

2015 National Institutes of Health Clinical Center Strategic and Annual Operating Plan

Environmental Assessment

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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

- Institutes
- Employees
- Patients

External

- Referring Physicians
- Clinical Research Trainees
- Outside Investigators

Key Influencing Factors in the Current Environment

- Ongoing Federal Budget Constraints
- Accountable Government Initiative — Update on Performance Management Agenda
- Executive Order to Promote Efficient Spending
- HHS Strategic Plan 2014-2018
- Health Care and Biomedical Science Trends
 - o Precision Medicine Initiative
 - o Ebola Preparedness and Care of Infected and Exposed Patients
 - 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 Facilities and Capital Equipment Management
- o Information Technology Development

Governance and Advisory Structure

[Graphic: Governance Structure]

There are two (2) advisory groups to the NIH Director:

1. Clinical Center Governing Board (IC Directors) (NIH Members Only)
2. NIH Advisory Board for Clinical Research (ABCR) (NIH & External Members)

The Deputy Director for Intramural Research and the Director, Clinical Center also advise the NIH Director.

Reporting to the NIH Advisory Board for Clinical Research (ABCR) are the following working groups:

- CC Finance (NIH & External Members)
- CC Operations & Planning (NIH & External Members)
- Clinical Research & Career Opportunities (NIH & External Members)

Reporting to the Director, Clinical Center are the following:

- Board of Scientific Counselors (External Members Only)
- Medical Executive Committee (NIH Members Only)
- Patient Advisory Group (External Members Only)

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. Discussions in 2014 included implementation of an insurance billing pilot for patient services at the Clinical Center and oversight of its subsequent curtailment as directed by Congress. Additionally, the Board advised on continuing efforts to open the doors of the Clinical Center to outside investigators and standardizing the 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.

For membership, visit www.cc.nih.gov/about/welcome/governance/advisoryboard.shtml.

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.

For membership, visit www.cc.nih.gov/about/welcome/governance/committee.shtml.

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.

For membership, visit www.cc.nih.gov/bsc/members_current.html.

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.

The American Association of Blood Banks (AABB)

The AABB provides general accreditation of all Department of Transfusion Medicine operations, including the donor center, transfusion service, hematopoietic progenitor cell activities, and immunohematology reference laboratory.

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 1,611 protocols in FY2014.

Institute Planning

As suggested at the joint meeting of the Scientific Directors and Clinical Directors on July 31, 2014, the Clinical Center conducted a new process for our annual planning with Institutes. In lieu of meeting with each Institute/Center (IC) individually to discuss their intramural clinical research program plans, the Clinical Center asked each IC to provide their FY2015 and 2016 patient activity and programmatic plans, using a template worksheet. The Clinical Center took all IC plans and compiled them to identify themes that represent the projected needs of the clinical intramural research program in FY2015 and beyond. In early 2015, the Scientific and Clinical Director community will be engaged in an open discussion on these themes and provide feedback on the Clinical Center's proposed budget scenarios and prioritization focus for FY2016.

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 2014 Fall Planning Process

A set of themes or highlights reflecting challenges, key areas of growth, and change in the intramural clinical research program are compiled from the Clinical Center's annual planning process.

1. Expansion of Operating Room Availability

By collecting and analyzing data available through the newly implemented Peri-Operative Information System (POIS), the Clinical Center worked with the Surgical Administrative Committee to redesign the block schedule, which has improved efficiency. However, a major limitation of the current OR block schedule is that surgical services end at 3:30pm. Stakeholders feel that this cutoff time should be later to schedule more patients and accommodate unforeseen delays and/or reschedule cancellations.

Additionally, stakeholders continue to have problems getting the offsite anesthesia they require, particularly in the areas of radiation oncology and pediatric oncology. Stakeholders support the use of alternative staffing models, including Certified Registered Nurse Anesthetists (CRNAs), to create more flexibility for scheduling offsite services. As a result of this feedback, the Department of Perioperative Medicine (DPM) has begun recruitment of four nurse anesthetists.

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.

3. Enhance the Scope of Available Laboratory Analysis (genomic testing) and recognize the Need for Increased Diagnostic Flow Cytometry

The Clinical Center has expanded its pharmacogenomics program under the thoughtful leadership of Juan Lertora, M.D., Ph.D. and a subcommittee of the Clinical Center Pharmacy and Therapeutics Committee. The pharmacogenomics program provides practitioners the opportunity to select the most appropriate agent for a specific patient based on the patient's genotype, thereby optimizing therapeutic options, minimizing adverse drug effects and contributing substantially to patient safety. The Clinical Center has also expanded the scope of genetic testing by creating significant new outside contracts for genetic testing and by developing processes to record the data in patients' electronic medical records. Historically, the NCI Laboratory of Pathology has provided diagnostic flow cytometry testing. Demand for these services has eclipsed the Laboratory's capacity. To address some of the increased demand, the Clinical Center Department of Laboratory Medicine's Hematology and Immunology Services have expanded diagnostic flow cytometry testing.

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

[Data Table of Workforce Information]

FTE utilization

- FY2011: 1,904
- FY2012: 1,865
- FY2013: 1,857
- FY2014: 1,875

Turnover rate (Most recent turnover data for MD hospitals = 16.7%)

- FY2011: 8.0%
- FY2012: 8.7%
- FY2013: 9.7%
- FY2014: 8.1%

% retirement eligible

- FY2011: 12.4%
- FY2012: 13.6%
- FY2013: 15%
- FY2014: 16.2%

Average age of employees

- FY2011: 46.3
- FY2012: 47.9
- FY2013: 49
- FY2014: 47.4

Average years of government service

- FY2011: 12.1
- FY2012: 13.4
- FY2013: 13.6
- FY2014: 13.3

Age (FY2013, n=2,100)

[Bar Chart]

- 0-29: 5%
- 30-39: 21%
- 40-49: 27%
- 50-59: 31%
- 60-69: 14%
- ≥ 70: 2%

Gender (FY2013, n=2,100)

[Pie Chart]

- Female: 72%
- Male: 28%

Race/Ethnicity (FY2013, n=2,100)

[Pie Chart]

- White/Non-Hispanic: 47%
- Black/Non-Hispanic: 32%
- Hispanic: 3%
- American Indian/Alaskan: <1%
- Asian/Pacific Islander: 17%

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, 46% of employees in senior leadership positions at the Clinical Center will be eligible to retire at the end of FY2018, as well as 42% 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. The Clinical Center also continues to offer the new 5-month cohort curriculum for employees who have demonstrated potential to be future leaders entitled Clinical Center Aspiring Leaders Program.

In FY2014, Clinical Center Team Lead Fundamentals was customized to support the restructuring of the CC Nursing Department (CCND) and leadership development needs for 30 Clinical Managers. The Clinical Center routinely offers consultative services, training, and team development interventions focused on effective communication, conflict management, and administrative best practices across departments. Such services in FY2014 supported in particular, the CCND Nurse Residency Program, Project SEARCH, the Veterans Incentive Program, and leadership development for all nursing services.

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 FY2014 Brown Bag series "Leveraging Diverse Perspectives" was extremely well received by staff with over 100 employees from 26 CC departments plus other ICs attending at least one session. Topics included 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.

In FY2015, the Clinical Center will launch a competency-based curriculum designed to deepen the technical and leadership administrative management skills needed by CC Administrative Officers to excel in the federal workplace hospital environment. This program will focus on developing hospital administrators working in alignment with administrative demands, department strategic directions, and administrative standardization to support collaborative problem-solving that reflects a high level of professionalism, efficiency, and consistency.

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 2014, the Clinical Center launched a PMAP toolkit to assist managers in holding authentic and effective employee performance conversations for retention and accountability. This toolkit includes: customized conversation guides for different levels of performers; self-assessment and individual development plans; the Employee Recognition Assessment tool introduced last year to explore the forms of recognition employees value most; and training assessment records. Supervisors felt this tool kit was very helpful in fostering authentic conversations with their employees 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

[Data Table of Workforce Information]

New Patients

- FY2011: 10,686
- FY2012: 10,694
- FY2013: 10,195
- FY2014: 10,053

Admissions

- FY2011: 6,082
- FY2012: 5,916
- FY2013: 5,887
- FY2014: 5,615

Inpatient days

- FY2011: 56,594
- FY2012: 54,971
- FY2013: 51,418

- FY2014: 48,142

Outpatient visits*

- FY2011: 101,942
- FY2012: 102,169
- FY2013: 102,119
- FY2014: 99,402

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

Average daily census

- FY2011: 155.1
- FY2012: 150.2
- FY2013: 140.9
- FY2014: 132

Average length of stay (days)

- FY2011: 9.2
- FY2012: 9.3
- FY2013: 8.9
- FY2014: 8.7

Geography (FY2013, n=23,543)*

[Pie Chart]

- Tri-State: 61%
- South: 10%
- East: 11%
- Central: 7%
- Not Reported: 2%
- West: 6%
- International: 3%
- US Territories: <1%

*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

Age (FY2013, n=23,626)

[Pie Chart]

- <18 yrs: 14%
- 19-40 yrs: 28%
- 41-60 yrs: 34%
- >60 yrs: 24%

Gender (FY2013, n=23,543)

[Pie Chart]

- Male: 51%
- Female: 49%

Race (FY2013, n=23,543)

[Pie Chart]

- White: 66%
- Multiple: 3%
- Not Reported: 5%
- Hawaiian/Pacific Islander: <1%
- Asian: 5%
- American Indian/Alaskan: <1%
- Black/African American: 18%

Ethnicity (FY2013, n=23,543)

[Pie Chart]

- Not Hispanic/Latino: 88%
- Hispanic/Latino: 11%
- Not Reported: 1%

Patient Input

Sources of Input

1. Patient Advisory Group – See page 4

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?

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.). In 2014, imaging results were added to the Portal and the release

timeframe was modified based on feedback from the PAG. Imaging results are automatically released to the Portal 3 days after being finalized and non-imaging results (lab, etc.) are automatically released to the Portal every 8 hours after being finalized. Previously non-imaging results were released after 7 days. The ongoing feedback from the PAG regarding the Patient Portal has been immensely helpful to the Medical Record Department and the Medical Executive Committee in determining the appropriate release schedule for medical information to patients, which will have a substantial impact for all patients enrolled in the Portal. Several PAG members have considerable experience with portals in outside healthcare agencies and offered important guidance for the CC planning.

While patients cannot change their electronic medical record information through the Portal, in early 2015 they will be able to use the Portal to communicate electronically and securely with their NIH healthcare 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 2014)

[Data Table of Patient Portal Activity]

Accounts Created

- Activity Count: 6,593

Logins

- Activity Count: 48,861

Demographics/Contacts Viewed

- Activity Count: 9,096

Results Viewed

- Activity Count: 91,942

Documents Viewed

- Activity Count: 49,457

Insurance Billing Pilot

Members of the PAG participated regularly in a number of discussions regarding implementation of the insurance billing pilot at the Clinical Center. In one instance, a telephone conference was arranged to solicit input from members regarding communication needed for patients related to the implementation. Throughout these discussions, the PAG offered a number of frank perspectives about the potential impacts of the pilot including: concerns about the possible impact on participation in clinical research, influence on the demographics of the Clinical Center patient population, and changes in the relationship between doctor and patient. These concerns were shared with NIH leadership and ultimately, the NIH was directed by Congress to curtail the pilot.

Wayfinding

Over the years the Clinical Center has continued to hear from patients that the Clinical Center complex is difficult to navigate. As a result, the Clinical Center explored various technologies in an effort to harness software to assist patients, visitors, and staff with directions and wayfinding. Through a partnership with

Google Indoor Maps, the Clinical Center has been able to create building floor plans that can be accessed through mobile devices. The mapping feature allows users to navigate between floors to see the respective floor plans. Additionally, the software provides a 'blue dot' icon, much like a 'You Are Here' sticker to identify where, accurate within several meters, a user is within the building. To enhance the floor plans, the Clinical Center added photos of common landmarks or points of interest within the complex and a virtual tour to assist as users navigate the facility. The PAG was pleased with the progress of this project and asked for additional features including navigation to specific rooms or units, and to explore if the application is able to speak directions to the user, much like navigations systems for vehicles. The Clinical Center continues to explore capabilities from other indoor mapping companies and pursue additional programming that will enhance the capability of these mobile device applications within the facility.

Clinical Center Website and Social Media

The PAG was approached twice in 2014 to discuss the Clinical Center website. Many useful and practical ideas were offered, resulting in a completely revised Clinical Center homepage. The Office of Communications and Media Relations (OCMR) recently initiated a phased project to review and update all pages within the Clinical Center website, driven in large part by feedback received from the PAG.

The Clinical Center has also experienced significant growth in followers on both Facebook and Twitter. Tweets are sent Monday-Friday at 9am, 11am and 1pm while regular posts are shared via Facebook at 9am and 1pm. Suggestions for enhancements of services provided by patients, family members and visitors via social media are shared with Clinical Center leadership as necessary. The PAG continues to engage in discussions regarding the Clinical Center's social media practices and provides input on strategies to further expand the Clinical Center's audience.

Enhanced Patient Advisory Group Meeting Process

For several years, it has been possible to include members from a distance with telephone conferencing. Within the past year, the capacity for participation has increased dramatically with the addition of video to the audio connection. The video permits the caller to see the people present at the meeting. Viewing the slides has improved the quality of remote participation as well, along with the ability for feedback from callers outside the hospital. Users seem pleased with this new feature and as usual have provided suggestions for further enhancements.

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 preregistration phone call prior to their visit at the Clinical Center.

Key Referring Physician Data

[Data Table of Referring Physician Information]

Referring Physician Network (all active patients)*

- 2011: 34,285
- 2012: 36,202
- 2013: 38,652
- 2014: 40,758

*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)*

[Pie Chart]

- Tri-State: 36%
- South: 17%
- East: 20%
- Central: 13%
- West: 10%
- International: 4%
- US Territories: <1%

*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

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 be implementing a referring physician portal to provide convenient and secure electronic access to critical patient information in late 2015. 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 through clinical residency and fellowship training at the NIH. In addition, the Clinical Center has a very broad portfolio of courses and programs accessible for students and other trainees from the NIH intramural program, academic medical centers and private industry from domestic and international locations.

Key Clinical Research Trainee Data

[Data Table of Clinical Research Trainee Information]

Number of Residents and Clinical Fellows

- FY2011: 295
- FY2012: 286
- FY2013: 294
- FY2014: 278

ACGME accredited training programs (representing 10 NIH Institutes & Centers)

- FY2011: 18
- FY2012: 18
- FY2013: 18
- FY2014: 18

Enrollees in core clinical research courses

- FY2011: 2,536
- FY2012: 2,345
- FY2013: 3,387
- FY2014: 3,596

Remote sites participating in core clinical research courses

- FY2011: 67
- FY2012: 66
- FY2013: 75
- FY2014: 105

Applicants for slots in the NIH Medical Research Scholars Program for medical/dental/veterinary students

- FY2011: --
- FY2012: 151
- FY2013: 135
- FY2014: 115

-- 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 (OCRTME), in collaboration with the Clinical Center’s Office of the Deputy Director for Clinical Care and the NIH Graduate Medical Education Committee (GMEC), prepared the NIH Clinical Center for its first Clinical Learning Environment Review (CLER) Program institutional site visit on September 9-10, 2014. CLER is a new program initiated by the ACGME under its Next Accreditation System (NAS). In accordance with the NAS, all institutions sponsoring graduate medical education nationally must undergo CLER site visits at regular intervals in order to maintain accreditation by the ACGME. The CLER site visit generated a report providing the Clinical Center with feedback about the status of patient safety, healthcare quality (with a special focus on healthcare disparities), supervision, transitions in patient care, duty hours/fatigue management and mitigation, and professionalism related to graduate medical education within the learning environment of the Clinical Center. The OCRTME and the NIH GMEC will utilize the findings in the report to ensure optimal patient care and safety through the policies and procedures that govern the process of graduate medical education at the Clinical Center. The next CLER site visit is anticipated to occur in March 2016.

The Office of Clinical Research Training and Medical Education continue to work with NIH training programs to ensure their continuing accreditation.

In 2014, the OCRTME worked with NINDS leadership to complete an ACGME accreditation site visit for the 7-year Neurological Surgery residency training program, which is beginning its 6th year of operation. The results of this accreditation site visit are expected in early 2015. The number of training programs accredited by the ACGME and institutionally sponsored by the Clinical Center remains at 18.

Continuing its focus on improvement of patient care through graduate medical education, the OCRTME, ClinFelCom and the NIH GMEC worked with the professional staff of the Clinical Center's Office of the Deputy Director for Clinical Care to maintain successful integration of clinical fellows as voting members on key Clinical Center quality improvement and quality assurance committees. Membership on these committees allows clinical fellows to actively participate in initiatives to improve patient care delivery through the process of graduate medical education at the Clinical Center.

Career and Professional Development

The Clinical Center hosted the second Clinical Fellows Day for all clinical fellows in training at the NIH. Through a series of presentations by NIH leadership, including Drs. Francis Collins and NIH Institute Directors Anthony S. Fauci (NIAID), Harold Varmus (NCI), Gary H. Gibbons (NHLBI), and Nora D. Volkow (NIDA), NIH clinical fellow attendees learned about academic and professional career development, including goal setting, time management, worklife balance, and research support. A clinical fellow Town Hall session also provided useful feedback to Clinical Center leadership about ways to possibly improve both the learning and patient care environments at the Clinical Center.

In collaboration with the NIH Clinical Fellows Committee and the National Cancer Institute's Division of Cancer Epidemiology and Genetics Office of Education, the OCRTME organized and hosted an inaugural four-part NIH Clinical Fellows Grant Writing and Grantsmanship Course from May 29 – July 11, 2014. This highly interactive course included half-day teaching sessions entitled: "The Anatomy of a Grant: Grants and Grantsmanship in Practice," "K Funding Mechanisms and Tips for Clinical Grant Writing," "Grant Writing Practice: Specific Aims Review," and "Preparing a Career Transition Award-Tips for Intramural Applicants." In addition, clinical fellows participated in a mock study section session in which their "mini-grant" proposals were peer reviewed.

Finally, 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 2014 included sessions on: fundamentals of effective physician-patient communication, including difficult physician-patient conversations and breaking bad news; elements of a successful informed consent process, cross cultural medicine and working with interpreters; and fundamental principles of patient safety and quality improvement.

Residency and Clinical Fellowship Training Outcomes

In 2011, the OCRTME began tracking outcomes of residency and clinical fellowship training programs at the NIH utilizing self-reporting on-line survey methodology. Three-year follow-up of the 2010 cohort of training program graduates responding to the on-line survey indicated that 58% were currently in academic settings, and 57% were conducting clinical research in addition to providing patient care in these settings. Forty-four percent reported publishing 1-3 manuscripts, and 22% reported publishing 4-6 manuscripts since graduation. OCRTME plans to survey residents and clinical fellows prospectively at intervals of 1, 3, 5, 7 and 10 years after the completion of their graduate medical education training at the NIH.

The Clinical Center continues to annually track professional development of alumni of the former Clinical Research Training Program (CRTP). Cumulatively, 23 former CRTP fellows have returned to the NIH for clinical fellowships. Four former CRTP fellows currently hold staff positions in the NIH intramural program; three assistant clinical investigators and one staff clinician.

Courses and Long Distance Learning

The participation in the courses of the core curriculum in clinical research remains high both domestically and internationally. The number of remote sites increased by 40% for FY2014. In September 2014, the “Principles and Practice of Clinical Research” course was offered in Rio de Janeiro, Brazil. An HHS delegation, composed of four NIH faculties and the Director of the DHHS Office for Human Research Protections, taught a version of the course in collaboration with Brazilian colleagues. More than 130 individuals participated in the course which was held at the Foundation Oswaldo Cruz [FIOCRUZ] as part of their Clinical Research Week. How to conduct rigorous scientific investigation, research ethics, and other topics, all utilizing examples from the medical literature, were highlighted.

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 2014, the CEP offered a total of 34 distinct short-term rotations and received a total of 369 applications from U.S. and international medical students. 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 percentage of US allopathic and osteopathic medical student applications to the CEP from 21% in 2013 to 29% in 2014.

The NIH Medical Research Scholars Program (MRSP) 2013-2014 class represented 32 U.S. medical schools. Females made up 44% of the class and 27% of the class were under-represented minorities. The selection process for the 2014-2015 class concluded in March 2014. The program received 115 applications. Ninety-one candidates were interviewed and 42 students were selected to participate. The MRSP exposes participants to a meaningful, unique, and highly mentored experience early in their training. The MRSP excites and encourages the best and brightest of American health professional students to pursue careers in research. The program’s ultimate goal is to help provide the United States with a highly trained workforce of clinician scientists who can conduct the full range of biomedical research necessary to develop the next generation of scientific discoveries that will benefit human health.

Expanding Clinical Training Opportunities for Graduate Students

Twenty-eight graduate students pursuing doctoral degrees in the biomedical sciences participated in the third annual Clinical and Translational Research Course for Ph.D. students. Representing 22 different academic institutions from across the nation, the 2014 students attended lectures and interactive sessions designed to expose talented young scientists to the exciting and collaborative nature of clinical and “bench-to-bedside” research. Students also toured the FDA White Oak Campus, learned about postdoctoral training opportunities, and took part in a mock IRB and learned the process of filing an IND application.

A major component of the course involved these students engaging with Ph.D. role models conducting clinical and translational research at the NIH. In addition to course lectures, students also participated in small group meetings with NIH investigators to discuss their research ideas and to learn more about NIH intramural research related to their areas of interest.

Centralizing and Sharing Information

The OCRTME has continued its use of social media tools and electronic communications including Twitter, LinkedIn, Flickr, and alumni email listserves to disseminate information and stay in touch with current and past trainees. Data for all trainees is maintained in electronic databases allowing for in depth analysis

and enhanced tracking of career progression after graduation from training programs or completion of formal coursework.

Outside Investigator Input

Overview

The Clinical Center continues its partnership with the NIH Office of Extramural Research and institute stakeholders to promote the NIH grant mechanism, “Opportunities for Collaborative Research at the NIH Clinical Center.” This cooperative agreement is in the third cycle of funding and provides support for research projects that take advantage of the special resources and opportunities available at the Clinical Center. Through these collaborations, external researchers can access cohorts of patients with rare diseases, as well as, diverse Clinical Center resources, expertise, and infrastructure to investigate promising laboratory discoveries that have the potential for advancing the diagnosis, treatment, and prevention of diseases. This U01 grant provides funds up to \$500K/year x 3 years, renewable. The budget developed 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 in order to qualify, teams must have an extramural and NIH 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. With a success rate in cycle 1 of 20% (10 awards total); decisions for cycle 2 are pending.

Another existing program that encourages intramural-extramural partnerships is the Bench- to-Bedside (B2B) Awards Program. 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 ICs and approximately 80 extramural institutions with approximately \$50M 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 FY2015 cycle of awards, 102 letters of intent were received with approximately 10 awards anticipated, depending on available funding sources.

Sources of Input

A website entitled “Collaborating with NIH Intramural Investigators at the Clinical Center” provides a toolkit for collaborators and includes 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.

What Are The Outside Investigators Telling Us?

Information about the grant opportunity for intramural-extramural collaborations at the Clinical Center was disseminated widely throughout the extramural and intramural communities. More than 400 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. As a first step in the evaluation, a customer satisfaction survey was issued to all U01 applicants in the first two cycles: FY2013 and FY2014. 155 respondents (a 59.4% response rate) provided generally positive program feedback. Applicants indicated satisfaction with the application process and felt this is an important program. Clarity for the budget process was indicated as an opportunity for improvement and methods are underway to address this need.

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. A comprehensive program report was completed to highlight program metrics and research successes to-date that are associated with these awards.

Key Influencing Factors in the Current Environment

Ongoing Federal Budget Constraints

The Congressionally-appropriated NIH annual budget (approximately \$30.1B for FY2015) has seen only modest growth since FY2006, increasing a total of 5.3% 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 2005 through 2014 as compared to the hospital industry increase of ~34% 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 Agenda¹

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.

NIH Clinical

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 achieving 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 Spending²

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. 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 2014-2018³

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 Administrations 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
- 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 Programs

- 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

Precision Medicine Initiative⁴

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. While significant advances in precision medicine have been made for select cancers, the practice is not currently in use for most diseases. Many efforts are underway to help make precision medicine the norm rather than the exception. To accelerate the pace, President Obama has launched the Precision Medicine Initiative with a \$215M investment in the President's 2016 Budget. The Initiative will pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients.

The objectives of the Precision Medicine Initiative include:

- More and better treatments for cancer
- Creation of a voluntary national research cohort
- Commitment to protecting privacy
- Regulatory modernization
- Public-private partnerships

The President's \$215M investment will be shared by the NIH, the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC) as follows:

- \$130M to NIH for development of a voluntary national research cohort of a million or more volunteers to propel the understanding of health and disease, and set the foundation for a new way of doing research through engaged participants and open, responsible data sharing.
- \$70M to the National Cancer Institute specifically to scale up efforts to identify genomic drivers in cancer and apply that knowledge in the development of more effective approaches to cancer treatment.
- \$10M to FDA to acquire additional expertise and advance the development of high quality, curated databases to support the regulatory structure needed to advance innovation in precision medicine and protect public health.
- \$5M to ONC to support the development of interoperability standards and requirements that address privacy and enable secure exchange of data across systems.

Ebola Preparedness and Care of Infected and Exposed Patients

The Clinical Center has been one of four centers in the US that has been asked to provide care for repatriated healthcare personnel who were infected with or exposed to Ebola Virus. The Clinical Center's Special Clinical Studies Unit (SCSU) is a high-containment infectious diseases ward that provides an optimal environment for providing care to patients who have highly transmissible infectious diseases. The core SCSU nursing and physician staff had been planning and practicing for several years to provide care

for such patients. To be prepared for providing care for Ebola patients, the staff refined donning and doffing techniques for personal protective equipment, infection control policies, and a range of standard operating procedures. Staff from the Office of Research Facilities provided several infrastructural upgrades. Additionally, SCSU staffing rosters were developed, additional nursing and physician staff were trained, and supplies were restocked. In September 2014, the NIH Clinical Center admitted as a patient a physician who had been working in an Ebola treatment unit in Sierra Leone and who had sustained a high-risk needlestick exposure to Ebola virus. He did not develop the infection and was discharged 10 days later. In October 2014, a nurse who was diagnosed with Ebola Virus Disease (EVD) after providing care to a Liberian man who had developed fulminant EVD and died at the Dallas hospital where she worked, was transferred to the NIH Clinical Center. She received supportive care, recovered from her infection and was discharged eight days later. A third patient, a nurse who sustained a needlestick exposure with a contaminated needle was also hospitalized at the Clinical Center. This patient also did not develop the infection and was discharged. NIAID staff also completed a promising Phase 1 trial of a candidate Ebola vaccine.

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 optimizing therapeutic options and 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' electronic 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. The Office of the NIH Deputy Director for Intramural Research, in collaboration with NHGRI has offered, as part of a two-year initiative called the Clinical Center Genomics Opportunity, to have the NIH Intramural Sequencing Center sequence the exomes of up to 1,000 NIH Clinical Center patients. Ten investigators' proposals have already been selected and this project is underway. The Clinical Center envisions such sequencing becoming 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 precise measurement of chemicals and biochemicals in blood and other body fluids, as well as for the identification of microorganisms, including bacteria, yeasts and molds. This

technique represents a substantial improvement in microbe detection when compared to immunological or biochemical tests. MALDI/TOF is rapidly becoming the standard method for species identification in the Clinical Center's Department of Laboratory Medicine's Microbiology Service and is also broadly applied in the Department's Clinical Chemistry Service.

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,"⁵ and the follow-up report, "Crossing the Quality Chasm: A New Health System for the 21st Century,"⁶ called for an aggressive approach to identify, understand and mitigate risks associated with medical care. The Clinical 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:

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

Clinical Quality/Patient Safety Performance Measures Dashboard
[Data Table of Clinical Quality/Patient Safety Performance Measures]

Medication Management

- Overall medication errors
- High-risk medication errors
- Bar-code technology utilization

Provision of Care

- Falls
- Pain Management
- Pressure Ulcers
- Management of moderate sedation

Information Management

- Use of Computerized Practitioner Order Entry (CPOE)
- Countersignature use
- Abbreviation use

Patient Experience

- Perception of care and services
- Wait times

Emergency Response

- Rapid response outcomes
- Code Blue outcomes

Infection Control and Prevention

- Hand hygiene
- Catheter-associated urinary tract infections (CAUTI)
- Central line and bloodstream infections
- Surgical site infections
- Peri-operative use of antibiotics

Key Influencing Factors in the Current Environment

Facilities and Capital Equipment Management

Making informed capital investment decisions for facilities and health care technology is a challenge common to hospitals and, in light of the tight budgetary climate, the Clinical Center is not immune from such pressures. The Clinical Center's planning process incorporates the use of multiple data sources, including stakeholder input, to facilitate the acquisition of modern technology in support of patient care and research. To this end, the Clinical Center is responsible for maintaining the hospital's capital equipment inventory and physical environment.

Facilities

The Clinical Center facility is managed through a partnership between the Clinical Center and the NIH Office of Research Facilities (ORF). The Clinical Center is responsible for upkeep of the visible physical environment (e.g., carpet, paint, drywall repair) and minor facility modifications while ORF funds and oversees the 'behind-the-walls' infrastructure (e.g., heating, ventilation, elevators) and major construction.

Due to the need for collaboration between the Clinical Center and ORF regarding maintaining the hospital infrastructure and physical environment, a team with representation from the Clinical Center and ORF meets monthly to assure compliance with the Joint Commission life safety and environment of care guidelines.

Capital Equipment

The Capital Equipment Resource Committee (CERC) is responsible for maintaining the Clinical Center's capital equipment inventory, prioritizing clinical and IT equipment replacement, and developing a quarterly acquisition plan for submission to the Clinical Center Director. The goal of the CERC is to develop a predictable outlay of capital equipment expenditure, assess useful life of equipment to assure timely replacement, and plan for the purchase of emerging technologies in support of science and patient care.

Since its inception, the CERC has achieved cost savings from increased visibility and accountability of funds, bulk purchasing (IT equipment, etc.) , and consolidated equipment maintenance opportunities. Additionally the CERC has refined equipment replacement methodology and utilization of the Biomedical Engineering equipment database to assist in future planning and budgeting; implemented standardized IT replacement schedules for PCs, laptops, copiers, and printers; created quarterly spending plans to improve tracking and management of capital purchases; and, improved collaboration, planning and coordination between department, administrative, finance/budget, facilities management and procurement staff.

Emerging technologies are evaluated on an ongoing basis and added to the capital equipment inventory and often prioritized. The Clinical Center partners with ICs to co-invest in technology needed to support the NIH mission and the programs specific to the partnering ICs. Additionally, the Clinical Center has received equipment through partnerships with industry.

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 NIH Care and Research Teams; NIH Care and Research Team and Referring Physicians; and NIH Care and Research Team and Patients
- Mobile technologies
- Enterprise scheduling system
- Electronic procedure and protocol consents
 - Referring physicians portal
 - Pharmacogenomics utilizing Exome Sequencing
 - Medication Reconciliation

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:

- Medication bar-coding
- Continual integration of automated solutions for Procedure Area, Pain and Palliative Care Documentation, Transplant Consortium Documentation, Ebola Screening, Scheduling and ordering for the Dental Clinic, Ordering and Resulting for the CCGO Project and the interfacing of laboratory results from IC Systems such as CRIMSON

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
- Links to 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 FY2015, 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 have been removed, and an updated website.

Footnotes:

¹ Full memorandum to the Senior Executive Service was accessed on January 4, 2015 and can be found at www.whitehouse.gov/sites/default/files/omb/memoranda/2010/AccountableGovernmentInitiative_09142010.pdf

² Full Executive Order accessed on January 4, 2015 and can be found at www.whitehouse.gov/the-press-office/2011/11/09/executive-order-13589-promoting-efficient-spending

³ Full HHS Strategic Plan was accessed on December 16, 2014 and can be found at www.hhs.gov/strategic-plan/priorities.html

⁴ Fact Sheet: President Obama's Precision Medicine Initiative was accessed on January 30, 2015 and can be found at www.whitehouse.gov/the-press-office/successful2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.

⁵ 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.

⁶ 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.