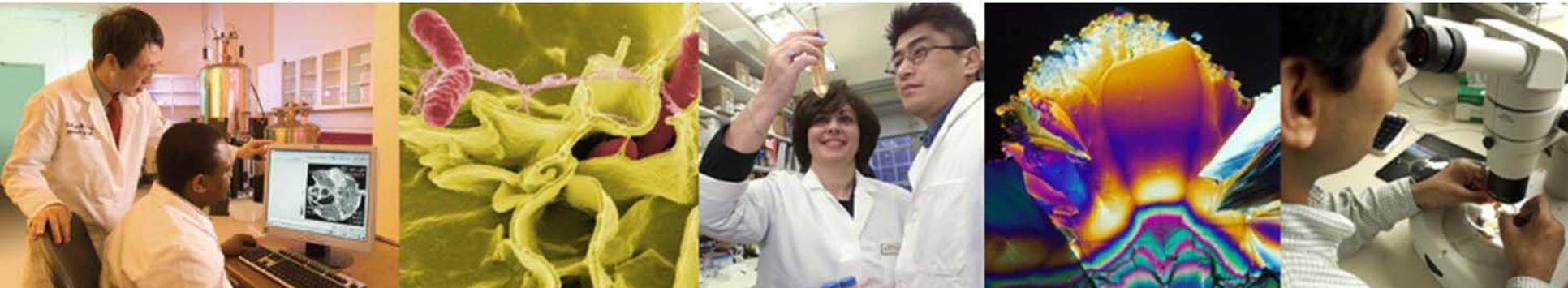


Implementation of ACD Working Group “Red Team” Report on Clinical Center

112th Meeting of the Advisory Committee to the Director

June 9th, 2016



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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

Accepted by the ACD and Dr. Collins on April 21, 2016

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Fortify a Culture and Practice of Safety and Quality

- Science and safety must go hand-in-hand
- There can be no “tradeoffs” between innovation and safety and compliance
- Our collective goal will be to exceed all safety and compliance “standards” and become a leader in safety science

Fortify a Culture and Practice of Safety and Quality (cont.)



Understand the Science of Safety

The Science of Safety

- Every system is perfectly designed to achieve its end results
- Safe design principles must be applied to technical work and teamwork
- Teams make wise decisions when there is diverse and independent input



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AHRQ

CUSP

Fortify a Culture and Practice of Safety and Quality (cont.)

- Why Leadership Matters*
 - Leaders drive values, values drive behaviors, and behaviors drive performance in an organization
 - Collective behaviors of an organization define its culture
 - Leadership must be reliable, standardized in its operations, and accountable to those being served (J. Touissant)

Fortify a Culture and Practice of Safety and Quality (cont.)

- Implement enhanced reporting, event tracking, and follow-up system and plan to ensure transparency
- Enhance and (where needed) create performance metrics for the IC clinical programs and CC departments
 - Consider ways to identify the best metrics, their analysis, dissemination, and approaches to follow-up

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Strengthen Leadership for Clinical Care Quality, Oversight, and Compliance

- Formation of a centralized Office of Research Support and Compliance (ORSC) within the Office of Intramural Research
 - Kathy Zoon, Interim Director
 - Central office responsible for setting policy and standards; quality assurance, regulatory support, education; auditing; remediation where required
- Link Central office to IC quality/compliance offices

Strengthen Leadership for Clinical Care Quality, Oversight, and Compliance (cont.)

- Form a “clinical practice committee” that will:
 - Review/revise “Standards for Patient Care at the NIH CC”
 - Develop policies for patient transfers among clinical services
 - Build on the experiences and information gathering of multiple clinical experts to develop creative approaches to further enhancement of patient safety and quality
 - Provide “real time” input to leadership on patient care and safety issues at the CC

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Re-align Authority with Responsibility to Ensure Optimal Leadership of CC

- Formation of new external Hospital Board* – first meeting in July
 - Laura Forese, COO, NY-Presbyterian, Chair Designate
 - Carolyn Clancy, Deputy Undersecretary, VHA
 - Jeanette Ericson, SVP for Patient Care Services, CNO, MGH
 - Paul O’Neill, former CEO, Alcoa; former Sec of Treasury
 - Peter Pronovost, SVP, Safety and Quality, JHU
 - Richard Shannon, Executive VP of Health Affairs, UVA Health System
 - TBD, including Patient Representative

Re-align Authority with Responsibility to Ensure Optimal Leadership of CC (cont.)

- Establish position of Hospital CEO with authority over all NIH staff using the CC to:
 - Evaluate patient safety and compliance elements that will be included in the performance plans of all relevant staff
 - If warranted, suspend admitting privileges of staff regardless of “home”
- A search committee for the Hospital CEO has been established
 - Chaired by Tony Fauci and Steve Katz
 - Includes members of the Hospital Board
- CEO will inform future recruitments
 - COO, CMO, CSO, Physician-in-Chief?

Re-align Authority with Responsibility to Ensure Optimal Leadership of CC (cont.)

- Create senior leadership position to develop and implement a systematic approach to distribution of CC resources
 - Will require harmonizing scientific review process of protocols across ICs
 - Will require prioritization of protocols/product and service requests from across ICs by CC leadership
 - Will convene a group of ICDs and (where necessary) additional experts for necessary reviews

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CC Sterile Products

- ORSC overseeing the completion of the systematic review of all facilities producing sterile products
- Continue remediation of facilities producing sterile products
- Consolidate, where possible, facilities producing sterile products
- Once current facilities are stabilized, develop contingency plans for unanticipated events

Ongoing Discussions Between NIH Leadership and Multiple CC Stakeholders

- Town Hall Meeting with Drs. Collins, Gottesman, and Gallin
- Multiple meetings with CC, IC leadership
 - ICDs, SDs, CDs
- NIH leadership meeting with representatives of MEC, CDs, and Chairs of Clinical Departments

Ongoing Discussions Between NIH Leadership and Multiple CC Stakeholders (cont.)

- Experts in Hospital Safety to visit and address NIH/CC leadership
- Future meetings planned with CC research partners including Patient Advisory Group
- A series of “town meetings”, focus groups, and surveys, will be conducted to hear from and engage with IC and CC communities

Questions?