

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

112th Meeting of the Advisory Committee to the Director

June 9th, 2016



Michael Gottesman, MD

Kathy Hudson, PhD

Lawrence A. Tabak, DDS, PhD



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

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

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



6

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. Toussant)

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

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

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

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

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

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**

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?