

Introduction to the NIH Clinical Center



July 15, 2016

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Director, NIH Clinical Center**



Outline

- **Overview**
- **Budget**
- **Governance**
- **Safety and Quality Improvement**
- **Assuring a Vibrant Future**

Overview

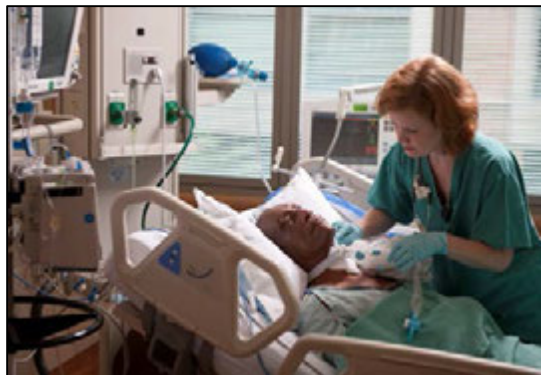
What is the Clinical Center?

**The NIH Clinical Center
is the largest hospital in the world
totally dedicated to clinical research**

Key Mission Elements



Clinical Research



Patient Care



Training

Distinguishing Features

- **Every patient is a partner on a research protocol**
- **Research emphasis:**
 - Enables clinical research of 17 institutes
 - Study of the pathophysiology of disease
 - First in human with new therapeutics
 - Study of patients with rare diseases
- **Not a full service hospital (e.g., no ER, OB)**
- **Budget allocated at beginning of each year**
 - No revenue stream
 - No billing for care
 - No philanthropy
- **Hospital enveloped by research labs**
- **Renowned for contributions to medicine**
 - 2011 Lasker~Bloomberg Public Service Award



Selected Accomplishments

- **Chemotherapy for cancer**
- **Blood lipids as biomarkers of cardiovascular disease**
- **Fluoride gels to treat dental caries**
- **Lithium for depression**
- **First drugs for AIDS**
- **Identification of genes for stuttering**
- **Immune therapy for metastatic melanoma**
- **New imaging approaches for prostate cancer**
- **Microbial genome sequencing in hospital epidemiology**
- **First in human Ebola vaccines**

Clinical Center Profile

- **CC Patients:**

- >509,000 patients since opening in 1953
- Travel/housing provided as needed
- Average LOS is 8.5 days; ADC: 130.8
- 2015: 47,847 inpatient days; 100,507 outpatient visits; 10,761 new patients

- **Current budget: \$419.2M**

- **200 beds; 13 ambulatory clinics; 93 day hospital stations; 11 ORs**

- **2,657 CC staff; 6,764 IC staff**

- **1,332 credentialed physicians (CC: 184; ICs: 1148)**

- **1,606 active protocols**

- Interventional/Clinical Trials – 780 (49%)
- Natural History – 730 (45%)
- Screening – 69 (4%)
- Training – 27 (2%)

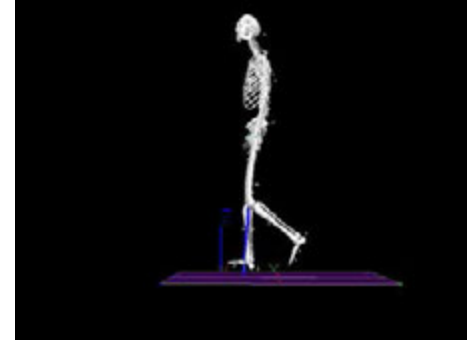


Inpatient Units

- **Pediatrics**
- **Alcohol/Behavioral Health**
- **Pediatric Behavioral Health**
- **Hematology-Oncology/Transplant**
- **Adult Surgical and Medical Oncology (2)**
- **ICU**
- **Special Clinical Studies Unit**
- **General Medicine**
- **Medicine - Telemetry**
- **Metabolic**
- **Adult Behavioral Health**
- **Neurology/Sleep Lab**

Specialized Facilities

- **Biomechanics laboratory**
- **Metabolic chambers**
- **Cell processing in transfusion medicine**
- **MRI center**
- **PET research-3 cyclotrons**
- **Special clinical studies unit**



EHR and Research Data Repository

CRIS

Clinical Research Information System

- Platform: Allscripts, Sunrise Clinical Manager
- Fully integrated EHR
 - Computerized Physician Order Entry
 - Clinical Documentation
 - Barcoding
 - Facilitates collection of research data
 - Clinical Decision Support (triggers, alerts, protocol order sets, and pharmacogenomics)
- Patient and Referring Physician Portals

BTRIS

Biomedical Translational Research Information System

- Merges clinical and research data
- Total rows of data: 20 billion
- Provides reporting and analytical capabilities
 - Identified and de-identified data analysis
 - Facilitates reporting to clinicaltrials.gov

July 31, 2015



Honors facilities operating in a paperless environment and representing best practices in implementing the electronic health record

Training

- **Clinical Center is the sponsoring institution for 17 ACGME accredited programs**
 - 2 primary residencies
 - 15 clinical fellowships
 - 2 CLER site visits: September 2014 and April 2016
- **~30 other clinical fellowships**

**Training on regulatory and hospital/clinical quality
and patient safety issues**

Historical Reviews

1994	External Advisory Committee of the Director's Advisory Committee (<i>Marks-Cassell Report</i>)
1996	Opportunity: Revitalizing the NIH Clinical Center for Tomorrow's Challenge (<i>HHS Options Team Report</i>)
1997	Report of the NIH Committee on the Recruitment and Career Development of Clinical Investigators and Implementation Plan (<i>Straus Report</i>)
2004	The Future of Intramural Clinical Research (<i>Blue Ribbon Panel</i>)
2010	Scientific Management Review Board (<i>Congressionally-mandated</i>)
2011	Feasibility Study for Third Party Reimbursement (<i>PwC</i>)
2016	The Clinical Center Working Group Report to the Advisory Committee to the Director, NIH (<i>Red Team</i>)

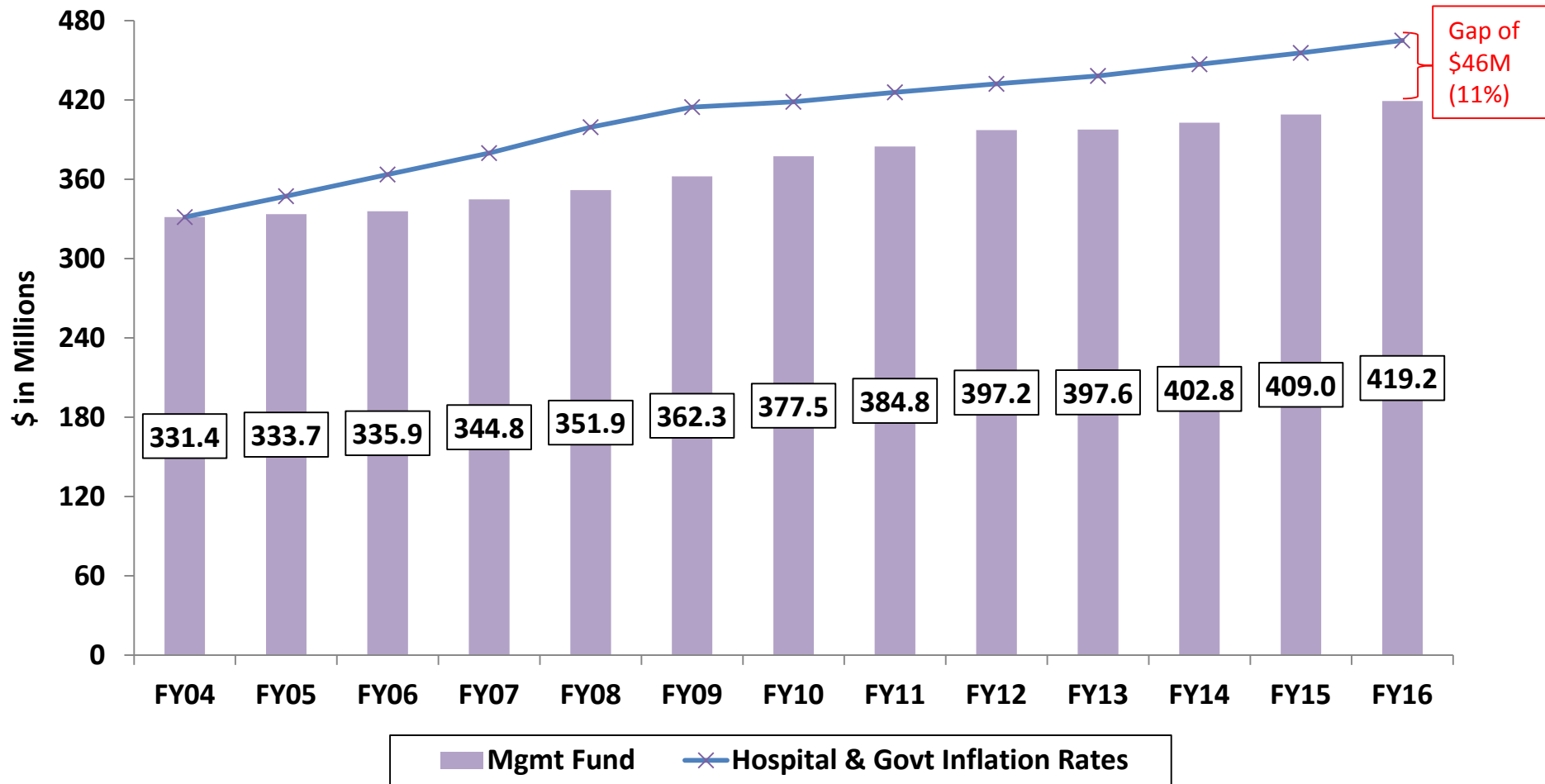
Major Themes

- **Patient Safety**
- **Budget**
 - How should CC be funded
 - Appropriate size hospital to fund
 - Underfunded facility/capital equipment
 - Feasibility of 3rd party reimbursement
- **Governance**
 - Simple structure important
 - Prioritization of science; strategic planning
 - Fragmented authority/responsibility of CC leadership
- **Staff Recruitment**
 - Pipeline of clinical investigators
 - Challenges with Federal personnel system
- **Sharing Scarce Resources**

These themes represent the Clinical Center's fundamental challenges

CC Budget

CC Budget (FY 2004 - FY 2016)



**Hospital inflation rate source: R-C Healthcare Management*

Funding Challenges

- Inflation gap ~\$46M over last 12 yrs
- Red team remediation as much as \$50M

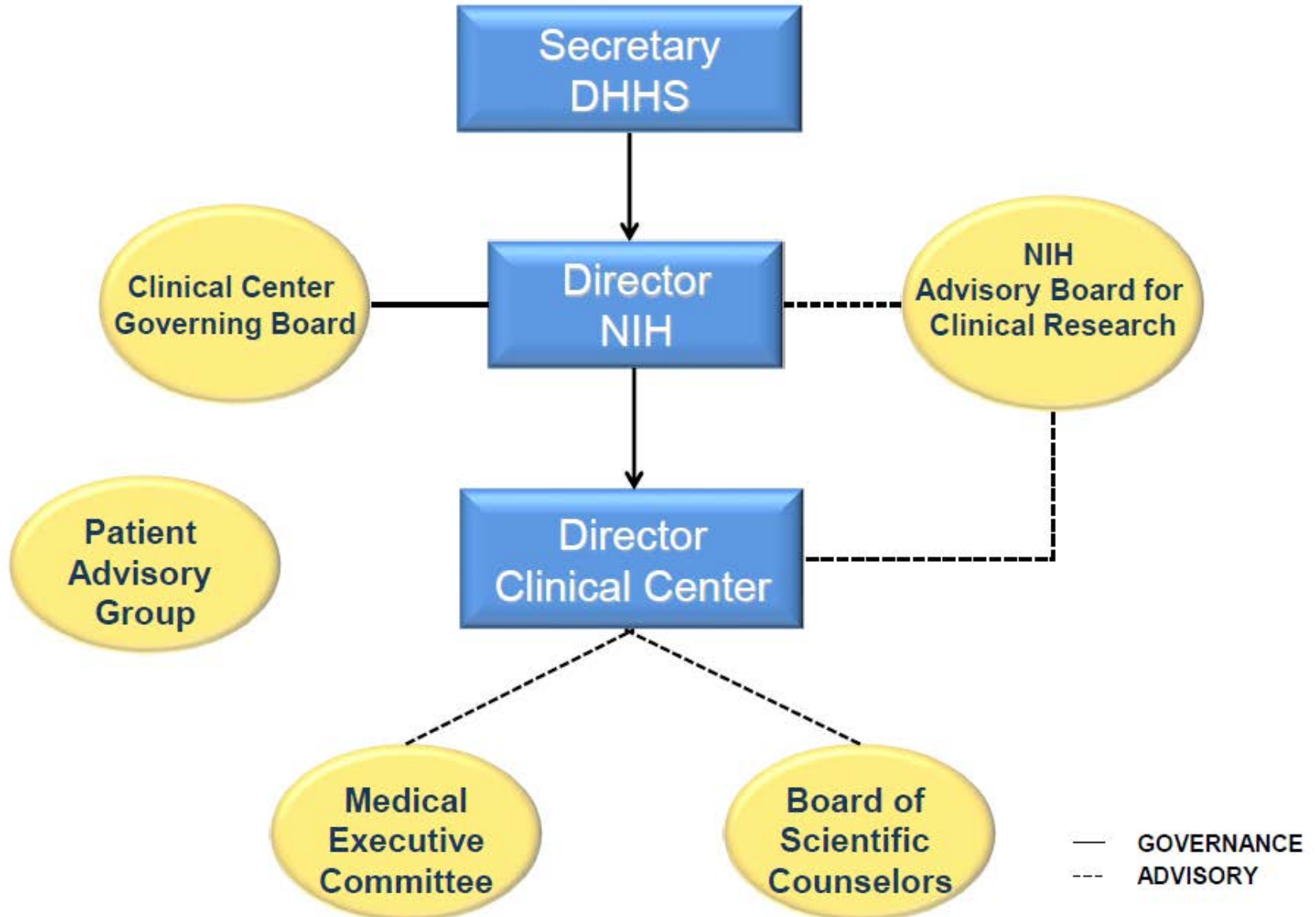
Impact

- Capital equipment and critical initiatives
- Critical facility upgrades

Governance

Clinical Center Governance

March 2016



Accreditation and Other Reviews

Accreditation

- Joint Commission
- College of American Pathologists (CAP)
- Clinical Laboratory Improvement Amendments (CLIA)
- Food and Drug Administration (FDA)
- American Association of Blood Banks (AABB)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- Nuclear Regulatory Commission (NRC)
- American College of Radiology Accreditation Program
- Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
- Accreditation Council for Graduate Medical Education (ACGME)

Other Reviews

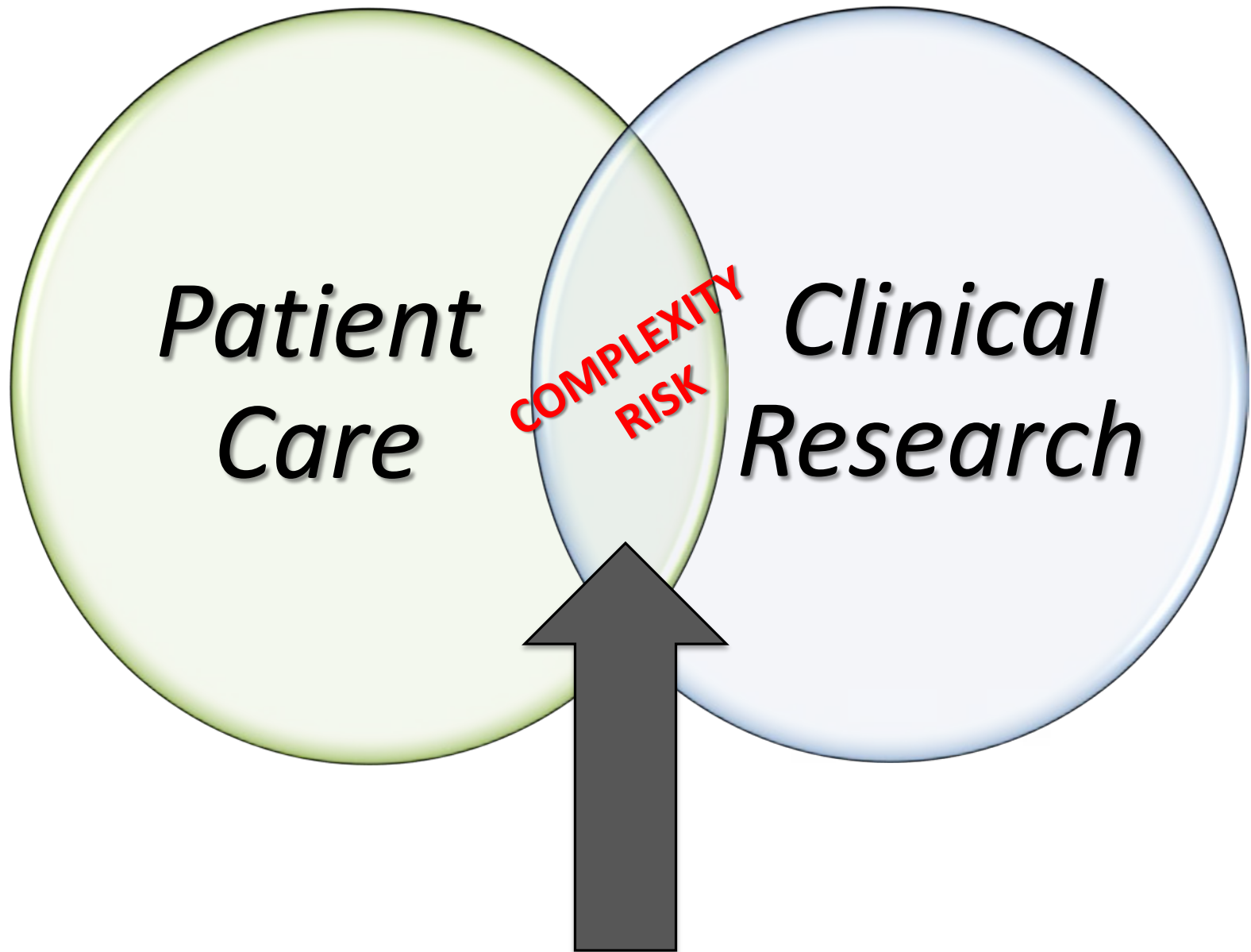
- Operational reviews of CC Departments
- Board of Scientific Counselors

Patient Safety and Clinical Quality

Laura M. Lee, RN, M.Sc.
Director, Office of Patient Safety and Clinical Quality
NIH Clinical Center

Overview

- Present the framework for patient safety and quality
- Review select NIH CC performance measurement activities
- Discuss the current state of the NIH CC program
- Discuss future opportunities



Patient Safety and Clinical Quality Framework



Patient Safety and Clinical Quality Activities

Risk Assessment

- Scientific and IRB Reviews
- Pre-IRB Protocol Review Impact Assessment
- Failure Modes and Effects Analyses
- Independent external accreditation/certification

Surveillance

- Patient Safety Event Reporting
- Quality and Safety Performance Metrics
- Clinical Research Monitoring
- Infection Control Surveillance
- Trigger Tool Surveillance
- Tracers
- Patient Safety WalkRounds™
- Culture of Safety Survey

Event Analysis

- Root Cause Analysis
- Apparent Cause Analysis
- Reason's Unsafe Acts Analysis
- Morbidity and Mortality Rounds

QI/Org Learning

- Quality Improvement Initiatives (PDCA)
- Patient Safety and Quality Curriculum
- Quality and Safety Rounds/Meetings

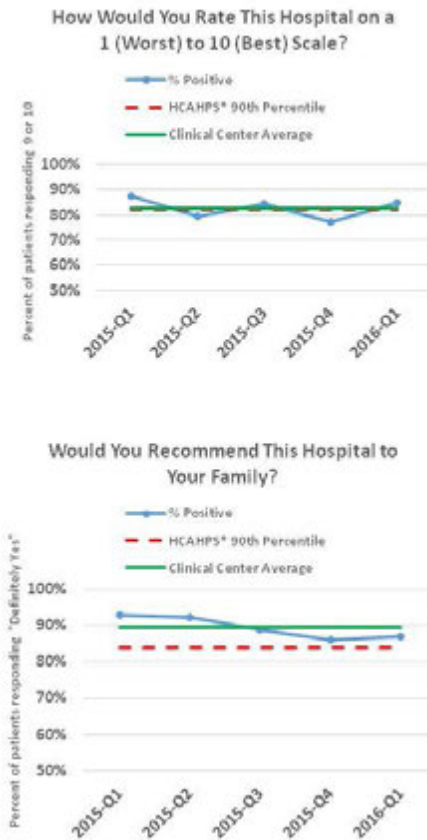


Measuring Patient Safety and Quality

Current State

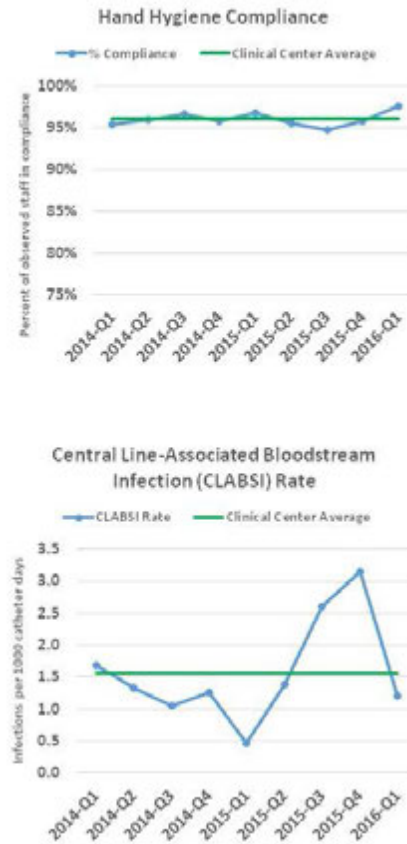
- Key hospital metrics collected - most for a decade or longer

Patient Experience

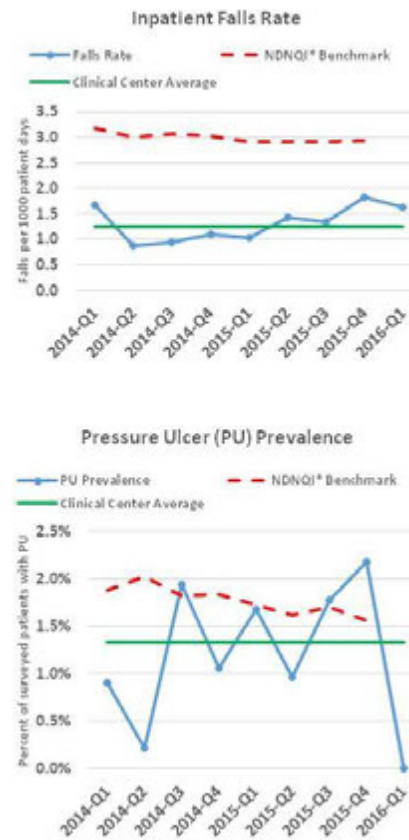


*HCAHPS = Hospital Consumer Assessment of Healthcare Providers and Systems

Infection Control



Hospital Acquired Conditions



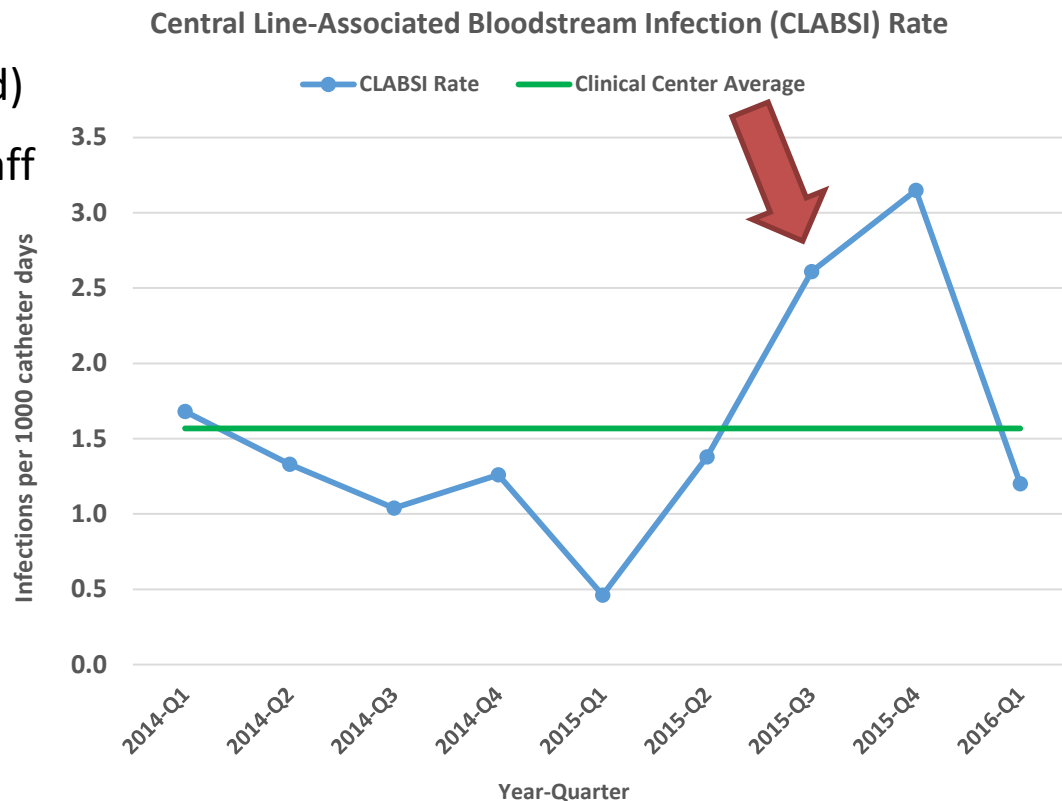
*NDNQI = National Database of Nursing Quality Indicators

Surgical Care



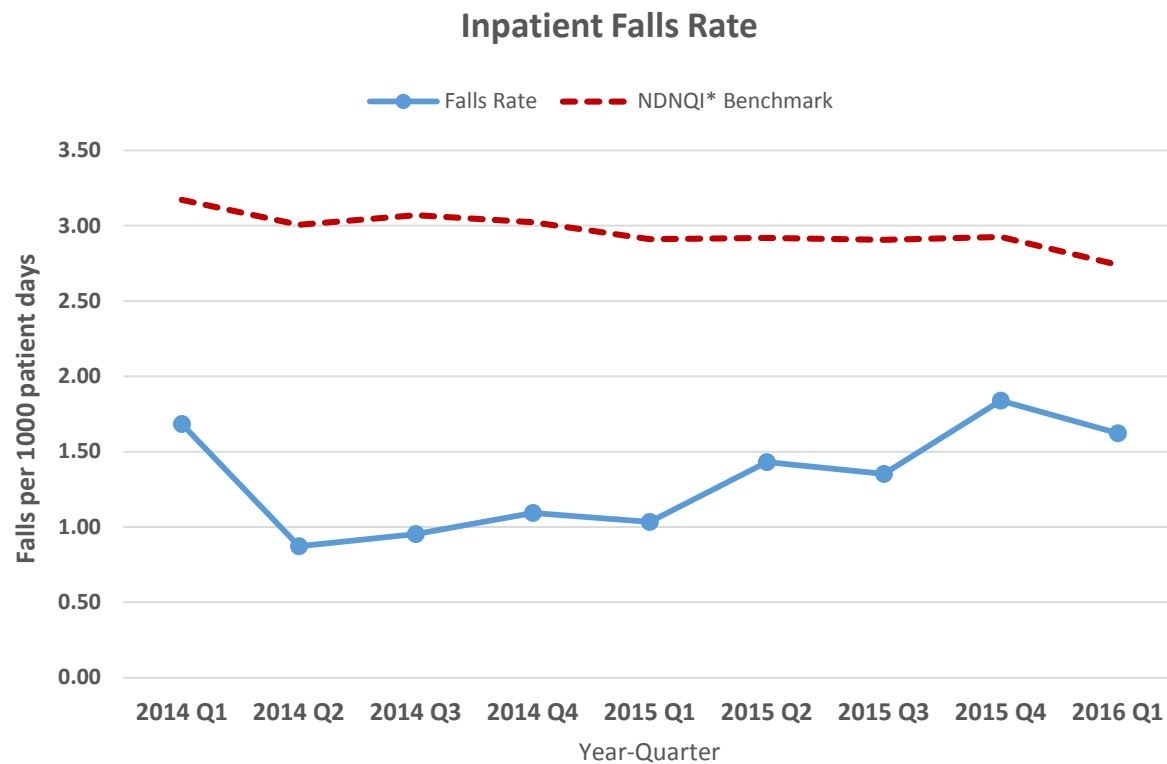
Central Line Associated Bloodstream Infections

- Hospital Acquired Infections data are reviewed quarterly at the Hospital Infections Committee; Nursing Quality meetings, the Clinical Quality Committee and the Medical Executive Committee
- Q3 2015: CLABSI rate started an upward tick
- October 2015: Interdisciplinary group convened to discuss increase in CLABSIs
- Interventions:
 - Standardize practice (SOPs updated)
 - Extensive (re)training of nursing staff
 - Standardize equipment/supplies
 - Education/Awareness raising
 - Patient and staff engagement
 - Scrub the Hub education



Falls Prevention

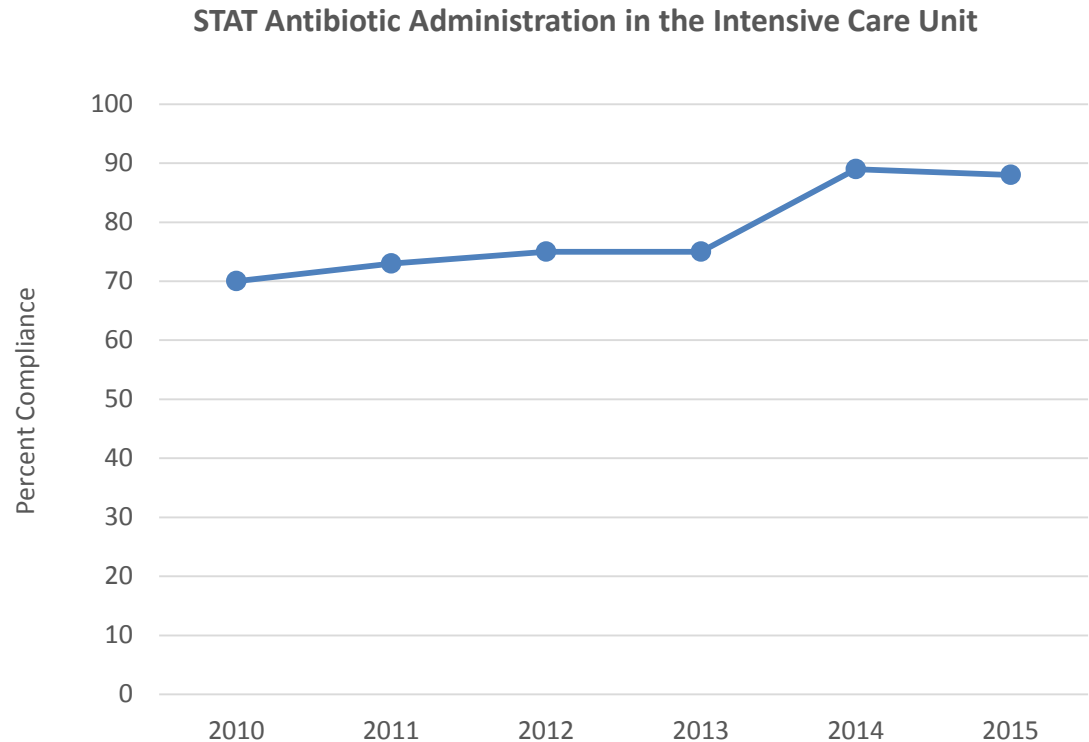
- 2013: Rate of reported falls was consistently low; suspected under-reporting
- Initiated an awareness raising effort about reporting; led to increased number of reported falls
- 2014: Nursing launched an initiative to evaluate the current state of falls prevention strategies
- Interventions included:
 - Increase visibility of high fall risk patients (e.g., Falling Star, fall alert wristband, unit safety huddles);
 - Patient engagement strategies (e.g., patient-friendly data displays, purposeful rounding, *Call Don't Fall* signs, patient educational brochure);
 - Staff engagement to analyze contributing factors (e.g., post-fall huddles)
 - Bed alarms
 - 1:1 Patient Care Technician role



*NDNQI = National Database of Nursing Quality Indicators

STAT Antibiotic Management in the ICU

- 2010: Time to administration of STAT antibiotics was suboptimal
- Improvement goal: 100% of STAT antibiotic infusions initiated within 60 minutes of electronic order entry
- Interventions
 - Education and training about early communication of new orders
 - Alert to the pharmacy for STAT orders
 - Standardized order sets to assist pharmacy verification and approval
 - Established standard premixed formulations
 - Staged preparations of antibiotics in the ICU Omnicell®
 - Modified orders to maximize infusion rates
 - Modified field in the medication administration record to track contributing factors



Measuring Patient Safety and Quality

Current State

- NIH CC collects many “typical” hospital metrics
- Collecting certain hospital metrics is challenging in this environment
 - Population-based metrics (e.g., stroke, heart failure, acute myocardial infarction, community acquired pneumonia, pregnancy)
 - Surgery-specific metrics (e.g., orthopedics, cardiac)
- NIH CC clinical departments have active measurement programs
 - Nearly 200 metrics are used to monitor performance and drive improvement
 - “Critical few” guide operations/management
- Few Institute programs focus on “clinical care” related measures; rather the Institute programs monitor patient safety and quality in the context of a clinical research;
 - Protocol compliance
 - Serious adverse events, protocol deviations
 - Data Safety Monitoring Boards
 - Research-related outcomes

Measuring Patient Safety and Quality

Opportunities for Improvement

- Revise NIH CC “Patient Safety and Clinical Quality Plan” based on visits to external hospitals

	Initial Contact	Liaison
New York Presbyterian	Laura Forese, MD, MPH	Henry Ting, MD, MBA
Johns Hopkins	Paul Rothman, MD	Peter Pronovost, MD, PhD
Dana Farber	Edward Benz, MD	Joseph Jacobson, MD
Brigham and Women’s	Elizabeth Nabel, MD	Allen Kachalia, MD, JD

Measuring Patient Safety and Quality

Opportunities for Improvement

- Revise NIH CC “Patient Safety and Clinical Quality Plan” based on visits to external hospitals
- Expand measurement activities based on gap analysis of industry metrics
- Leverage safety and quality activities related to the conduct of clinical research when developing IC-based metrics
- Expand existing patient safety and quality education/training programs
- Standardize processes for reporting metrics and improvement efforts throughout the organization
- Expand investment to:
 - Enhance existing NIH CC programs patient safety and clinical quality
 - Stand-up Institute-based programs that are aligned with the NIH CC

Assuring a Vibrant Future

- **Instill a stronger culture of safety and quality improvement**
- **Align responsibility and authority of CC leadership**
 - **Clinical care**
 - **Facility oversight**
- **Stabilize budget**
 - **Establish independent budget line**
 - **Correct underfunding**
- **Upgrade facilities**
 - **New wing for aged, “stranded” departments**
- **Revitalize antiquated personnel system**
 - **Raise salaries for scarce medical specialties**
 - **Address arcane position classification methodology**

QUESTIONS

