CEO Update to CCRHB

20 July 2018

James K. Gilman, MD

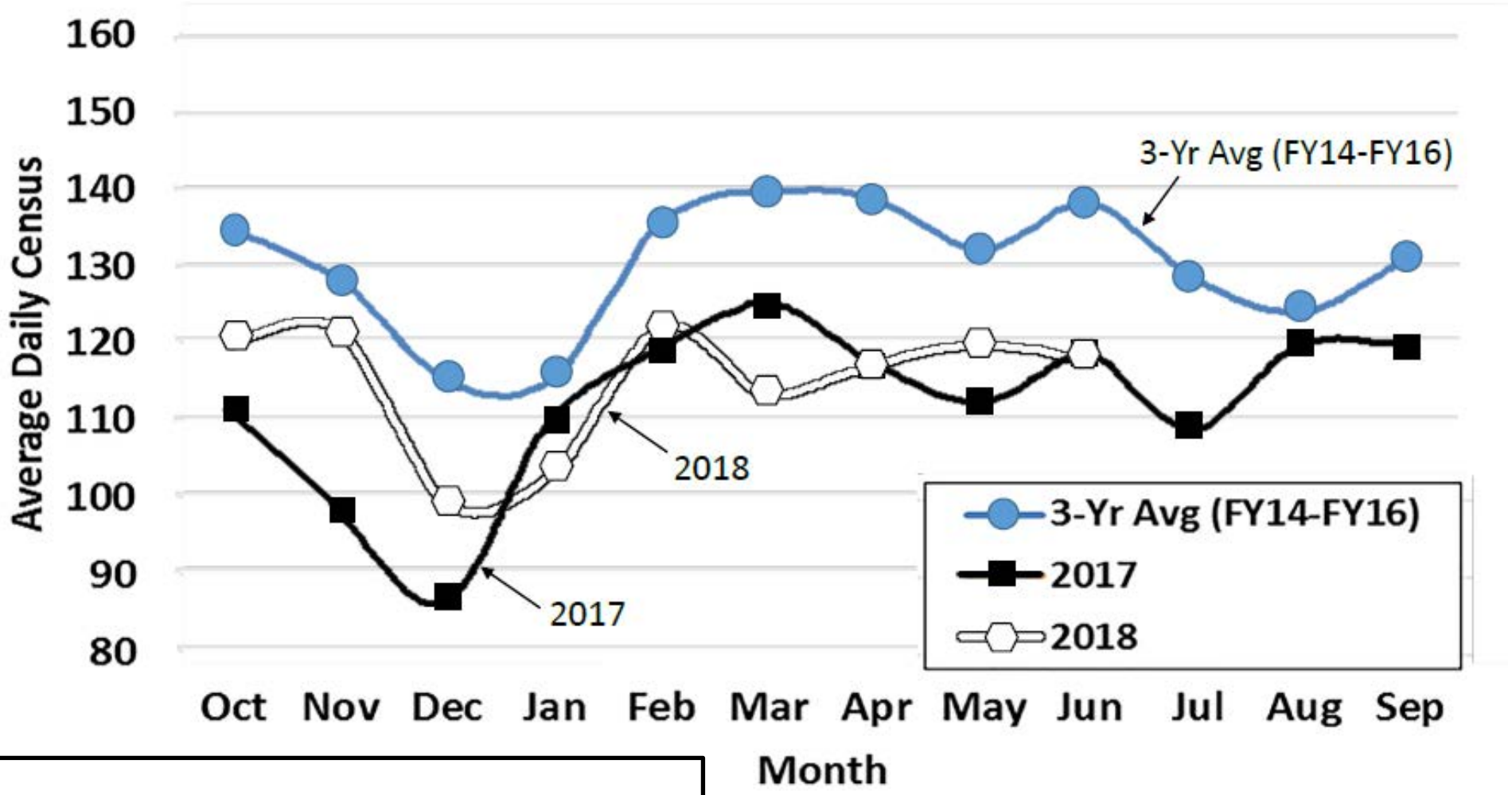
MG, USA (ret)

Today's Agenda

9:00 AM	**Welcome & Board Chair's Overview** ➢ **Laura Forese, MD,** *NewYork-Presbyterian, and Hospital Board Chair*
9:05 AM	**NIH Principal Deputy Director's Remarks** ➢ **Lawrence A. Tabak, PhD**, *Principal Deputy Director, NIH*
9:10 AM	**NIH CC CEO Update** ➢ **James Gilman, MD,** *Chief Executive Officer, NIH Clinical Center*
10:10 AM	**Discussion**
10:30 AM	**Break**
10:45 AM	**Patient Safety & Clinical Quality Update** ➢ **Laura M. Lee, MS, RN,** *Director, Clinical Center Office of Patient Safety & Clinical Quality*
11:25 AM	**Patient Safety, Clinical Practice and Quality (P_sQ_s) Committee** ➢ **Janice Lee, DDS, MD, MS,** *Clinical Director, National Institute of Dental & Craniofacial Research* *Chair, Patient Safety, Clinical Practice and Quality Committee*
12:05 PM	**Lunch**
1:05 PM	**Patient Safety at the CC – Right Path?** ➢ **Maryland Pao, MD,** *Clinical Director, National Institute of Mental Health*
1:45 PM	**Patient Safety at the CC – Right Path?** ➢ **Brian Brooks, MD,** *Clinical Director, National Eye Institute* ➢ **Elizabeth Wendell, BSN, MS,** *Nurse Manager, OP7, OP10, OP11, NIH Clinical Center*
2:25 PM	**Patient Safety at the CC – Right Path?** ➢ **James Balow, MD,** *Clinical Director, National Institute of Diabetes and Digestive and Kidney Diseases*
3:05 PM	**Adjournment**

Average Daily Census

through June 30, 2018



ADC Stats

- **3-Year Average (FY 2014-2016) = 130.0**
- **Year End FY 2017: 111.5**
- **Year-to-Date FY 2018 (as of 6/30/2018): 114.8**

People

It's Official: Elizabeth Jones, MD, MPH, MBA, Chief, RADIS

Department of Laboratory Medicine

- Karen Frank, MD, PhD, D(ABMM), Acting Chief

Rehabilitation Medicine Department

- Adam Politis, M.S., CCC-SLP, Chief, Speech Language Pathology Section

Nursing

- James (Jim) Paterson, MS, RN, CNRN, Service Chief (Acting) Neuroscience, Behavioral Health, & Pediatrics

- Barbara Jordan, DNP, RN, NEA-BC, Service Chief Nursing Operations

Congratulations, Nursing!

“On May 29, 2018,
the NIH Clinical Center Clinical Research Nursing Residency Program
was awarded Accreditation with Distinction,
as a Practice Transition Program,
by the American Nurses Credentialing Center’s Commission on Accreditation.”

3 Year Accreditation
29 May 2018 – 31 July 2021

Pictured Right: Rachel Perkins, CC Nursing residency coordinator
Left: Sheryl Cosme, ANCC Director for Practice Transitions Accreditation Program and Nursing Skills Competency Program

Facilities & Space

- **Hospice Rooms:** Ribbon-Cutting July 10th
- **MRI Suites:** Almost done!
- **East Terrace Module:** for CCE
- **Pharmacy:** Series of projects to increase capacity and start on permanent IVAU
- **5SWN:** 4 inpatient rooms to NEI

BLDG 10 E Wing Renovation:
By fall, all E Wing floors closed for 4 years
Plan to reopen in April 2021

Rendering of future FAES teaching laboratory relocating from Bldg. 60 to B1 level of E wing

Renderings of typical open laboratory (left) to be installed on floors 3 through 10

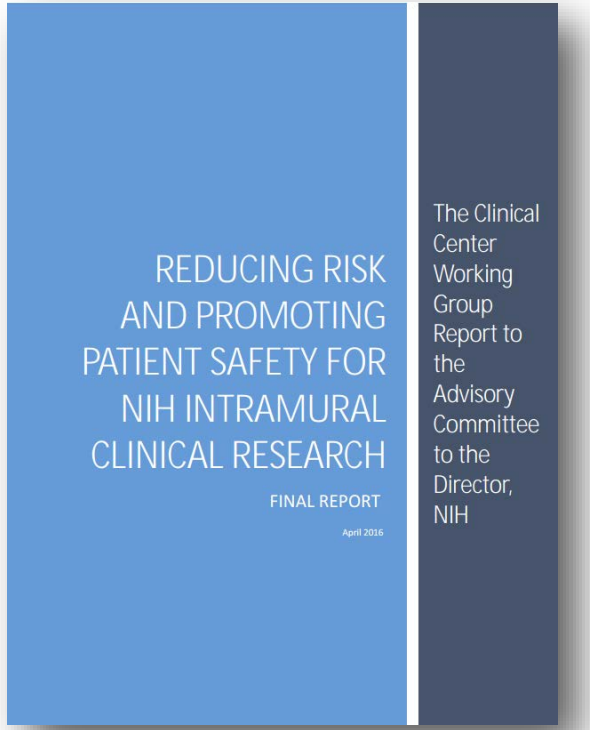
New NIH Blood Bank (right), including stem cell and gene therapy collection, to be located on 1st floor of new E wing

Capital Investment Fund

- **Facilities:** **e.g., refresh of all inpatient rooms**
- **Equipment:** **CT in ICU**
- **IM/IT:** **Allscripts Mobile Care**
- **Total of $18M**

57%

Response Rate



2 Years After the Red Team Report

- 24 May 2018 Presented to IC Directors
- 6 June 2018 Presented to IC Scientific & Clinical Directors
- 10 – 11 July 2018 Presented to CC Staff at 3 Town Hall Sessions

7 Opportunities for Improvement

- **Absence of** a readily apparent and **anonymous avenue to escalate concerns** within NIH beyond immediate supervisors
- **Failure of supervisors to appropriately address and escalate important deficiencies** that were reported by staff
- Evolution of a culture and practice in which **patient safety** gradually, and unintentionally, **became subservient to research** demands
- **Insufficient expertise in regulatory affairs,** compounded by misunderstandings about how to comply with regulations for a federal research institution conducting clinical operations
- **Fragmentation of authority and responsibility for clinical operations,** driven by a unique decentralized structure, authority, and funding for intramural clinical research, resulting in accountability and quality assurance gaps that could compromise patient safety
- **Inadequate independent oversight of safety and regulatory compliance** within NIH
- **Insufficient regular monitoring and metrics** for identifying and tracking needed steps for improvement

3 Major 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**

15 Findings

Theme 1: Fortify a culture and practice of safety and quality

- Failure to prioritize patient safety
- Uniqueness of the CC patient population
- Dearth of regulatory expertise
- Inadequate research and clinical support systems
- Variable standards
- Failure to report or address concerns

Theme 2: Strengthen leadership for clinical care quality, oversight, and compliance

- Fragmented governance, responsibility, authority, and accountability
- Lack of funding transparency
- Outdated facilities
- Lack of adequate compliance expertise

Theme 3: Address sterile processing of all injectables and the specifics of the sentinel event

- Compliance failures
- Failure to certify facilities
- Reporting failures
- Inadequate attention to capacity and prioritization
- Potential to expand use of BDP (NCI's Biopharmaceutical Development Program)

11 Recommendations

Theme 1: Fortify a culture and practice of safety and quality

1. Adopt new CC mission and values statements that reflect the critical linkage and synergism of science and safety.
2. Establish a Research Support and Compliance Office.
3. Establish systems to monitor and enforce safety and quality standards.
    - 3a: Implement strengthened reporting systems.
    - 3b: Enhance accountability by establishing metrics for quality and safety measures.

Theme 2: Strengthen leadership for clinical care quality, oversight, and compliance

4. Establish a hospital board.
5. Enhance clinical research leadership authority and responsibility.
    - 5a. Centralize authority for intramural clinical research.
    - 5b. Clarify the responsibilities of CC leadership.
    - 5c. Integrate patient safety in individual performance plans.
6. Establish a Clinical Practice Committee (CPC).
7. Identify and eliminate potential gaps among clinical services.

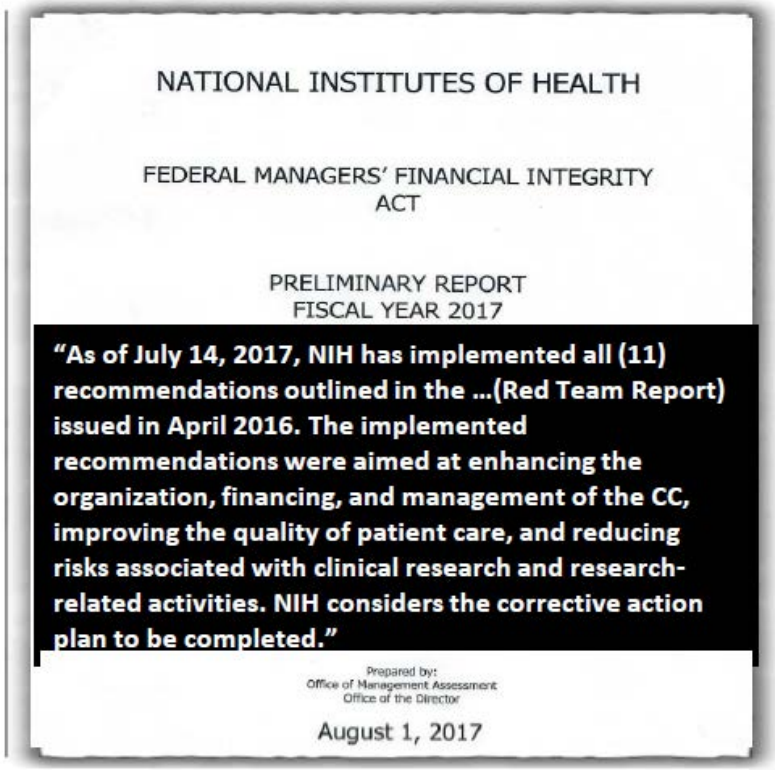
11 Recommendations (continued)

Theme 3: Address sterile processing of all injectables and the specifics of the sentinel event

8. Do not rebuild the PDS in the CC.
9. Create a prioritization and governance system for sterile products.
   - 9a. Centralize authority for intramural clinical research.
   - 9b. Enhance resource sharing across ICs.
10. Ensure that the IVAU and non-sterile PDS are fully remediated.
11. Assess all facilities at NIH producing sterile materials.

Background: May 2015 - Present

- **May 2015 US FDA inspection** – system issues in pharmacy department
- **Subsequent assessment** – issues not limited to pharmacy
- **April 2016** – Report out of the Clinical Center Working Group (aka Red Team)
  "Reducing Risk and Promoting Patient Safety for NIH Intramural Clinical Research"



NATIONAL INSTITUTES OF HEALTH

FEDERAL MANAGERS' FINANCIAL INTEGRITY ACT

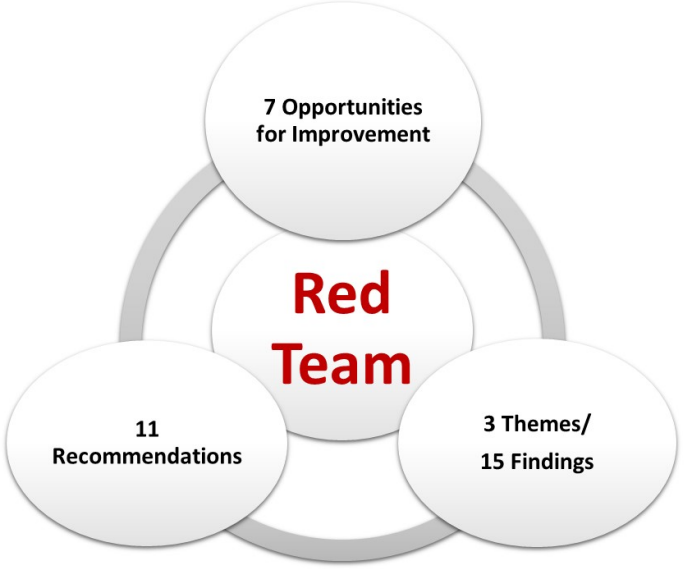
PRELIMINARY REPORT
FISCAL YEAR 2017

"As of July 14, 2017, NIH has implemented all (11) recommendations outlined in the …(Red Team Report) issued in April 2016. The implemented recommendations were aimed at enhancing the organization, financing, and management of the CC, improving the quality of patient care, and reducing risks associated with clinical research and research-related activities. NIH considers the corrective action plan to be completed."

Prepared by:
Office of Management Assessment
Office of the Director

August 1, 2017

- 7 opportunities for improvement
- 3 themes/15 findings
- 11 areas of recommendations



Responses to Theme #1: Fortify a culture and practice of safety and quality

1. New Clinical Center Research Hospital Board formed.
2. CEO position created – function separated from science, research:
    - Selection made on basis of commitment to patient safety.
3. Clinical directors' organizational reporting changed so that Clinical Directors now report directly to Institute Directors.
4. PDS closed
5. Complete turnover of pharmacy leadership
6. Interim intravenous admixture unit constructed – opened April 2017
7. Pharmacy staffing expanded
8. Additional resources provided to the Office of Patient Safety & Clinical Quality
9. Daily patient safety huddles
10. New safety tracking and recording system fielded
11. Empowerment of nurses and staff clinicians
12. Additional resources provided for care of pediatric patients – pediatrics observation unit established.
13. Introduced changes in the way leadership positions in the Clinical Center are assigned and how search efforts for key positions are conducted.
14. Reinforced efforts to proactively assess clinical risk in a research-related activity and the advisability of saying "no"
15. Established the Patient Safety Clinical Practice and Quality Committee

Responses to Theme #2: Strengthen leadership for clinical care quality, oversight, and compliance

1. New CEO position established, separating scientific responsibilities under the Chief Scientific Officer but ensuring CEO had authority over quality and compliance.
2. Office of Research Support & Compliance initially formed under the auspices of the Deputy Director for Intramural Research but later moved under the authority of CEO of the Clinical Center.
3. Provisions made in 2018 Clinical Center budget for Research Support Office to facilitate clinical research, including regulatory compliance.
4. Trans-NIH re-education efforts regarding the importance of compliance and the means to achieve and maintain it
5. Both self-assessment and outside independent audits of compliance with all relevant laws, rules, regulations and policies
6. Purchase of a unified IT system for use by all institutes that will facilitate compliance but also facilitate compliance oversight
7. Initial steps to centralize institutional review board operations to standardize processes across all institutes. Centralization facilitates oversight.

Responses to Theme #3: Address sterile processing of all injectables

1. Sterile manufacturing expertise provided via Intergovernmental Personnel Act with Duke University – expert with career in the pharmaceutical manufacturing field added to Office of Research Support & Compliance.
2. Manufacturing in the pharmaceutical development section terminated.
3. Interim intravenous admixture unit constructed to meet cGMP compliance.
4. Standards of operating procedure re-written to meet cGMP standards.
5. Staff all trained to meet cGMP standards.
6. New intravenous admixture unit maintained in strict environmental control with careful micro-biological monitoring to ensure quality compliance.
7. cGMP standards, methods and procedures applied outside the pharmacy as well as to areas like cell processing facilities in the Department of Transfusion Medicine.
8. Sterile Products for Human Administration Committee established to review all preparation of injectables in the intramural program as well as all products procured from external sources to ensure patient safety.
9. Any injectable product without documentation to ensure compliance with all standards is reviewed, before administration, by a subgroup of the Sterile Products for Human Administration Committee. Only after a careful risk/benefit analysis is the investigator(s) allowed to proceed with administration.
10. Routine and recurrent use of outside subject matter expertise to advise, audit, and inspect facilities, standard operating procedures, documentation, and operations to insure compliance with highest industry standards.

Theme 1: Fortify a culture and practice of safety and quality

1. Adopt new CC mission & values statements that reflect the critical linkage & synergism of science & safety.	✓
2. Establish a Research Support and Compliance Office.	✓
3. Establish systems to monitor and enforce safety and quality standards. 3a: Implement strengthened reporting systems. 3b: Enhance accountability by establishing metrics for quality and safety measures.	✓

Theme 2: Strengthen leadership for clinical care quality, oversight, and compliance

4. Establish a hospital board.	✓
5. Enhance clinical research leadership authority and responsibility. 5a. Centralize authority for intramural clinical research. 5b. Clarify the responsibilities of CC leadership. 5c. Integrate patient safety in individual performance plans.	✓
6. Establish a Clinical Practice Committee (CPC).	✓
7. Identify and eliminate potential gaps among clinical services.	✓

Theme 3: Address sterile processing of all injectables and the specifics of the sentinel event

8. Do not rebuild the PDS in the CC.	✓
9. Create a prioritization and governance system for sterile products. 9a. Centralize authority for intramural clinical research. 9b. Enhance resource sharing across ICs.	✓
10. Ensure that the IVAU and non-sterile PDS are fully remediated.	✓
11. Assess all facilities at NIH producing sterile materials.	✓

A Few Points Before Open Discussion

- **Never prepared a formal matrix to address the Red Team Report – started working on the most obvious items and then moved on from there**
- **Each checkmark represents substantive efforts**
- **The Red Team was far from exhaustive in their analysis – we continue to stumble over other issues that might have been included (at least 2 since the last CCRHB)**
- **The Red Team Report represents an important inflection point – as such, our response will never truly be a completed action**

Open Discussion