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NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER



2011 Clinical Center Strategic and Annual Operating Plan

Warren G. Magnuson Clinical Center
Mark O. Hatfield Clinical Research Center



Message from the Clinical Center Director



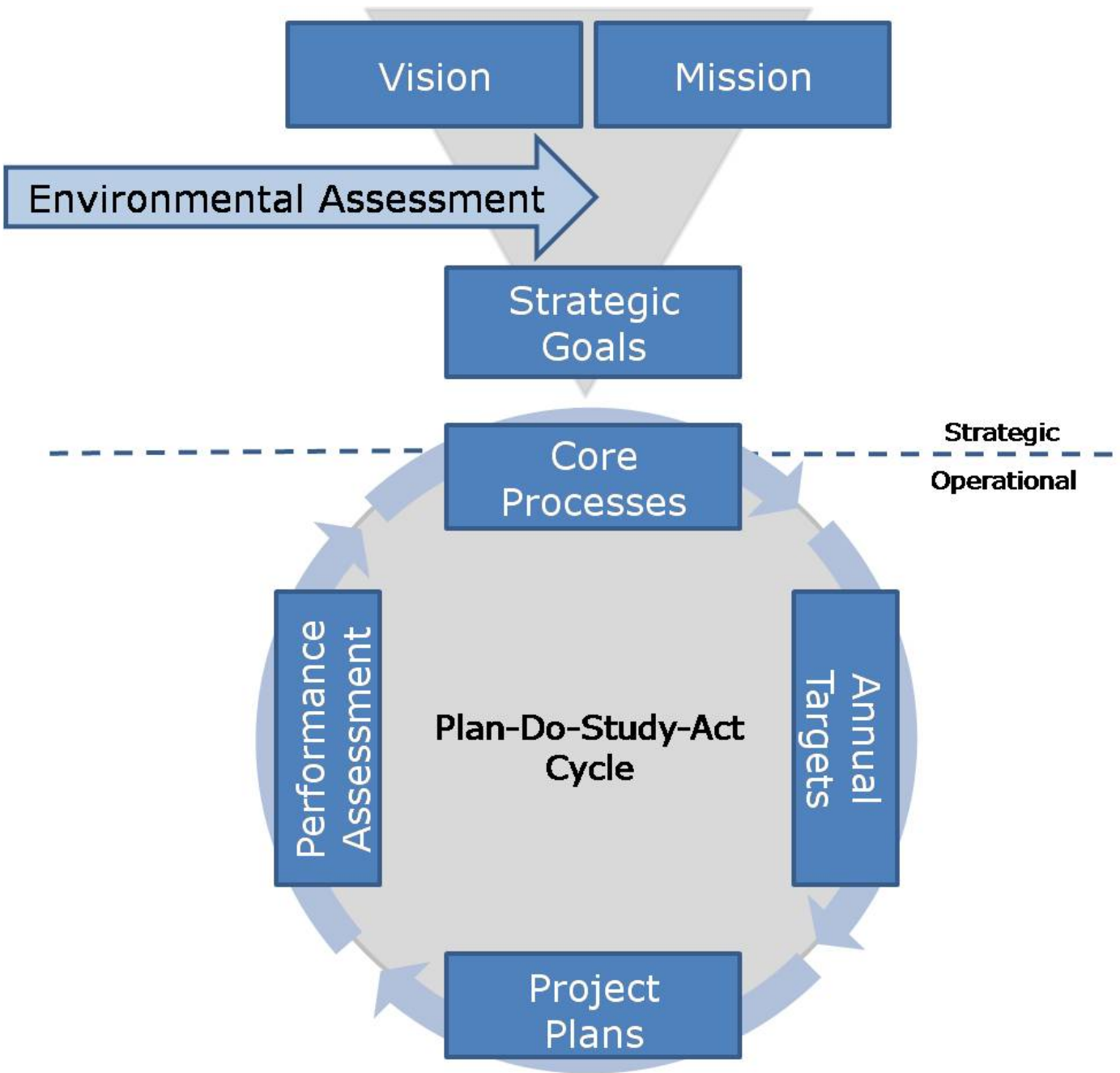
John I. Gallin, M.D.
Director, NIH Clinical Center

In 1951, as President Harry Truman laid the cornerstone of the NIH Clinical Center, he challenged onlookers that “Modern medicine must find ways of detecting these destructive diseases in their early stages and of stopping their destructive force.” This is exactly what we have done over the past six decades. Our outstanding environment for clinical research is made up of a team of world-class clinical investigators who work side by side with the caregivers, administrative professionals, and support staff to provide patient care, clinical research support, and hospital services to our diverse patient population who are registered in one of over 1,400 active protocols. It is our job to provide continued excellence in science and patient care with competent and caring staff, novel clinical and laboratory approaches, and the latest technologies.

The development of this year’s strategic and annual operating plan comes in the midst of pending changes brought about by the Congressionally-mandated NIH Scientific Management Review Board. Specifically, we will see improvements to the stability of our budget and the clarity of our governance processes, both of which signal support for the future vitality of clinical research. Additionally, a recommendation to open the Clinical Center to external investigators from across the country will help fulfill our vision as America’s research hospital. This opening of our doors to outside investigators will allow them access to selected specialized resources, fostering the development of new collaborations and providing enhanced opportunities to accelerate translational research. The Clinical Center has long been a valuable resource for NIH intramural researchers and will continue to build on this long and rich history.

The Clinical Center has taken great strides in the past, and now more can be done to improve and expand. In 2011 we will focus on continued support of and training in clinical research as well as development of new approaches to support the NIH translational research agenda.

Strategic and Annual Operating Plan Framework



Vision Statement

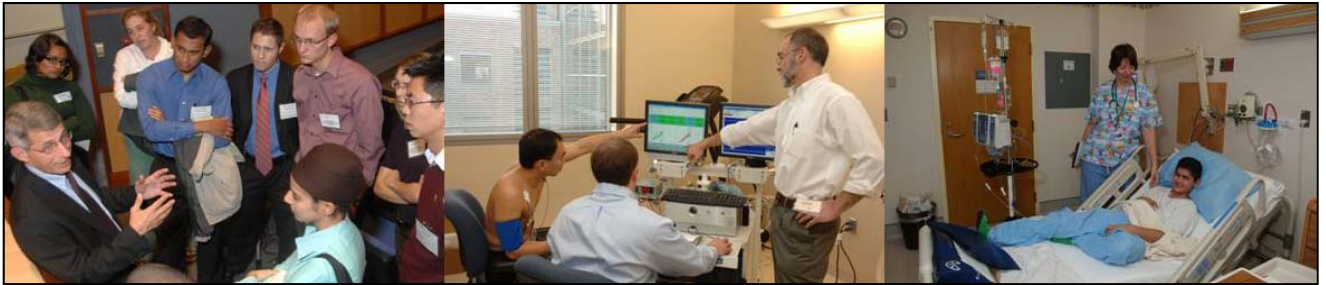
A vision statement answers the question: "What do we strive to be?" and is a shared view that defines what the organization wants to do or become.



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

Mission Statement

A mission statement answers the question:
“What is our fundamental purpose?”



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

- investigating the pathogenesis of disease;
- conducting first-in-human clinical trials with an emphasis on rare diseases and diseases of high public health impact;
- developing state-of-the-art diagnostic, preventive and therapeutic interventions;
- training the current and next generations of clinical researchers; and,
- ensuring that clinical research is ethical, efficient, and of high scientific quality.

Environmental Assessment

The Clinical Center's environmental assessment consists of stakeholder input; recommendations from governance, advisory, and review groups; and an evaluation of the major factors influencing change. For a full text version of this assessment, see *National Institutes of Health Clinical Center Environmental Assessment, 2009*.

Stakeholders

The Clinical Center considers the interests of its stakeholders when developing the strategic and annual operating plan. As part of the environmental assessment, stakeholder input feeds into the development of strategic goals and annual targets. Managing effective relationships with key partners of the Clinical Center drives accountability and informs priority setting.

Internal	External
<ul style="list-style-type: none">• Institutes• CC Employees• Patients	<ul style="list-style-type: none">• Referring Physicians• Trainees• Collaborators

Governance, Advisory, and Review Groups

- NIH Scientific Management Review Board
- NIH Advisory Board for Clinical Research
- Medical Executive Committee
- Board of Scientific Counselors
- Joint Commission

Other Key Factors Influencing Change

- Ongoing Federal Budget Constraints
- Health Care and Biomedical Science Trends
 - Patient Safety and Clinical Quality
 - Information Technology Development
 - Pharmaceutical/Supply Inflation
 - Proteomics
 - Molecular Medicine
 - Genomics
 - Microbiomics
 - Pharmacogenomics
- Accountable Government Initiative – Performance Management Agenda
- HHS Strategic Plan 2010-2015

Strategic Goals

Strategic goals translate the vision, mission, and core processes into performance-based action plans and are intended for the next five years.

- Contribute to the national translational research effort by supporting a robust intramural program and extending availability of the Clinical Center's special resources to external research collaborators.
- Continually generate novel approaches to train investigators and care for patients participating in clinical research.
- Maintain a highly-skilled, diverse workforce, enabling organizational goals.



Core Processes

Core processes are the major activities that support the mission.



Clinical Research

Provide optimal environment for the conduct of clinical research with judicious use of resources.

Patient Care

Develop and promote best practices for safe, effective, and efficient care of patients participating in clinical research.

Training and Workforce Development

Train clinical researchers through an up-to-date and easily accessible curriculum and develop innovative approaches for staff development.

Annual Targets

Annual targets are the key initiatives identified to support the strategic goals of the Clinical Center and are aligned under the three organizational core processes. Each target is assigned to a member of the executive team for leadership, oversight and development and monitoring of the project plan.

Core Processes	Clinical Research	Patient Care	Training and Workforce Development
2011 Annual Targets	<ol style="list-style-type: none"> 1. Install full body MR/PET machine to enable simultaneous, integrated functional imaging. 2. Employ mass spectroscopy to streamline microbiology and clinical chemistry diagnosis. 3. Develop comprehensive plan for opening the Clinical Center to investigators throughout the United States, including: <ul style="list-style-type: none"> • compendium of available resources and opportunities for collaboration; • application and review process; • methodology for covering costs; and, • website for transparent communications. 	<ol style="list-style-type: none"> 1. Implement bar-coding for medication administration. 2. Install outpatient pharmacy system with a process to track costs. 3. Improve and automate the patient admissions, scheduling and registration process. 4. Improve electronic access to medical records for patients and referring physicians. 5. Create a pharmacogenomics program to improve patient safety. 	<ol style="list-style-type: none"> 1. Develop a national program for PhD students and post-doctoral fellows to enhance their knowledge of clinical research. 2. Enhance web-based tools for long-distance learning. 3. Complete pilot of Project SEARCH, a collaboration to provide job training for students with disabilities. 4. Implement new leadership development curriculum for supervisors/managers.
<p>Engage Institute leaders and front line investigators to develop a plan for extending cost containment efforts to the protocol level.</p>			

Financial Assessment of Annual Targets

Annual Targets		Financial Impact for 2011
Clinical Research	Full body MR/PET machine	Funded by Department of Defense (DoD) as part of joint initiative in Post-Traumatic Stress Disorder/Traumatic Brain Injury
	Mass spectroscopy	Funded out of FY 2010 capital budget.
	Comprehensive plan for opening to investigators throughout the US	Planning will occur in FY 2011. Incremental funding will be requested in FY 2012 budget.
Patient Care	Bar-coding for medication administration	Final phase funded by American Reinvestment and Recovery Act (ARRA).
	Outpatient pharmacy system	Funded by ARRA.
	Patient admissions, scheduling and registration	Funded by ARRA.
	Electronic access to medical records	Funded by ARRA.
	Pharmacogenomics program	Planning will occur in FY 2011. Incremental funding will be requested in FY 2012 budget.
Training & Workforce Development	Program for PhD and post-doctoral students to enhance clinical research knowledge	Pilot funded by existing budget in FY 2011.
	Web-based tools for long-distance learning	Reprogrammed resources within FY 2011 budget.
	Project SEARCH pilot	Costs covered by non-profit sponsor; CC staff time involved.
	Leadership development curriculum	Reprogrammed resources within FY 2011 budget.

Drivers and Beneficiaries of Annual Targets

The matrix below provides a graphic of how stakeholders and other key factors influencing change are both drivers and intended beneficiaries of the annual targets.

Annual Targets		Stakeholders					Governance, Advisory, and Review Groups	Other Key Factors Influencing Change			
		Internal			External			Ongoing Federal Budget Constraints	Health Care and Biomedical Science Trends	Accountable Government Initiative	HHS Strategic Plan
		Institutes	CC Employees	Patients	Referring Physicians	Clinical Research Trainees					
Clinical Research	Full body MR/PET machine	+					✓		✓	✓	
	Mass spectroscopy	+	✓	+	+	+			✓	✓	
	Comprehensive plan for opening to investigators throughout the US	+					+	✓		✓	
Patient Care	Bar-coding for medication administration		+	+	+				✓	✓	✓
	Outpatient pharmacy system	✓+	+	+	+			✓	✓	✓	
	Patient admissions, scheduling and registration	✓+	+	✓+					✓	✓	✓
	Electronic access to medical records			✓+	✓+				✓	✓	✓
	Pharmacogenomics program	✓		+					✓		✓
Training & Workforce Development	Program for PhD and post-doctoral students to enhance clinical research knowledge	✓+				+		✓			✓
	Web-based tools for long-distance learning					✓+			✓	✓	✓
	Project SEARCH pilot		✓+				✓			✓	✓
	Leadership development curriculum		✓+							✓	✓

KEY:
 Drivers = ✓
 Beneficiaries = +

Stakeholder Input - Institutes

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.

Key Data	FY2007	FY2008	FY2009	FY2010
ICs conducting research at the Clinical Center	17	18	18	18
Active research protocols	1,390	1,449	1,451	1,443
Rare diseases under investigation*	--	--	--	758

* Data not available for previous years.

Method for Obtaining Input

Institute Planning Meetings

A set of “themes” reflecting key areas of growth and change in the intramural clinical research program are compiled from the Fall Institute/Clinical Center Planning Meetings. Institute Directors, Scientific Directors, and Clinical Directors contribute to these ongoing discussions, and the resulting “themes” inform annual Clinical Center department budget requests. As a result, interactions with the Institutes guide the Clinical Center’s development of its operating plan and help ensure effective allocation of resources. Aligning Clinical Center resources with Institute priorities optimizes support for both clinical research and patient care.

Since new Institute initiatives are generally implemented over multiple years, many of the themes documented represent affirmation of Institute requests from prior years with updates provided.

“What are the Institutes telling us?”

Themes from 2010 Fall Planning Meetings

1. Increased Demand for Imaging

Several Institutes commented that their studies will require increasing reliance on sophisticated imaging studies, including magnetic resonance imaging (MRI), functional MRI (fMRI), high resolution computed tomography (CT and co-registered positron emission, computed tomography (PET/CT) and complex interventional procedures. Increasing demand on all imaging groups may place additional stress on an already constrained schedule for such studies.

Stakeholder Input - Institutes

2. Expansion of Cell Processing

Several institutes (NCI, NHLBI, NIAID) will continue and, in some instances, expand research of stem cell therapies. These studies – many of which involve matched unrelated donors require extensive effort on the part of both the HLA/Immunogenetics and the Cell Processing Sections of the Department of Transfusion Medicine (DTM). When such transplant recipients develop complications of their therapies (e.g., graft-versus-host disease), they often require protracted hospitalization, including intensive care. In addition, the DTM Cell Processing Section is gearing up to support translational research related to the inducible pluripotent stem cell (iPSC) initiative, a high NIH priority. Developing a strategy for translating basic science discoveries relating to these cells into clinical medicine will require additional resources, including restructuring and expansion of the DTM Cell Processing Section.

3. Interest in Orthopedic Surgery

NIAMS has long expressed interest in establishing an orthopedic surgery program. Nonetheless, neither the science opportunities nor the anticipated patient volume justify the required magnitude of investment to create such a program. Orthopedic consultative services have traditionally been ranked among the weakest of all consultative services at the Clinical Center.

Recently, the Clinical Center and NIAMS have jointly established 24/7/365 coverage for orthopedic emergencies, through a partnership NIAMS built with a local, academically-trained orthopedist. The Medical Executive Committee has unanimously endorsed this new approach, and the Clinical Center will work this year to ensure seamless service with thorough follow-up for orthopedics consults. The Clinical Center is willing to develop a plan for expansion of orthopedic surgery if there is sufficient IC interest.

4. Tracking Institute Contributions to Clinical Care

Many institutes provide clinical support, including consultative services (e.g. neuropsychological testing, psychiatric consults, dermatology, etc.) to Clinical Center patients from all ICs. The services are provided either in designated clinics (such as the dental and eye clinics) or as consults on any of the patient care units. Several institutes have expressed interest in having the Clinical Center create a mechanism for tracking the volume of consult service activity, by IC, which would be used to analyze the breadth of services provided in support of other IC's patient care and research. The Clinical Center already captures this type of activity for two institutes — NIDCR and NEI – whose clinics are almost uniformly filled with patients from other ICs.

Stakeholder Input - Institutes

5. New Good-Manufacturing Practices (GMP) Facility

The Clinical Center is about to open a new 'good-manufacturing practices' (GMP) facility in the Pharmaceutical Development Section (PDS) of the Pharmacy Department. Although the Clinical Center has had a facility dedicated to similar activities for more than 40 years, the older facility did not meet GMP standards. The new facility can make capsules, tablets, solutions, biologics, vaccines, and other kinds of delivery modalities with remarkable daily volumes for a small facility, e.g., 75,000 capsules, 150,000 tablets, 220 liters of solution, 5,000 syringes, or 8,000 vials (including vaccines and biologics) in an 8-hour day. Particularly if strategies are developed to allow the facility to run for a second and third daily shift, this unique facility could provide support for investigators from the external community. Several institutes (NINDS, NEI) expressed interest in exploring new opportunities for developing pharmaceuticals in support of current and planned protocols.

6. Continued Support for Clinical Research Training

The Clinical Center's clinical research core curriculum's three courses are: The Introduction to the Principles and Practice of Clinical Research, The Principles of Clinical Pharmacology, and The Ethical and Regulatory Aspects of Clinical Research. Through these courses, the CC has cumulatively trained 21,500 students since 1995; about 3,000 students are enrolled for the 2010/2011 year from more than 60 sites (30 international). This includes more than 200 students from Eli Lilly and Johnson & Johnson. Several institutes (NINDS, NIDDK) would like to leverage the Clinical Center's research training infrastructure to support their growing efforts to train associate investigators (NIDDK), grow the area of clinical pharmacology (NINDS) and provide training opportunities to investigators at international sites (NINDS). The Clinical Center will continue to foster its training programs and look for ways to enhance and expand research across the globe.

7. Continued Expansion of Genetic Testing and Pharmacogenomics

The past several years have witnessed a marked growth of genetic testing, mutation analysis, and sequencing in protocols across ICs (NHGRI, NCI, NINDS, NICHD, NHLBI, NIAID). With the assistance of staff from the Clinical Center's Department of Laboratory Medicine (DLM), the NHGRI, and Clinical Center Senior Administrative Officers, the Clinical Center has developed a contracting mechanism to make testing more readily available. The new mechanism will facilitate direct payment by the ordering IC and include the result in the Clinical Research Information System (CRIS). Though most institutes clearly favor inclusion of these expensive tests into the DLM portfolio, current budgetary constraints make this unfeasible.

Over the past decade, a number of genetic predispositions have been found to dramatically increase the risks for toxicity associated with specific pharmaceutical agents. The field of pharmacology that evaluates the influence of genetic variation on responses to pharmaceuticals by correlating gene expression or single nucleotide

Stakeholder Input - Institutes

polymorphisms with drug toxicity or efficacy is known as pharmacogenomics. With the assistance of scientists from NCI, NHGRI and the Clinical Center Pharmacy Department, the Office of Clinical Research Training and Medical Education is leading an initiative to make relevant pharmacogenomic testing more widely available to IC investigators. Several ICs applauded this effort.

8. Provision of Care for Very Small Children (i.e., less than 2 years old or less than 10 kg.)

Historically, the Clinical Center has not provided care for very small children; the age and size cutoff being 2 years and 10 kg, respectively. During this year's planning meetings several Institutes (NCI, NICHD, NIAID and NHGRI) revealed increasing desire for the Clinical Center to provide the infrastructure necessary to support the care of very small children, including neonates, reflecting 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 CC should provide care for very small children is an NIH community decision. Possibilities include providing resources on site or establishing partnerships with neighboring institutions.

Stakeholder Input - Employees

Overview

The Clinical Center continues to attract excellent professionals with diverse backgrounds and a strong commitment to clinical research. The Clinical Center has a small Office of Workforce Management & Development (OWMD) which strives to foster a committed, high-performing Clinical Center workforce by providing tools, services and training that will: 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 improving the work environment to optimize productivity and engagement.

Key Data	FY2007	FY2008	FY2009	FY2010
Total employees	1,929	1,987	2,076	2,068
Turnover rate (~3% less than average rate for MD hospitals)	13%	12%	9.0%	7.8%
% retirement eligible	10.6%	12.4%	11.0%	12.1%
Average age of employees	45.9	45.8	45.9	45.9
Average years of government service	12.3	12.0	11.9	11.9

Method for Obtaining Input

- 1. Clinical Center Annual Workforce Reports** - Annual analysis of the Clinical Center workforce by department, occupational series and pay plan, including statistics on turnover, retirement eligibility, age, years of service, awards, pay rates and pay increases in comparison to previous years and other Maryland hospitals.
- 2. Office of Workforce Management & Development Course Evaluations** – Evaluations that are distributed to all participants of any OWMD courses and then collected for analysis.
- 3. Employee Viewpoint Survey** – Government-wide survey distributed to gather employee perceptions that drive job satisfaction, commitment, and engagement.

Stakeholder Input - Employees

What are the Employees telling us?

Succession planning needed for aging workforce

Reflective of the larger federal workforce, the Clinical Center workforce is getting older. About 11% of eligible Clinical Center employees retired last year, similar to 2008, but a significant decline from 23.1% in 2009. Over the past nineteen years, the average age of employees increased by 6.2 years to the current average of 45.9 years. As a result, occupational groups with the greatest increases in average working age have been targeted for strong succession planning. One strategy is the continuation of the Clinical Center's professional development courses and brown bags for all employees, in addition to an executive coaching program.

Quality of work-life is of increasing importance

To address growing concerns around quality of work-life, a large increase in telework has offered a more flexible workplace for those who are eligible.

New supervisory training

In response to employee input, and in accordance with Office of Personnel Management's (OPM) new mandate for supervisory training, the Clinical Center has developed a New Supervisory Curriculum for all supervisors that are new to the Clinical Center or have been recently promoted to a supervisory position. This twelve month cohort curriculum includes monthly development courses targeting technical and interpersonal/leadership supervisory skills. Coursework includes performance management, effective recruitment and retention, team building, contracts and budget as well as a myriad of other critical supervisory skills. A peer mentor program pairs each new supervisor with a more seasoned supervisor, who is able to guide the mentee through day-to-day obstacles and consequently lead them to higher productivity and increased engagement at the Clinical Center. This program was launched in December 2010 and the first cohort (beginning January 2011) is already full of enthusiastic participants.

Positive feedback for New Employee Orientation

This year approximately 600 new staff completed the New Employee Orientation. In addition, the OWMD partnered with the Social Work Department to provide competency training for 126 volunteers and partnered with the Housekeeping and Fabric Care Department to provide training for 113 staff (contractor and federal).

Participants were impressed with the "energy and professionalism." One employee declared, "I wouldn't change anything. The Clinical Center orientation was a great first experience as a new employee at the NIH." Another commented, "Best orientation I've attended."

Stakeholder Input – Patients

Overview

Patients come to the NIH from across 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 Data	FY2007	FY2008	FY2009	FY2010
New patients	9,435	9,460	10,315	10,086
Admissions	5,825	6,105	6,426	6,000
Inpatient days	51,189	51,311	55,664	56,502
Outpatient visits	90,889	90,254	96,372	96,664
Average number of patients in hospital per night	148.6	148.6	161.6	163.1
Average length of stay (days)	8.6	8.5	8.7	9.4
Telephone inquiries to Clinical Center Recruitment Office*	36,739	19,541**	35,188	37,915
Emails requesting information about participation in clinical research*	12,840	10,219	9,969	9,459

* Does not include calls/emails to individual Institutes which are not tracked centrally.

** FY2008 drop reflects contract change and disruption in standardized data collection.

Method for Obtaining Input

- 1. Surveys** - Patients are mailed a written survey within one month of discharge assessing perceptions of their Clinical Center experience. The survey assesses the experience using eight dimensions of care, including: Respect for Patient Preferences; Coordination of Care; Involvement of Family and Friends; and, Access to Care.
- 2. Patient Representative** – The Clinical Center has a designated representative 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, and serves as an advocate as needed.

Stakeholder Input - Patients

- 3. Online Feedback Mechanism** – In addition to post-discharge surveys, patients have the opportunity to submit online feedback through the Patient Portal using the bedside computers available in each inpatient room. The online form captures Clinical Center strengths in addition to opportunities for improvement.
- 4. Patient Advisory Group** – A forum open to patients and their families, the Patient Advisory Group meets semiannually with Dr. Gallin to identify issues of concern and recommendations to improve efforts to provide the highest quality research and patient care services.

“What are the Patients telling us?”

Highly rated quality of care and customer service

Survey results indicate that quality of care provided at the Clinical Center is consistently rated above the 95th percentile, and that as appropriate, patients would highly recommend the Clinical Center to friends and family.

During 2010, feedback received through the Patient Portal consistently applauded the care received by patients from nurses, physicians, social workers, nutritional staff, housekeeping and recreational therapists. Common words and phrases such as dedicated, kind, professional and friendly atmosphere were found throughout the submitted comments.

Scheduling problems and long wait times

The Patient Representative conveyed patient concerns about long wait times in clinics and scheduling issues in radiology. In 2010, members of the Patient Advisory Group provided valuable input to help the Clinical Center launch a redesign of the admissions process. Suggestions related to streamlining the process were very useful to the team of Clinical Center and Institute partners leading the redesign effort. The Patient Advisory Group will continue to play an integral role in the redesign.

Opportunities for improvement in obtaining medical records

In 2010, the Patient Advisory Group discussed issues around communication of medical records to patients and referring physicians, recognizing the need for timely and accurate information, while balancing patient confidentiality. Recommendations have been made and incorporated into plans to enhance electronic dissemination of patient information at the Clinical Center. Beginning in September, the Medical Record Department began automatically sending paper copies of these reports to those patients who consented to receive them at the time of admission/registration.

Stakeholder Input – Referring Physicians

Overview

Timely and effective bi-directional communication with referring physicians is essential to continuity of care and maintaining open and effective patient referral networks. This network of referring physicians span 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 in the past year. Comparison data to previous years is not available.

Key Data	FY2010
Referring Physician Network (all active patients)*	30,421

*Number of referring physicians for active Clinical Center patients as of 12/31/2010

Method for Obtaining Input

- 1. Surveys** – A new survey tool is being developed to send to referring physicians along with copies of patients' medical records. The survey will assess the usefulness and timeliness of the medical information shared with referring physicians regarding the care patients received at the Clinical Center.
- 2. Online Feedback Mechanism** – A new referring physician website was developed in 2010. In addition to providing information to referring physicians, it also offers health care providers the opportunity to submit online feedback regarding any aspect of the referral and communication process.

What are Referring Physicians telling us?

Importance of accurate referring physician listing in patient record

Maintaining the most up-to-date information on outside physician's names and addresses is vital to continuity of patient care. Several changes have been made to facilitate this process. New functionality has been provided within the existing Admission, Travel, Voucher request database (ATV) to enable requestors to enter patients' referring physicians' and other outside physicians' names and addresses for new patients. Enhancements to the ATV database now also enable search and automated import of outside physician information with a direct interface to CRIS,

Stakeholder Input – Referring Physicians

minimizing data entry errors. In addition, new patients and patients with a future, scheduled inpatient admission are contacted by phone in advance of their appointment in order to validate demographic information as well as the listed referring physician contact information.

A service request has also been added to CRIS enabling research nurses and other authorized users to request updates to patients' outside physicians. Patients can also provide updates to their outside physicians through an automated demographics update form that prints in outpatient clinics and day hospitals for any patient with a scheduled appointment. In addition, a secure email system has been developed to follow up with patients when necessary to obtain outside physician addresses.

Need for improved communication of patient medical information

A 2008 survey of referring physicians indicated that the NIH should improve the provision of discharge reports to provide timely and proactive patient follow-up. In response, the Clinical Center has implemented several improvements to the communications processes with referring physicians. The centerpiece of these enhancements is the redesign of the patient information provided to the referring physicians upon immediate discharge of the patient. New reporting functionality has been added to CRIS which enables the Medical Record Department (MRD) to generate a preliminary discharge report package. This package is sent the day following discharge and includes a discharge problem list, diagnostic study results, consultation reports, discharge medications and discharge instructions provided to the patient. Data enhancements have also enabled MRD staff to automatically mail out a copy of patients' first registration reports to outside physicians. A new referring physician website has been developed by the Office of Communications, Patient Recruitment and Public Liaison (OCPRL). Looking forward, the Clinical Center is designing a referring physician portal to provide convenient and secure electronic access to critical patient information.

Stakeholder Input – Clinical Research Trainees

Overview

Training the next generation of clinical researchers 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 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 private industry and abroad.

Key Data	FY2007	FY2008	FY2009	FY2010
Residents and Clinical Fellows	277*	305*	281	302
ACGME accredited training programs (representing 10 NIH Institutes & Centers)	15	16	17	18
Enrollees in core curriculum clinical research courses	1,785	1,916	2,451	3,290
Remote sites participating in core clinical research courses (34 international)	32	34	53	73
Applicants for 30 slots in Clinical Research Training Program for medical/dental students	86	97	118	140

* Approximations

Method for Obtaining Input

- 1. Graduate Medical Education Committee (GMEC)** – Trans-NIH committee.
 - Directors of clinical residency and fellowship training programs
 - Graduate medical education administrators (ICs)
 - Clinical Center’s Office of Clinical Research Training and Medical Education
- 2. Clinical Fellows Committee (ClinFelCom)** – A committee of clinical fellow representatives from all Institutes and Centers that meets quarterly with the Clinical Center Director.
- 3. Program and course evaluations**
- 4. Technology tools** – Social media and other communication tools.

“What are the Training Directors and Trainees telling us?”

Expanding and Improving Graduate Medical Education Programs

Clinical Center and NINDS training directors achieved initial ACGME accreditation for 3 GME programs, including a new Neurosurgery program, bringing the total number of accredited programs under Clinical Center institutional sponsorship to 18.

Stakeholder Input – Clinical Research Trainees

The GMEC conducted internal reviews and issued quality improvement recommendations for 10 graduate medical education programs to maintain ACGME accreditation.

Career and professional development

ClinFelCom formulated a “Professional Development Roadmap” developed in conjunction with the CC Office of Clinical Research Training and Medical Education (OCRTME), and the NIH Office of Intramural Training and Education (OITE). The Roadmap combines current and new courses to address important topics such as establishing a career development plan, working with a mentor, and conducting a job search.

OCRTME in collaboration with the GMEC and CC administration created a new institutional curriculum designed to teach trainees principles of professionalism and refine interpersonal and communication skills.

Through exit interviews, medical and dental students have provided feedback on the Clinical Research Training Program’s impact on career development, noting the importance of seeing patients at all Clinical Teaching Rounds.

Quality of performance

A ClinFelCom survey of the education and workplace environment resulted in Clinical Center housekeeping initiating a new process to assess and maintain all “call rooms” and to monitor housekeeping staff performance daily.

Clinical fellows also identified areas for improvement in the electronic system, CRIS. The Department of Clinical Research Informatics has reinvigorated a subcommittee of clinical fellows to improve CRIS, addressing issues including order entry, clinical note templates, medication/laboratory data retrieval, and structured hand-offs.

Centralizing and sharing information

ClinFelCom enhanced the “Clinical Fellows Corner” on the OCRTME website by centralizing and expanding information regarding benefits, training and career development, institutional policies and procedures, IT and online research tools, and participation on NIH committees of interest.

OCRTME uses social media tools to stay in touch with current and past trainees, including Twitter and Facebook.

Stakeholder Input – External Collaborators

Department of Defense – Traumatic Brain Injury and Post-Traumatic Stress Disorder

In April of 2009, Congress appropriated \$70M to create the Center for Neuroscience and Regenerative Medicine (CNRM), a center of research excellence for Traumatic Brain Injury (TBI) and Posttraumatic Stress Disorder (PTSD). The CNRM is a collaboration between the Uniformed Services University (the military's medical school), Walter Reed Army Medical Center, Bethesda Naval Medical Center, NIH (intramural), and the Henry Jackson Foundation. The Clinical Center's Rehabilitation Medicine Department (RMD) and the Radiology and Imaging Sciences Department play an integral role in supporting this new TBI research collaboration through management and participation on a number of NIH-CNRM protocols, as well as leadership of 3 of the center's cores (Imaging, Image Processing, and Phenotyping). The goals of the CNRM are to improve the diagnosis and treatment of TBI for injured service men and women, by creating one of the largest gatherings of TBI researchers in the world.

Social Security Administration

The RMD at the NIH Clinical Center is currently working with the Social Security Administration (SSA) through a multiyear, \$10M inter-agency agreement (IAA). In August of 2007, the SSA approached the NIH Institutes and Centers (ICs) for advice on new technologies, diagnostic tools and novel assessment methods that might inform their disability evaluation process. An IAA, established in 2008, provides support for the RMD to conduct two major lines of research focused on improving the SSA's disability determination process: 1) assess the feasibility of comprehensively examining function through development of Computer Adaptive Tests that could improve the SSA disability determination process, and 2) analyze existing SSA data to help inform programmatic decisions. For example, RMD is using a data-driven approach to analyze existing SSA data to identify potential additional Compassionate Allowance (CAL) conditions. The CAL program focuses on "severe and life-threatening conditions" and is an expedited claims process that identifies conditions for allowances based on minimal, and quickly obtained, objective medical information.

Project SEARCH

Project SEARCH is a not-for-profit program that began at Cincinnati Children's Hospital in 1996 that provides employment and education opportunities for individuals with significant disabilities. The goal of the year-long internships is to provide an opportunity for participating students to gain employability skills and work experience to prepare them for competitive employment. The Clinical Center currently has twelve interns situated in ten departments including Pharmacy, Nutrition, Medical Record and Perioperative Medicine. Following completion of the program, the participating departments will have the opportunity to hire the interns.

Governance, Advisory, and Review Groups

NIH Scientific Management Review Board

The NIH Scientific Management Review Board (SMRB) was authorized by the NIH Reform Act of 2006 and signed into law by the President in January 2007. This act was the first omnibus reauthorization of NIH in 14 years. A major element of the Reform Act of 2006 was the new authority it gave to the NIH Director to improve program coordination, assemble and analyze accurate data, implement strategic plans based on institute- and center-determined priorities, ensure proper allocation of resources, and further maximize investigator-initiated research in high impact and emerging research areas. Former NIH Director Elias A. Zerhouni, M.D., nominated individuals to serve as members of the SMRB and the Board was announced in September 2008. Through the efforts of four workgroups, the SMRB examined NIH's organizational structure and balance and provided recommendations for enhancing the agency's mission through greater agency flexibility and responsiveness. The NIH Intramural Research Program (IRP) workgroup focused specifically on the Clinical Center and the Intramural Research Program. Based on input collected from Clinical Center /NIH leadership and past/current members of the NIH Advisory Board for Clinical Research (ABCR), and working group deliberations, formal recommendations were made in December of 2010.

The SMRB voted unanimously on the following recommendations, which are pending endorsement by Secretary Sebelius and Congress:

- Vision – Recognize the Clinical Center as a national resource, with resources optimally managed to enable use by both internal and external investigators.
- Governance - Streamline the governance structure to enable development and oversight of a clear, coherent plan for clinical research.
- Budget - Create the Clinical Center budget as a line item in the NIH/OD to guarantee fiscal sustainability by ensuring that funding is stable in source, and equitable in distribution.

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 NIH Director 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. A major focus in 2010 was supporting efforts of the Congressionally-mandated Scientific Management Review Board (SMRB) tasked with providing recommendations about the funding, governance and vision of the Clinical Center, including access to outside investigators.

Governance, Advisory, and Review Groups

Medical Executive Committee

The Medical Executive Committee (MEC) advises the Clinical Center Director on clinical aspects of operations and develops policies governing standards of medical care in the Clinical Center. The group consists of Clinical Directors from each Institute and other senior clinical and administrative representatives.

Board of Scientific Counselors

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 on the Clinical Center's intramural clinical research programs. This is accomplished through periodic visits to the laboratories, assessing the research of, and evaluating the performance of, independent investigators. The purpose of this group is to secure unbiased and 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. The Clinical Center has a small portfolio of independent research conducted by the clinical departments which provides the essential clinical support services to Institute clinical researchers.

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 received full accreditation in 2009.

Ongoing Federal Budget Constraints

The Congressionally-appropriated NIH annual budget (approximately \$31.2B for FY 2010) has been modest since FY 2004, increasing a total of 12% during this period. Consequently the growth in NIH Central Services, including the Clinical Center, has also been modest. The Clinical Center budget has grown a comparable amount of 12% from 2004 through 2010 as compared to the hospital industry increase of approximately 26% during the same period. As a result of these constrained budgets, the following actions have been taken:

- Major efforts have been employed to contain costs while simultaneously ensuring continued development of new programs to carry out clinical research and also during a period of significant growth in patient activity that occurred in FY 2009 and was sustained in FY 2010 (~10% increase in inpatient days and 7% increase in outpatient visits).
- The purchase of some capital equipment has been deferred, resulting in a significant multi-year capital funding gap although the receipt of \$23.5M in ARRA funds in 2009 and 2010 helped offset the gap.
- The funding challenge faced by the Clinical Center continues to be discussed by NIH governance groups and has been formally evaluated by the Scientific Management Review Board (SMRB), a Congressionally-mandated review team. The SMRB approved a formal recommendation in December 2010 to move the Clinical Center budget to a line item within the NIH Office of the Director appropriation. This change, if approved by Congress, is not expected to be realized before FY 2013.
- The NIH Advisory Board for Clinical Research has 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 should be developed for how to contain costs at the protocol level.

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

Health Care and Biomedical Science Trends

Patient Safety and Clinical Quality

Safe and effective care of patients who come to the Clinical Center as participants in clinical research protocols is an essential aspect of the mission.

- The landmark Institute of Medicine report, "To Err is Human: Building A Safer Health System,"* and the follow-up report, "Crossing the Quality Chasm: A New Health System for the 21st Century,"** called for an aggressive approach to identify, understand and mitigate risks associated with medical care.
- Clinical Center staff and investigators continually review the patient environment using the following to proactively identify risks associated with clinical care and clinical research:
 - Clinical Center Occurrence Reporting System
 - Failure Mode and Effects Analysis
 - Root Cause Analyses

Once identified, strategies to reduce or lessen risk are devised and implemented.

The NIH Clinical Center's unique patient population and innovative research portfolio requires the use of a variety of methods and tools to assess the quality of the care and services provided to patients. Measures tailored to the research mission as well as traditional hospital-based clinical performance measures provide a comprehensive assessment of the quality of care provided at the intersection of clinical care and the conduct of clinical research.

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

*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.

** 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.

Health Care and Biomedical Science Trends

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.

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

- Patient portals
- Secure messaging between physicians
- Mobile technologies

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

- Bar-coding applications for:
 - laboratory/specimen management
 - blood product transfusion and medication administration processes
- Medication distribution systems
- Enterprise scheduling system
- Integration of automated solutions for Anesthesia, Post-Anesthesia Care Unit (PACU) and Intensive Care Unit (ICU)

These efforts, when completed, will enable the Clinical Center to be in full compliance with “meaningful use” of an electronic health record.

The Clinical Center has also developed the Biomedical Translational Research Information System (BTRIS), which is bringing data from the Clinical Center and other Institutes together in a single repository providing NIH researchers 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., nursing documentation and pharmacy data)
- Archived Clinical Center data from the Medical Information System (MIS)
- Data from systems at NIAID, NIAAA and NCI
- Radiographic images in the Clinical Center's Picture Archiving and Communication System (PACS)

In FY 2011, the Clinical Center will expand BTRIS to include additional data from NICHD and NHGRI systems.

Health Care and Biomedical Science Trends

Pharmaceutical/Supply Inflation

The Clinical Center budget is impacted each year by the rising costs of drugs and medical supplies.

- ~ \$1 of every \$10 spent by the Clinical Center is for drug purchases
- Drug inflation (including the replacement of older, less expensive drugs with newer, expensive agents) increases by 5-8% per year
- Medical supplies inflation increases by 4-6% per year
- Although the Clinical Center participates in a drug purchasing consortium, these costs must be contained in an era of flat budgets.
- The Clinical Center continues collaborating with Institutes as they negotiate with pharmaceutical manufacturers to reduce Clinical Center costs for marketed drugs that are being studied for non-approved indications. Through these negotiations, the Clinical Center has seen an increase in sponsor supplied drugs of approximately \$5M/year over the last two years.
- Inflation of medical supplies, although at a slower rate of approximately 4 to 6 percent annually, also requires cost containment efforts.

Proteomics

Proteomics is the large-scale study of proteins and their structure and function. The proteome is the entire complement of proteins produced by an organism, including the modifications made to a particular set of proteins.

- These modifications occur in response to stress, physiological changes, and other stimuli and contribute to the physiological metabolic pathways within cells.
- These proteins and modified proteins can be detected and measured in maps using mass spectroscopy and other sensitive techniques.
- NIH scientists are using proteomics to evaluate:
 - Host-parasite interaction
 - Normal and abnormal physiology
 - Body's response to infection, sepsis, malignancy and in a variety of other settings

Evaluating how proteins are modified in these settings provides insight into molecular physiology and sheds light on possible interventions.

Both Institute as well as Clinical Center scientists are using proteomics in their basic and applied studies of human physiology. In addition, the CC Department of Laboratory Medicine is using proteomics as a novel approach to diagnosis in clinical chemistry and clinical microbiology.

Health Care and Biomedical Science Trends

Molecular Medicine

Molecular medicine represents the logical extension of scientific inquiry into human physiology and pathophysiology.

- Increasingly, NIH Intramural Research Program (IRP) scientists are using molecular approaches that employ a variety of physical, chemical, biological and medical techniques to:
 - Identify genus and species and possible clonality of microorganisms
 - Describe molecular structures and molecular mechanisms
 - Identify molecular and genetic errors associated with disease states
 - Develop tailored molecular interventions to correct them
- Beginning with the development of the radioimmunoassay and encompassing the tools of genomics, proteomics, microbiomics and pharmacogenomics, a variety of new techniques have been developed over the past four decades that effectively have created the discipline of molecular medicine.

Genomics

Genomics is the study of the genetic material of organisms and includes determining the complete DNA sequence of organisms as well as the creation of gene maps and the study of interactions that occur among genes.

- Techniques have been developed over the past two decades to make the field of genomics possible, including:
 - Techniques for DNA sequencing
 - Gene- and genome-mapping
 - Data storage
 - Analysis of the huge data sets produced by these studies
- Studies regularly analyze which genes are actively expressed and which are down-regulated in specific disease states.
- NIH scientists played a significant role in the sequencing of the entire human genome.

Health Care and Biomedical Science Trends

Microbiomics

Microbiomics is the study of the complete set of genetic material (i.e., all the genomic material) from all of the microorganisms in a specific environment (e.g., the gut or the skin). This burgeoning field uses molecular tools to evaluate the microbial diversity in specific environments and determine how changes in the microbiota in these environments contribute to health and disease. Many NIH scientists are aggressively using these molecular techniques to assess the impact of the microbiota of specific human environments (e.g., oral cavity, colon, skin, etc.) on health and in specific disease states.

Pharmacogenomics

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. NIH investigators are using these approaches to tailor cancer chemotherapy strategies for individual patients.

President's Management Council

Office of Management and Budget's Accountable Government Initiative - Update on Performance Management Agenda*

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

As part of the FY 2011 budget process, a small number of near-term, ambitious, outcome-focused priority goals were identified. Quarterly data-driven reviews will drive progress towards the goals, and leaders will analyze performance and other data to guide agency action.

2. Cutting waste

First and foremost, the Administration is working to eliminate programs that do not work, are out of date, or are duplicative. Through 'line-by-line' reviews, approximately \$20 billion in terminations, reductions and savings were proposed in both the FY 2010 and 2011 budgets. Agencies are taking the hard step to identify programs that are less central to achieving agency mission goals – the CC provided a list of possible programs to NIH leadership in early Fall. In addition, efforts to reduce and recapture improper payments and eliminate excess real property are underway.

3. Reforming contracting

In March 2009, President Obama directed agencies to save \$40 billion in contracting annually by FY 2011 while also reducing the use of high-risk contracts. In addition, agencies were encourage to utilize strategic sourcing by pooling the government's purchasing power. To sustain these improvements, focus on the capacity and capabilities of the acquisition workforce is crucial.

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

President's Management Council

Office of Management and Budget's Accountable Government Initiative - Update on Performance Management Agenda*

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 focus 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 through Performance.gov, a website that opened to the public this past Fall. Performance.gov will help create the clarity and culture of accountability required to achieve meaningful improvements, while providing access to management dashboards and agency priorities.

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

HHS Strategic Plan 2010-2015

Every 3 years, HHS updates its strategic plan, which aligns the work of the Administration, the department, and agencies across 5 strategic goals:

1. Transform Health Care

- Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured
- Improve healthcare quality and patient safety
- Emphasize primary and preventive care linked with community prevention services
- Reduce the growth of healthcare costs while promoting high-value, effective care
- Ensure access to quality, culturally competent care for vulnerable populations
- Promote the adoption and meaningful use of health information technology

2. Advance Scientific Knowledge and Innovation

- Accelerate the process of scientific discovery to improve patient care
- Foster innovation to create shared solutions
- Invest in the regulatory sciences to improve food and medical product safety
- Increase our understanding of what works in public health and human service practice

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
- Reduce the occurrence of infectious diseases
- Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies

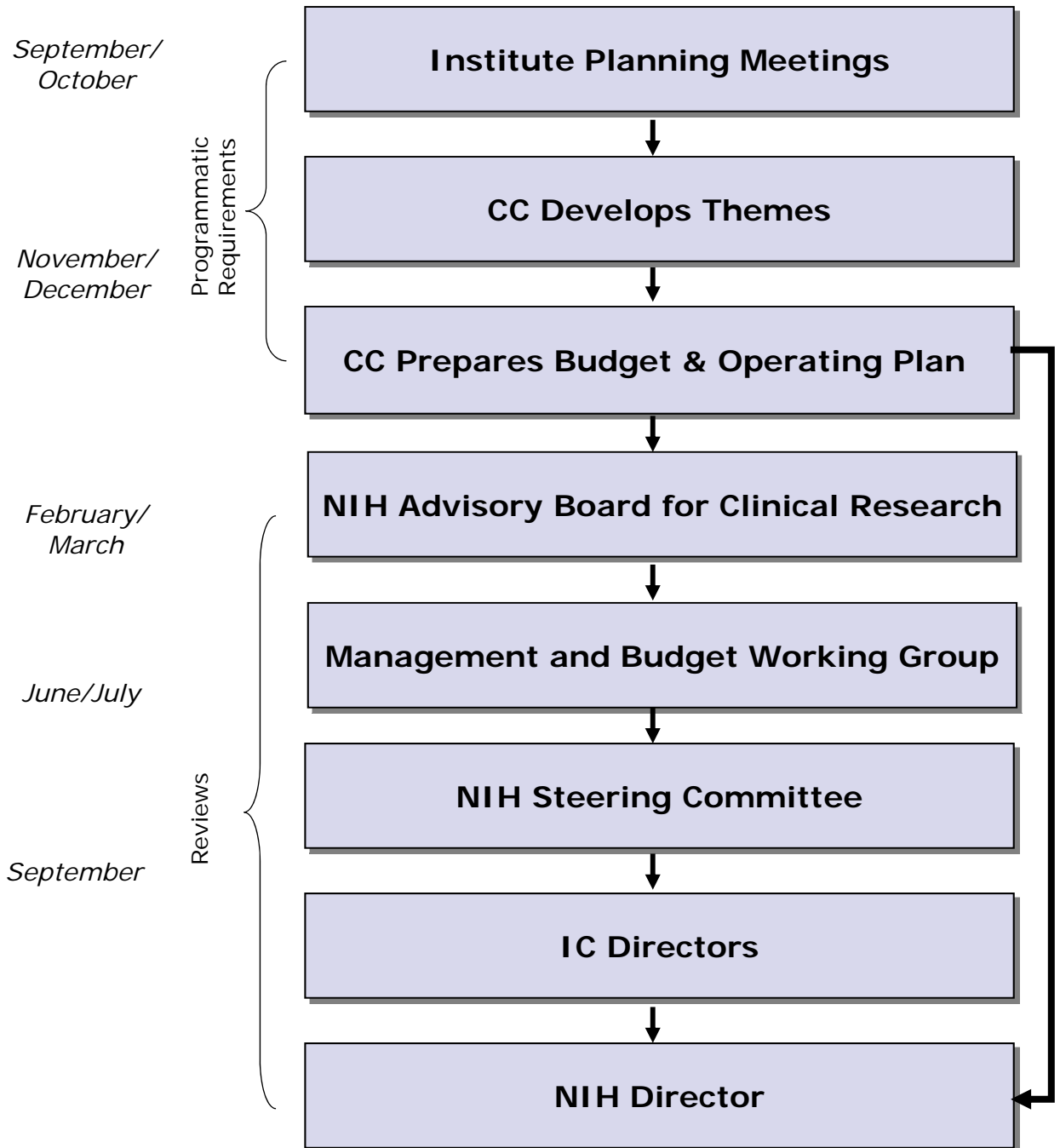
4. Increase Efficiency, Transparency, and Accountability of HHS Programs

- Ensure program integrity and responsible stewardship of resources
- Fight fraud and work to eliminate improper payments
- Leverage HHS data for maximum public good
- Improve HHS environmental, energy, and economic performance to promote sustainability

5. Strengthen the Nation's Health and Human Service Infrastructure and Workforce

- Ensure that the Nation's healthcare workforce can meet increased demands
- Improve the recruitment, retention, and training of our domestic and global public health workforce
- Strengthen the Nation's human service workforce
- Improve national, State, local, and tribal surveillance and epidemiology capacity

Clinical Center Planning/Budget Review Process*



*Current as of December 2010. Changes pending per Scientific Management Review Board recommendations on budget and governance.