcoding system was implemented in the Clinical Center in 2013, to assure accurate identification of patients and the delivery of safe care.

All patients are now assigned unique barcode identification wristbands upon admission to the hospital. These barcodes will function as point-of-care safety triggers, prompting health care providers to make sure that the match between the patient, the procedure, and the electronic health record is always correct. The patients’ extended visitor badges also include this unique bar-code.

An interdisciplinary team of clinical staff, research staff, admissions staff, and others worked tirelessly to deploy the new system throughout the hospital in phases, beginning with patient identification and expanding to include specimen collection for blood and other tissues, as well as transfusion verification for blood and blood products.

The final phase of the project—use of barcodes to verify medication type and dose—will be completed in early 2014.

Access to Medical Records and Key Information Now Available through Patient Portal

The Patient Portal, launched on July 10, 2013, offers patients the opportunity to electronically review parts of their medical record and access key information about the NIH and the Clinical Center through a secure internet connection. Just five months after the launch, there are nearly 4,000 active patient accounts in the new portal.

During the initial roll-out of the portal, patients had access to select pieces of information from their electronic medical records including discharge summaries/instructions, outpatient first registration reports and selected laboratory, neurology, and cardiology results dating back to January 2013. By the end of 2013, radiology results were available through the portal. Patients will also have the ability to electronically communicate securely with their NIH healthcare team through the portal by early 2014.

A multi-disciplinary project team, including NIH Institute and Center representatives, the Medical Executive Committee, and patient focus groups, worked together in the creation of the portal.
Returning Veterans Serve as Patient Care Technicians in New Training Program

The Veterans Incentive Program (VIP) is a new and innovative program that offers veteran corpsmen and medics the opportunity to continue serving their country as patient care technicians in the unique setting of the NIH Clinical Center while pursuing a degree in nursing.

Having served as medics and/or licensed practical nurses in the military, the inaugural four Veterans Incentive Program participants bring a valuable skill set to the Clinical Center Nursing Department. This experience, combined with the education and training they will pursue through the program, will add greatly to their own practice and enable them to become competent, successful clinical research nurses.

Those selected for the program are on initial 13-month temporary appointments with the potential for extension up to four years. Once completed, the Clinical Center will facilitate them in meeting their career goals, including potentially recruiting graduates to the permanent nursing staff.

New Android TV/Tablets Provide Patients Modern Bedside Technology

The Clinical Center, together with a communications systems manufacturer, developed from prototype to production the first set of hospital-grade Android TVs. The 260 bedside entertainment systems, which will be installed by spring 2014, are a cost-effective way to replace patient computers and televisions that are approaching the end of their life cycle.

Similar to a smart phone, with the touch of a finger, users can contact support groups through email and social media, watch the latest movies and TV shows with visitors, or engage in friendly competition with a companion located miles away through gaming apps. The wireless devices assure quick and easy online access and the touch screen will help reduce clinical staff’s time locating a keyboard or mouse. The 14-inch tablet is also made from a special antimicrobial glass that can be wiped clean between patients.

The devices are expected to save the Clinical Center $300,000 initially and a minimum of $100,000 annually in computer-support costs moving forward.
Clinical Center Researchers Receive Top Prize as Federal Employees of the Year

White House Chief of Staff Denis McDonough (far left) with (left to right) Dr. Julie Segre, Dr. Evan Snitkin, Dr. Tara Palmore, and Dr. David Henderson at The Samuel J. Heyman Service to America Medals Ceremony. Segre, Snitkin, Palmore, and Henderson earned the title of “Federal Employees of the Year” for their breakthrough in tracking and controlling a cluster of antibiotic-resistant bacterial infections at the Clinical Center with the use of DNA sequencing. The Samuel J. Heyman Service to America Medals are presented annually by the nonprofit, nonpartisan Partnership for Public Service to celebrate excellence in our federal civil service. They were also honored at the White House (see related story on page 24).

Dr. Harvey Alter Receives 2013 Canada Gairdner International Award

Dr. Harvey Alter, chief of clinical studies and associate director of research in the Department of Transfusion Medicine, received the prestigious Canada Gairdner International Award for demonstrated outstanding leadership in medicine and medical science and whose work has contributed significantly to improving the quality of human life. Dr. Alter also received the Distinguished Alumnus Award from the University of Rochester Medical School.
Dr. David Bluemke, director of Radiology and Imaging Sciences, was appointed as president of the North American Society of Cardiovascular Imaging, and as fellow of the International Society of Magnetic Resonance in Medicine.

Dr. Leighton Chan, chief of the Rehabilitative Medicine Department, received the Distinguished Academician Award from the Association of Academic Physiatrists. He is the youngest member ever to win this award.

Dr. Karen Frank, chief of the Microbiology Service in the Department of Laboratory Medicine, was named Distinguished Lecturer for the American Society for Microbiology for a 2013-2015 term.

Dr. Peter Herscovitch, chief of the Positron Emission Tomography Department in Radiology and Imaging Sciences, was elected president of the International Society for Cerebral Blood Flow and Metabolism, and he received the Presidential Distinguished Service Award from the Society of Nuclear Medicine and Molecular Imaging.

Dr. Anna Lau, clinical microbiology fellow in the Department of Laboratory Medicine, was named one of Forbes Magazine’s 2014 “30 Under 30” in the Science and Healthcare category for her work over the past year (see related story on page 21).

Dr. Juan Lertora, director of the Clinical Pharmacology Program in the Office of Clinical Research Training and Medical Education, received the 2013 PhRMA Foundation Award in Excellence in Clinical Pharmacology.

Dr. Henry Masur, chief of the Critical Care Medicine Department received the John E. Maher Memorial Laureate Award from the American College of Physicians, DC Chapter. He was also appointed Co-chair of the Guideline on Hepatitis C Committee for the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases.

Dr. Naomi O’Grady, staff clinician, was elected to the American Board of Internal Medicine Council and re-appointed for a second term as the Chair of the American Board of Internal Medicine, Subspeciality Board in Critical Care Medicine.

Dr. David Sacks, chief of the Clinical Chemistry Service in the Department of Laboratory Medicine, received the Excellence in Standards Development Award from the Clinical and Laboratory Standards Institute.

Dr. Michael Solomon, staff clinician, was appointed to the American College of Cardiology Board of Governors.
CAPT Margaret Bevans was appointed program director for Nursing Research and Translational Science in the Nursing Department.

Dr. Caitlin Brennan was appointed program director for Outcomes Management in the Nursing Department.

Kathleen Carpenter was appointed program director for Staffing and Workforce Planning in the Nursing Department.

Justin Cohen was appointed chief of the Office of Communications and Media Relations.

Joseph Cowling was appointed section chief of Environmental Services in the Materials Management and Environmental Services Department.

CDR Fortin Georges was appointed chief of the Outpatient Pharmacy Section.

Julie Kohn-Godbout was appointed program director for Nursing Education in the Nursing Department.

CDR Antoinette Jones was appointed operations manager in Radiology and Imaging Sciences.

Dr. Scott Kim was appointed to the Department of Bioethics as a new tenured senior investigator.

Jimmy Nazair was appointed section chief of Storage and Distribution in the Materials Management and Environmental Services Department.

Susan Nsangou was appointed director of the Office of Purchasing and Contracts.

Dr. Adam Pugacz was appointed section chief of the Inpatient Pharmacy Section, in the Pharmacy Department.

Lori Purdie was appointed program director for Recruitment Outreach and Workforce Management in the Nursing Department.
Nursing Executive Team
The 2013 NIH Clinical Center Nursing Department’s executive team assembled for a group photo with Dr. Clare Hastings, chief nurse officer, NIH Clinical Center (fifth from left). New staff appointments include from left to right: Dr. Barbara Jordan, service chief for Neuroscience, Behavioral Health and Pediatrics; Tannia Cartledge, deputy chief nurse, Clinical Operations; Dr. Gwenyth Wallen, deputy chief nurse, Research and Practice Development; Dr. Cheryl Fisher, senior nurse consultant for extramural collaborations; Dr. Clare Hastings, CDR Ann Marie Matlock, service chief, Medical Surgical Specialties; Dr. Deborah Kolakowski, service chief, Oncology and Critical Care; and Diane Walsh, special assistant to the chief nurse.
Organization and Governance

ADVISORY BOARD FOR CLINICAL RESEARCH
NATIONAL INSTITUTES OF HEALTH (2013)*

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.

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*As of December 31, 2013
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*As of December 31, 2013
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