

NATIONAL INSTITUTES OF HEALTH

CLINICAL CENTER ENGAGEMENT PROJECT

UPDATE TO THE CLINICAL CENTER RESEARCH HOSPITAL BOARD

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Clinical Center

Overview

Purpose:

- Learn from stakeholders (i.e., Intramural Research Program (“IRP”) staff and Clinical Center (“CC”) staff) how to enhance quality of care at the CC.
- Provide CC and IRP staff with an opportunity to be heard on concerns they have about the CC.

Status:

- Complete—Final Focus Group occurred January 3, 2017
- Seventy (70) Focus Groups sessions were held between September 6, 2016 and January 3, 2017.
- Total number of participants: 621

Overview (Continued)

Breakdown of Sessions

- Scientific Directors (1)
- Physician Groups (6)
- Staff Clinicians/Fellows (1)
- CC Engagement Working Group (1)
- Nutrition (2)
- Patient Advisory Group (1)
- NIH Legal Advisor (1)
- Bioethics (1)
- Office of Research Facilities (1)
- Office of Human Subject Research Protection (1)
- Protocol Navigation Group (1)
- Housekeeping (1)
- Vendors (1)
- General Sessions (51)

Overview (Continued)

Breakdown of Participants

- Physicians (184)
- Nurses (195)
- Dentists (2)
- PhD Scientists (30)
- Pharmacists (9)
- Dieticians (5)
- Social Workers (8)
- Bioethicists (14)
- Physical Therapists (2)
- Laboratory Technicians (6)
- **Other (166)** (includes, Administration, Food Service, Consultants, Lawyers, Epidemiologists, Chaplain, Genetic Counselors, Patient Advisory Group, Protocol Navigators, Office of Research Facilities (ORF))

Questions to Focus Groups

- What is great about the CC—what brought you here, what keeps you here?
- What tensions do you observe between patient care and clinical research?
- How, if at all, does the unusual (for a hospital) organizational structure of the CC affect patient care?
- What, if any, concerns related to patient safety weigh on you?
- If you could change one thing about the CC to improve patient safety, what, if anything, would you change?

Themes

Commitment and Mission

- Staff at all levels, whether Institute or CC, are dedicated to the CC's unique mission and want to provide the highest quality care.
- Since patients come to the CC to advance medical science, staff are committed to caring for patients with compassion and skill.
- Staff feel a genuine connection to patients and their families, many of whom have been coming to the CC for years.
- It is an honor to work at the CC: there is no other place like it.

Governance and Accountability

- CC leadership does not have authority over a substantial amount of activity in the hospital (e.g., approximately 8,000 people work in the CC only 2,000 of whom are employed by the Clinical Center)
- Basic CC functions are controlled by user institutes (e.g., anatomic pathology is an NCI responsibility) or the Office of the Director (e.g., facilities and HR).
- Lines of reporting authority are sometimes difficult to determine and this complicates holding staff accountable.

Themes (Continued)

Fragmentation and Inconsistency

- Seventeen Institutes undertake research at the CC and each has different procedures and processes.
- There is often confusion as to who is the cognizant medical provider for patients in multiple protocols.
- Twelve IRBs operating at the CC—most with different policies and procedures.
- Some consult services lack consistency with respect to availability, professionalism, accountability and quality.

Communications and Engagement

- Communication lapses occur and impact patient care.
- No consistent communication of best practices at the CC.
- No clear pattern for how Occurrence Reporting System (ORS) submissions are adjudicated and addressed.
- Insufficient transparency related to misadventures and unexpected events.
- Staff sometimes learn about significant CC incidents or events through the media, not by internal communication.
- Consistent involvement of non-CC NIH functions (e.g., NIH legal advisor) is often lacking in the development and implementation of Institute policies and procedures concerning the CC.

Themes (Continued)

Organizational Development and Human Resources

- There is insufficient succession planning at CC.
- When foreseeable vacancies occur (e.g., retirements), these positions often remain unfilled for extended periods of time.
- The delays commonplace in filling vacancies impact patient safety and quality of care.
- Non-tenure track staff (e.g., Staff Clinicians) feel that they are not valued to the same degree as tenure track staff.

Clinical Center Facilities

- A substantial investment in CC infrastructure is needed to protect patient safety and quality of care (e.g., facilities for the Department of Perioperative Medicine/Operating Rooms and Department of Laboratory Medicine).
- An investment in housekeeping is needed to ensure better infection control (e.g., the CC does not have a housekeeping management tool to schedule and tailor room cleaning).

Themes (Continued)

Resourcing and Risk Management

- The CC is not resourced properly to perform its core mission—the School Tax alone is insufficient to meet the needs of protocols approved for the CC at its optimal census.
- Since the CC is not a full service hospital, delays in access to care, therapies or interventions can occur when capabilities needed for a protocol (or clinical care) are not resident or consistently available at the CC.
- Greater emphasis should be given to contingency planning for high risk protocol (e.g., expediting emergency transfer from the CC).
- Resource requirements for protocols should be evaluated in greater detail prior to approval by the IRB, especially the availability, volume and time sensitivity of specific interventions and diagnostic procedures.

Draft Recommendations

- Develop consistent and harmonized clinical care policies and procedures applicable to all CC functions, whether performed by the CC or an Institute.
- Establish a risk management mechanism to develop and enforce CC-wide mandatory policies and procedures for related to high-risk patients and protocols.
- Require uniformity in core IRB procedures and policies so that all CC patients receive the same basic information that can be understood at the 8th grade level.
- Develop consistent admission, discharge, transfer and clinic visit documents for all CC patients.
- Enforce and hold staff accountable for minimum standards for required documentation in the medical record including the current medically responsible physician, history, physical examination and interventions.

Draft Recommendations (Continued)

- Develop a process to better track research blood draws and research diagnostic tests within the medical record for all patients including healthy volunteers.
- Develop and communicate a CC-wide procedure to swiftly transfer CC patients in need of emergency care to another institution (e.g., Suburban Hospital or Children's National Medical Center).
- Consistently involve non-CC NIH functions (e.g., NIH Legal Advisor, NIH Ombudsman) in the development of Institute policies and procedures concerning the CC as well as new employee orientation at the CC.
- Align Perioperative Medicine, Interventional Radiology and Department of Transfusion Medicine nurses to the CC Department of Nursing to facilitate consistency in communications and competency training.
- Undertake a review of CMS and Maryland patient safety and quality requirements and adopt those that are appropriate for the CC.

Draft Recommendations (Continued)

- Align NIH, CC and Institute orientation programs to facilitate navigation of a large complex organization and coordinate content conveying resources and services at the CC. Require participation in CC orientation program for all NIH staff who work at the CC.
- Increase the frequency of the Morbidity and Mortality Review Conferences at the CC.
- Institute quarterly town hall meetings for the CC and consider offering periodic focus group sessions to CC staff.
- In the annual review by the NIH director of each Institute director's performance include an evaluation of the Institute's research and patient safety at the CC.
- NIH Director, CC CEO, CC CSO and Institute Directors with their Clinical Directors jointly prepare a multi-year strategic plan for the CC. Such plan should address research, optimal census, patient care and safety at the CC, and include funding commitments to appropriately support same from each Institute in addition to such Institute's contribution to the School Tax.
- Develop a proactive strategy to communicate improvements that have occurred at the CC since the Red Team Report and subsequent coverage in scientific literature and other media.

Steps to Project Completion

- Complete drafting of the Summary of Themes and Recommendations (“Summary”).
- Present draft Summary to the CC Engagement Working Group, chaired by Dr. Griffith, for review and approval.
- Brief the CC CEO on the Summary as approved by the CC Engagement Working Group.
- Brief the CC Medical Executive Committee on the Summary as approved by the CC Engagement Working Group.
- Submit the Summary as approved by the CC Engagement Working Group to the Steering Committee Chaired by Dr. Gottesman.
- Estimated date of project completion: February 10, 2017.