

It's Only a Plan

CEO Presentation to the Clinical Center Research Hospital Board

15 July 2022

James K. Gilman, MD, CEO, NIH Clinical Center

Timeline

- **2015** – FDA inspects the CC Pharmacy
- **2016** – Red Team Report
- **January, 2017** – CEO arrives
- **2017-2018** – efforts focused on response to Red Team Report
- **2019** – Strategic Plan – “People, Places, & Capabilities” published
- **2019** – present – execution of Strategic Plan
- July 15, 2022 – how are we doing?

Corporate Rhetoric

- **Mission** – “We provide **hope** through **pioneering clinical research** to improve human health.”
- **Guiding Principles**
 1. Passion for high reliability in the clinical research environment
 2. Diversity and inclusion of people and ideas
 3. Compassion – patients, families, staff
 4. Innovation in solving **AND** preventing problems
 5. Accountability for resources
 6. Excellence in scientific discovery and application
 7. Commitment to professional growth and development

Four Strategic Aims

- Continuing to lead the world in conducting safe first-in-human clinical research in rare and refractory diseases.
- Increasing the use of the CC by the NIH intramural research program.
- Demonstrating profound respect for our patients, our full partners in the clinical research enterprise.
- Partnering with IC's to recruit, develop, and retain the next generation of NIH clinical researchers and the CC staff that will support their efforts.

People, Places, & Capabilities:

People

- **Personalized, inclusive healthcare leadership**
 1. Taking care of those on the front lines
 2. Accurate position descriptions
 3. Accurate time cards the first time
 4. It's the *staff member's* annual leave (not the supervisor's)
 5. Individual development plans
 6. Support for more leadership training
 7. Banished the terms “ancillary and support staff”

People, Places, & Capabilities

People, continued (2)

- **Recognition**

- Length of Service Recognition?
Annual CEO Awards Program (~700 honorees in 2021)
- Staff Clinician, APP (NPs & PAs), Administrator of the Year Program – began in 2018, with 16 awardees to-date
- CCND Awards
- Quarterly Patient safety “Superstars”
- Staff Clinicians as *Voting Members* on Search Committees
- Staff Clinicians selected to be Chief of Radiology, Lab Medicine, and Chief Medical Officer

- **Communication**

- Quarterly townhall meetings – 3 shifts until pandemic hit
- “3 Main Things” emails – weekly pre-pandemic, as needed (more frequently) during the pandemic
- CEO daily hospital walk-arounds

People, Places, & Capabilities

People, continued (3)

“A generation of clinical researchers who brought the CC to prominence are in the process of retirement or reducing their clinical research activities. These researchers were supported by CC staff who often spent their entire careers at the NIH. Finding and developing the next generation of great clinical investigators and the staff members who will support in the CC is a focal point of this plan....”

— **People, Places, and Capabilities, page 5**

People, Places, & Capabilities

People, continued (4)

- **COO** – Pius Aiyelawo
- **CMO** – **David Henderson**  Colleen Hadigan
- **CNO** – Gwenyth Wallen  **National Search**
- **CFO** – Maria Joyce  **Search**
- **Executive Officer** – Colleen McGowan  Dan Lonnerdal
- **Chief RADIS** – Elizabeth Jones
- Chief, Department of Lab Medicine – **Tom Fleischer**  Karen Frank
- Chief, Department of Transfusion Medicine – Center for Cellular Engineering – **Harvey Klein**  Barbara Bryant
- **Chief, Department of Pharmacy** – Majid Tanas  **National Search**
- **Chief, Office of Patient Safety & Clinical Quality** – Laura Lee  David Lang

People, Places, & Capabilities

People, continued (5)

- Code BRT (Behavioral Response Team)
- AHaRT (Anti-harassment Response Team)
- Spiritual Care Division presence for the CC staff
- Screening, testing, PPE, CC policies focused on staff safety throughout the pandemic

People, Places, & Capabilities

People, continued (6)

Federal Employee Viewpoint Survey (FEVS)

Latest results available from 2020

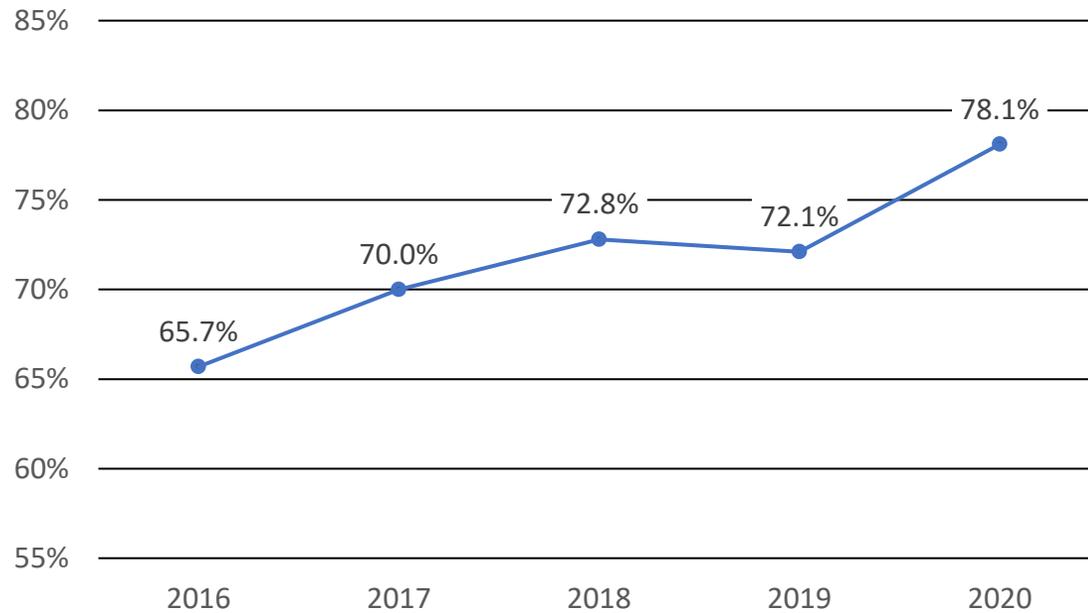
- ❖ 2021 not available, 2022 FEVS in progress, showing promising response rate **(37%)**
- Consistent improvement each year
 - ❖ 2020 results showed improvement in ALL 37 items, 28 items by >5% increase in positive rating
 - ❖ Highest increases in 2020 related to recognition, work-life programs and innovation
- Staff believe survey results used to improve CC
 - ❖ Belief in Action Indicator improved 7% in 2020, and 12% since 2017
- Employee Engagement and Global Satisfaction increased significantly in last 4 years (*data on next slide*)

People, Places, & Capabilities

People, continued (7)

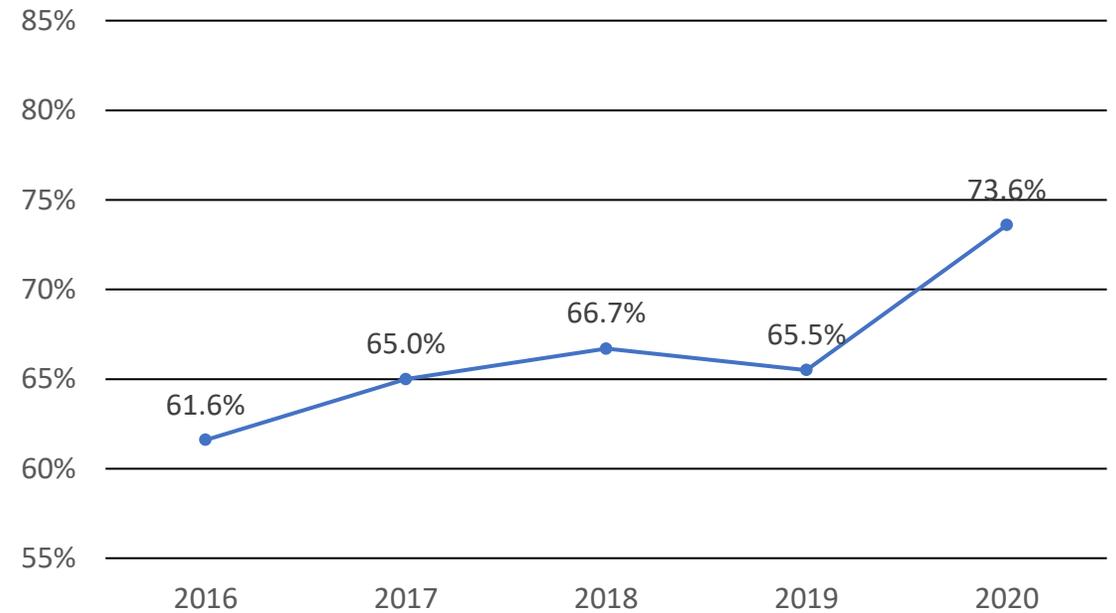
Federal Employee Viewpoint Survey (FEVS) *continued*

Employee Engagement Indicator



EEI has improved by **12.4%** in the last 4 years

Global Satisfaction Indicator



GSI has improved by **12.0%** in the last 4 years

People, Places, & Capabilities:

Places

- **Job #1 – get the Surgery, Radiology, & Laboratory Medicine Wing project moving**

Partnered with ORF, Chiefs of DLM, DPM, and RADIS

Met with the study group from the National Academies

Number of meetings with HHS and Congressional staff

CCRHB letter

Anyone else who would listen!

Groundbreaking later this summer – finish in 2028!

Strategic Communication – Same Message, Many Voices, Sustained over time

People, Places, & Capabilities

Places, continued (2)

- Pharmacy

Detailed presentation at last CCRHB by Dr. Farinre
\$50 M / 6 years.

Required construction of interim and swing spaces

Swing space move – fall of 2019 – with interim leadership

Out-patient pharmacy and unit dose pharmacy both back in position

Permanent IVAU (intravenous admixture unit) – winter of FY23

Recently also revamped the P & T Committee with new leadership

Places, continued (3)

- **Radiopharmacy**

p15. “The history of the radiopharmacy has been fraught with complexity and setbacks.”

Approved plan

Latest setback – project set back a year to make certain there were enough funds for the SRLM

Should get back to the plan in FY 23

People, Places, & Capabilities

Places, continued (4)

- **Center for Cellular Engineering**
 - ◆ 3T – best **20th** century facility money could buy
 - ◆ 2J – 21st century facility embedded in a poorly constructed 20th century building
 - ◆ Terrace modular – finally a 21st century facility – in qualifications now
 - ◆ 12th floor E wing – coming in FY 23
- **Status reports to CCRHB by Dr. Harvey Klein in February 2018 and Dr. David Stroncek in April 2021**

p. 16 “In a 2016 plan developed by IC Directors focused on the future of the CC, the growing demand for cellular engineering became apparent.”

People, Places, & Capabilities

Places, continued (5)

- **Enhanced Simulation Center**
 - ◆ No plans yet, may not be necessary
 - ◆ Will discuss more in Capabilities

People, Places, & Capabilities:

Capabilities (Patient Safety)

- Safety Tracking & Reporting System (STARS)
- Frequent use of Failure Mode and Effects Analysis – focus on problem prevention and not just problem solving
- Low threshold for communication with The Joint Commission, and using Root Cause Analysis methodology
- Institute for Safe Medication Practice visit with 90 recommendations – prioritized and addressed in a disciplined fashion since their visit
- Daily patient safety huddle
- Less insularity – more use of outside experts

Capital Investment Fund

- First made available in FY 18
- Up to \$50 M per year (usually spend \$20-30M)
- Facilities – re-sized the main supply line to reduce sludge & biofilm; re-piped patient rooms used by immunocompromised patients
- Facilities – renovated patient rooms, out-patient clinics, almost all of DLM, now starting on in-patient nurses stations
- Equipment – CT in ICU, new PET-MR, added 3rd CT in RADIS
- **IT – extensive investment in security, network re-design to eliminate single points of failure, now moving to 100 G from 10 G**

People, Places, & Capabilities

Capabilities: Patient & Staff Safety

- Code BRT (Behavioral Response Team)
- AHaRT (Anti-harassment Response Team)
- Spiritual Care Division presence for the CC staff
- Screening, testing, PPE, CC policies focused on staff safety throughout the pandemic

Capabilities: Clinical Care

- Transplantation and Cellular Therapy (TCT) initiative – NIAID, NCI, NHLBI, NHGRI, CC – one medical director, one operations program manager, and one program manager for donor services and quality assurance.
- Difficult Airway Response Team (DART) – 6/2022
- Pediatric hospitalists / Pediatric intensivists – 7/2022
- Reorganization of the resources for pediatric care to form an organization that looks more like a Department of Pediatrics in an academic medical center

Capabilities: Telehealth

1. No capability before COVID-19
2. Policy & standard operating procedures developed and put in place in a very short period of time
3. Replacing Microsoft Teams with a platform that interfaces more seamlessly with our electronic health record
4. Investigators and coordinators requesting still more capability (needs to be considered in the context of the CC's historical mission)
5. p.19 **“If the CC is to be a national resource, it must be a more robust virtual resource”**

People, Places, & Capabilities

Capabilities: Simulation

1. Not a new capability – CCMD & CCND both used simulation
2. Accessed Dr Mabel Gomez-Mejia who completed medical simulation training in Boston
3. Dr. Gomez-Mejia developed strategy focused on “in situ” simulation training – reduced need for a more robust center
4. Invested in better equipment, especially for simulation involving children and infants. Hired full-time, experienced simulation tech.
5. Train the trainer program
6. Provided executive sponsorship – Dr. Tom Burklow
7. Have executed a number of tailored programs in areas where simulation had not been deployed before
8. Just getting started!

p. 16 “As an institution focused on rare...issues committed to preventing lapses and errors..., improving our simulation capabilities is of high importance

People, Places, & Capabilities

Capabilities: Hospice Suites

- None prior to 2017 – NIH Clinical Center not a place where people come to die
- Championed by Pain & Palliative Care Service
- Supported by Spiritual Care Division, CCND, and many others
- Ribbon cutting by Dr Collins (July 10, 2018)
- Supports clinical research – protocols requiring rapid autopsy
- Dr Berger reported on hospice suite use at October 2021 CCRHB meeting



Miscellany

- **Organization**

Department of Clinical Research Informatics combined with Health Information Management Division

Animal Program realigned with Chief Scientific Officer (from CMO)

Sterile Processing Service realigned to CCND (from Materials Management)

Capstone Exercise (Live Fire)

- Summer 2021 – two infants with GM 1 Gangliosidosis – partnered with Children’s National Hospital
- NHGRI Investigator – Gene Therapy protocol
- 6 months of preparation – CCND, CCMD, Pediatrics, Nutrition, Radiology, Lab, Transfusion Medicine, Pharmacy
- Extensive FMEA – Office of Patient Safety & Clinical Quality
- Extensive training – didactic and simulation
- Experienced almost every contingency imaginable but they were all covered

People, Places, & Capabilities

Capabilities: Research in Pediatric Patients

- Historically limited
- For the past several years – only children older than 3 and larger than 15 kg
- GM 1 experience suggests we can do more with a good partner
- Only can be done if it is done safely
- Has been studied by one intramural working group assessing the near-term requirements
- Further evaluation by separate intramural work group
- Dr. Devaskar has agreed to lead group of extramural thought leaders to evaluate the work of the intramural groups

2020 Culture of Patient Safety Survey

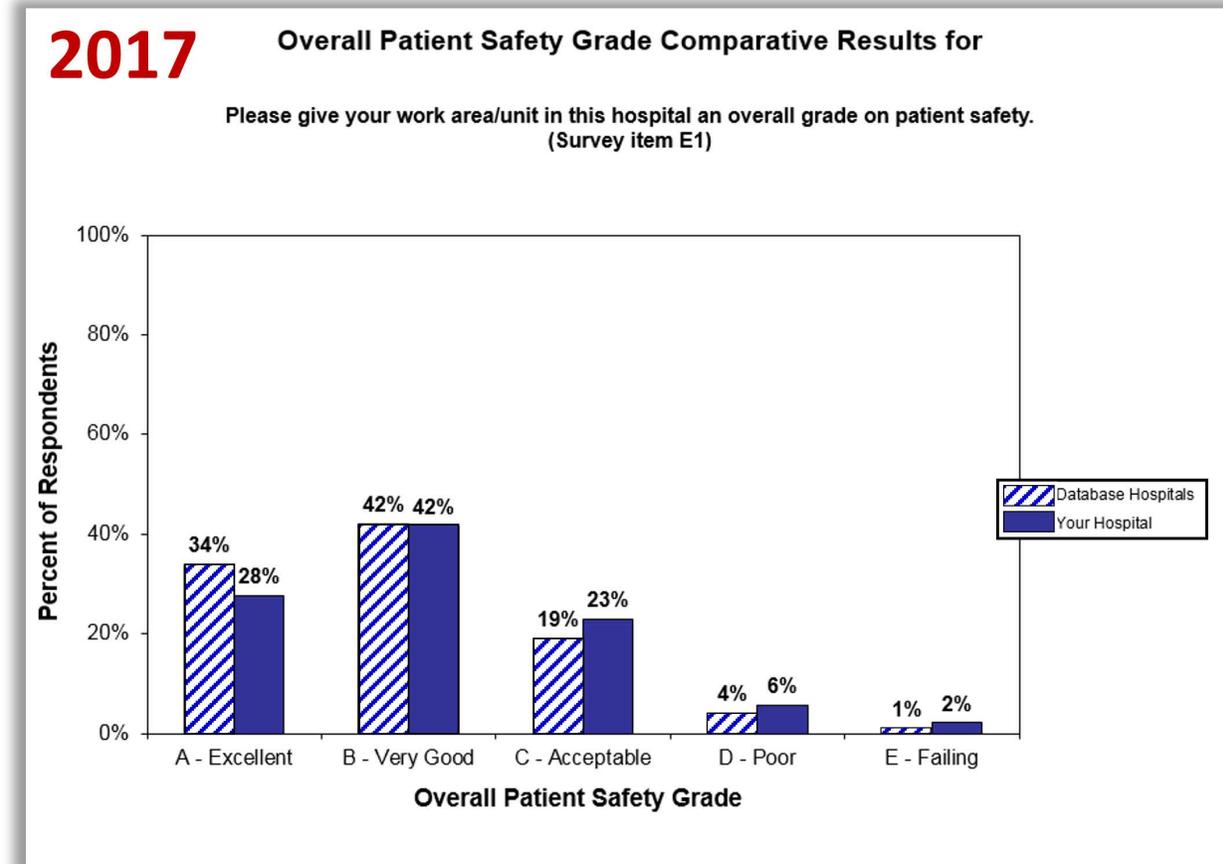
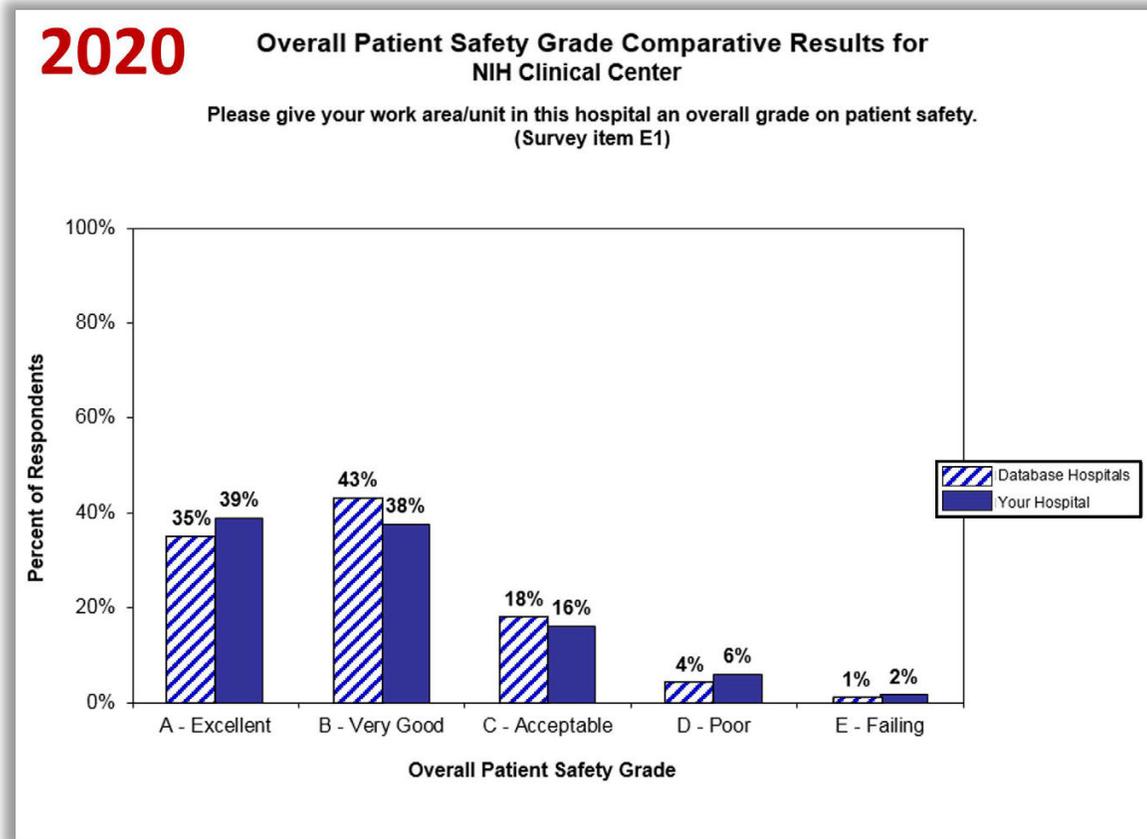


**CC improved in each of the
12 domains compared to
2017 scores!**

Overall Patient Safety Grade Comparative Results
for NIH Clinical Center

Excellent + Very Good	NIH	AHRQ
2020	77	78
2017	70	76

Overall Patient Safety Scores 2020 and 2017



Excellent + Very Good	NIH	AHRQ
2020	77	78
2017	70	76

Four Strategic Aims

- Continuing to lead the world in conducting first-in-human clinical research in rare and refractory diseases. **(Green)**
- Increasing the use of the CC by the NIH intramural research program. **(Red)**
- Demonstrating profound respect for our patients, our full partners in the clinical research enterprise. **(Green)**
- Partnering with IC's to recruit, develop, and retain the next generation of NIH clinical researchers and the CC staff that will support their efforts. **(Amber)**

It's Only a Plan

Unless You Try to Follow It