Implementation of Clinical Center Changes

113th Meeting of the Advisory Committee to the Director

December 9, 2016

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Principal Deputy Director, NIH

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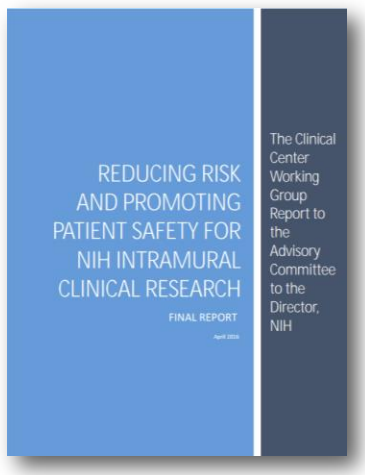
Red Team Report Themes

- Fortify a culture and practice of safety and quality
- Strengthen leadership for clinical care quality, oversight, and compliance
- (Re-align authority with responsibility to ensure optimal leadership of CC)
- Address sterile processing of all injectable products and the specifics of the sentinel event



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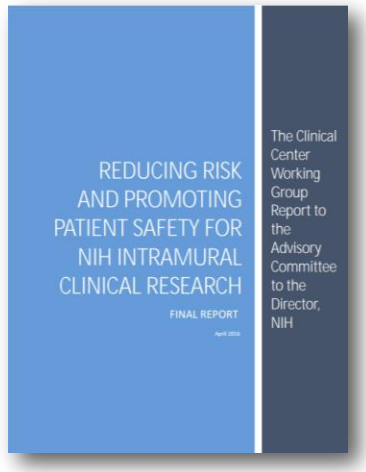

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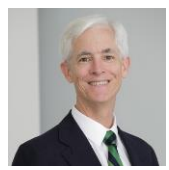
Fortify a Culture and Practice of Safety and Quality

- Held town hall meetings
  - April
  - June
  - September
- Established a CC Engagement Group
  - Chaired by Dr. Andy Griffith, NIDCD
  - Focus groups facilitated by Stewart Simonson, former HHS Assistant Secretary for Public Health Emergency Preparedness



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Fortify a Culture and Practice of Safety and Quality

- Changed performance plans for all clinical staff
  - Include patient safety elements that are consistent across NIH
- Deployed an anonymous toll-free hotline for staff, patients, and visitors to report patient safety and other care concerns
- Replacing/upgrading the Patient Safety Event Reporting System
- Posted patient and employee safety and quality metrics publicly

https://clinicalcenter.nih.gov/

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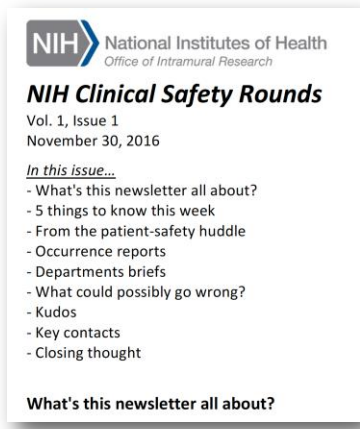
Fortify a Culture and Practice of Safety and Quality

- Developed a biweekly NIH Clinical Safety Rounds newsletter
  - Co-authored by Drs. Gottesman, Gallin, and Griffith
- Regular emails from CC leadership to all CC staff on clinical care matters of high importance
- Established institutional morbidity and mortality (M & M) rounds
- Hold daily morning safety huddles
- Modified protocol to review deaths within 24 hrs


NIH National Institutes of Health
Office of Intramural Research

NIH Clinical Safety Rounds

Vol. 1, Issue 1
November 30, 2016

In this issue...
- What's this newsletter all about?
- 5 things to know this week
- From the patient-safety huddle
- Occurrence reports
- Departments briefs
- What could possibly go wrong?
- Kudos
- Key contacts
- Closing thought

What's this newsletter all about?

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Fortify a Culture and Practice of Safety and Quality

- Hiring additional staff for the Department of Transfusion Medicine (DTM), the Pharmacy, and the Office of Research Support and Compliance (ORSC)
- Hired 2 leadership positions within CC-relevant sections of ORF
- Developing policy and procedure to expedite emergency transfers from CC to other local hospitals
- Purchased a new ambulance
- Upgrading the NIH EMT training

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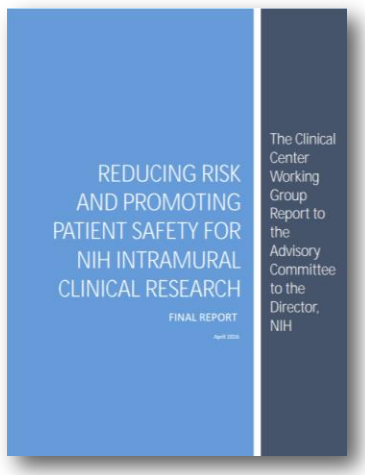

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Strengthen Leadership

- Changed IC Clinical Directors' reporting
  - Now report directly to their IC Director for all ICs with an intramural clinical research program
- Modified FY 2017 performance plans for IC Directors and IC Clinical Directors
  - Include language for:
    - Strengthening patient safety and quality of care
    - Documenting the direct involvement of IC Directors in overseeing the work of the Clinical Directors
  - Went into effect on October 1

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Strengthen Leadership

- Hired a new Chief of Pharmacy
  - Dr. Majid Tanas – recruited to NIH from the Oregon Health and Science University
- Created a Clinical Center Steering Committee
  - Reviews standards and current policies, develops new policies where necessary, and provides input on patient care and safety issues

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Strengthen Leadership

- Formed a centralized Office of Research Support and Compliance (ORSC) within the Office of Intramural Research
  - Overseen by Dr. Andrew Griffith, Scientific Director for NIDCD and Deputy Director for Intramural Clinical Research
  - Deputy Director – Valerie Bonham, JD
  - Advisor – Bruce Burnett, PhD
  - Central office responsible for setting policy and standards; quality assurance, regulatory support, education; auditing; and remediation where required
  - Creating 6 consolidated regulatory support/quality assurance officers to assist the ICs with compliance

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Strengthen Leadership

ORSC's Scope

- Facilities & Manufacturing Support
  - Remediation of several cGMP facilities and assessment of new and planned facilities
    - Quality System SOPs
    - GMP Guidance and Training
- Clinical Research Support
  - Develop best practices
  - Support internal and external audits (e.g., SAEs and UPs)
  - 2093 Clinical Studies; 773 FDA-regulated; 613 PIs

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Strengthen Leadership

ORSC's Scope (cont.)

- FDA
  - Inspections (both GMP and GCP), IND/IDEs, meetings
    - FDA audits of IVAU (4/16); DTM (7/16, 8/12); NCI clinical research protocol (9-10/16) and CTEP (10-11/16)
    - Leading a review/audit of all late reporting
  - Addressing specific regulatory queries
  - Supporting IND and other FDA filings
  - Coordinating FDA follow up questions on compliance issues

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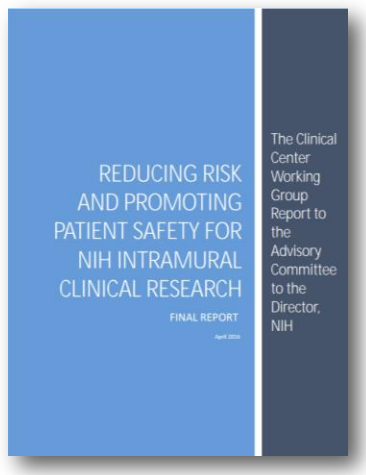

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Re-Align Authority with Responsibility

- Established the Clinical Center Research Hospital Board
  - Named Dr. Laura Forese (NewYork-Presbyterian) as Chair
  - Held two meetings (July and October 2016)
  - Received updates on patient quality and safety measures
  - Provided insight into processes for prioritizing safety measures, addressing calls to the hotline, etc.

https://ccrhb.od.nih.gov/

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Re-Align Authority with Responsibility

- Created hospital CEO position
  - Responsible for overall hospital operations and management
  - Search committee co-chaired by Drs. Anthony Fauci and Stephen Katz
  - Engaged a recruiting firm
  - CEO has been selected – Major General James Gilman

- Created dual position of NIH Associate Director for Clinical Research (ADCR) and Chief Scientific Officer (CSO)
  - Reports directly to NIH Director
  - Plays a major role in developing a systematic approach to distributing precious resources within the CC
  - Dr. John Gallin was named ADCR/CSO in August 2016

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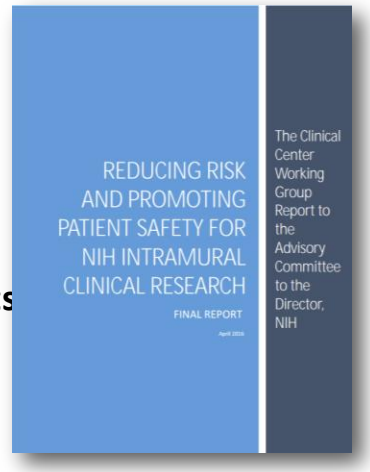

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Address Sterile Processing

- Identifying and vetting alternative sources
- Remediating facilities producing sterile products
- Completed a systematic review of all facilities producing sterile products
  - Engaged Working Buildings, Clinical IQ, and IPS Integrated Project Services

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Address Sterile Processing

Facilities' Status

- IVAU
  - Interim IVAU constructed – turned over to the Pharmacy this week for additional testing
    - Expected to be fully operational in January 2017
  - Once I-IVAU is operational, current IVAU will be closed for renovation (~2 yrs)
    - After renovations, IVAU operations will be returned to renovated facility and I-IVAU space will be used for additional cell processing
- DTM
  - Constructing a new facility (2J) and then will renovate current facility (3T)
    - New facility anticipated to be operational in early 2017

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Address Sterile Processing

Facilities' Status (cont.)

- Positron Emission Tomography (PET) Facilities
  - Consolidated NIMH facility's manufacturing activities into the CC PET Department
- Nuclear Medicine Department Radiopharmacy
  - Construction to enable sterile manufacturing
  - Expected to be fully operational in mid-2017
- NCI Surgery Branch Vector Production Laboratory and Thoracic Epigenetics Laboratory
  - 2 trailers purchased to enable work to continue

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Address Sterile Processing

Facilities' Status (cont.)

- NCI Surgery Branch Cell Processing Laboratory
  - Construction/renovations to remediate the space, as well as administrative efforts (e.g., SOPs, equipment)
  - Reopened with restricted manufacturing with moderate facility control
  - Following an independent assessment, increased to accommodate 6 patients/month
  - To expand capacity, an unused facility on the Bethesda campus will house a cGMP facility constructed with prefabricated modular components
    - Anticipated to be operational in late 2017

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Address Sterile Processing

Facilities' Status (cont.)

- Additional remediation:
  - NCI Biopharmaceutical Development Program
    - Remediation expected to be complete in early 2017
    - Production continuing
  - Leidos Radiopharmacy
    - Minimal remediation
  - NIAID Vaccine Stock Manufacturing
    - Administrative controls changed
    - Renovations to be completed in early 2017

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Comments/Questions?

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