NIH CC CEO Update for the ACD

James K. Gilman, MD MG, USA (ret) FACC/FACP 8 June 2017 Mission: We provide hope through pioneering clinical research to improve human health.

Guiding principle #1: Individual and collective passion for high reliability in the safe delivery of patient-centric care.

Fill Key Positions

- CNO /CNE well into search process
- Radiology and Imaging Science Chief just appointed Search Committee*
- COO still awaiting green light from HHS

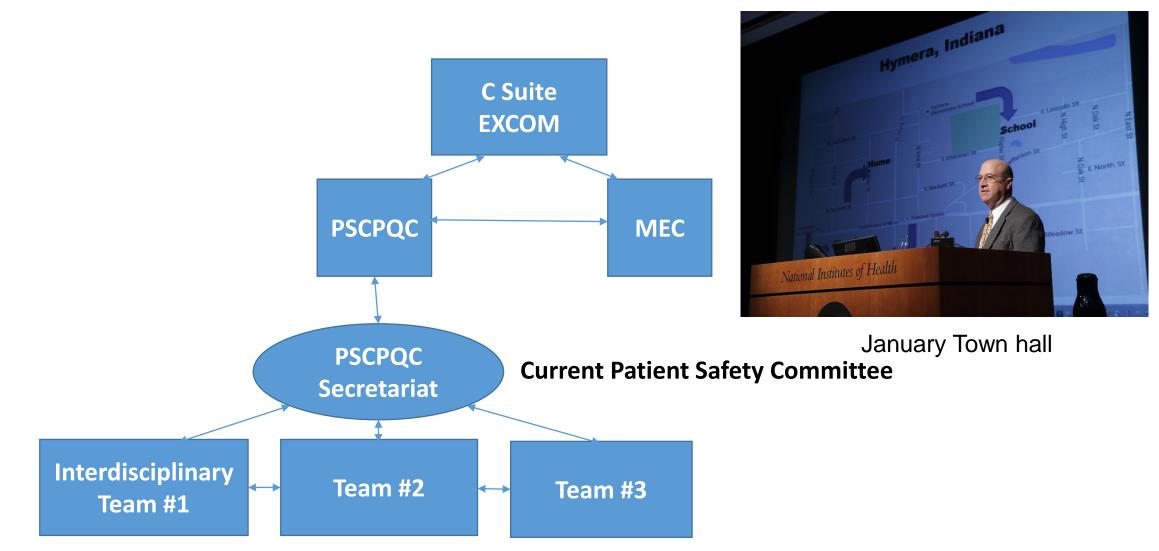
Priority Area #1 – Patient Safety & **Clinical Quality**



January Town hall

- 1. Red Team Practice Committee
- 2. January Medical Executive Committee **Clinical Care Committee**
- 3. Involve the MEC
- 4. Get patient safety out of the Office of Patient Safety & Quality, move toward **High Reliability**
- 5. No filter safety and clinical quality info goes directly to the CEO
- 6. Avoid marginalizing those staff members who had carried the effort before the reorganization

Concept Approved by Medical Executive Committee



Patient Safety, Clinical Practice & Quality Committee

Chair: Janice Lee, DDS, MD, MS Clinical Director, NIDCR

Members:

- Lauren Bowen, MD, NINDS
- Jeremy Davis, MD , NCI
- Colleen Hadigan, MD, MPH, NIAID
- Lisa Horowitz, PhD, MPH, NIMH
- Deldelker James, MSN, RN, CC
- Dachelle Johnson, PharmD, BCPS, CC
- CAPT Toni Jones, MSOD, RN, CC
- Jen Kanakry, MD, NCI

- Carrie Kennedy, JD, OGC
- Chris Koh, MD, MHSc, NIDDK
- David Lang, MD, CC
- Laura Lee, RN, MSc, CC
- Tara Palmore, MD, CC
- Nitin Seam, MD, CC
- Janet Valdez, PA, NHLBI
- Ford, Gina, RN, MSN, staff



Dr. Janice Lee

Clinical Center Quarterly Medical M&M Conference

"Systems Failures in a Complex Patient: A Case Based Report for Lessons Learned"

- When: Thursday March 16th, 2017 at 12:00pm
- **Location:** Lipsett Auditorium

Kinder, gentler M & M Overflow crowd Est 250 hrs prep!

- **Case Presentation:** Phuong Vo, MD, Clinical Fellow, NHLBI
- **System Failures:**
- Lin Tang, MD, Anesthesiology; Jennifer Jo Kyte, DNP, CNS, Critical Care Medicine;
- Nadia Biassou, MD, Neuroradiology; Naomi O'Grady, MD, Critical Care Medicine
- Discussion: Laura Lee, RN, M.Sc., Office of Patient Safety and Clinical Quality

CC Grand Rounds – 22 March



Dr. Gilman: Macro Medical Errors & The Just Culture Dr. Pronovost: Working Toward High Reliability



Masur Auditorium filled to capacity!

11 April 2017 – Interim IVAU Opened



NEW! Patient Safety Event Reporting System

- Retiring the 30 year old "Occurrence Reporting System";
- Improved user interface (event entry and tracking);
- Enhanced data management capacity
- Robust data analytics
- Roll out in mid-April
- Test drive the system this week....



Continued

- Daily patient safety huddles
- Follow patient safety rounds each week in one or two patient care areas
- Focus on communication, transitions, and hand-offs (IPASS)

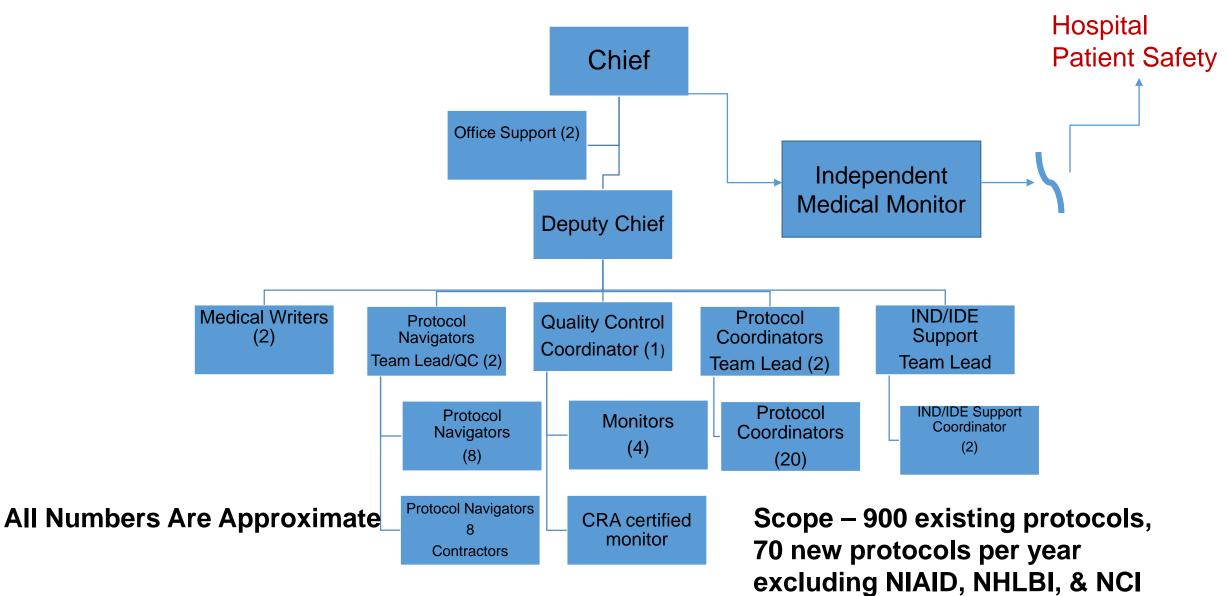
Priority Area #2 – Improve Support for Clinical Research in the CC

- Issue brought to the forefront CNS lymphoma study serious adverse events not reported to FDA by PI or sponsor
- Self-reporting by institutes indicated late reporting of adverse events and unanticipated problems is a systemic issue
- Retraining initiated aggressively
- Began development of proposal to reorganize support for clinical research centered on the CC

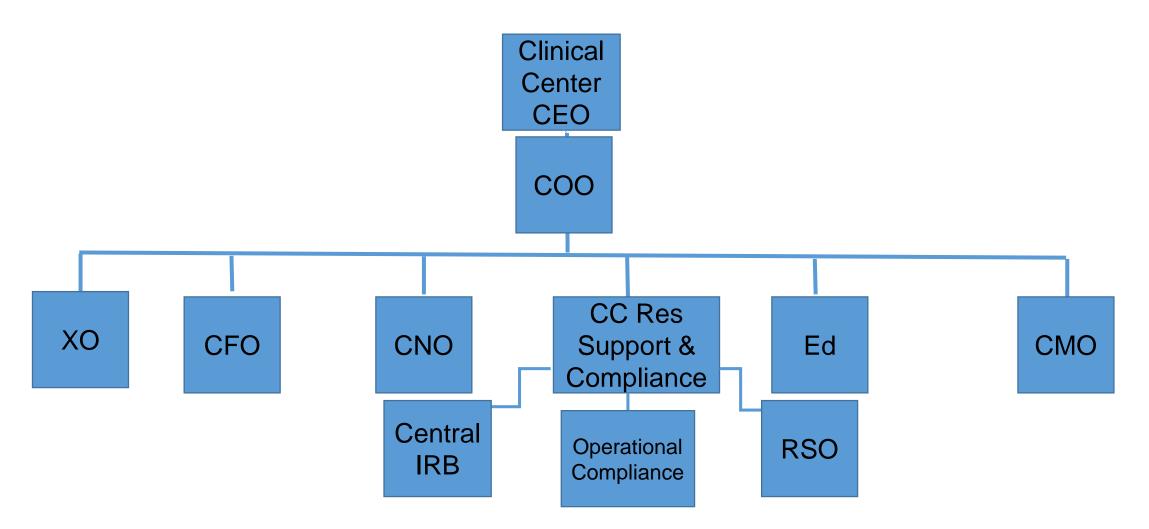
What Are We Trying to Accomplish?

- Build a culture of quality & compliance while facilitating compliance compliance with FDA regulations compliance with AAHRP, ORP, & OHSRP regulations and policies compliance with HHS & NIH policies and regulations
- Reduce gaps in clinical research support between larger institutes and smaller institutes
- Facilitate clinical research especially for early investigators
- Separate policy and operations
- Improve patient safety and clinical quality at the same time that clinical research support is enhanced

CC Research Support Office



Organizational Chart



Priority Area #3 – Understand Our Business

- Billing is a forcing function for cost consciousness
- We do not bill
- As we approached mid-year, one off emails asking for support for unanticipated and, therefore, unfinanced requirements
- During budget build for FY 18, occasional requests for large increases with little supporting justification
- NIH CC is more than a business but it is a business!

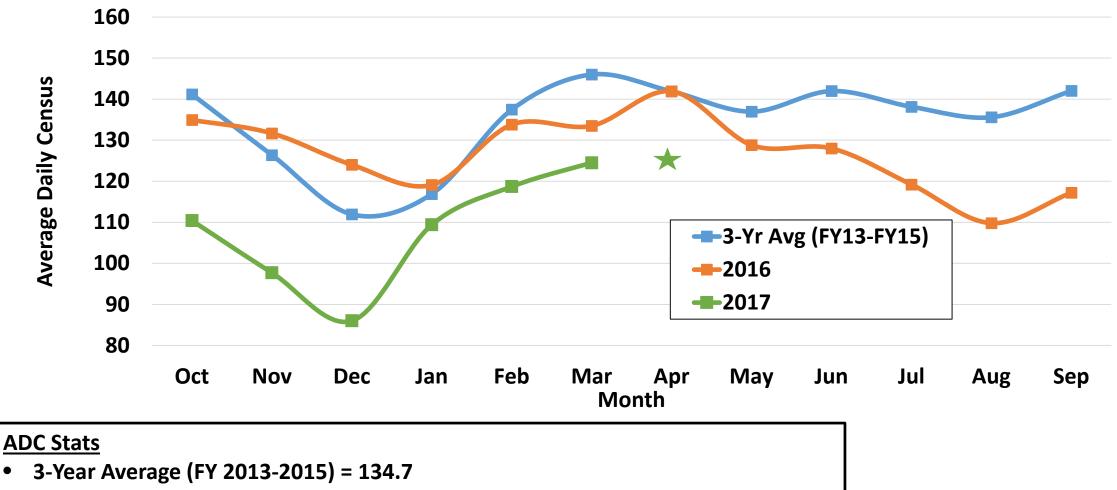
Understand Our Business

- Use mid-year sweep to begin the process of understanding our business
- Unfinanced requirements evaluated transparently from across the entire CC rather than considered individually
- Institute quarterly business meetings 1st is in July evaluate workload metrics and budget execution data in open forum. Less capable fiscal planners and managers will learn from those more accomplished.
- Build the airplane while in flight work for 2018 budget continues

Priority Area #4 – Develop Concept for the Center for Cellular Engineering

- Re: Working Group led by Dr. Steve Katz focusing on low census
- Short-term recommendation to increase OR availability we are in the process of doing (hiring additional staff)
- More mid-term recommendation increase capacity to produce engineered cellular products
- Demand is already high and continues to increase
- Protocols will be prioritized by processes overseen by Dr. Gallin
- Department of Transfusion Medicine (Drs. Klein and Stroncek) will oversee operations.

Average Daily Census (ADC)*



Year End FY 2016: 126.8 •

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Year-to-Date FY 2017 (through April 10): 108.2 ٠

*ADC = average number of inpatient days on a daily basis.

Year-to-Date Activity*

	Year-to-Date FY16	Year-to-Date FY17	% Change FY16-17
Inpatient Admissions	2,842	2,360	-17%
Average Length of Stay	8.4	8.7	3%
Inpatient Days	25,015	20,770	-17%
Average Daily Census (7-Day)	129.6	108.2	-17%
Outpatient Total Visits	51,145	46,916	-8%
Clinic Visits	41,474	38,337	-8%
Day Hospital Visits	9,671	8,579	-11%
New Patients	5,191	5,053	-3%

*Through April 10th

Cell Processing



- The aseptic, state-of-the-art module is a mini version of a large, sterile product manufacturing facility
- Located at CRC ambulance entry on the west side of the hospital
- Trailer 1, the viral vector unit, will be devoted to NCI's immunotherapy research
- Three other trailers are on order
- Modular facilities are in addition to work on 2J, 3T, future renovation of 12-E, and the interim IVAU when it is no longer needed by the pharmacy

CC Focus Groups Action Items/Recommendations

April Town hall

Risk management for high risk patients/protocols	 Patient Safety, Clinical Practice & Quality Committee (details to follow) Pediatric program expansion 'Ward doctor' concept endorsed by MEC
IRB uniformity/unification	 Single IRB Goal of Clinical Research Centralization Group with oversight by DDIR
Consistent documents and documentation requirements for patient care	• Implementation of standard progress notes in February 2017 (<i>details to follow</i>)
Swift transfer of patients to other facilities in emergency situations	 Response needs identified for ambulance transfers identified and associated administrative tasks assigned (details to follow)
Align CC and IC orientation programs and require all NIH staff who work in CC to attend CC orientation	 CC orientation program streamlined Online option being pursued for non-CC employees/contractors who work in clinical care positions Involvement of NIH HR orientation staff
Increase frequency of M&M Conferences	Quarterly M&M Conferences
Increase frequency of town hall meetings and consider more focus groups	• Quarterly Town Halls 23

What's Next

- Continue work on FY 18 budget
- Continue to develop the plan for the Center for Cellular Engineering
- Await final decision on the CC Research Support Office
- Continue to fill key positions
- 3-5 year plan ideas that have come up during meetings with IC directors

NIDA – phase 1 trials of medications to combat opiate addiction

NIA – dementia

NHGRI – whole genome sequencing for all CC patients

Looking Ahead!!



'First In Human: The Trials of Building 10' 3-part documentary series



Series narrated by Jim Parsons



Questions

Miscellaneous

- Visited 1 on 1 with every Institute Director who subscribes to the CC
- Two trips to Capitol Hill one social and one to talk about the CC
- Group meeting with Secretary of HHS, Dr. Price
- Met by teleconference with staffers for the Senate's HELP Committee
- Met with both the Clerk of the Senate Committee on Appropriations and the Staff Director of the Subcommittee on Labor, HHS, Education, and Related Agencies