2014

National Institutes of Health Clinical Center Strategic and Annual Operating Plan

Environmental Assessment

Demographics, Activity, and Stakeholder Input

Warren G. Magnuson Clinical Center
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NIH Clinical Center

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Environmental Assessment

The Clinical Center's environmental assessment consists of stakeholder input, recommendations from governance and advisory groups, and an evaluation of the key influencing factors in the current environment.

Governance and Advisory Groups

- Clinical Center Governing Board
- NIH Advisory Board for Clinical Research
- Medical Executive Committee
- Board of Scientific Counselors
- Joint Commission
- Other Accreditation Bodies

Stakeholder Input

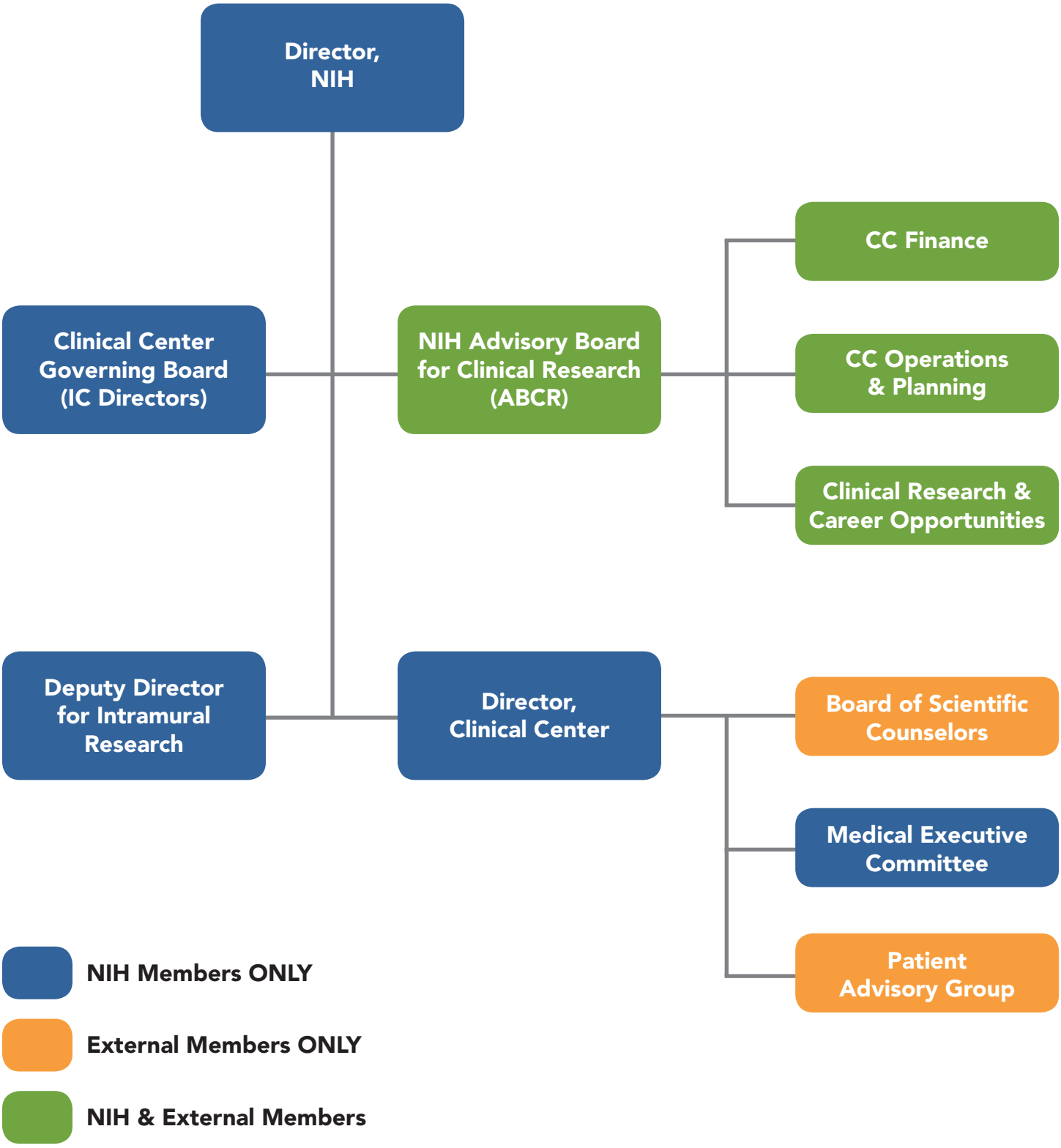
The Clinical Center considers the interests of its stakeholders when developing the strategic and annual operating plan, informing development of strategic goals and annual targets. Managing effective relationships with key partners of the Clinical Center fosters accountability and guides priority setting.

INTERNAL	EXTERNAL
Institutes	Referring Physicians
Employees	Clinical Research Trainees
Patients	Outside Investigators

Key Influencing Factors in the Current Environment

- Insurance Billing Pilot for Patient Services/U.S. Congress
- Ongoing Federal Budget Constraints
- Accountable Government Initiative — Update on Performance Management Agenda
- Executive Order to Promote Efficient Spending
- HHS Strategic Plan 2010-2015
- Health Care and Biomedical Science Trends
    - o Patient Safety and Clinical Quality
    - o Pharmacogenomics and Molecular Genetic Testing
    - o Whole Exome Sequencing
    - o Platforms for Microbial Diagnosis (MALDI-TOF) Mass Spectrometry
    - o Patient Safety and Clinical Quality
    - o Information Technology Development

Governance and Advisory Structure



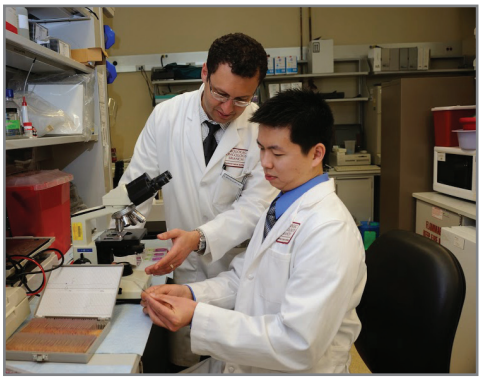
Governance Bodies

CLINICAL CENTER GOVERNING BOARD

The Clinical Center Governing Board (CCGB), consisting of Institute/Center Directors, was established in December 2010 following recommendations by the Congressionally-appointed NIH Scientific Management Review Board (SMRB). The CCGB serves as the internal advisory board to the Director, NIH, providing advice and recommendations of both a strategic and operational nature. Additionally, the CCGB addresses cross-cutting scientific and administrative issues, such as the financial policies and structure underpinning the Clinical Center budget. The CCGB also provides:

- Strategic and operational policy direction and oversight of the Clinical Center that aligns with the broader goals of the NIH, and its mission meets Institute and Center (IC) research needs, given available resources.
- Policy and operational recommendations on cross-cutting scientific and administrative issues that affect both the NIH's ICs and the Clinical Center.
- Recommendations on the Clinical Center's annual budget request in light of the overall NIH budgetary environment.
- Recommendations on the optimal size and scope of the Clinical Center and how best to maximize the quality of research conducted, given available resources.
- Strategic and operational oversight over changes to the mission of the Clinical Center, including its proposed expansion as a national resource available to both intramural and extramural investigators.
- Oversight of the implementation of SMRB recommendations that have been accepted by the Director, NIH.

The CCGB is complementary to the role of the NIH Advisory Board for Clinical Research (ABCR), providing a more comprehensive perspective on NIH budgetary matters, strategic planning, and operational integration of the intramural clinical research programs. The CCGB keeps abreast of the work of the ABCR, considering ABCR recommendations as it carries out its advisory and board responsibilities.



Advisory Groups

NIH ADVISORY BOARD FOR CLINICAL RESEARCH

The NIH Advisory Board for Clinical Research (ABCR) is charged with providing guidance to integrate the vision, planning, and operations of the intramural clinical research programs of the NIH. The Board advises, consults with, and makes recommendations to the Director, NIH, and other key leaders. Composed of nine extramural scientists and experts in health care administration and eight NIH intramural scientists, the Board provides guidance for trans-NIH strategic planning and advises on the budget and operating plan of the Clinical Center. The Board spent much of 2013 discussing the feasibility of insurance billing for patient services at the Clinical Center, the efforts to open the doors of the Clinical Center to outside investigators, and the variation in role of staff clinicians across the organization. The ABCR works closely with the CCGB, providing an essential perspective on academic medical center hospital administration, extramural clinical research, and contemporary leadership and management strategies.

MEDICAL EXECUTIVE COMMITTEE

The Medical Executive Committee (MEC) advises the Clinical Center Director on issues related to clinical quality and patient safety, develops policies governing standards of medical care in the Clinical Center, and has oversight of medical staff activities. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives. The group meets twice monthly and, among its many tasks, is responsible for development and oversight of the medical staff bylaws.

BOARD OF SCIENTIFIC COUNSELORS

The Clinical Center has a small portfolio of independent research conducted by the investigators who work in its clinical departments and who provide essential clinical support services to Institute clinical researchers. The Board of Scientific Counselors (BSC) of the Clinical Center was established in October 1990 and advises the NIH Director, NIH Deputy Director for Intramural Research, and the Clinical Center Director regarding the Clinical Center's intramural clinical research programs. The BSC conducts quadrennial reviews of Clinical Center research to assess the quality of the science and to evaluate the performance of independent investigators. These reviews provide an objective evaluation of the independent research programs of the Clinical Center and the work of individual scientists. Expert scientists from outside the NIH participate as members of this review group.

PATIENT ADVISORY GROUP

A major source of patient feedback is the Patient Advisory Group (PAG), a forum established in 1998 and open to all patients and their families. The PAG meets semiannually, and as needed, with the Director of the Clinical Center and senior staff to discuss issues of concern and make recommendations to improve efforts for providing the highest quality research and patient care services.

JOINT COMMISSION

The Joint Commission evaluates and accredits nearly 16,000 health care organizations and programs in the United States. An independent, not-for-profit organization, the Joint Commission is the nation's predominant standards-setting and accrediting body in health care. Since 1951, the Joint Commission has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations. For example, standards are set for such areas as medical and nursing staff credentialing, fire and emergency responses, patient safety, and continuous improvement of the services provided for patients. The Clinical Center is surveyed every three years and received full accreditation in its last survey in 2012.

OTHER ACCREDITATION BODIES

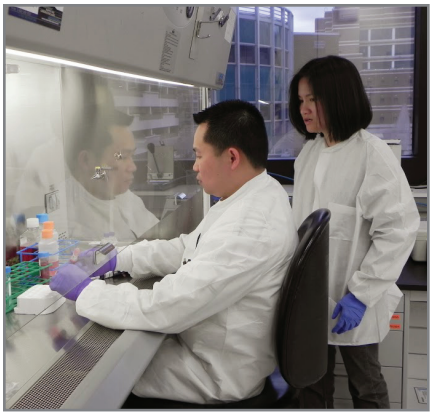
The Clinical Center seeks accreditation from the following subspecialty bodies:

Accreditation Council for Graduate Medical Education (ACGME)

ACGME is responsible for the accreditation of graduate medical training programs within the United States. Accreditation is accomplished through a peer review process and is based upon established standards and guidelines. The NIH and Clinical Center are institutional sponsors of 16 ACGME-accredited programs.

College of American Pathologists (CAP)

The Clinical Center's Department of Laboratory Medicine was accredited in 2012 by the CAP. The peer-to-peer inspection is conducted every two years as part of the CAP's Commission on Laboratory Accreditation. The Clinical Center's Department of Laboratory Medicine is one of more than 6,000 nationwide CAP-accredited laboratories.



Institute Input

OVERVIEW

The NIH is comprised of 27 Institutes and Centers (ICs) whose scientific activities include basic research that explores the fundamental workings of biological systems and behavior, studies that examine disease and treatments in clinical settings, prevention, and population-based analyses of health needs. The NIH Office of the Director, Deputy Director for Intramural Research, provides leadership, oversight, and coordination for the intramural research enterprise. Eighteen of the NIH ICs conduct clinical research at the Clinical Center generating a total study portfolio of 1,530 protocols in FY2013.

INSTITUTE PLANNING MEETINGS

Every fall the Clinical Center holds meetings with each Institute (Institute Directors, Scientific Directors, and Clinical Directors) to explore clinical research priorities. The Clinical Center budget is developed to support these goals. Additionally, ongoing interactions with the Institutes throughout the year inform the development of the Clinical Center's operating plan and help ensure effective allocation of scarce resources. The goal is to align Clinical Center plans with Institute priorities for clinical research while delivering high quality patient care.

Since new IC initiatives are generally implemented over multiple years, many of the themes captured represent affirmation of issues carrying over from prior years with updates provided.

Highlights from the 2013 Fall Planning Meetings

A set of themes or highlights reflecting challenges, key areas of growth, and change in the intramural clinical research program are compiled from annual IC/Clinical Center Planning Meetings.

1. Increased Demand for Transfusion Medicine Services

Several institutes indicated increased demand for apheresis services provided by the Department of Transfusion Medicine (DTM). This increased demand has occurred in an environment in which the DTM facility infrastructure requires upgrade and modernization. Institute stakeholders uniformly endorsed the short, intermediate, and long-term plans developed by the Clinical Center and the NIH Office of Research Facilities (ORF) to address these needs, including the concept for a CRC addition that addresses the needs of the five departments that did not move into the CRC when it was built. In this plan, DTM will have adequate room to meet anticipated demands for its services and will be relocated to four floors of the E-wing of Building 10 into fully renovated space.

2. Increased Demand for Pediatric Services

Historically, the Clinical Center has not provided care for very small children and has always followed the general guideline of not admitting children less than 2 years of age and/or less than 10 kg in size. Several Institutes (NCI, NICHD, NIAMS, NIAID and NHGRI) continued to express desire for the Clinical Center to provide the infrastructure necessary to support the care of smaller children, ultimately perhaps even neonates. Investigators want to be able to conduct these studies as a logical extension of Clinical Center investigators' long-standing interest in genetically-determined rare diseases and desire on the part of investigators to intervene as early as possible for maximum patient benefit. The determination as to whether the Clinical Center should provide care for very small children is an NIH community decision.

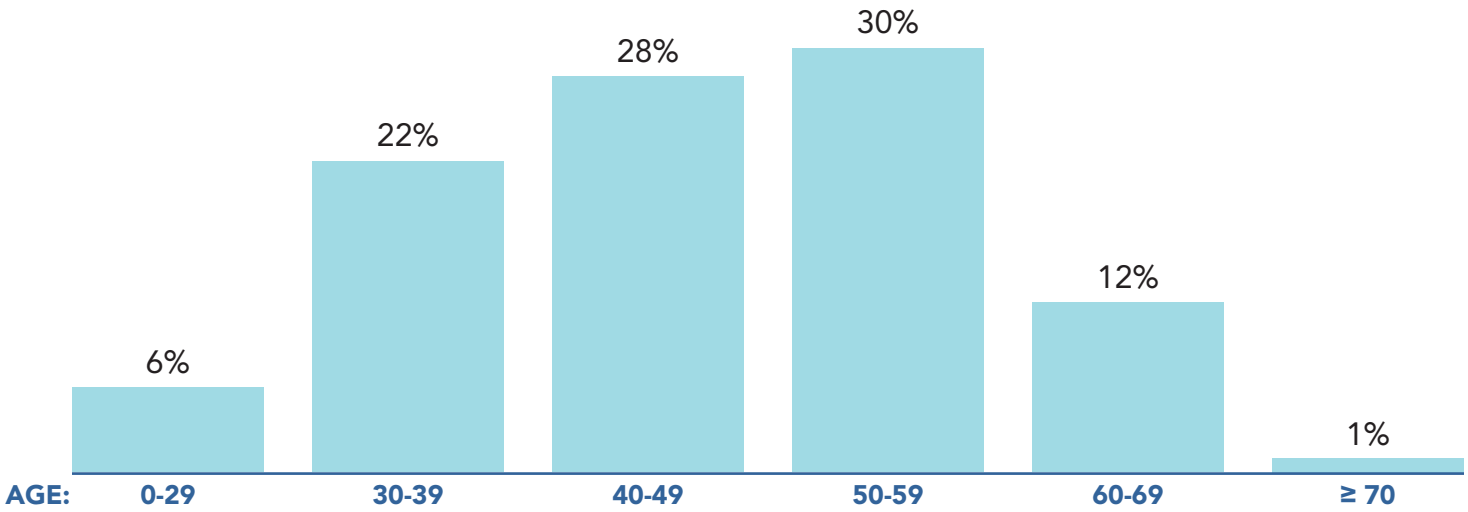
Employee Demographics

OVERVIEW

The Clinical Center attracts professionals with diverse backgrounds and a strong commitment to clinical research. The Clinical Center's Office of Workforce Management & Development (OWMD) strives to foster a committed, high-performing workforce by providing tools, services and training that: empower leaders with the knowledge and skills to manage a federal workforce; develop staff to enhance performance and foster the next generation of leaders; assist supervisors and managers to address organizational and personnel issues; and ensure effective recruitment, retention and engagement strategies. The Clinical Center is dedicated to developing its workforce and enhancing the work environment to optimize staff productivity and engagement.

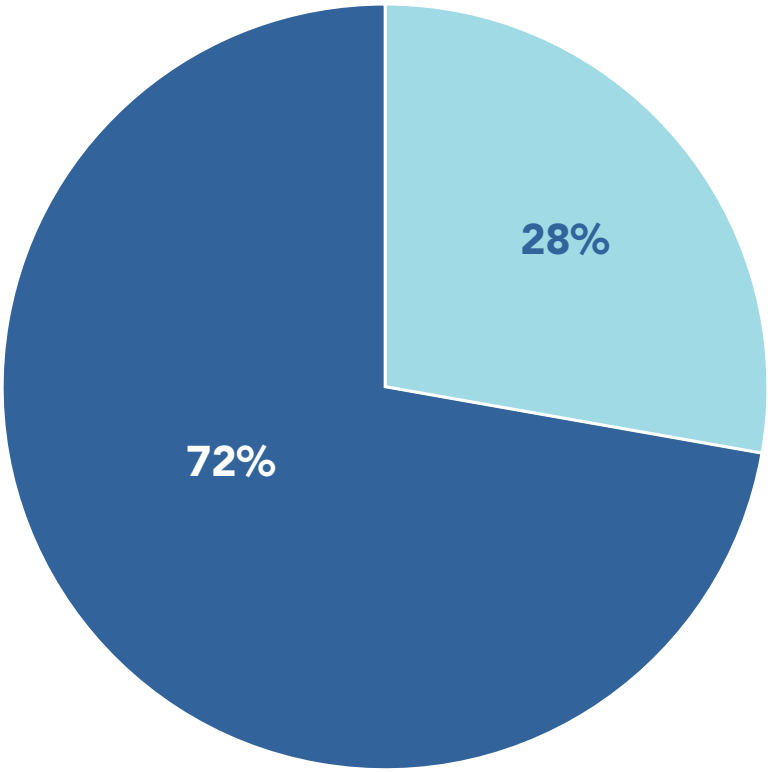
Key Workforce Data	FY2010	FY2011	FY2012	FY2013
FTE utilization	1,898	1,904	1,865	1,857
Turnover rate (Most recent turnover data for MD hospitals = 14.8%)	7.8%	8.0%	8.7%	9.7%
% retirement eligible	12.1%	12.4%	13.6%	15%
Average age of employees	45.9	46.3	47.9	49
Average years of government service	11.9	12.1	13.4	13.6

CC Employees by Age (FY2013) (N = 2,100)



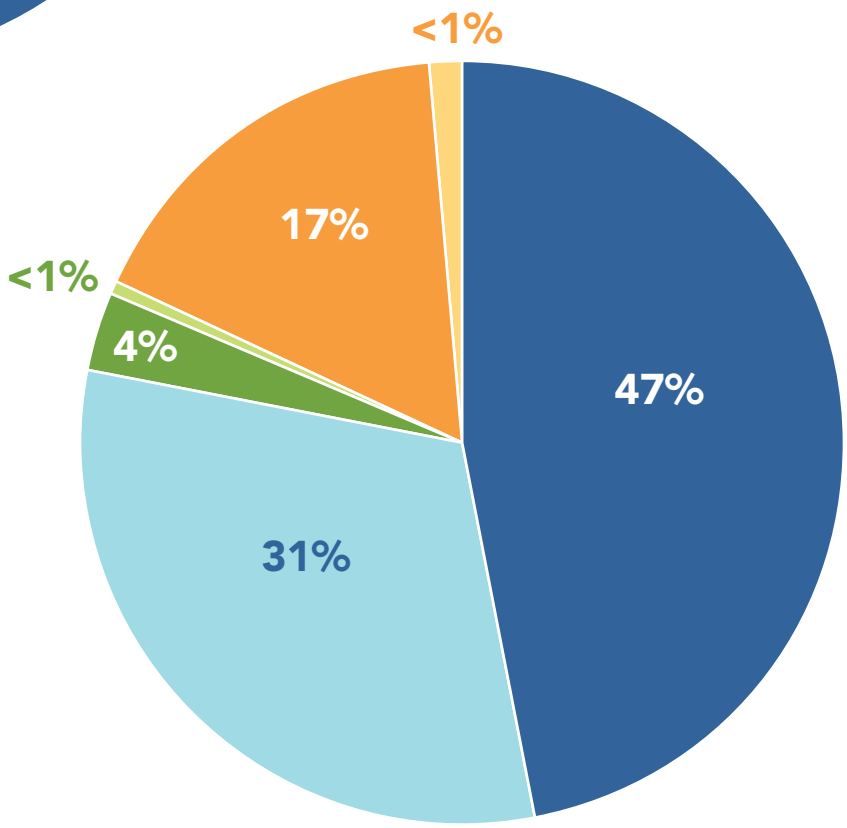
Employee Demographics

CC Employees by Gender and Race/Ethnicity (FY2013) (N = 2,100)



Gender

- Female
- Male



Race/Ethnicity

- White/Non-Hispanic
- Black/Non-Hispanic
- Hispanic
- American Indian/Alaskan
- Asian/Pacific Islander
- Not Reported

Employee Input

SOURCES OF INPUT

1. **Clinical Center Annual Workforce Analysis Report** – Annual analysis of the Clinical Center workforce by department, occupational series and pay plan on statistics such as turnover, retirement eligibility, age, years of service, awards, and pay rates.
2. **Leadership/Supervisory Course Evaluations** – Evaluations distributed to participants of Clinical Center leadership and supervisory training programs to obtain feedback on issues facing the organization, content, and presentation.
3. **Employee Viewpoint Survey** – Government-wide survey, administered by the Office of Personnel Management, to obtain employee perceptions on drivers of job satisfaction, commitment, and engagement.
4. **Clinical Center Recruitment and Exit Surveys** – Brief surveys sent to new and departing Clinical Center employees to gather feedback for employee engagement and retention.

WHAT ARE THE EMPLOYEES TELLING US?

Developing Our Future Leaders – Succession Planning

In workforce surveys, employees express a desire for additional training and development opportunities. In addition to its robust training curriculum in clinical research, the Clinical Center makes a concerted effort to develop leaders (both scientifically and administratively). Consistent with the federal workforce in general, 39% of employees in senior leadership positions at the Clinical Center will be eligible to retire at the end of FY2017, as well as 43% of Clinical Center supervisors. This reality highlights the need for effective succession planning. The Clinical Center continues to ensure that all supervisors receive leadership training via the 12-month cohort curriculum, "Clinical Center Fundamentals of Supervision," and also offers the 8-month cohort curriculum "Clinical Center Team Lead Fundamentals" for Clinical Center Team Leaders. In order to ensure staff engagement and development at all levels of the organization, in FY2013 the Clinical Center also launched a new 5-month cohort curriculum for employees who have demonstrated potential to be future leaders. The program, entitled "Aspiring Leaders," is designed to increase their knowledge of effective communication, managing change, use of power and influence, systems thinking, and collaboration.

The capacity for leadership exists at all levels in an organization, which is the premise for offering the Clinical Center Brown Bag Series--a program open to all Clinical Center staff. The FY2013 Brown Bag series "Back to the Basics: Essentials for Employee Success" was extremely well received by staff with over 170 employees from 25 departments attending at least one session. In FY2014, the Clinical Center will be launching the next Brown Bag Series focusing on leveraging diverse perspectives. Topics will include using self-awareness to appreciate and manage differences, recognizing micro-inequities in the workplace, examining power differentials, and exploring lessons learned from diverse perspectives on the furlough.

Training and mentoring future leaders are cornerstones of succession planning. In addition to offering training and mentoring programs, the Clinical Center conducts a robust workforce analysis to assist managers in workforce planning and development.

Employee Input

Clinical Center Employee Surveys

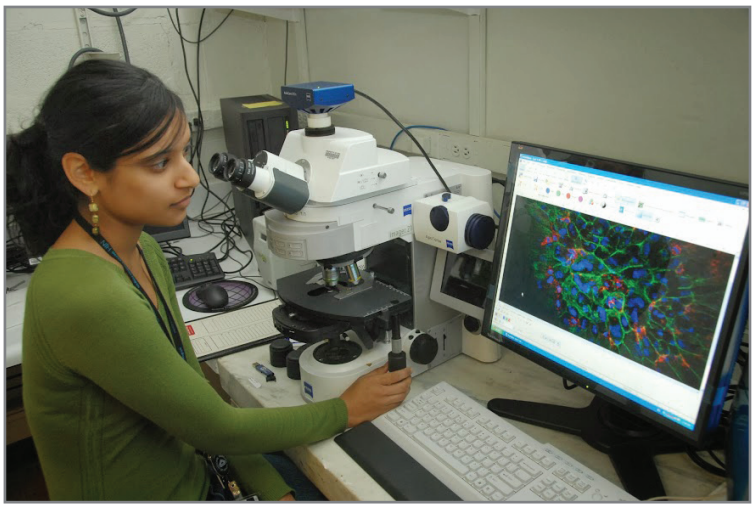
To obtain additional feedback from employees, the Clinical Center conducts a variety of employee surveys. The results are analyzed to offer customized recommendations for each Clinical Center Department to increase employee retention and engagement.

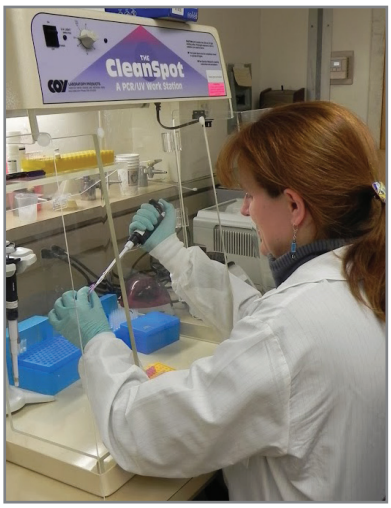
Employee Recognition

Employee recognition has been deemed critical by not only Clinical Center employees but employees throughout NIH and the federal workforce, especially given current federal limits on cash awards and tight budgets. In 2013, the Clinical Center introduced a new Employee Recognition Assessment tool for supervisors to use during their PMAP meetings. This tool is designed facilitate communication with staff regarding the forms of recognition they value most. Supervisors felt this tool was very helpful in getting to know their employees' preferences and found it to be a great resource for engaging and assisting in retaining their staff.

Surveys Related to Quality of Care and Services Provided by Clinical Center Departments

The Clinical Center conducts operational reviews of its departments on a 4-year cycle, evaluating the efficiency and quality of their operations. External and internal NIH experts in the particular area being reviewed dedicate a day and a half at the Clinical Center to develop recommendations on improvements in cost, productivity and effectiveness. As part of these reviews, the Clinical Center elicits feedback from Clinical Center and IC staff on the quality of the care and services provided by each department undergoing review. Feedback is collected through a web-based survey administered over a two-week period preceding each review. Survey results are reported to Clinical Center leadership and the review team. These results are used by the review team as they develop their findings and recommendations.





Patient Demographics

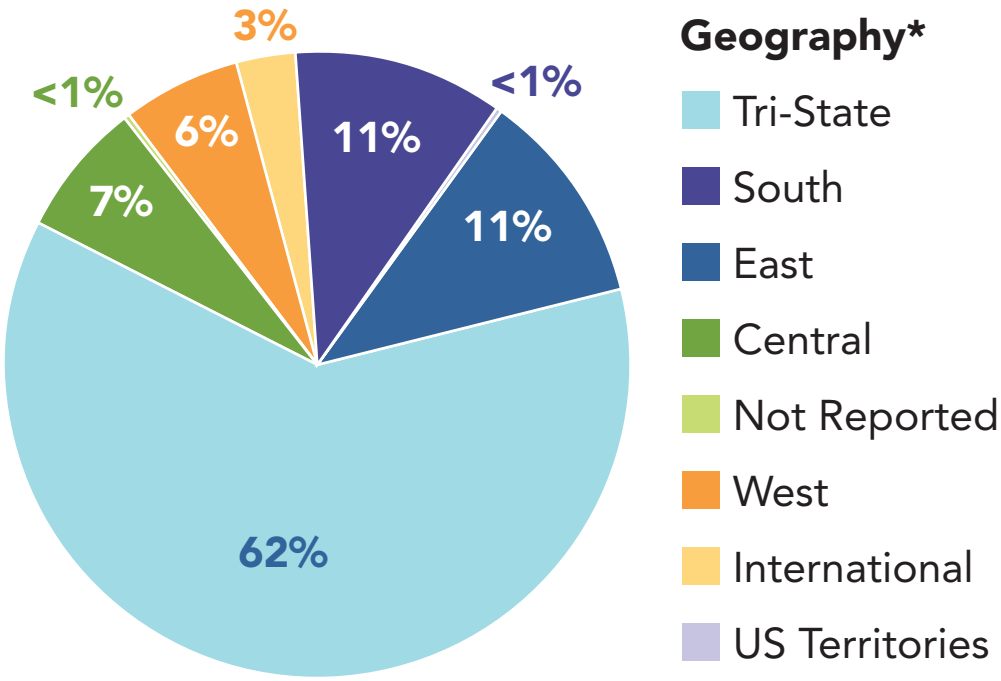
OVERVIEW

Patients come to the NIH from the United States and abroad to participate in clinical research. Together with their physicians, patients are partners in the search for scientific and medical answers. Clinical Center patients represent a diverse mix of ages, races, cultures, and socio-economic groups.

Key Patient Activity Data	FY2010	FY2011	FY2012	FY2013
New patients	10,086	10,686	10,694	10,195
Admissions	6,000	6,082	5,916	5,887
Inpatient days	56,502	56,594	54,971	51,418
Outpatient visits*	95,799	101,942	102,169	102,119
Average daily census	154.8	155.1	150.2	140.9
Average length of stay (days)	9.4	9.2	9.3	8.9

*A system modification was performed on outpatient census in January 2013. The results of this modification more accurately align historical outpatient census.

CC Patients by Geographic Area (FY2013) (N = 23,543)



***Regions**

Tri-State: DC, MD, VA

South: WV, NC, KY, TN, SC, AR, LA, TX, MS, AL, GA, FL

East: ME, NH, VT, MA, NY, RI, CT, NJ, PA, DE

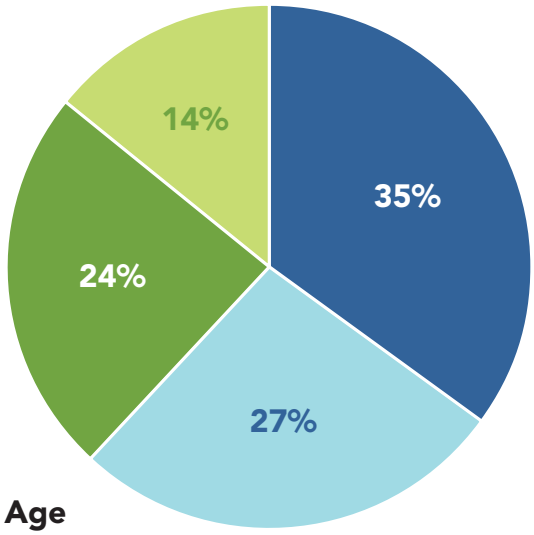
Central: OH, IN, IL, MI, MO, WI, IA, MN, ND, SD, NE, KS, OK

West: AK, WA, MT, ID, OR, WY, CO, UT, NV, CA, AZ, NM, HI

US Territories: Puerto Rico

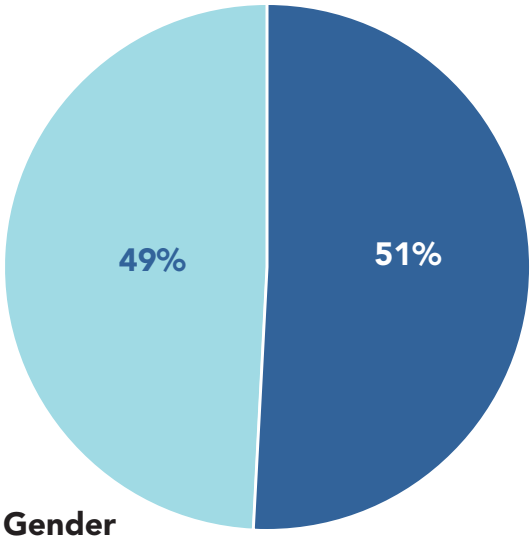
Patient Demographics

CC Patients by Age, Gender, Race and Ethnicity (FY2013) (N = 23,543)



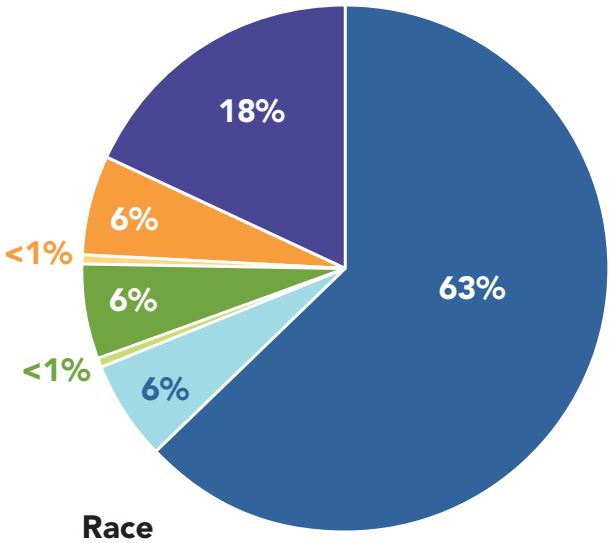
Age

- <18 yrs
- 19-40 yrs
- 41-60 yrs
- >60 yrs



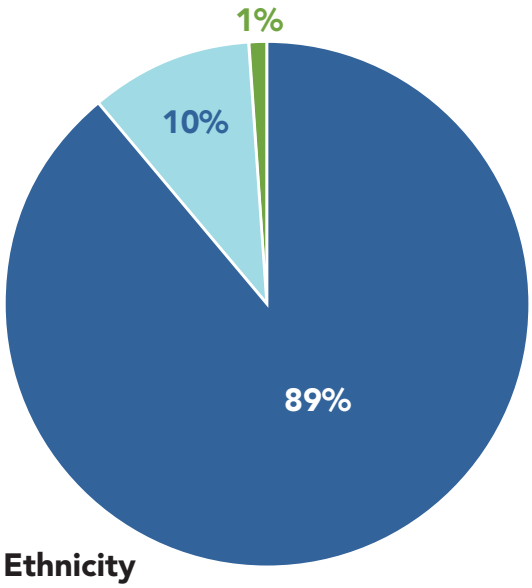
Gender

- Male
- Female



Race

- White
- Multiple
- Not Reported
- Hawaiian/Pacific Islander
- Asian
- American Indian/Alaskan
- Black/African American



Ethnicity

- Not Hispanic/Latino
- Hispanic/Latino
- Not Reported

Patient Input

SOURCES OF INPUT

1. **Patient Advisory Group** – See page 6
2. **Patient Perception Surveys** – Understanding patients' perceptions of their Clinical Center experiences is critical to providing high quality, safe and patient-centered care. The Clinical Center actively seeks information from patients regarding their perceptions about the hospital-based care and services provided to them and their perceptions of their experience as a research participant. These surveys assess the patients' experiences in the following dimensions of care and service: Respect/Trust, Information/Education, Informed Consent, Involvement of Family and Friends, and Coordination of Care.
3. **Patient Representative** – The Clinical Center makes available a designated representative as a resource to assist patients with emerging issues as they participate in the clinical research process. The representative assists with questions and complaints, provides information about hospital services and patient rights, serves as an advocate for patients, and functions as a liaison to patients, if needed, to the NIH Office of Human Subjects Research Protections.

WHAT ARE THE PATIENTS TELLING US?

Admissions, Patient Access and Communication Materials

In 2013, members of the Patient Advisory Group (PAG) provided suggestions to the team of Clinical Center and Institute partners leading the admissions redesign effort. 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. A member of PAG continued to sit on the team, leading efforts to identify improvements focused on patients' needs and perspectives. 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; 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 accurate information about getting to the NIH, entering campus, security and campus amenities. Also, a standardized welcome letter has been developed for new patients which will be rolled out for use will new patients across the NIH. The Clinical Center has also worked closely with the Medical Executive Committee (MEC) 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 broadly and quickly with the appropriate audience.

Patient Input

Patient Access to Medical Records

Recognizing the need for timely and accurate information while balancing patient confidentiality, the NIH Clinical Center implemented a secure internet-accessible Patient Portal in July 2013. The NIH Clinical Center Patient Portal enables Clinical Center patients to view selected results and documents from their NIH Clinical Center electronic medical record and obtain key information about the NIH and the Clinical Center (directions, clinical trials, etc.). While patients cannot change their electronic medical record information through the Portal, in early 2014 they will be able to use the Portal to communicate electronically and securely with their NIH health care team. The Patient Portal complies with the Privacy Act and other legal requirements that protect patient privacy and confidentiality.

Since implementation of the Patient Portal, activity has been tracked and is summarized in the table below:

Activity (July-December 2013)	Activity Count	Unique Patients
Accounts Created	3,825	– –
Logins	14,238	2,492
Demographics/Contacts Viewed	2,686	1,605
Results Viewed	21,564	1,660
Documents Viewed	11,318	768

Future enhancements of the Patient Portal will feature inclusion of imaging results and a secure health messaging component.

Insurance Billing Pilot

The PAG members participated in a number of discussions about implementation of the insurance billing pilot at the Clinical Center. They offered candid perspectives about the potential impact this effort may have on patients' participation in clinical research. Concerns were expressed about the metrics that will be used to evaluate the pilot. Likewise, the possible influence on the demographics of patients, changes in patients' insurance rates, cost of implementation, the potential loss of physicians and the change in the relationship between doctor and patient were all raised as potential negative effects. Suggestions were offered for ways to help with the implementation and for communicating with patients about the pilot. Patient input on this topic is ongoing and is regarded as especially valuable by those charged with planning the pilot.

Engaging Patients in Patient Safety

The PAG members were invited to participate in the Clinical Center's program for Patient Safety. They expressed a great deal of interest in this program and shared important insights. Their comments helped increase the understanding about patient reluctance to "speak up." The suggestions offered provide valuable information to staff responsible for this program.

Patient Nutrition Services

As in most hospitals, nutrition and food service is an ongoing concern for patients. The members of the PAG enjoy an excellent relationship with Nutrition staff and leadership that encourages their participation in planning and their direct expression of concerns and questions. It is expected that this open exchange of information and suggestions will be continual.

Referring Physician Demographics

OVERVIEW

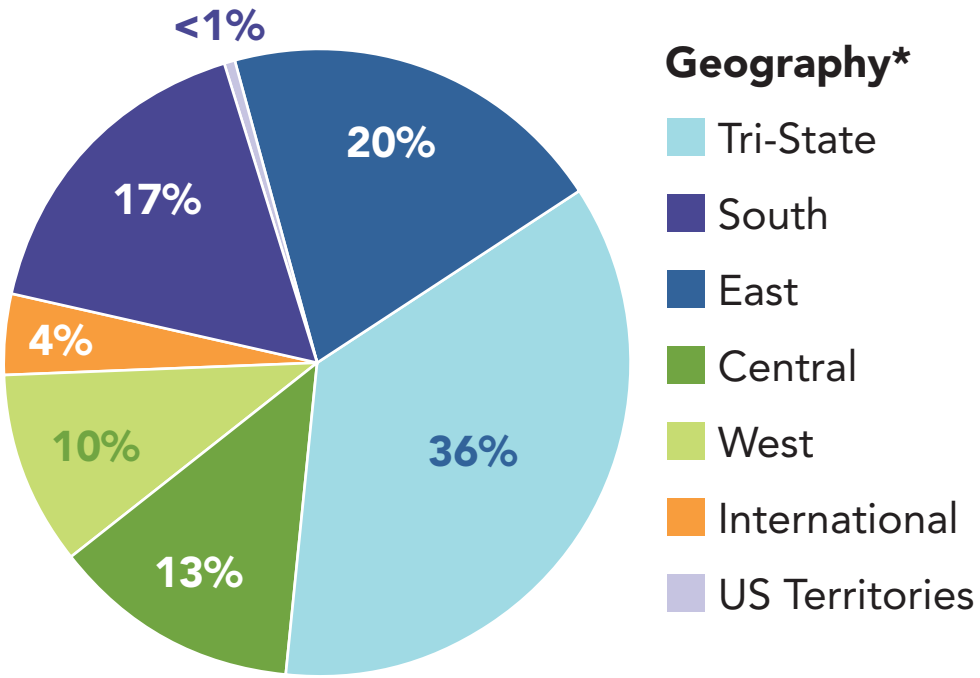
Timely and effective bi-directional communication with referring physicians is essential for assuring continuity of care as well as maintaining strong patient referral networks. The Clinical Center's network of referring physicians spans the U.S. and abroad, balancing the need for adaptability to ensure the most up-to-date records, with the need for patient confidentiality and data integrity.

Many improvements in the area of communicating with referring physicians have been implemented over the past several years. The Clinical Center's network of referring physicians continued to expand over the past year and the accuracy of referring physician contact information continued to improve. The capture of referring physician information has improved because it is now collected from patients during a pre-registration phone call prior to their visit at the Clinical Center.

Key Referring Physician Data	2010	2011	2012	2013
Referring Physician Network (all active patients)*	30,421	34,285	36,202	38,652

*Number of referring physicians for active Clinical Center patients on 12/31 of each year

CC Referring Physicians by Geographical Area (2013) (N = 38,652)



***Regions**

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South: WV, NC, KY, TN, SC, AR, LA, TX, MS, AL, GA, FL

East: ME, NH, VT, MA, NY, RI, CT, NJ, PA, DE

Central: OH, IN, IL, MI, MO, WI, IA, MN, ND, SD, NE, KS, OK

West: AK, WA, MT, ID, OR, WY, CO, UT, NV, CA, AZ, NM, HI

US Territories: Puerto Rico

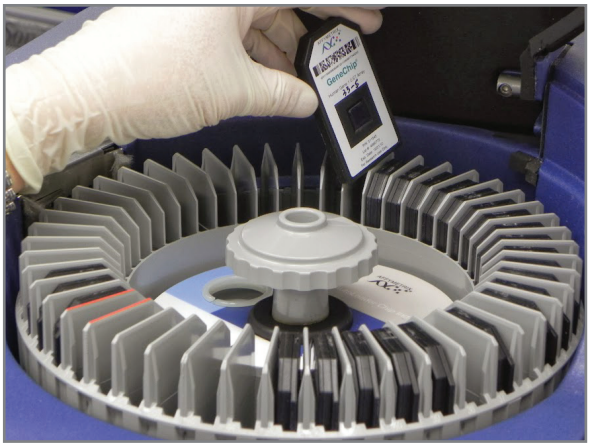
Referring Physician Input

WHAT ARE REFERRING PHYSICIANS TELLING US?

Need for Improved Communication of Patient Medical Information

The Medical Record Department (MRD) provides preliminary discharge report packages to patients' authorized outside physicians following inpatient admissions. These packages are sent the day following discharge and include a discharge problem list, diagnostic study results, consultation reports, discharge medications and discharge instructions provided to the patient. The preliminary report package is followed up with a copy of the final discharge summary, upon completion. Data enhancements have also enabled MRD staff to automatically mail out a copy of patients' outpatient first registration reports to authorized referring physicians.

The Clinical Center will begin to work on designing a referring physician portal to provide convenient and secure electronic access to critical patient information within the next year. In the interim, the Clinical Center is continuing to work on improving mechanisms of sharing medical information with referring physicians following patients' outpatient follow-up visits to the Clinical Center.



Clinical Research Trainee Demographics

OVERVIEW

Training the next generation of biomedical researchers and clinician-scientists is a core function of the Clinical Center. As the sponsoring institution for graduate medical training programs accredited by the Accreditation Council for Graduate Medical Education (ACGME), the American Board of Medical Specialties, and the United Council for Neurologic Subspecialties, the Clinical Center fosters the development of a broad investigator base, from clinical residency and fellowship training at the NIH to courses accessible for students from academic medical centers, private industry and abroad.

Key Clinical Research Trainee Data	FY2010	FY2011	FY2012	FY2013
Number of Residents and Clinical Fellows	302	295	286	294
ACGME accredited training programs (representing 10 NIH Institutes & Centers)	18	18	18	18
Enrollees in core clinical research courses	3,290	2,536	2,345	3,387
Remote sites participating in core clinical research courses	73	67	66	75
Applicants for slots in the NIH Medical Research Scholars Program for medical/dental/ veterinary students	--	--	148	148

-- Program launched in FY2012

Clinical Research Trainee Input

SOURCES OF INPUT

1. **Program and Course Evaluations** – Evaluations are given to participants at the conclusion of courses and programs to measure the efficacy of the curricula.
2. **Alumni Surveys** – Alumni surveys of participants in Office of Clinical Research Training and Medical Education (OCRTME) programs to evaluate efficacy of programs and the professional growth of those who participated.
3. **Technology Tools** – Web-based collaboration software is used for processing applications and selecting participants of OCRTME courses and programs. The web-based collaboration software allows for the collection of statistical data of the applicant and matriculant pools.
4. **Clinical Fellows Committee (ClinFelCom)** – A committee of clinical fellow representatives from all Institutes and Centers that meets quarterly with the Clinical Center Director.
5. **Graduate Medical Education Committee (GMEC)** – Trans-NIH committee.
   i. Directors of clinical residency and fellowship training programs
   ii. Graduate medical education administrators from the institutes and Clinical Center
   iii. Clinical Center's Office of Clinical Research Training and Medical Education

WHAT ARE THE TRAINING DIRECTORS AND TRAINEES TELLING US?

Maintaining and Improving Graduate Medical Education Programs

The Office of Clinical Research Training and Medical Education, in collaboration with the NIH Graduate Medical Education Committee (GMEC), prepared the NIH Clinical Center for an ACGME institutional accreditation review that occurred in May, 2013. The institutional review resulted in the ACGME awarding the NIH Clinical Center continued accreditation as a sponsor of graduate medical education training programs for a 12-year period. The next accreditation review is scheduled for October, 2025.

NIH Clinical Center and NIMH training directors also worked collaboratively to successfully achieve continued ACGME accreditation for the Critical Care Medicine fellowship program and the Psychiatry residency program which operates under NIH Clinical Center institutional sponsorship. The Office of Clinical Research Training and Medical Education continues to work with NINDS leadership to achieve full accreditation for the 7-year Neurological Surgery residency training program, which currently is in its 5th year of operation. The number of accredited ACGME training programs sponsored by the Clinical Center remains at 18.

Focusing on improvement of patient care through graduate medical education, the NIH GMEC worked with the professional staff of the Clinical Center's Office of the Deputy Director for Clinical Care to successfully integrate clinical fellows as voting members on key Clinical Center quality improvement and quality assurance committees. Membership on these committees will permit clinical fellows to actively participate in initiatives to improve patient care delivery through the process of graduate medical education at the Clinical Center. In addition, the Clinical Fellows Committee worked collaboratively with the Clinical Center's Department of Clinical Research Informatics to develop a patient sign out template in the Clinical Center's Clinical Research Information System to improve the accuracy and efficiency of transitions of care among residents and clinical fellows.

Clinical Research Trainee Input

Career and Professional Development

The Clinical Center hosted the inaugural Clinical Fellows Day for all clinical fellows in training at the NIH. Through a series of presentations by NIH leadership, including Drs. Francis Collins, Anthony S. Fauci, John I. Gallin, and Steven Holland, NIH clinical fellow attendees learned about academic and professional career development, including goal setting, time management, work-life balance, research support, and grantsmanship. A clinical fellow Town Hall session also provided useful feedback to Clinical Center leadership about ways to improve both the learning and patient care environment at the Clinical Center.

The Clinical Center Office of Clinical Research Training and Medical Education, in conjunction with the NIH GMEC, continued to offer interactive seminars and workshops to enhance interpersonal and communication skills, professionalism, and competency in systems-based practice among clinical fellows. This professionalism and interpersonal and communications skills development curriculum in 2013 included sessions on: fundamentals of effective physician-patient communication, conflict resolution, elements of a successful informed consent process, mindfulness and stress management, cross cultural medicine and working with interpreters, difficult physician-patient conversations including breaking bad news, and fundamental principles of patient safety and quality improvement.

The Clinical Center has continued to track professional development of the alumni of the former Clinical Research Training Program (CRTP). Cumulatively, 25 former CRTP fellows have returned to the NIH for clinical fellowships, with five former CRTP fellows currently holding junior faculty/staff positions in the intramural program.

The courses in the core curriculum in clinical research remain well subscribed domestically and internationally. In October 2012, the "Principles and Practice of Clinical Research" course was taught in New Delhi, India at the India International Center in partnership with the Clinical Development Services Agency, an extramural unit of the Department of Biotechnology, Government of India. A total of 126 registrants from a number of medical specialties and institutions across India participated in the course. Of the 126 registrants, 117 took the final examination with a successful pass rate of 90%.

The Clinical Center's *Principles of Clinical Pharmacology* course was offered in Moscow, Russia from May 13-17, 2013 at the Kulakov Research Center. This course was offered to over 200 students. Topics included principles of clinical pharmacokinetics, population pharmacokinetics and disease-progression modeling, drug metabolism, drug interactions, and pharmacogenomics.

Expanding Clinical Training Opportunities for Medical Students

The Clinical Center continued to expand clinical elective rotations available to visiting senior year medical or dental students through its Clinical Electives Program (CEP). In 2013, the CEP offered a total of 33 distinct short-term rotations and received a total of 416 applications from US and international medical students, representing an 11% increase in applicants from 2012. Through its continued participation as a host site for clinical elective rotations in the Visiting Student Application Service, administered by the Association of American Medical Colleges, the Clinical Center successfully increased the number of US

allopathic and osteopathic medical student applications to the CEP during 2013 by 12% when compared with 2012.

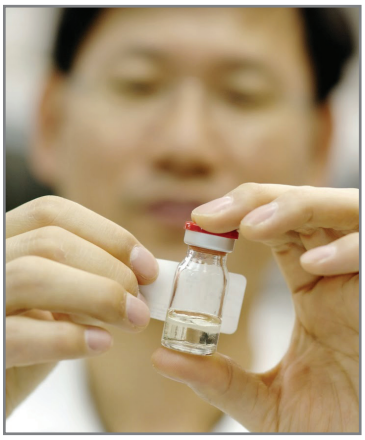
The Medical Research Scholars Program (MSRP) for medical, dental and veterinary students welcomed its second class in September 2013. The program received more than 130 applications and 91 students were invited to the NIH campus for interviews on March 3-4, 2013. Of the 91 interviewees, 46 were accepted into the program. The program offers research experiences with intramural investigators across NIH. Participants engage in a mentored basic, clinical, or translational research project in an area that corresponds to their personal research interests and career goals.

Expanding Clinical Training Opportunities for Graduate Students

The second Clinical and Translational Research Course for PhD students began July 8, 2013 with 27 doctoral students from 16 various academic institutions. The two-week curriculum builds a foundation in clinical and translational research in an effort to encourage young basic scientists to consider a future career as an investigator or collaborator in clinical and translational research. Students met with Ph.D. role models in the basic sciences from across the NIH Intramural Research Program who contribute vital roles in the clinical research enterprise. Through lectures and interactive sessions, students learned principles of clinical and translational research design, implementation, and analysis, and the process of scientific and ethical review. The curriculum arose from a recommendation from the Clinical Center's Advisory Board for Clinical Research.

Centralizing and Sharing Information

The Clinical Center has continued its use of social media tools to disseminate information and stay in touch with current and past trainees, including Twitter, YouTube and Facebook. In addition, information about all trainees is maintained in a database which incorporates software and automatic messaging; this allows for enhanced tracking of career progression after graduation from training programs or completion of formal coursework.



Outside Investigator Input

OVERVIEW

Last year, the Clinical Center partnered with the NIH Office of Extramural Research and institute stakeholders to launch a new NIH grant mechanism, *"Opportunities for Collaborative Research at the NIH Clinical Center."* This new cooperative agreement provides funding for research projects that take advantage of the unique resources and opportunities available at the Clinical Center. Through these collaborations, external researchers could potentially have access to cohorts of patients with rare diseases as well as access to additional, diverse Clinical Center resources, expertise, and infrastructure to investigate promising laboratory discoveries that have the potential for advancing the diagnosis, treatment, and prevention of disease. This new U01 grant provides funds up to $500K/year x 3 years, renewable. The budget development for this grant allows for these funds to be allocated to extramural investigators, intramural investigators (to cover extra costs associated with the project) and to the Clinical Center to cover project-related costs. A unique requirement of this grant is that to qualify, teams must have one extramural and one intramural co-Principal Investigator and some of the work must be done at the Clinical Center. These projects must align with NIH efforts to translate basic biologic discoveries into interventions that improve health. The first funding cycle was completed in the Fall of 2013 with the announcement of awards. There was enthusiastic interest in this funding opportunity, both intramurally and extramurally. Over 50 applications from institutions across the country were received. The second cycle is underway with enhancements to the process introduced based upon lessons learned from the first cycle.

Another existing program that encourages intramural-extramural partnerships is the Bench-to-Bedside (B2B) Awards Program. Originally established in 1999 and managed by the Clinical Center, the B2B program was created to speed translation of promising laboratory discoveries into new medical treatments by funding collaborations among basic scientists and clinical investigators. The program was initially open only to NIH intramural investigators. In 2006, the program expanded to encourage partnerships between intramural and extramural NIH clinical researchers, and 86 extramural investigators have received B2B funds via administrative supplements. Since 1999, over 200 collaborative projects have received funding, representing partnerships among multiple NIH institutes and centers and over 70 extramural institutions with approximately $48 million distributed in total B2B funding. Expansion of the program in 2006 has served as an ideal model for the current trans-NIH interest in establishing new intramural-extramural partnerships at the Clinical Center. For the FY2014 cycle of awards, 166 letters of intent were received with 10-12 awards anticipated, depending on available funding sources.

SOURCES OF INPUT

A new website entitled "Collaborating with NIH Intramural Investigators at the Clinical Center" was launched last year and upgraded significantly in the early Fall, 2013. This site provides a toolkit for collaborators with content describing Clinical Center and institute equipment, technology, and tools that are potentially available to extramural researchers (www.cc.nih.gov/translational-research-resources). These resources include state-of-the-art imaging equipment, specialty clinics focused on a broad range of disorders, and support services for designing and managing clinical trials. The toolkit also provides searchable descriptions of NIH studies currently underway at the Clinical Center, details on funding opportunities for extramural collaborators, and a step-by-step guide for identifying and collaborating with NIH intramural investigators. The website encourages inquiries about these new collaborations via email to the Clinical Center Partnerships Mailbox: ClinicalCtrPartner@mail.nih.gov or phone calls to 301-496-4121. An interactive webinar was held for the second cycle to provide potential applicants an overview of the initiative.

Outside Investigator Input

WHAT ARE THE OUTSIDE INVESTIGATORS TELLING US?

Information about the new grant opportunity for intramural-extramural collaborations at the Clinical Center was disseminated widely throughout the extramural and intramural communities. More than 300 inquiries about this program have been received to-date. A formal program review is underway to assess satisfaction with the new funding opportunity and success in meeting the program goals.

For the B2B Program, investigators remain very satisfied with the collaborations and positively assessed the impact of the collaborations on their research. In annual progress reports, almost all investigators rated the overall productivity of the collaboration as "good" or "excellent." Several investigators praised the collaboration's ability to capitalize on the strengths of different researchers as excellent. When asked about the value of intramural-extramural partnerships on these awards, responses were very positive, and all agreed that the outside partner added value to the project. Investigators reported that intramural-extramural partnerships resulted in meaningful exchanges of ideas and long-term partnerships. Researchers reported that the B2B award promoted awareness of NIH and Clinical Center resources, resulted in a long-term project that would continue after B2B funding ended, and that the outside partner had added value to the project.

PILOT OF INSURANCE BILLING FOR PATIENT SERVICES

Over the past several decades, the Clinical Center has been asked periodically to consider third party reimbursement (from now on referred to as "insurance billing") for patient services. Following independent contractor reviews in 1997 and 2005, the Clinical Center concluded that charging for services may not be financially advantageous and could potentially adversely impact the Clinical Center's mission. Since 2005, a number of fundamental changes have occurred in the health care landscape that led Congress to again request the NIH perform an updated feasibility of insurance billing at the Clinical Center.

In 2011, an updated feasibility study was performed to determine potential revenues, estimated expenses to implement and conduct ongoing operations, and opportunities and challenges associated with the implementation of an insurance billing pilot. As a result of the new study, late in 2011, Congress directed the NIH to conduct a three-year pilot to assess the feasibility of insurance billing at the NIH. In response, in the Fall of 2012, the Clinical Center engaged in a thorough pilot analysis and design project. The project goals included: defining the pilot scope to include outpatient Radiology and outpatient Special Procedures, identifying best practices and challenges from numerous sources for consideration prior to the pilot, and developing the functional requirements and necessary process changes required to implement an insurance billing pilot program. Results of the pilot analysis and design project were shared with Congress in March 2013.

Since briefing Congress, the Clinical Center, with the help of an integration contractor and billing vendor, has begun implementing the pilot using the functional requirements and process changes identified as a result of the 2012 design project. Efforts are currently underway to develop and modify processes and systems in support of the following workflow areas: patient access, clinical documentation and coding, segregation of non-billable research services, IT/data flow, financial services, and HIPAA compliance. The Clinical Center plans to send its first bill in early 2014, after which, the Clinical Center has three years to conduct and evaluate the pilot. It's important to note that a guiding principle of the pilot is that patients will not face any financial burdens; additionally, no patient will be turned away from being treated at the Clinical Center because of their insurance status. Throughout the remainder of the pilot, the NIH will continue to brief Congress as necessary.

ONGOING FEDERAL BUDGET CONSTRAINTS

The Congressionally-appropriated NIH annual budget (approximately $31.1B for FY2013) has seen only modest growth since FY2004, increasing a total of 10% over this time period. Consequently, the growth in the NIH Central Services budget, out of which the Clinical Center is funded, also has been modest. The Clinical Center budget has grown ~20% from 2004 through 2013 as compared to the hospital industry increase of ~37% during the same period.

In these tight budgetary times, careful planning of clinical research resources assists us in meeting the needs of both patients and investigators. To mitigate the impact of constrained resources, major efforts have been employed to contain costs while simultaneously ensuring continued development of new programs to carry out clinical research. Key examples follow.

- The purchase of some capital equipment has been deferred, resulting in a significant multi-year capital funding gap. However, it is

important to note that the receipt of $23.5M in ARRA funds in 2009 and 2010 provided some temporary relief to offset this gap.

- The CCGB and ABCR have emphasized that opportunities for cost containment must reach beyond the staff of the Clinical Center to front line Institute investigators who are major consumers of Clinical Center resources. Along these lines, new strategies are being developed to engage investigators in cost containment at the protocol level.
- The Clinical Center continues to meet resource demands through use of management strategies to stretch its dollars. Examples include consolidation of contracts, use of purchase cards to avoid costly contract actions, reverse auctions for purchase of supplies, reengineering job functions to save FTE, and bulk purchasing for pharmaceuticals and medical surgical supplies.

The Clinical Center remains strongly committed to maintaining a vigorous clinical research infrastructure even within the budget constraints.

ACCOUNTABLE GOVERNMENT INITIATIVE — UPDATE ON PERFORMANCE MANAGEMENT AGENDA[1]

The Performance Management Agenda (PMA) focuses on six strategies with the highest potential for achieving meaningful improvements within and across Federal agencies:

1. **Driving agency top priorities**
   With increasing pressure to focus on policy development and crisis management instead of implementation, program effectiveness and service delivery have suffered, and programs have multiplied without good reason. To break this paradigm, the Administration is working with agency leaders to identify the top outcome-focused priorities and focus management attention on delivering progress against those priorities.

2. **Cutting waste**
   First and foremost, the Administration is working to eliminate programs that do not work, are out of date, or are duplicative and agencies are taking the hard step to identify programs that are less central to achieving agency mission goals. In addition, efforts to reduce and recapture improper payments and eliminate excess real property are underway.

3. **Reforming contracting**
   Despite being the world's largest purchaser, the Federal Government does not always get the best price or value for the money spent, and the contracting processes involved are slow and cumbersome. Efforts are ongoing to save money, reduce risk, and get better results. Agencies have been encouraged to utilize strategic sourcing by pooling purchasing power. Focusing on the capacity and capabilities of the acquisition workforce is crucial in order to sustain these improvements.

1. Full memorandum to the Senior Executive Service was accessed on February 7, 2014 and can be found at http://www.whitehouse.gov/sites/default/files/omb/memoranda/2010/AccountableGovernmentInitiative_09142010.pdf

4. **Closing the IT gap**
   The Federal Government must strive to better utilize IT transformation efforts to improve efficiency, convenience and effectiveness similar to those regularly used by the private sector. In addition, cybersecurity should be a continued focus, especially as the Government increasingly leverages technology to deliver services to the American people.

5. **Promoting accountability and innovation through open government**
   Through his 2009 Memorandum on Transparency and Open Government, President Obama committed his Administration to an unprecedented level of openness. To strengthen accountability, all strategic goals and key metrics are being publicized. In addition, the Administration recognizes that an open and innovative government relies on active collaboration with private sector individuals and companies, not-for-profit organizations and other governments.

6. **Attracting and motivating top talent**
   Many efforts are ongoing to improve the Federal Government's outdated personnel system. In addition to improved hiring, the Federal Government must work to engage and maintain top talent to ensure the success of performance improvement efforts. OPM is working with agencies to address weaknesses in the performance feedback and appraisal process, and the Employee Viewpoint Survey continues to be administered annually to help agencies identify potential areas for improvement.

The Obama Administration is not only focusing on selecting the appropriate strategies, but also on how to systematically approach those strategies. Through emphasis on outcomes, the Administration hopes to achieve positive and long lasting improvements.

In order to ensure leaders remain focused, unprecedented transparency of objectives, targets, progress and action plans is crucial. As a result, identified management priorities have been integrated into the annual budget process. To support transparency efforts, performance information was made available to federal managers and the public through Performance.gov, a website fostering the culture of accountability required to achieve meaningful improvements by providing access to management dashboards and agency priorities.

The Clinical Center has been responsive to all requests generated by the PMA and continues to strive to implement performance improvements that align with Federal Government efforts. Goals may evolve as new initiatives are implemented and the Clinical Center will continue to stand ready to respond quickly and with flexibility.

EXECUTIVE ORDER TO PROMOTE EFFICIENT SPENDING[1]

In November 2011, President Obama signed an Executive Order to cut waste and promote more efficient spending across the federal government. The order builds on progress made through the Campaign to Cut Waste and directs agencies to reduce spending on travel; limit the number of information technology devices that can be issued to individual employees; stop unnecessarily printing documents that can be posted online; shrink the executive fleet of the federal government; and stop using taxpayer dollars to buy swag. Details of the directives for each target area are listed below.

1. Full Executive Order accessed on January 7, 2014 and can be found at www.whitehouse.gov/the-press-office/2011/11/09/executive-order-13589-promoting-efficient-spending

Key Influencing Factors in the Current Environment

1. Reduce Spending on Travel and Conferences

- Limit travel to circumstances where the activity can only be performed away from the employee's primary office whenever possible
- Expand use of teleconferencing or videoconferencing technology to participate in long-distance meetings or conferences
- When hosting or sponsoring conferences, use conference space controlled by the federal government whenever possible
- Designate a senior-level official to be responsible for reducing travel costs

2. Cut Duplicative and Unnecessary Employee Information Technology Devices

- Limit the number of devices issued to employees
- Establish new policies to ensure that agencies are not paying for IT equipment that is not being used

3. End Unnecessary Printing and Put It Online

- Provide written information electronically
- Limit the production of hard copy documents

4. Limit Motor Vehicles

- Limit executive transportation across the federal government
- Improve performance of the Federal fleet

5. Stop Swag – or Government Promotional Handouts

- Stop wasting taxpayer money on non-essential items used for promotional purposes such as clothing, mugs, and non-work related gadgets

HHS STRATEGIC PLAN 2014-2018[1]

Every four years, HHS updates its strategic plan, which describes its work to address complex, multifaceted, and evolving health and human services issues. Through its strategic plan, HHS defines its mission, goals, and the means by which it will measure its progress in addressing specific national problems over a four-year period. In developing its goals the Clinical Center is, in turn, cognizant of the plans laid out by the Administration and HHS.

The four broad strategic goals of the HHS Strategic Plan include:

1. Strengthen Health Care

- Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured

1. Full HHS Strategic Plan was accessed on March 10, 2014 and can be found at www.hhs.gov/strategic-plan/priorities.html

Key Influencing Factors in the Current Environment

- Improve health care quality and patient safety
- Emphasize primary and preventive care, linked with community prevention services
- Reduce the growth of health care costs while promoting high-value, effective care
- Ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations
- Improve health care and population health through meaningful use of health information technology

2. Advance Scientific Knowledge and Innovation

- Accelerate the process of scientific discovery to improve health
- Foster and apply innovative solutions to health, public health, and human services challenges
- Advance the regulatory sciences to enhance food safety, improve medical product development, and support tobacco regulation
- Increase our understanding of what works in public health and human services practice
- Improve laboratory, surveillance, and epidemiology capacity

3. Advance the Health, Safety, and Well-Being of the American People

- Promote the safety, well-being, resilience, and healthy development of children and youth
- Promote economic and social well-being for individuals, families, and communities
- Improve the accessibility and quality of supportive services for people with disabilities and older adults
- Promote prevention and wellness across the life span
- Reduce the occurrence of infectious disease
- Protect Americans' health and safety during emergencies, and foster resilience to withstand and respond to emergencies

4. Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programss

- Strengthen program integrity and responsible stewardship by reducing improper payments, fighting fraud, and integrating financial, performance, and risk management
- Enhance access to and use of data to improve HHS programs and to support improvements in the health and well-being of the American people
- Invest in the HHS workforce to help meet America's health and human services needs
- Improve HHS environmental, energy, and economic performance to promote sustainability

HEALTH CARE AND BIOMEDICAL SCIENCE TRENDS

Pharmacogenomics and Molecular Genetic Testing

Pharmacogenomics is the evaluation of the impact of genetic variation on patients' responses to the administration of pharmacologic agents, by attempting to correlate gene expression or single nucleotide polymorphisms with either efficacy or toxicity of the agent. The pharmacogenomic approach provides the practitioner with an opportunity to select the most appropriate agent for a specific patient based on the patient's genotype, thereby minimizing adverse drug effects. Use of this approach contributes substantially to patient safety. In addition to pharmacogenomics testing, IC investigators are increasingly relying on the detection of specific genes in the evaluation of protocol patients. Detection of specific genetic abnormalities in such genes often has both prognostic and therapeutic implications. To facilitate ordering these tests in a cost-effective manner, the Clinical Center let a contract and developed streamlined procedures, both for ordering these tests and for assuring that the results of such tests are incorporated into the patients' medical records.

Whole Exome Sequencing

Sequencing patients' complete coding regions (exomes) offers a powerful tool to detect relevant genetic information associated with subsequent disease risk, prognosis and treatment. This approach is particularly relevant to the Clinical Center's unique patient population (in which nearly 50% of patients are participating in natural history/disease pathogenesis studies, and in the majority of the remaining patients are participants in interventional trials and have underlying diseases for which their coding region sequences may also be highly relevant to their care). Whereas whole exome sequencing has, historically, been prohibitively expensive, new technology has made broad scale use of this approach increasingly economically practical. Several Institutes have expressed interest in significantly expanded use of whole exome sequencing, and NHGRI is aggressively pursuing this strategy. We envision such sequencing to become nearly routine in the next five to ten years.

Platforms for Microbial Diagnosis - MALDI-TOF Mass Spectrometry

Matrix Assisted Laser Desorption/Ionization Time-of-Flight MALDI/TOF spectrometry is a fast, precise, and cost-effective method for the identification of microorganisms, including bacteria, yeasts and molds, when compared to immunological or biochemical tests. MALDI/TOF is rapidly becoming the standard method for species identification in the Clinical Center Laboratory of Microbiology.

Patient Safety and Clinical Quality

Providing safe and high quality care and mitigating the risks associated with health care and research participation are central to the Clinical Center's mission.

The landmark Institute of Medicine report, "To Err is Human: Building A Safer Health System,"[1] and the follow-up report, "Crossing the Quality Chasm: A New Health System for the 21st Century,"[2] called for an aggressive approach to identify, understand and mitigate risks associated with medical care. The Clinical

1. Kohn, L., Corrigan, J., Donaldson, M., Institute of Medicine: Committee on Quality of Health Care in America: "To Err is Human: Building a Safer Health System." The National Academy Press, 2000.
2. Institute of Medicine: Committee on Quality of Health Care in America: "Crossing the Quality Chasm: A New Health System for the 21st Century." The National Academy Press, 2001.

Key Influencing Factors in the Current Environment

Center continually strives to mitigate the risk inherent in providing care at the intersection of clinical medicine and the conduct of clinical research. Clinical Center staff and investigators use myriad tools and methodologies to identify, understand, and mitigate risks associated with clinical care and clinical research:

- o Clinical Center Occurrence Reporting System
- o Failure Mode and Effects Analyses
- o Root Cause Analyses
- o Performance Measurement Systems
- o Patient Perception Surveys of Hospital Care and Clinical Research Participation
- o Culture of Safety Survey
- o Clinical Quality/Patient Safety Measures (depicted in dashboard below)

Clinical Quality/Patient Safety Performance Measures Dashboard

Infection Control	Hand Hygiene Compliance
	Catheter-Associated Urinary Tract Infections
	Central Line Associated Bloodstream Infections
	Ventilator-Associated Pneumonia
	Surgical Antibiotic Prophylaxis
	Surgical Site Infections
Invasive Procedures	Unanticipated Returns to the Operating Room
	Re-Admissions Following Outpatient Procedures
	Invasive Cardiology Complications
	Procedural Pain Interventions
Culture of Safety	Overall Rating of Culture of Safety
	Specific Culture of Safety Survey Questions
	Patient Measure of Safety
Patient Perception	Overall Rating of Care
	Perception of the Clinical Research Experience
	Service/Unit Level Perceptions of Care and Services
Clinical Care	Medication Errors
	Patient Falls
	Pressure Ulcers
	Restraints and Seclusion
	Pain Reassessment (pediatrics)
Wait Times	Pharmacy
	Outpatient Clinics
	Radiology
	Phlebotomy
	Admissions
	Peri-Operative Medicine

Information Technology Development

Health care information technology continues to advance at a rapid pace by offering ever-improving technologies to support clinical research and patient care. The Clinical Center is committed to investing in these improvements and system enhancements to support cutting-edge research and the highest quality of patient care possible, within the confines of our funding.

Specifically, the Clinical Center is working on new methodologies to share and communicate critical information including the use of:

- Patient portal (including activities to enhance and expand the patient portal)
- Secure messaging between physicians
- Mobile technologies
- Enterprise scheduling system
- Electronic consents

In addition, the health care industry has developed several new system enhancements to reduce medical errors and improve patient safety. The Clinical Center recently implemented such technologies, including:

- Bar-coding applications for:
  - o laboratory/specimen management
  - o blood product transfusion and medication administration processes
  - o medication bar-coding; the final component is underway and expected to be implemented in FY2014
- Medication distribution systems (i.e., Inpatient and Outpatient systems)
- Continual integration of automated solutions for Anesthesia, Post-Anesthesia Care Unit (PACU) and Intensive Care Unit (ICU)

The Clinical Center continues to develop the Biomedical Translational Research Information System (BTRIS), bringing data from the Clinical Center and other Institutes together in a single repository and providing NIH researchers with new capability for efficient use and reuse of data collected in clinical trials. To date, BTRIS includes:

- Laboratory, radiology, cardiology and other ancillary system data
- Data generated in the Clinical Research Information System (CRIS) (e.g., clinical documentation and pharmacy data)
- Archived Clinical Center data from the Medical Information System (MIS)
- Data from systems at NIAID, NIAAA, NCI, NHGRI, NICHD, NIDDK and NIMH
- Addition of personal researcher data sets using spreadsheets
- Radiographic images in the Clinical Center's Picture Archiving and Communication System (PACS)
- Mass spectrometry data from the Clinical Microbiology Laboratory
- Automated reporting for ClinicalTrials.gov
- Data visualization tools for temporal analysis of events
- Hypothesis testing using data sets without personal identifiers (de-identified data application)

In FY2014, the Clinical Center will add new functionalities to BTRIS: inclusion of CRIS orders in the database, enhanced query times using upgraded database technology, the ability to search and retrieve text documents from which personal identifiers to have been removed, and an updated website.