NIH CC CEO Update for the ACD

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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

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

Current Patient Safety Committee

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

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

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

Masur Auditorium filled to capacity!

Dr. Pronovost: Working Toward High Reliability
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 with FDA regulations, AAHRP, ORP, & OHSRP regulations and policies, and 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

Chief
- Deputy Chief
- Office Support (2)
- Independent Medical Monitor

- Medical Writers (2)
- Protocol Navigators Team Lead/QC (2)
- Quality Control Coordinator (1)
- Protocol Coordinators Team Lead (2)
- Protocol Coordinators (20)
- Monitors (4)
- IND/IDE Support Team Lead
- IND/IDE Support Coordinator (2)
- Protocol Navigators (8)
- Protocol Navigators 8 Contractors
- CRA certified monitor

All Numbers Are Approximate

Scope – 900 existing protocols, 70 new protocols per year excluding NIAID, NHLBI, & NCI

Hospital Patient Safety
Organizational Chart

CEO

COO

CC Res Support & Compliance

Operational Compliance

Central IRB

XO

CFO

CNO

Ed

RSO

CMO
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)*

**ADC Stats**
- 3-Year Average (FY 2013-2015) = 134.7
- Year End FY 2016: 126.8
- Year-to-Date FY 2017 (through April 10): 108.2

*ADC = average number of inpatient days on a daily basis.*
## Year-to-Date Activity*

<table>
<thead>
<tr>
<th></th>
<th>Year-to-Date FY16</th>
<th>Year-to-Date FY17</th>
<th>% Change FY16-17</th>
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<tbody>
<tr>
<td>Inpatient Admissions</td>
<td>2,842</td>
<td>2,360</td>
<td>-17%</td>
</tr>
<tr>
<td>Average Length of Stay</td>
<td>8.4</td>
<td>8.7</td>
<td>3%</td>
</tr>
<tr>
<td>Inpatient Days</td>
<td>25,015</td>
<td>20,770</td>
<td>-17%</td>
</tr>
<tr>
<td>Average Daily Census (7-Day)</td>
<td>129.6</td>
<td>108.2</td>
<td>-17%</td>
</tr>
<tr>
<td>Outpatient Total Visits</td>
<td>51,145</td>
<td>46,916</td>
<td>-8%</td>
</tr>
<tr>
<td>Clinic Visits</td>
<td>41,474</td>
<td>38,337</td>
<td>-8%</td>
</tr>
<tr>
<td>Day Hospital Visits</td>
<td>9,671</td>
<td>8,579</td>
<td>-11%</td>
</tr>
<tr>
<td>New Patients</td>
<td>5,191</td>
<td>5,053</td>
<td>-3%</td>
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*Through April 10th*
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.
| 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 (*details to follow*) |
| 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 |
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

Begins airing in August on Discovery

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