



NIH Clinical Center Director's Annual Report

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2015
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Report on 2014 Activities



National Institutes of Health
Clinical Center

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VISION

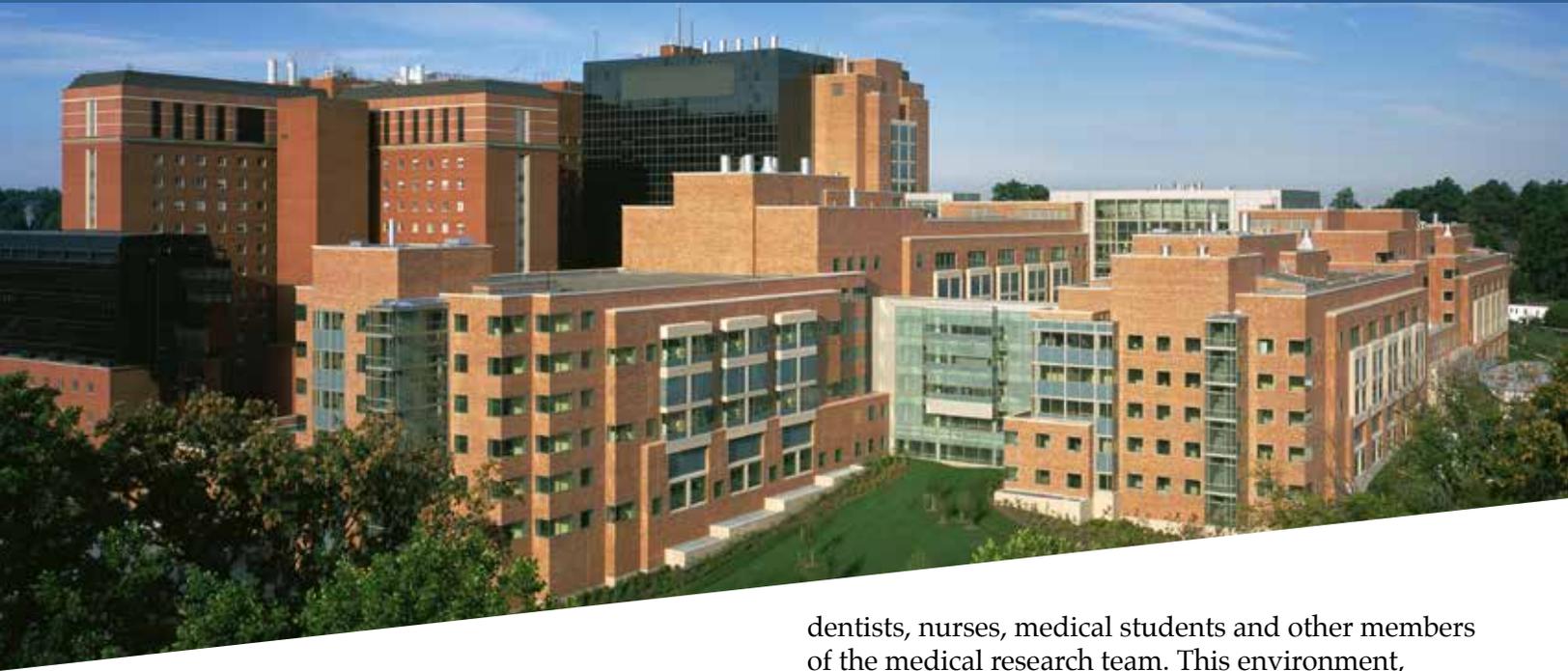
As America's research hospital, we will lead the global effort in training today's investigators and discovering tomorrow's cures.

MISSION

The NIH Clinical Center provides a model environment for:

- » clinical research
- » patient care
- » training

» About the NIH Clinical Center



The Clinical Center is the research hospital at the National Institutes of Health (NIH) campus in Bethesda, Md. Since the hospital's opening in 1953, NIH scientists have worked with volunteer patients to create medical innovations.

Clinical Center successes include pioneering the cure of cancerous solid tumors with chemotherapy; the use of nitroglycerin to treat heart attacks; identifying a genetic component in schizophrenia; conducting the first successful replacement of a mitral valve to treat heart disease; and the creation of blood tests to identify both Acquired Immune Deficiency Syndrome (AIDS) and hepatitis.

These and other research concepts pioneered by the Clinical Center have been adopted as standard practice in medical treatment throughout the world. The rapid translation of scientific observations and laboratory discoveries into new approaches for diagnosing, treating and preventing disease have improved and saved countless lives.

The Clinical Center has been a leader in the "bench-to-bedside" concept. Its specialized hospital design places patient care units in close proximity to research laboratories. This model supports interaction and collaboration among clinical researchers. The Clinical Center also offers world-class training in clinical research for physicians,

dentists, nurses, medical students and other members of the medical research team. This environment, offering access to the most advanced techniques, equipment and ideas, attracts a global network of scientists.

The original Warren G. Magnuson Clinical Center, built in 1953, adjoins the Mark O. Hatfield Clinical Research Center, which opened in 2005. The hospital has 240 inpatient beds, 11 operating rooms, 82 day hospital stations, critical care services and research labs, an ambulatory care research facility and a complex array of imaging services. The Clinical Center is also one of the few facilities in the world with state-of-the-art infrastructure that allows for isolation capabilities and infection control while patients participate in clinical research studies.

Patients at the Clinical Center consent to participate in research studies, also called protocols, and are treated without charge. Admission is selective: only those patients who have a medical condition being studied by NIH Institutes or Centers and who meet the specific inclusion criteria can enroll in the studies. There are currently about 1,500 clinical research studies underway at the Clinical Center including those focused on cancer, infectious diseases, blood disorders, heart disease, lung disease, alcoholism and drug abuse.

More than 480,000 patients from all 50 states, and from countries around the world, have participated in clinical research at the Clinical Center.

Throughout the past year, the NIH Clinical Center made remarkable contributions to medical discoveries in important new ways, while launching initiatives that reflect our commitment to being a model hospital for patient care and safety, as well as training. I believe we stand taller than ever as a “House of Hope” for the nation and, in many respects, for the world.

In 2014, the NIH Clinical Center built on its proud history of tackling the world’s toughest public health challenges, for example emerging at the forefront of addressing the Ebola crisis. The report details how the Clinical Center’s unique isolation facility, known as the Special Clinical Studies Unit, enables state-of-the-art care for patients with Ebola who are participating in research protocols to mitigate this deadly outbreak. Also, the Clinical Center is supporting the work of National Institute of Allergy and Infectious Diseases with the launch of first-in-the-world human clinical trials of two promising Ebola vaccines.

While the Ebola crisis thrust us into the spotlight, achievement abounded in countless other ways. We expanded use of genetic mapping and sophisticated diagnostic tools, with the goal to better understand not just how to manage and treat chronic diseases, but to undertake interventions that prevent diseases. Also, our exciting new partnership program between intramural and extramural researchers is gaining

momentum while our training programs grow and diversify. With their unparalleled expertise and tireless dedication, our staff earned renown from prestigious medical societies throughout the world. I invite you to peruse the pages ahead to learn more about a year rich in accomplishment.

The health challenges we face change over time, but the Clinical Center’s resolve to fight them never diminishes. Our strategies evolve and we embrace innovation and more efficient powerful technologies, but our core commitment to providing safe, top notch patient care and excellent training to new researchers remains steadfast.

John I. Gallin, MD
Director, NIH Clinical Center



»» Recent Achievements



Patient Care and Safety

»» **Medication Barcoding Enhances Patient Safety** A state of the art system has been implemented that improves the accuracy of medication administration.

»» **Admissions Redesign Improves the Patient Experience** Several changes have been made to the patient admissions process to enhance the patient experience. These improvements reduced waiting times by 41% for patients arriving at the Clinical Center's busiest periods.

»» **Successful Treatment of Ebola Virus** On October 16, 2014, a Texas nurse infected with the Ebola virus was admitted to the NIH Clinical Center's Special Clinical Studies Unit, one of a small number of high-level containment facilities in the United States designed to provide high-level isolation capabilities. She was discharged on October 24, after blood tests showed that she was free of the Ebola virus.

»» **Advanced Electronic Medical Records** The Clinical Center was recognized as a Stage 6 institution by the Healthcare Information and Management Systems Society (HIMSS). The Clinical Center joins the top 20% of U.S. hospitals for its adoption and integration of electronic medical records.

»» **New Medical Equipment Focused on Protecting Patients** The Clinical Center Radiology Department installed the latest generation, high-speed Computerized Tomography (CT) scanner that will use the lowest possible radiation levels. Patients at the Clinical Center undergo more than 25,000 CT scans every year.

Clinical Research

»» **Clinical Center Opens Doors to Outside Researchers** Starting in 2014, researchers from academia and industry were able to conduct clinical research at the Clinical Center. This opportunity involves three-year, renewable awards of up to \$500,000 per year, along with access to the research hospital's extraordinary facilities and staff.

»» **Clinical Center Leads DNA Research** The Clinical Center Genomics Opportunity will fund the DNA (or Deoxyribonucleic acid) sequencing and analysis of a total of 1,000 exomes over a two-year period. Understanding how DNA transfers attributes from generation to generation, and how it regulates the development of the human body, are critical for medical research.

»» **Clinical Center Receives the MatchMaestro Award** The Clinical Center Office of Patient Recruitment received the MatchMaestro trophy from the ResearchMatch program for encouraging the highest number of volunteers to join research studies through "innovation" and "diligent and creative marketing." The program matches people who want to participate in research with scientists who need volunteers for their studies.

Training and Workforce Development

» Clinical Center Supports Surgical Education

Eighteen accredited medical or surgical specialty and subspecialty graduate medical education training programs have the Clinical Center as their sponsoring institution.

» **Veterans Incentive Program Focuses on Transitioning Professionals** The Nursing Department participated in the second year of the Veterans Incentive Program, an initiative to help

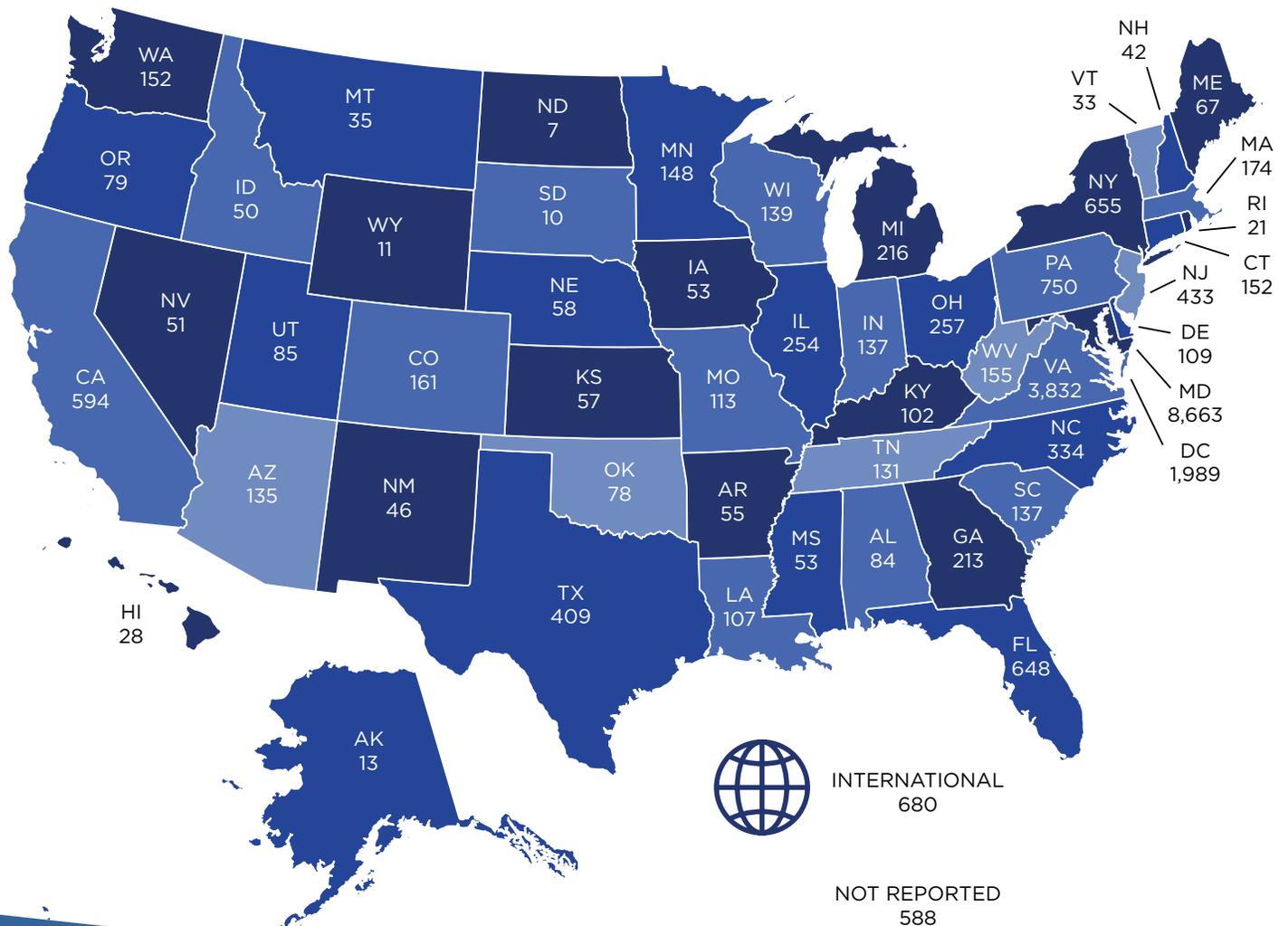
Corpsmen or Medics transition into civilian life. This program helps veterans use the training they received while serving in the military and apply it to the unique setting of the Clinical Center.

» Sabbatical in Clinical Research Management Celebrating its Fifth Anniversary

The Clinical Research Management Sabbatical assists professionals interested in developing clinical research programs or enhancing the skills of researchers and administrators in certain core areas. Twenty-six participants representing seven countries (the U.S., Brazil, China, France, Malaysia, Russia and Tanzania) have taken part in the courses.

Serving Patients and Supporting Research

Home States of All Active Clinical Center Patients - 2014



» Key Facts and Figures

2014 Workforce Distribution

The Clinical Center has a workforce of 1,939 permanent federal employees.

42.4%

Nursing and patient care/support services - 821



40.8%

Clinical and imaging sciences departments - 791



11.9%

Operations - 230



4.9%

Administration - 96



All workforce figures from October 1, 2014.

2014 Budget by Major Category

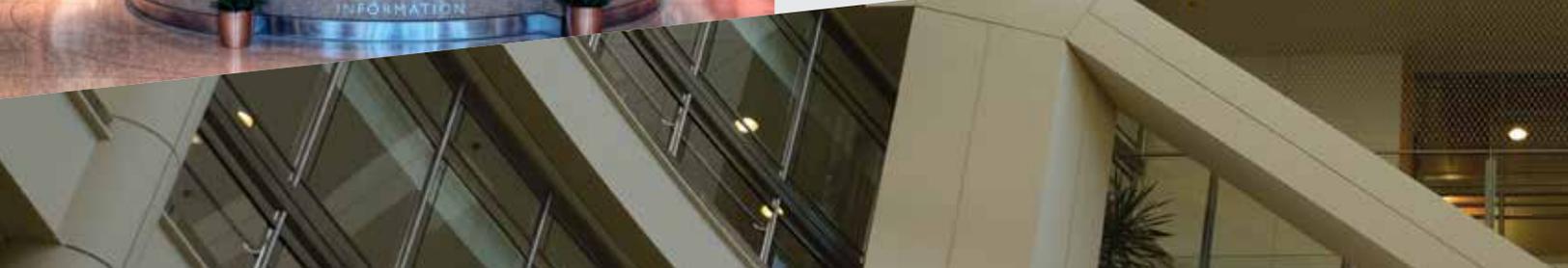
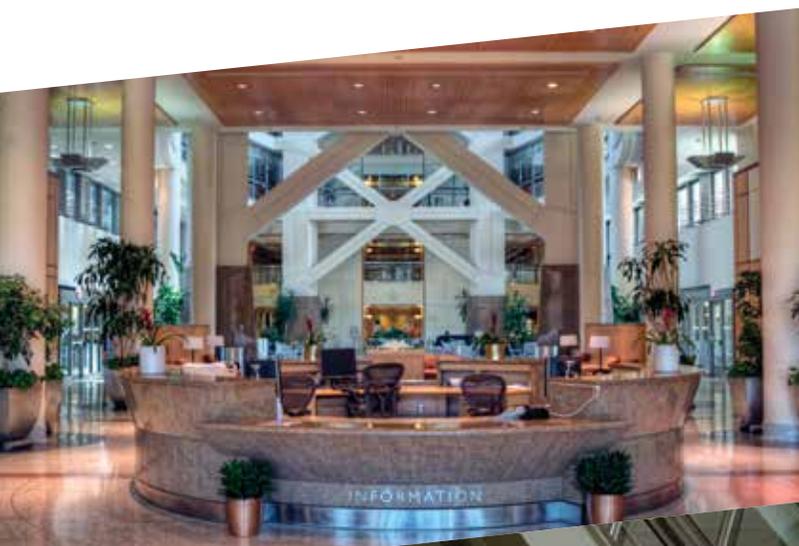
Clinical Center Budgets by Major Category for Fiscal Year 2014 (\$402.8M) (In Millions of Dollars)

Category	FY14 Budget
Salaries & Benefits	220.7
Contract Labor	30.4
Equipment	17.6
Medications	37.2
Supplies	25.1
NIH Assessments	28.2
Other *	43.6
TOTAL	402.8

*All Other: Contracts (non-labor), Travel, Maintenance Agreements and Training. All budget figures from October 1, 2014.

Patient Activity 2012-2014

	2012	2013	2014
Admissions	5,916	5,887	5,615
New patients	10,694	10,196	10,053
Inpatient days	54,971	51,418	48,182
Average length of stay (days)	9.3	8.9	8.7
Outpatient visits	102,169	102,115	99,402



Clinical Research Activity 2010–2014

	2010	2011	2012	2013	2014
Active Onsite Protocols	1,443	1,513	1,530	1,570	1,611
New Onsite Protocols	158	207	167	162	168
Principal Investigators	474	489	482	499	499

2014 Active Onsite Protocols (by type)		
Interventional/Clinical Trials	773	48%
Natural History	744	46%
Screening	67	4%
Training	27	2%
TOTAL	1,611	



Clinical Trials by Research Type

773

Onsite Intramural Protocols



Total Active Onsite Clinical Trials	
Phase 1 (toxicity)	261 (23%)
Phase 2 (activity)	462 (60%)
Phase 3 (efficacy)	39 (5%)
Phase 4 (safety)	11 (2%)
TOTAL	773

Clinical Trial Phases

Phase 1: 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 2: The study drug or treatment is given to a larger group of people (100–300) to evaluate its effectiveness and to further assess its safety.

Phase 3: 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 4: 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.



» 2014 Highlights

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Legislators Welcomed to the Clinical Center, Briefed on NIH Research Advances

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1 Senator Dick Durbin (D-Ill.) (left) meets with Dr. Francis S. Collins, NIH director (foreground) prior to touring the National Institute of Neurological Disorders and Stroke Center for Neuroscience and Regenerative Medicines lab at the NIH Clinical Center.

2 Congressman Joe Pitts (R-Pa.) (right) views a model of the Clinical Center during his visit to NIH. Pitts received an overview of the building from its Director, Dr. John I. Gallin, and engaged in a round-table discussion with institute clinical directors.

3 Senator Barbara Mikulski (D-Md.) (far right) visits the Clinical Center to tour a lab of the NCI Urologic Oncology Branch, meet with patients and address staff in Masur Auditorium.

4 Congressman Leonard Lance (R-N.J.) speaks in Masur Auditorium at Rare Disease Day, a day-long celebration and recognition of the rare diseases research activities supported by the NIH.

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African leaders tour the Clinical Center with Dr. John I Gallin (far right). From left to right: Dr. Jean Vivien Mombouli, Director of Research, Ministry of Health, Republic of the Congo; Dr. Seif Rashid, Minister for Health and Social Welfare, Tanzania; President Denis Sassou Nguesso, Republic of the Congo; and President Jakaya Kikwete, Tanzania.

Macedonian Health Minister Nikola Todorov (left) speaks with Dr. David Henderson, the deputy director for Clinical Care and associate director for Hospital Epidemiology and Quality Improvement at the NIH Clinical Center. Minister Todorov visited several locations in the U.S., including the Clinical Center, to discuss best practices in healthcare delivery.

African Heads of State Discuss Research Advances



Dalai Lama Visits Clinical Center, Views Innovations in Rehab Medicine

In early August, leaders from several African nations toured the Clinical Center and spoke with NIH's top scientists about how best to collaborate to improve health across Africa. The visit was in conjunction with the first-ever U.S.-Africa Leaders Summit in Washington, D.C.

The leaders, invited to NIH by the Fogarty International Center, included Jakaya Mrisho Kikwete, the President of Tanzania; Dennis Sassou Nguesso, the President of the Republic of the Congo; Ibrahim Boubacar Keïta, the President of Mali; Guy Scott, the Vice President of Zambia; as well as other government officials.

During the visit, Dr. Francis S. Collins, NIH director, Dr. John I. Gallin, Clinical Center director, and other NIH directors showcased NIH-supported research in African countries and discussed how these investments are making a difference in the lives of Africans and Americans.

His Holiness, the 14th Dalai Lama, Tenzin Gyatso, visited the National Institutes of Health in March, making a stop at the Clinical Center. After taking the time to greet staff, patients and visitors, the Dalai Lama watched a demonstration of two different portable brain imaging systems. The systems use nearinfrared spectroscopy (NIRS) to study motor coordination in people with and without brain injuries.

With NIRS, scientists can compare cortical activation patterns during a range of motor tasks in children with cerebral palsy compared to a group of children of the same age with no neurological impairment.

Through this work, investigators expect to improve movement technologies and quality of life for people who suffer from diminished mobility.



NIH Opens Hospital to Outside Scientists, Tackles Disease on Many Fronts

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Starting in 2014, academic and industry scientists were able to conduct medical research at the Clinical Center. This opportunity involves three-year, renewable awards of up to \$500,000 per year and access to the research hospital's extraordinary facilities and staff. The National Institutes of Health (NIH) regularly provides funding for scientists outside of its organization, called extramural researchers, and government scientists who work for NIH directly, called intramural researchers. With this new program, outside scientists will now be able to test promising laboratory discoveries using

emerging technologies and tools. Researchers will also be able to collaborate on clinical protocols, often for extraordinarily rare diseases, in partnership with NIH investigators to help advance disease diagnosis, treatment and prevention.

The awards will support projects focusing on a variety of diseases and health conditions that affect children and adults in the United States and worldwide. *(See text below for more details.)*

"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 ongoing efforts translating scientific discovery into tomorrow's cures at the Clinical Center and in partnering institutions around the country," said Dr. John I. Gallin, director of the NIH Clinical Center.

Research Collaboration

The Clinical Center is hosting new collaboration projects with outside researchers, including:

- » A clinical trial for a new drug treatment for Niemann Pick C, a rare, fatal disease caused by the loss of the ability to break down cholesterol and other fats. Sponsored by Washington University.
- » A clinical trial of a new drug treatment to prevent relapse in a form of childhood leukemia. Sponsored by the Children's Research Institute.
- » A clinical trial to understand the genetic makeup of certain types of prostate cancer, to gain insights that could yield new information for prevention and treatment efforts. Sponsored by the University of Michigan.
- » Development of a new catheter that can be threaded into the heart to relay high-quality images needed for making surgical and treatment decisions. Sponsored by the Georgia Institute of Technology.
- » A long-term, follow-up study of patients treated for *Cryptococcus gattii*, an airborne fungus that

can cause severe, sometimes fatal, respiratory infections. Sponsored by John's Hopkins University.

- » A clinical trial of a new vaccine to prevent malaria. Sponsored by Sanaria, Inc.
- » A clinical study of Moebius Syndrome, a birth defect that limits the ability to make facial expressions like smiles or frowns and can create difficulty in swallowing, blinking or breathing. Sponsored by the Icahn School of Medicine at Mount Sinai.
- » A clinical study to evaluate if a chemotherapy treatment regimen used to treat cancer is also effective in treating the human immunodeficiency virus (HIV). Sponsored by City of Hope and the Beckman Research Institute.
- » A clinical study of a medication to treat the immune disorder common variable immune deficiency (CVID) enteropathy. Sponsored by Oregon State University.
- » A long-term study of patients with a genetic mutation of the STAT1 protein that regulates cell growth and development. Sponsored by Rockefeller University.

Patient Portal Delivers Quick Results

Using an online tool, patients at the Clinical Center can now rapidly access their lab tests and imaging results. Access times have been reduced from weeks to days.

The Patient Portal, launched in 2013, provides patients with access to their medical records and NIH resources and information. In response to patient feedback, the portal was updated in 2014 to provide quicker access to patients' medical tests. Once data are finalized in the Clinical Research Information System (CRIS), imaging results, such as x-rays and ultrasound scans, are now released in three days. Non-imaging results, such as lab tests, are posted within eight hours. Previously, patients had to wait one to two weeks to view their results.

By the end of 2014, 6,500 patients were actively using the Patient Portal, and there had been more than 134,000 patient views of test results and documents.

"This is a major accomplishment," said Dr. John I. Gallin, director of the Clinical Center. "We are now able to provide patients with important information about their health in a fraction of the time that was needed before."

Jump-starting Genomic Opportunities at the Clinical Center

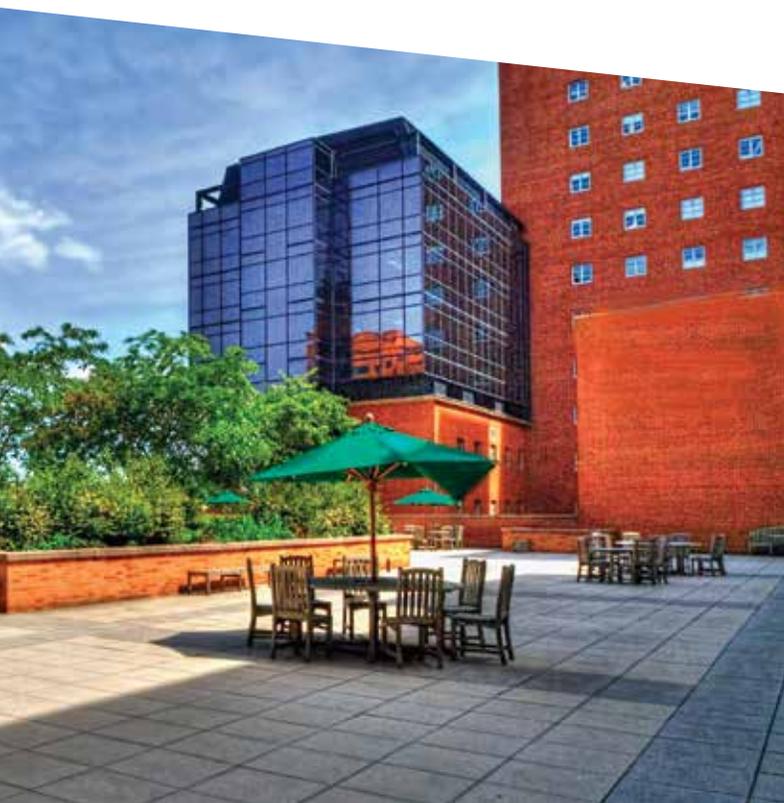
Deoxyribonucleic acid, or DNA, is the hereditary material in humans and almost all other organisms. Understanding how DNA transfers attributes from generation to generation, and how it regulates the development of the human body is critical for medical research.

The Clinical Center Genomics Opportunity will fund the DNA sequencing and analysis of a total of 1,000 exomes, which are the functionally important 1-2 percent of an individual's genome that codes for proteins. Until now, only a few clinical research projects in the NIH intramural program have included exome sequencing.

The program, launched during the summer of 2014, began with a review committee's selection of projects that take optimal advantage of Clinical Center phenotyping resources—imaging, detailed documentation of physiological changes in patients and annotations of medical consequences of diseases.

Clinical researchers whose projects are chosen will be awarded 50 to 300 exome sequences derived from patient samples. The samples will be collected at the Clinical Center and sequenced at the NIH Intramural Sequencing Center, a specialized facility operated by the National Human Genome Research Institute.

"The NIH Clinical Center is the best place in the world to do detailed characterization of the disease phenotypes and natural histories of rare and unusual disorders. This program will harness genomics to help us solve otherwise insoluble problems and get answers in much less time," said Dr. John I. Gallin, director of the Clinical Center. "It's a great synergy of resources and an important project that will transform our emphasis on disease prevention."



Medication Barcoding Enhances Patient Safety

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The Clinical Center has implemented a new system to help avoid medication administration errors and keep patients safe. The Institutes of Medicine estimate that at least 44,000 deaths per year are associated with preventable harm in hospitals.

Upon admission, each patient is given a wristband with a personalized barcode. All medications used in the Clinical Center are logged and also have an individual barcode. Before a medical professional administers a drug to a patient, the medication and the patient's barcodes are scanned. If the barcode scans do not match, then the healthcare professional is immediately notified and the order is reviewed.

Barcodes have been used in admissions to the Clinical Center since 2007. Since then, their use has expanded to medications stocked in automated dispensing cabinets in 2009, tracking patients' lab specimens in 2010 and dispensing take home medications from the outpatient pharmacy system in 2011.

Medication bedside barcoding began as a pilot on selected units in January 2014 and was fully implemented throughout the Clinical Center in March 2014.

The barcode initiative was a collaborative effort by the Clinical Center's Department of Clinical Research Informatics, the Pharmacy Department, the Respiratory Care and Therapy Service, the Nursing Department and the Office of the Director.

To support this technology and manage the increased volume of data, the Clinical Center provides a wireless network that can reach all areas of the facility where patients are being treated.

To prepare for this program, the Pharmacy Department had to review all of the medications in its inpatient inventory and track all of the new investigational medications released for use by the Pharmaceutical Development Section of the



Pharmacy. To ensure the program works effectively, the individual barcode for each individual dose of medication must be scanned and entered into the Pharmacy's database. Scanning all of the barcodes of the Clinical Center's inventory took pharmacy staff over four months to complete. Pharmacy staff continue to scan and track each medication brought into the Clinical Center on a daily basis.

Finally, nurses who provide the medication to patients were fully trained on how to work with the system, learning in a hands-on environment that reflected the daily realities that nurses and patients face.

Medication Barcoding, by the Numbers

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1,600
new barcodes added to
the Clinical Center database.

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4,400
Medications in the
Clinical Center inpatient inventory.

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35,000
barcodes scanned by the Clinical Center
Pharmacy Department.

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Source: Pharmacy Department, NIH Clinical Center



First Installation of new CT Technology in Clinical Setting

An estimated 62 million Computerized Tomography (CT) scans are conducted in the U.S. every year, including more than 25,000 at the Clinical Center. With patient safety of primary importance, the Clinical Center’s Radiology Department installed a latest generation, high-speed CT scanner that uses the lowest radiation levels available.

CT scanners use special x-ray equipment to create detailed pictures, or scans, of areas inside the body. The detailed anatomical images they create can help physicians enhance treatment and avoid unneeded medical procedures. However, they use ionizing radiation, a known human carcinogen, which poses a potential drawback for patient health. Some patients require CT scans once a week during critical phases of their therapy trials.

The equipment installed at the Clinical Center was recently approved by the Food and Drug Administration and is the first clinical installation in the U.S. “This new CT scanner represents another ‘first’ for the NIH Clinical Center,” said Dr. David Bluemke, director of the Radiology and Imaging Sciences Department. “It reinforces the commitment of the NIH to the highest level of safety and technology for our patients.”

Bedside Android Televisions

The Clinical Center provides a model environment for patient care by making the latest technology available to patients. In 2014, the hospital installed bedside android televisions that consolidated the TV and computer into one easy-to-use tool that is familiar to patients.

This touchscreen device has tablet functions such as internet access, media playback tools and customized applications for gaming, social media and watching movies. The device also provides one-touch links to the Nutrition Department’s website, the NIH Clinical Center Patient Portal, patient surveys and NIH resources.

The 14-inch tablet weighs about seven pounds and is made from a special antimicrobial glass that can be wiped clean between patients. Devices will automatically eliminate any past data or personal identifying information from previous users.

The Clinical Center Online (2012 - 2014)

In 2014, the Clinical Center achieved steady growth in social media and online outreach.

	2012	2013	2014
Clinical Center Website Visits	1,058,311	2,391,566	2,460,852
Clinical Center Twitter Followers	20,823	33,356	44,693
Clinical Center Facebook Page “likes”	3,207	5,209	8,745



Source: www.facebook.com/NIHClinicalCenter

Take Your Child to Work Day Offers Hands-on Learning



Take Your Child to Work Day, an annual event hosted on the NIH campus, provided an opportunity to inspire future generations of scientists by showcasing the work done at the Clinical Center and the shared mission of the nation's medical research agency: supporting scientific studies that turn discovery into health.

NIH staff members brought their school-aged children, from grades 1 to 12, to the NIH campus. With 333 children registered, the Clinical Center hosted ten unique activities that highlighted medical research.



Dr. Muhammad Yousef, an anesthesiologist (left), demonstrates medical procedures with Alexandra Besch in the Clinical Center operating room. Besch, a youth participant at Take Your Child to Work Day, practices inserting a tube to provide an open airway on a dummy.

Admissions Redesign Enhances the Patient Experience

In 2011, an Admissions Redesign Team consisting of representatives from a number of Institutes and Clinical Center Departments began an extensive assessment of the quality of the patient experience during the admissions process. The team wanted to look at people, processes, policies, communications, actions and the environment that patients encounter when they arrive at the Clinical Center.

“Our goal is always to provide the highest quality patient-centered care. In keeping with that goal, we wanted to find ways to make the experience of patients as they arrive at the Clinical Center as positive as it can be, and to find ways to help minimize stress,” said Dr. Maureen Gormley, chief operating officer of the NIH Clinical Center.

In 2014, the project instituted a number of facility changes based on the recommendations of the team and subsequent surveys conducted by Patient Support Services.

- » New consulting rooms now provide private spaces where researchers can meet with new patients.
- » The addition of two new intake interview rooms to allow more rapid intake of patients.
- » New educational and informational materials were created, and are now sent to patients prior to their first visit to the Clinical Center to help prepare them for their visit.
- » New furniture, carpeting and plants have refreshed the look of the waiting area.
- » The Patient Voucher and Cashier's Offices were moved to a different location, to create a more relaxed atmosphere.

These changes have resulted in 41% shorter waiting times for patients arriving at the busiest periods: a reduction from an average of 17 minutes in 2011, to 10 minutes in 2014.

“It was a very productive, collegial and collaborative process,” says Karen Kaczorowski, chief of Patient Support Services. “Everyone worked well together as a team. The result is a less stressful and more comfortable experience for patients.”



Participants in Project SEARCH, a program dedicated to providing education and training to young adults with intellectual and developmental disabilities.

Project SEARCH

Program that focuses on abilities celebrates five years at the Clinical Center

Launched at the Clinical Center in 2010, the Project SEARCH program gives individuals with intellectual disabilities opportunities to develop workforce skills and training for mainstream employment. In the project's five years at the National Institutes of Health (NIH), 45 interns have served in various positions across the NIH campus as participants in the nationwide program.

After completing a 30-week unpaid internship, participants graduate from the program with new skills, abilities, experiences and confidence. Seventy-

three percent of them have been hired in the Clinical Center, in the Institutes or Centers where they completed their internships.

But the best reward of all has been the presence of the Project SEARCH interns and graduates on campus.

"Project SEARCH interns bring an excellent work ethic, competent job skills, along with hope and inspiration to the workplace," said Dr. Maureen Gormley, chief operating officer of the NIH Clinical Center, who has been a strong champion of this effort.

"With the support of our colleagues from across the NIH, we have created a sustainable future for a terrific program."

Project SEARCH Outcomes to Date

	Year 1 2010-2011	Year 2 2011-2012	Year 3 2012-2013	Year 4 2013-2014	Overall
Interns Graduated	12	10	11	12	45
Interns Hired at NIH	8	5	7	8	28
Interns Hired in Community	2	1	2	0	5
Hire Rate	10/12	6/10	9/11	8/12	33/45
Hires Still Employed (NIH & Community)	8/10	5/6	9/9	8/8	30/33

73% HIRE RATE

91% HIRES SUSTAINED

» Spotlight on Ebola

Treatment and Solutions in the Ebola Crisis

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The Ebola outbreak in West Africa and subsequent isolated cases in the United States dominated the news headlines in late 2014. NIH has played a leading role in research on potentially lifesaving Ebola vaccines and providing crucial scientific knowledge on the virus's genetic makeup and transmission. This year, the NIH Clinical Center was also in the spotlight for providing highly specialized, state-of-the-art isolation and treatment for one of the first patients to become infected with Ebola on U.S. soil.

History

For much of its history, Ebola was simply one of an estimated 7,000 rare diseases that NIH and other research organizations investigate. However, in 2014 the number of Ebola cases in West Africa exploded, with the Director-General of the World Health Organization, Dr. Margaret Chan, calling the outbreak “the greatest peacetime challenge that the United Nations and its agencies have ever faced.”

Ebola was first recognized in 1976 in Zaire (now the Democratic Republic of Congo). Over the next four decades, only small, sporadic outbreaks (typically in remote, rural villages) were reported. Then the recent epidemic struck West Africa in March 2014. This epidemic for the first time involved large cities and was magnitudes larger than all previous outbreaks combined: as of November 14, 2014, more than 13,000 people were infected and 37% of the afflicted had died. A concurrent outbreak in the Democratic Republic of Congo started in August 2014 and infected 66 people through November 2014, with a 74% mortality rate.

Scientists, including NIH researchers, have used advanced genomic sequencing technology to map the origins of the disease. They determined that the current outbreak was caused by a single transmission from animal to human, followed by exclusively human-to-human transmissions. The virus can be spread among humans through direct contact (through broken skin or mucous membranes in, for example, the eyes, nose or mouth) with blood or body fluids of a person who is sick with Ebola or

through virus-contaminated objects like needles and syringes.

Ebola in the U.S.

Only a small number of confirmed Ebola cases have been confirmed in the United States. As of November 2014, five cases were detected in medical or other professionals who had returned from West Africa after helping to contain or monitor the health crisis. One case involved a man who had traveled from Liberia to Dallas, Texas. Two subsequent cases were detected in nurses who had been involved in his care. The two Dallas nurses are the only two confirmed cases of Ebola transmission in the United States.

Treatment at the Clinical Center

On October 16, 2014, Nina Pham, one of the nurses from Texas who was infected, was transferred to the NIH Clinical Center's Special Clinical Studies Unit, one of a small number of containment facilities in the United States designed to provide high-level isolation capabilities.

For each patient infected with a highly contagious virus such as Ebola, a large number of specially trained professionals, including physicians, nurses and support staff, are required to provide constant care and maintain stringent infection control procedures.

“We are thoroughly convinced that the policies at the highest levels of safe containment were effective,” said Dr. Richard Davey of the National Institute of Allergy and Infectious Diseases (NIAID), who runs the Special Clinical Studies Unit. He noted that dozens of unit staff “all pulled together in an

Nina Pham, the Texas nurse who was the first patient diagnosed with Ebola to be treated at the Clinical Center, joins her family and the NIH health care team that cared for her to celebrate her discharge from the hospital.



amazing way. I can't compliment them enough. The esprit was overwhelming. Our infection control measures exceed the guidelines and have been thoroughly tested."

"This was our first opportunity to study a patient with Ebola," said Dr. H. Clifford Lane, clinical director of NIAID. "There's an enormous amount we think we'll be able to learn with one patient... Even though this is a tiny percent of what's going on in West Africa, it could extend the benefits of our research there... This patient [Pham] is part of a substantial research program."

Pham received no experimental drugs at the Clinical Center during her treatment. She did receive a transfusion of plasma that had been donated by Dr. Kent Brantly who had previously recovered from Ebola virus infection. One hypothesis, not yet proven, is that antibodies circulating in those who have recovered from Ebola offer protection to patients who have been exposed to or are developing infection with Ebola.

Pham was discharged on October 24, after five polymerase chain reaction (PCR) blood tests showed that she was free of the Ebola virus. PCR tests detect the genetic material of the virus and are the most sensitive tests available to identify Ebola infection.

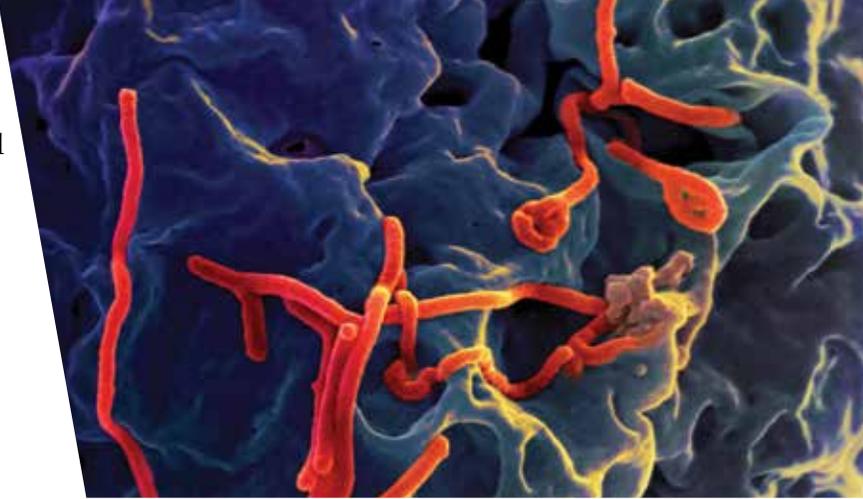
In addition to Pham, the NIH Clinical Center treated two medical personnel who were exposed to the Ebola virus while treating patients in Africa. Both were treated in the SCSU and were discharged when it was confirmed that they had not developed symptoms of infection.

Vaccine Development

NIH is playing a key role in international collaborations among private and public partners to accelerate the translation of decades of research into safe, effective Ebola vaccines.

Starting in September 2014, NIAID began testing two versions of an investigational vaccine co-developed by NIAID and GlaxoSmithKline at the NIH Clinical Center. Twenty healthy adult volunteers received a version containing genetic material derived from both the Zaire and Sudan Ebola virus strains, and another 20 adults received a monovalent version derived from only the Zaire Ebola species. This current candidate vaccine builds on three earlier NIAID-developed investigational Ebola vaccines which began Phase 1 clinical trial testing in 2003.

Separately, the NIH also began collaborate with



Scanning electron micrograph of Ebola virus budding from the surface of a Vero cell (African green monkey kidney epithelial cell line). Credit: National Institute of Allergy and Infectious Diseases (NIAID)

the U.S. Department of Defense to support NewLink Genetics Corp., a biopharmaceutical company in Iowa, in conducting Phase 1 safety studies of the investigational recombinant vesicular stomatitis virus Ebola vaccine, called VSV-EBOV, developed by and licensed from the Public Health Agency of Canada. Those clinical trials began in the fall at the Clinical Trials Center of Walter Reed Army Institute of Research in Maryland.

In addition to the investigational vaccines entering Phase 1 clinical trials, NIAID is supporting a variety of organizations in developing other vaccine approaches, including a multivalent Ebola/Marburg vaccine and investigational vaccine candidates against the Ebola, Marburg and rabies viruses.

For more information on the Ebola virus, visit www.cc.nih.gov/ebola.html

President Barack Obama visited the Clinical Center and Vaccine Research Center at the National Institutes of Health on Dec. 2, 2014. Obama was briefed on the investigational Ebola vaccine currently being tested at NIH. He then spoke at the Clinical Center on the need for continued research into the Ebola virus, U.S. assistance in treating Ebola in West Africa and the exemplary work of Clinical Center staff in treating Dallas nurse Nina Pham's Ebola infection.



International Collaborative Research Effort Brings Ugandan Family to the Clinical Center

Nodding Syndrome is a neurological condition – an epileptic encephalopathy – that affects thousands of children in South Sudan, Uganda and Tanzania. NIH researchers in the National Institute of Allergy and Infectious Diseases, the National Institute of Neurological Disorders and Stroke, the National Human Genome Research Institute and the NIH Undiagnosed Diseases Program, along with experts from the Centers for Disease Control and Prevention (CDC) and the World Health Organization, are working with experts in Uganda to try to identify the cause of this disease.

The CDC, working with the Ugandan Ministry of Health, has been studying a possible connection between Nodding Syndrome and river blindness (onchocerciasis), which is transmitted by blackflies and is endemic in the region. Researchers are interested in determining whether there might be genetic variations or autoimmune conditions that could make children more susceptible to Nodding Syndrome, especially if they have been infected with the parasitic worm that causes river blindness.

In the spring of 2014, through a collaboration between the CDC, the U.S. State Department and NIH, three teenagers affected by this disease came to the Clinical Center from their small rural village in Uganda, along with other members of their family and two Ugandan health workers, to participate in an extensive evaluation by the Undiagnosed Diseases Program. The three affected members of the family underwent a procedure to filter their blood as a treatment for possible autoimmunity, and all the members of the family who were present underwent a range of medical tests. The information collected from both affected and unaffected family members during their visit to the Clinical Center will help researchers determine whether there is a genetic predisposition to contract this disease.

While the most direct benefit may be for the thousands of children who suffer from this disease – which results in frequent seizures, a decline in mental capacity and even early mortality – insight into rare diseases frequently leads to important insights into common diseases as well, benefitting all of us.



Translator Irene Nakamya (far left) and translator Tom Azalia (far right) visit with the Ugandan family at the NIH Clinical Center in May 2014. Credit: Maggie Bartlett, National Human Genome Research Institute, NIH

Director's Awards Focus on Excellence

The 2014 Clinical Center Director's Annual Awards Ceremony presented over 300 awards to Clinical Center staff from multiple disciplines and departments.

Highlights included recognition for excellence in customer service, mentoring, enhancing the hospital's electronic medical records system, patient care and safety, teaching and training and the comprehensive response needed to treat a patient infected with the Ebola virus.

"Some of the hospital's unique facilities and amazing staff have been in the spotlight during the current Ebola crisis, but we also know that extraordinary work quietly happens here every day in countless ways to combat a wide range of both common and rare diseases. I believe that all of our staff plays a role in our success in furthering the nation's health – and that of the world," said Dr. John I. Gallin, director of the Clinical Center.



» Advancing Clinical Research

A Better Understanding of how Antibiotic Resistance Spreads Among Bacteria

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Around the globe, antibiotic-resistant bacteria render common healthcare-associated infections difficult, and at times, nearly impossible to treat. To advance understanding of this growing issue, researchers from the NIH Clinical Center and the National Human Genome Research Institute oversaw a two-year genomic and epidemiologic collection of more than 1,000 patient surveillance cultures and more than 400 environmental samples within the research hospital. They discovered that some bacteria are exchanging genes that cause antibiotic resistance.

In their paper, published in *Science Translational Medicine*, researchers described how they used a powerful new form of DNA sequencing to study the complete genome of bacteria samples and identify their antibiotic-resistance genes. They found that antibiotic-resistance genes could move from one bacterial species to another through the exchange of plasmids – small, mobile pieces of DNA – and thus transfer the ability to inactivate certain antibiotics.

This was among the first studies to use such detailed genomic sequencing methods to look at plasmid transfer in a hospital environment, and it demonstrated how the action may be contributing to

the increase in antibiotic-resistant bacteria around the world.

The study showed the tremendous value of accurate whole-genome sequencing to differentiate bacterial transmissions within the hospital from introductions of multidrug-resistant bacteria in patients who acquired them before admission to the Clinical Center.

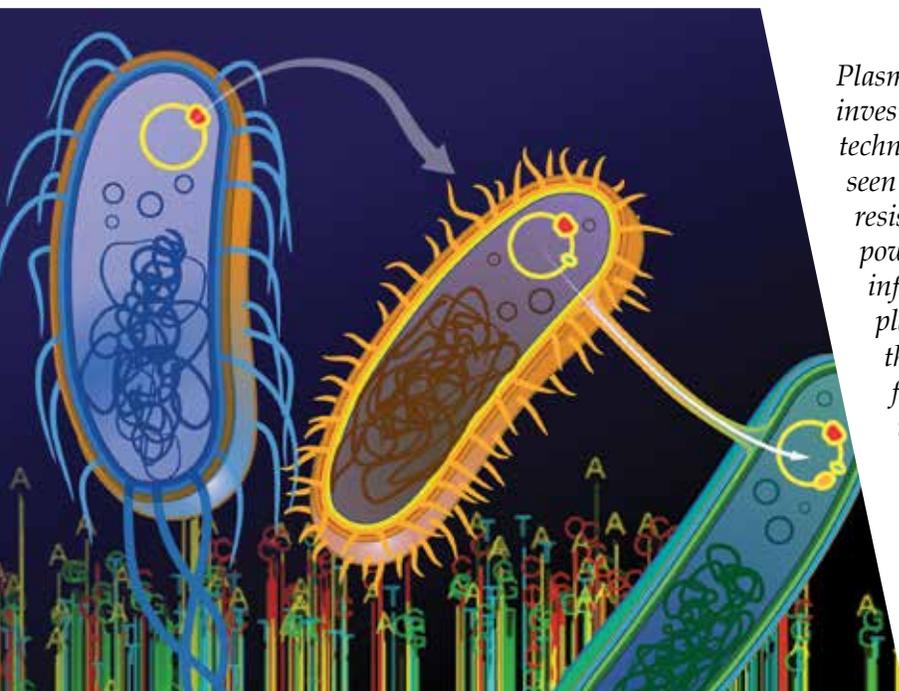
Overall, only a few bacterial isolates had swapped their antibiotic-resistance genes. Many plasmids carrying these genes are incompatible with each other or with some bacterial strains. Understanding the ground rules regulating plasmid trafficking is one of the most important research topics the NIH is currently involved in.

Regardless of the source of drug-resistant bacteria, the Clinical Center takes rigorous steps to monitor and minimize the spread of these infections. The Clinical Center performs approximately 15,000 surveillance tests per year, with some areas being tested twice weekly and others on a monthly basis. A positive culture of an antibiotic-resistant bacteria is found less than one percent of the time.

The NIH is committed to preventing healthcare-associated infections, isolating patients who are carriers of the bacteria, containing these bacteria when they do arise and researching global applications to prevent, treat and cure them.

More information:

www.ncbi.nlm.nih.gov/pubmed/25232178



Plasmid transfer between bacterial species can be investigated with single-molecule DNA sequencing technology. Plasmids, small circular mobile pieces of DNA seen in these three bacteria, can carry genes encoding resistance to antibiotics, including carbapenems, a powerful class of antibiotics used to treat serious infections. The bacterium on the left has a circular plasmid that moves to the bacterium in the middle. Once there, it acquires the second bacterium's unique gene for antibiotic resistance and continues to transfer that gene characteristic to the third bacterium, thus spreading the ability to resist antibiotics.

Credit: Darryl Leja, National Human Genome Research Institute NHGRI/NIH.

Improving Patient Safety Through Rapid Detection of Antibiotic-Resistant Microorganisms

Antibiotic-resistant bacteria and other microorganisms represent an urgent public health threat worldwide, and a particular challenge for the safety of patients in hospitals. Each year at least two million people in the United States alone are infected with antibiotic-resistant microorganisms, and at least 23,000 die as a direct result of their infections. Many more die from related complications.

Researchers in the Clinical Center microbiology lab are using a state-of-the-art mass spectrometry tool, the MALDI-TOF MS, to study bacteria and fungi. The MALDI-TOF is an analytical chemistry tool that helps identify the amount and type of chemicals present in a sample based on the mass of molecules involved. The researchers are developing techniques that will allow for rapid tracking of specific antibiotic-resistant microorganisms, including *Klebsiella pneumoniae*, which has been associated with outbreaks in hospitals around the world.

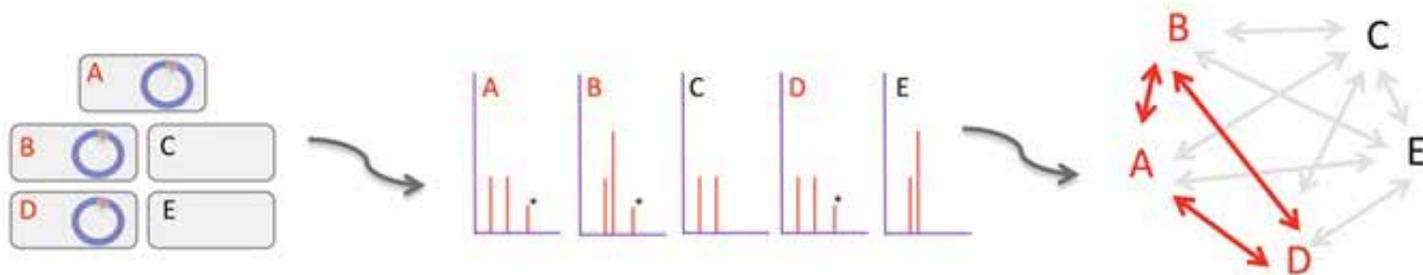
These techniques can help clinicians fight the spread of antibiotic resistance and decrease the exposure of patients to the kinds of bacteria that are most difficult

to treat. (See related story on page 21.)

“We’re also using mass spectrometry and next generation sequencing to investigate the biology of these organisms,” says Dr. Karen Frank, chief of the Microbiology Service in the Clinical Center’s Department of Laboratory Medicine. “By understanding the biology, we hope to find better ways to stop the spread of resistance genes between the bacteria. And thorough genetic analysis of these organisms and their patterns of resistance to antimicrobial drugs are helping us track changes in the organisms over time and in different geographic locations.”

The lessons learned from this work have important implications for ongoing, detailed investigation in the control of disease. The diverse patient population at the Clinical Center and the highly specialized teams of medical specialists treating them provide an opportunity for comprehensive investigations that could not be conducted anywhere else. All of this work helps physicians deal as effectively and as quickly as possible with the infections they are treating, and provides researchers with avenues for the study of potential future lifesaving therapies.

More information:
www.ncbi.nlm.nih.gov/pubmed/24850353



An illustration demonstrating how MALDI-TOF mass spectrometry-based plasmid identification could facilitate rapid epidemiologic tracking of a plasmid carrying an antibiotic-resistant carbapenemase gene in an outbreak. Isolates A, B, D contain a plasmid tracked by a unique mass spectrometry peak (marked with asterisks), allowing linkage of these isolates in the transmission map.



Screening of Adults with Chronic Health Care Needs

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A critical question facing the nation is how to manage the health of adults with ongoing, elevated and costly needs for care. Individuals with disabilities or with chronic health conditions that span entire lifetimes often experience major health problems and consume health care services at a higher rate than other adults. Many adults with chronic health conditions experience some form of disability related to their diseases.

Compared to healthy adults, adults with chronic health conditions use significantly more health care services and have more difficulty in accessing care. The Medical Expenditure Panel Survey of the Department of Health and Human Services estimates that the total medical costs for adults with chronic health care needs are roughly four times those of adults without chronic conditions. The out-of-pocket expenses for adults with chronic health care needs are almost nine times greater.

Identifying and caring for the needs of adults with chronic health conditions is important not only to the individuals, but also to health care providers. Through research sponsored by the Social Security Administration, the Clinical Center Rehabilitation Medicine Department developed a promising

method of screening and characterizing working-age adults with costly, elevated and sustained needs for health care services, including those with chronic health conditions and disabilities. This tool will assist in identifying patients with disabilities.

This methodological advance provides the rehabilitation field with a new tool for measurement, surveillance and service for those with chronic health care needs and is consistent with the Clinical Center's goal of providing research that will ultimately lead to improved patient care.

The knowledge gained by identifying, tracking and characterizing this important population will allow medical professionals to develop novel, coordinated, person-centered models of care that optimize health outcomes while containing costs.

"This work represents an important first step toward a more proactive and informed approach to improving health care for working age adults with chronic conditions and disabilities," said Dr. Elizabeth K. Rasch, staff scientist and chief of the Epidemiology and Biostatistics Section of the Rehabilitation Medicine Department.

More information:
www.ncbi.nlm.nih.gov/pubmed/21800744

Revised Blood Policy to Improve Patient Health

Each year, almost five million Americans need blood transfusions. Blood transfusions include the transfer of red blood cells (RBCs), which are critical cells in the blood that move oxygen from the lungs to the tissues and organs throughout the body. Patients with anemia, who do not produce enough RBCs on their own, and patients who lose RBCs following trauma or during surgery require transfusions to replace these vital cells. Patients receive RBC transfusions from the Clinical Center Department of Transfusion Medicine, which collects, stores and distributes RBCs to Clinical Center patients.

To provide the best care possible, the Department of Transfusion Medicine partnered with the Critical Care Medicine Department to study the shelf-life of RBCs. In tests with very sick dogs, the researchers found that RBCs in “older” blood were less effective than RBCs in “fresh” blood at keeping the dogs alive.

After having the collaborative research published in the journals *Blood* and *Transfusion*, and a review of this topic in the *British Journal of Haematology*, the Department of Transfusion Medicine has implemented a policy for shortening the storage of RBCs for transfusion to a shelf-life of 35 days. This is one week less than the current Food and Drug Administration-licensed shelf-life of 42 days. The scientific hypothesis is that shortening the shelf-life by seven days will improve the quality of stored RBCs and ensure improved patient outcomes after transfusions.

“The importance of RBC storage requires further study,” said Dr. Willy Flegel, the chief of the Laboratory Services Section. “In the meantime, the Department of Transfusion Medicine has implemented a transfusion strategy for using ‘fresher’ RBCs without disrupting blood availability.”

The NIH Clinical Center is the first institution in the U.S. to restrict the use of RBCs before the last seven days of the FDA-licensed shelf-life.

More information:
www.ncbi.nlm.nih.gov/pubmed/24460532

New Diagnostic Technique Helps Identify At-Risk Patients

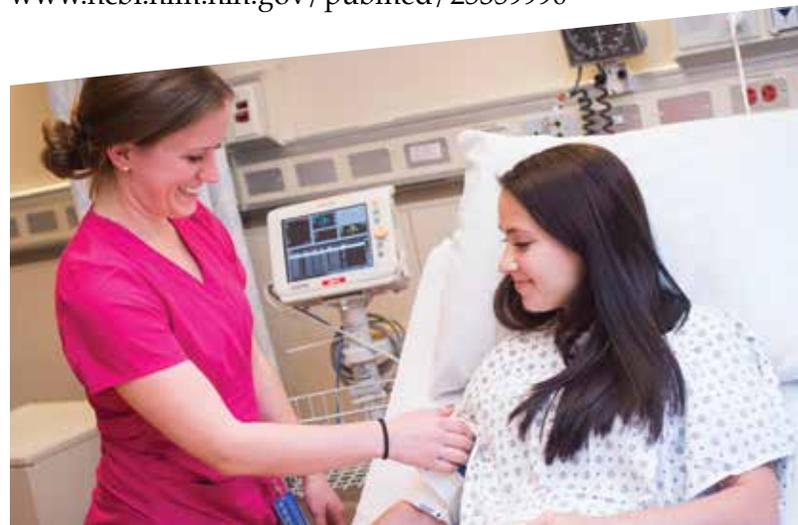
GATA2 deficiency is a genetic disease that predisposes patients to a higher risk of developing a number of medical complications and diseases, including acute myeloid leukemia, a type of blood cancer that begins in the bone marrow. GATA2 deficiency can share features with another bone marrow disease called aplastic anemia, making a correct diagnosis difficult.

With proper diagnosis and treatment, patients with GATA2 deficiency and leukemia have improved survival rates. Because the optimal treatment for GATA2 deficiency is very different from that for aplastic anemia, making a correct diagnosis is critically important.

Using flow cytometry, an antibody and fluorescence laser-based technique that can be used for studying cells in the blood, Dr. Katherine Calvo in the Hematology Section of the Clinical Center’s Department of Laboratory Medicine, in collaboration with Dr. Steven Holland in the National Institute for Allergy and Infection Diseases and Dr. Neal Young in the National Heart, Lung and Blood Institute, has developed a method for identifying patients with a high likelihood of having GATA2 deficiency, who should be referred for genetic testing.

This research, published in the journal *Blood*, will have a direct impact on diagnosing and caring for patients, as well as lead to a better understanding of both of these diseases.

More information:
www.ncbi.nlm.nih.gov/pubmed/25359990



Clinical Center Collaboration Tool Helps Researchers Unlock Data

Biomedical Tool Focuses on Sharing Information, Patient Privacy

Researchers at the NIH Clinical Center have a treasure trove of 40 years' worth of data. The challenge is making it available to scientists while protecting patients' confidentiality.

The Biomedical Translational Research Information System (BTRIS) provides access to clinical research data collected at the Clinical Center and other NIH Institutes and Centers. The Laboratory for Informatics Development, headed by Dr. James J. Cimino, developed this tool to advance research by letting scientists explore data in an uninhibited way and providing researchers with the flexibility to analyze different data sets.



500,000
patient volunteers



5 billion
distinct pieces of data



40 years
of data collection
from 1976 to 2015

This system, unique to NIH, is a "self-service" tool that allows researchers to access information in real time. It is configured to allow scientists to instantly expand or limit the data they want to examine. BTRIS also fosters a collaborative environment by notifying scientists when their research data has been accessed.

"We hope this will spur collaboration between the user and previous investigators," said Cimino.

Over the past year, BTRIS improved the user's experience and updated compliance with the 1996 federal Health Insurance Portability and Accountability Act (HIPAA) guidelines to protect patient data. The system was also upgraded to ensure

What Data Reside in BTRIS?

- » The Biomedical Translational Research Information System (BTRIS) has five billion distinct data points contributed mainly by 500,000 patients.
- » Scientists can access NIH data collected since 1976.
- » Data on currently active protocols are available to NIH intramural, or onsite, research team members.
- » Information is available in two ways: an identified format (with personally-identifiable information) and limited data set (which includes no personally-identifiable information).
- » The limited data sets offer four types of data: demographic, laboratory, medication and diagnosis.
- » Future plans include adding full-text documents, once patients' personal information has been removed, to enhance the information available to researchers.

that information is communicated more effectively to the investigators who collected the data. The updated database came online in July 2014, and allows the system's administrators to monitor how researchers approach the medical data while providing continuous enhancements.

Cimino emphasized, "We owe it to our human subjects, who have literally given their blood, sweat and tears, to make the maximum use of this data."

More information:
www.ncbi.nlm.nih.gov/pubmed/24303258

Innovative Imaging Software Assists Infectious Disease Research

Molecular and radiologic imaging is often used in clinical settings to detect and study infectious diseases. Researchers in the Clinical Center's Center for Infectious Diseases Imaging (CIDI) use state-of-the-art methods for Positron Emission Tomography (PET), Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI) scans to identify, analyze and treat severe diseases.

This year, CIDI produced imaging software innovations that can go one step further. Instead of simply identifying the existence of infectious disease, this new technology will help researchers highlight specific characteristics of a disease, such as how the body responds to infection. Understanding how infections operate and affect patients will help healthcare professionals better understand how to more effectively treat them.

CIDI is using this software to support multiple protocols at NIH, such as a tuberculosis study in the Clinical Center, where the imaging software will provide more information about this disease, which plagues one-third of the world's population. This software is also used in preclinical studies at the National Institute of Allergy and Infectious Diseases' Integrated Research Facility, which studies diseases such as Ebola, Middle East Respiratory Syndrome (MERS) and severe influenza.

Recent Ebola outbreaks have accelerated efforts to study and respond to this lethal disease. MERS killed about 30% of the patients infected with the disease in the Middle East, and influenza puts about 200,000 people in the hospital every year from seasonal flu-related complications.

CIDI also is implementing tools for 3D assessments of pulmonary disease, such as wall thickening, cavity formation and the development of other airspace abnormalities. This new technology can help medical professionals better understand the symptoms, measure severity and optimize treatment of these infectious diseases.

Clinical Center Researchers Develop Prostate Cancer Detection System

An estimated 29,480 men will die of prostate cancer this year, and 233,000 new cases will be diagnosed; however, clinicians are concerned that the disease is both under-diagnosed and over-treated. Clinical Center researchers have developed a technology that is rapidly changing the landscape of standard prostate cancer diagnosis and treatment.

Through a Cooperative Research and Development Agreement (CRADA), the Clinical Center's Radiology and Imaging Sciences Department has partnered with In Vivo/Philips to jointly develop an innovative biopsy system.

The technology is highly sensitive to the more aggressive prostate cancers and can diagnose prostate cancer in an office setting, without magnetic resonance imaging (MRI) machinery. In this way, the application simplifies the approach, workflow and overall cost of diagnosing and monitoring this disease.

This partnership leverages the multidisciplinary atmosphere of the Clinical Center alongside the tools of In Vivo/Philips to produce a novel system for identifying and better characterizing such a prevalent disease.

This partnership has allowed for the advances of increased prostate cancer detection in a vulnerable population and more effective monitoring of known cancers. The hope is that this will lead to longer, higher-quality lives and reduce the costs of medical treatment.

What are Cooperative Research and Development Agreements (CRADA)?

CRADAs provide Clinical Center researchers the opportunity to work with industry partners in collaborations that reduce the time it takes for research to advance from idea to testing and then to patients. By combining resources, government scientists and industry partners use the unique environment of the Clinical Center to test, refine, develop and facilitate the technology needed to address urgent clinical needs.

Clinical Center Launches First U.S. Clinical Research Nursing Residency Program



Participants in the 2014 Clinical Research Nursing Residency Program at the NIH Clinical Center.

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In a hospital focused on research as well as patient care, nursing teams require a distinctive set of skills. To help initiate new nurses to the unique needs of the Clinical Center, the Nursing Department's Nursing Education team developed a program to assist newly-licensed graduate nurses in the transition from nursing school to professional practice in clinical research nursing. This Clinical Research Nursing Residency Program is a rigorous, twelve-month curriculum to build critical thinking, professional practice skills and clinical skills in the context of a clinical research setting. The program is highly competitive and is attracting new graduate nurses from prestigious universities across the United States.

This program, the first of its kind in the United States, brings nurse residents together every one to two weeks for structured learning experiences. Education includes instructive classroom sessions, hands-on simulation, case studies, reflective practice, activities in

nursing units, shadowing colleagues and professional development and leadership activities. All of these experiences are conducted under the direction of nurse educators, individual instructors and unit leadership and all focus on the role of the nurse in clinical research. The first group of eight nurses began the program in the summer of 2013, and a second group of six nurses started in August 2014.

Significant effort has been invested in incorporating the extensive experience and expertise of colleagues across all fields of research in the NIH community. A major, indirect benefit of the residency program has been the simultaneous education of the nurse residents' instructors. This program strengthens the entire nursing team, which helps support both research and patient care.

Barriers to Stem Cell Treatments Discovered

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NIH scientists discovered a new complication in using stem cells therapies: many commonly used medications can interfere with stem cells' ability to treat diseased tissue.

Human stem cells have the ability to regenerate, which makes them useful for both research and for therapies for a wide range of diseases, including the treatment of Parkinson's and leukemia. Stem cells grown in the lab can become a variety of cell types to restore lost, damaged or aging muscle, nerve, blood or tissue. In regenerative medicine, stem cells are often "sent" by molecular agents to help treat diseased tissue.

Researchers at the Clinical Center Department of Radiology and Imaging Sciences are the first to observe the effects of medication interactions and the implications for stem cell therapy.

Medications such as ibuprofen can prevent stem cells from reaching their desired target.

Commonly-used medications such as ibuprofen can prevent stem cells from reaching their desired target, the diseased tissue. Right now, these medication interactions remain essentially unexplored and are not well-controlled for during cell therapy clinical trials. By controlling for these substances, healthcare professionals may improve the effects of cell therapy in research and treatment.

» Training the Next Generation



Nearly 80 clinical fellows from across the NIH attended the second annual Clinical Fellows Day on September 8, 2014.

Participants learned about how to develop new clinical research projects and enhance the NIH knowledge base, as well as how to take full advantage of the broad spectrum of available opportunities in a clinical research career.

NIH Earns Continued Accreditation for Graduate Medical Education

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The NIH Clinical Center serves as the sponsoring institution for 18 medical or surgical specialty and subspecialty graduate medical education training programs accredited by the Accreditation Council for Graduate Medical Education (ACGME), a nongovernment professional organization responsible for the accreditation of about 9,500 residency education programs nationally. The Institutional Review Committee of ACGME conducted a comprehensive review of the NIH Clinical Center as the sponsoring institution for these 18 training programs.

In recognition of its substantial compliance with the ACGME's institutional requirements for maintenance of accreditation, the Clinical Center was awarded the status of Continued Accreditation as a sponsor of graduate medical education programs for a period of 12 years. The ACGME's next institutional accreditation review of the Clinical Center will be conducted in October 2025.

Career and Research Support for NIH Clinical Fellows

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In collaboration with the NIH Clinical Fellows Committee, the NIH Clinical Center's Office of

Clinical Research Training and Medical Education organized and hosted the NIH Clinical Fellows Day on September 8, 2014. This trans-NIH event was a full-day, campus-wide professional and career development conference, open to all clinical fellows. In addition to presentations addressing career development, Clinical Fellows Day provided opportunities for attendees to build academic skills, including research manuscript and grant writing.

Presenters included Drs. Francis S. Collins, John I. Gallin, Anthony S. Fauci, Steven A. Rosenberg, W. Marston Linehan, Henry Masur, H. Clifford Lane, Steven M. Holland, Elaine S. Jaffe and Cynthia E. Dunbar.

Clinical Center Hosts the Operation Warfighter Internship Program

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Providing job skills training to injured military members who are awaiting medical discharge or a return to military service, the Operation Warfighter Internship Program is a workforce initiative supported by the Clinical Center. Participants have interned in rotations through the Rehabilitation Medicine Department, the Department of Clinical Research Informatics, the Materials Management and Environmental Services Department, the Family Lodge and the Office of the Deputy Director of Clinical Care/Nursing.

Students Sharpen Career, Research Skills

For eight weeks, the Clinical Center hosted students enrolled in high school, college and graduate schools to participate in a yearly Summer Internship Program. Nearly 40 students worked with mentors who are researchers and other health professionals and attended weekly lectures presented by Clinical Center investigators and administrators. The students also participated in the annual NIH Summer Poster Day and shared their research with the NIH community. Best intern and best mentor awards were presented at the closing reception.

Sabbatical in Clinical Research Management Shares Expertise

In 2009, the NIH Clinical Center launched the pilot for a Sabbatical in Clinical Research Management, designed for mid-career clinical research professionals. The program aims to assist those who are interested in developing clinical research programs at their local institutions, or to enhance the skills of researchers and administrators in certain core areas. Maintaining clinical quality, ensuring patient safety, institutional accreditation and legal and regulatory infrastructure are among the topics addressed.

In 2014, five professionals participated in the program, including two international physician-scientists and three U.S. researchers. As of September 2014, a total of 26 participants representing seven countries (the U.S., Brazil, China, France, Malaysia, Russia and Tanzania) have taken part in the program. The average length of sabbaticals has been 2.5 months. Although the majority of participants are physicians, nearly 40 percent are professionals from basic science, research administration or other backgrounds.

Participants select from a list of 26 electives, representing six core module areas. Leaders from across the Department of Health and Human Services (HHS), other federal agencies and

other entities provide participants with a combination of informative and experiential training related to the clinical research infrastructure.

Attendance at meetings and orientations, as well as shadowing experiences help participants fulfill their career development objectives and meet the needs of their specialized interests.

During his sabbatical from January to March 2014, Dr. Arvinder Loomba, a professor of Organization and Management from San Jose State University, focused on building his expertise in technology transfer and international development. Immediately after completing his sabbatical he was accepted into the Fulbright Specialist Program, where he will serve a five-year term focusing on business administration and medical product development.

Dr. Julie Makani, senior lecturer and Wellcome Trust fellow in hematology and blood transfusion at the Muhimbili University of Health and Allied Sciences in Dar es Salaam, Tanzania, is continuing her sabbatical through the spring of 2015. Her sabbatical is helping her build expertise in protocol development and collaborative research, as well as to enhance educational programs in clinical research in Tanzania.





A Clinical Center initiative supports Native Americans who pursue research careers. Program participants (from left to right) Kristen B-M Regini, BS, Tule River Yokuts Nation; Teresa Brockie RN, PhD, White Clay Nation; and, Deana Around Him, DrPH, ScM, Cherokee Nation, conducted NIH-supported research in 2014.

In 2014, four Native American scholars participated in this initiative, including a high school student, two recipients of NIH Intramural Research Training Awards and a Nurse Specialist for Research.

Members of the team studied depression and mental health-related outcomes in pregnant women who are on reservations and historical trauma and suicide risk in reservation-based youth. The Nursing Department provided research topic presentations via video conference, research training and yearly community visits with a rural reservation community located in Montana.

Bobby Pourier, the high school participant, was trained and mentored by postdoctoral and graduate students to better understand research. Pourier said the Clinical Center Nursing Department staff gave him a new perspective.

“I came through the gates of the NIH so nervous and unsure and I’m leaving with a plan, a new set of goals and a whole new outlook about my future.”

Initiative Addresses Shortage of Native American Scientists and Clinicians



Bobby Pourier

Native Americans, defined as American Indians and Alaska Natives, make up 1.2% of the U.S. population but are underrepresented in clinical trials and face acute shortages as nurse scientists and clinicians. The Clinical Center has developed an initiative to recruit Native American students into trainee positions. The goal is to create a long-term, sustainable plan for community and tribal-based research and research-career development.

Program for Veterans Encourages Diversity and Clinical Research Training

As a part of the NIH commitment to strengthen the outreach, recruitment and retention of veterans as employees, the Clinical Center Nursing Department is participating in the second year of the Veterans Incentive Program (VIP). This program helps corpsmen or medics re-enter civilian life while using the training they received in the military. Program participants have, or will be receiving, an honorable discharge from the military.

“It’s a wonderful opportunity for veterans — and a wonderful opportunity for the Clinical Center,” said Dr. Clare Hastings, chief of Nursing Research and Translational Science. “This project has been designed by staff leaders in both NIH Human Resources and the Clinical Center Nursing Department, who themselves have service as corpsmen or medics. The VIP program allows us to explore another avenue

for recruiting talent into clinical research while at the same time providing a unique opportunity for our returning veterans.”

The four candidates accepted in 2014 were highly-motivated individuals interested in pursuing new careers as registered nurses. Individuals who successfully complete the program, receive their nursing degree and become state-licensed will be encouraged to apply for permanent nursing positions at the Clinical Center as a Clinical Research Nurses.

Clinical Center Employs One Out of Eight Veterans at NIH



1,016

Total U.S. military veterans at NIH

13.5%

of that total at the Clinical Center - 138

» Staff Achievements



Commander Margaret Bevans, PhD, RN, AOCN, program director and a clinical nurse scientist in the Nursing Department, was inducted as a fellow into the American Academy of Nursing.



Juan J.L. Lertora, MD, PhD, director of the Clinical Pharmacology Program in the Office of Clinical Research Training and Medical Education, was selected as one of the 2014 recipients of the “Premio RAICES” (Roots Award) instituted by the Argentine Ministry of Science, Technology and Innovation. He also received the 2014 Henry W. Elliott Distinguished Service Award from the American Society for Clinical Pharmacology and Therapeutics (ASCPT).



Frederick P. Ognibene, MD, FCCM, FACP, deputy director of Educational Affairs and Strategic Partnerships and director of the Office of Clinical Research Training and Medical Education was named Master of Critical Care Medicine by the Society of Critical Care Medicine.



Helen Mayberry, RN, MS, nurse consultant at the Clinical Center was presented with the NIH ‘Mission First, Safety Always’ award by the Office of Research Services Division of Occupational Health and Safety.



Gwenyth Wallen, PhD, RN, the chief of Nursing Research and Translational Science was awarded the NIH National Heart, Lung, and Blood Institute Director’s Award for Diversity in recognition of exceptional work to expand the diversity of the populations recruited in NHLBI protocols.



Peter Herscovitch, MD, FRCP(C), FACP, director of the Positron Emission Tomography (PET) Department became President of the Society of Nuclear Medicine and Molecular Imaging.



Ronald M. Summers, MD, PhD, FSAR, senior investigator and staff radiologist chief of Clinical Image Processing Service and Imaging Biomarkers and Computer-Aided Diagnosis for the Laboratory Radiology and Imaging Sciences, was appointed a consultant to the Editor for the journal Radiology.



David Bluemke, MD, PhD, MsB, FAHA, FACR, director of Radiology and Imaging Sciences and senior investigator, for the National Institute of Biomedical Imaging and Bioengineering received the Alexander R. Margulis Award for Scientific Excellence from the Radiological Society of North American (RSNA).



Leighton Chan, MD, MPH, chief of the Rehabilitation Medicine Department received two of highest honors in the field of Physical Medicine and Rehabilitation. In March, the Association of Academic Physiatrists presented him with the Distinguished Academician Award. He is the youngest individual ever to receive this honor. In November, he also received the Distinguished Public Service Award from the American Academy of Physical Medicine and Rehabilitation.



Elizabeth K. Rasch, PT, PhD, staff Scientist in the Rehabilitation Medicine Department won the Rene Jaheil Award for Excellence in Disability Research for her work on Understanding the Connection between Heavy Health Care Use, Chronic Conditions and Disabilities among Working Age Adults in the U.S. This award was presented at the Academy Health Meeting in San Diego, Calif.



Marion Danis, MD, head of the section on Ethics and Health Policy in the Department of Bioethics was awarded the 2014 ABIM Foundation Prize for the Top Article in Medical Professionalism. The article: “Views of US Physicians About Controlling Health Care Costs” was co-authored by eight colleagues and published in the Journal of the American Medical Association.

» Staff Achievements



James J. Cimino, MD, chief of the Clinical Center's Laboratory for Informatics Development, was added as one of 70 new IOM members. Election to the IOM is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.



Franklin G. Miller, PhD, senior faculty with the Department of Bioethics was notified by Thomson Reuters that he is among the top 1% of researchers for most cited documents in their specific field.



Michael Iadarola, PhD, CC, DPM, senior research scientist in the Department of Perioperative Medicine, received the prestigious Frederick W. L. Kerr Basic Science Research Award from the American Pain Society.

» New appointments



Dr. Tara Palmore will serve as the new Hospital Epidemiologist at the Clinical Center. Palmore was Deputy Hospital Epidemiologist for the past seven years, working alongside the previous lead, Dr. David Henderson. Henderson will continue as Deputy Director for Clinical Care and Associate Director for Hospital Epidemiology and Quality Improvement.



Eric Cole, MS, was appointed as the new chief of the Office of Administrative Management for the Clinical Center in August 2014. He had previously served as the Clinical Center's deputy chief of the Office of Administrative Management and as the chief information officer at the NIH Office of Research Services and Office of Research Facilities.

Advisory Board for Clinical Research

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 the 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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University of Chicago Medical Center

Vice Chair: Kate E. Walsh, MPH
President and CEO
Boston Medical Center

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Gary H. Gibbons, MD
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Alan Guttmacher, MD
Director
Eunice Kennedy Shriver National Institute of Child Health and Human Development

Steve M. Holland, MD
Chief, Laboratory of Clinical Infectious Diseases
National Institute of Allergy and Infectious Diseases
Deputy Director for Intramural Clinical Research, National Institutes of Health

Rebecca D. Jackson, MD
Director, Center for Clinical and Translational Science
Associate Dean for Clinical Research
The Ohio State University College of Medicine

T. Jake Liang, MD
Chief, Hepatology Service
Chief, Liver Diseases Branch
Deputy Director for Translational Research
National Institute of Diabetes and Digestive and Kidney Diseases

Lilly Marks
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University of Colorado
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Professor of Medicine
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Medical Director, Pediatric Clinical Research Center, UCSF Clinical and Translational Sciences Institute

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Medicine and Pharmacology
Associate Director, Institute for
Translational Medicine and
Therapeutics, Perelman Medical School,
University of Pennsylvania

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Indiana University
Associate Dean for Translational Research,
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Director, Indiana Clinical and Translational Sciences Institute

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Director
National Institute of Drug Abuse

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Scientific Director for Basic Research
Director, Center for Cancer Research
National Cancer Institute

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Chief, Genitourinary Section,
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National Cancer Institute

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Director, Clinical Center

Michael M. Gottesman, MD
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National Institutes of Health

Executive Secretary

Maureen E. Gormley, RN, MPH, PhD
Chief Operating Officer, Clinical Center

Senior Staff Support

Richard G. Wyatt, MD
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Office of Intramural Research
National Institutes of Health

Medical Executive Committee Members

The Medical Executive Committee, comprised of the various clinical directors of the NIH intramural clinical research programs and other senior medical and administrative staff, advises the Clinical Center Director and develops policies governing standards of medical care in the Clinical Center. The Committee represents and acts for the Medical Staff and other clinical professionals in the Clinical Center, and enforces the rules and policies of the Clinical Center.

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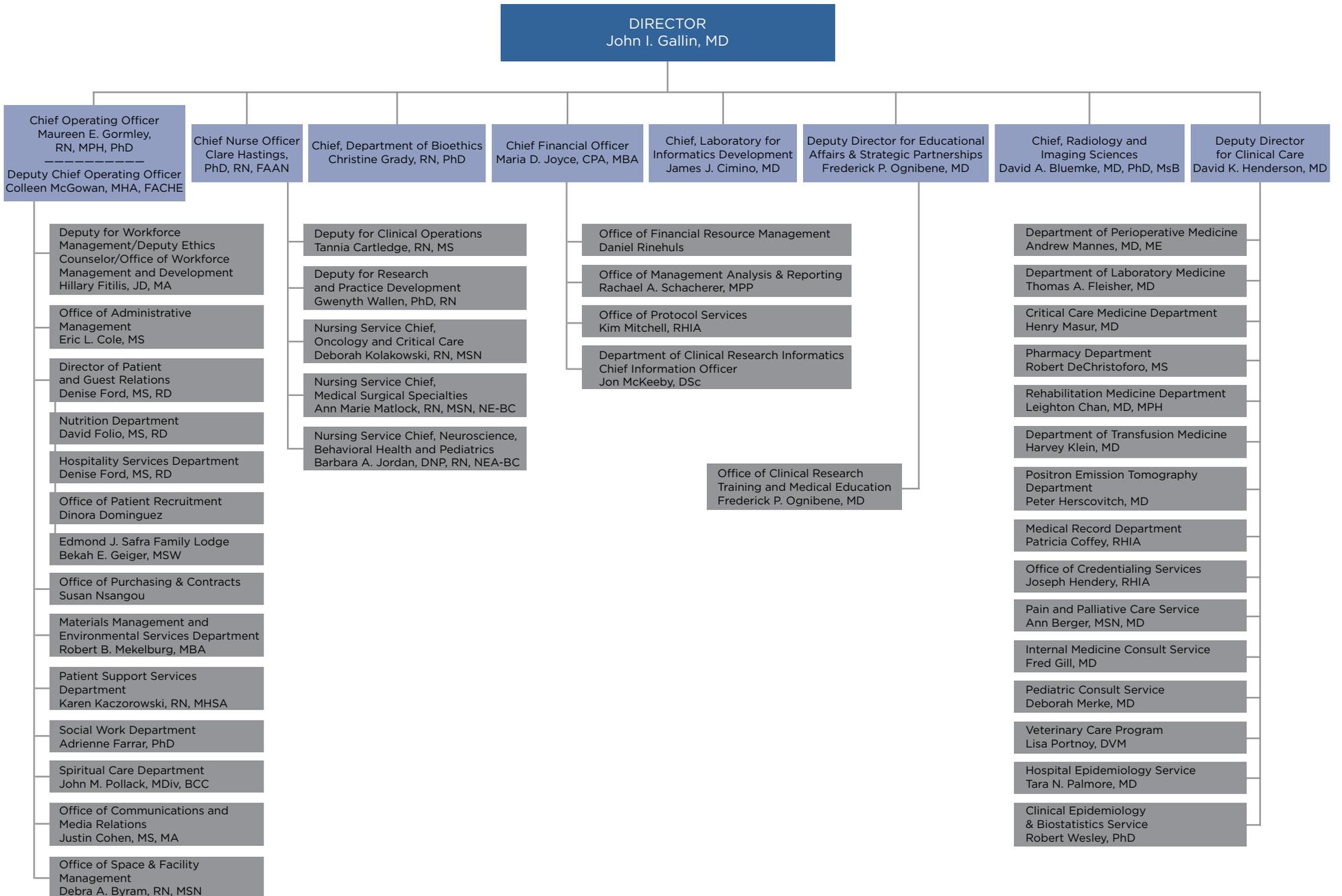
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NIH Clinical Center Organizational Chart

December 2014



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)

Unice 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 on Minority Health and
Health Disparities (NIMHD)

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 for
Advanced Study in the Health Sciences (FIC)

National Center for Complementary and
Integrative Health (NCCIH)

National Center for Advancing Translational
Sciences (NCATS)

NIH Clinical Center (CC)

