

**U.S. Department of Health and Human Services  
National Institutes of Health**

**Eighth Meeting of the  
Clinical Center Research Hospital Board  
April 20, 2018**

**Contents**

Clinical Center Research Hospital Board ..... iii

Executive Summary .....iv

Welcome and Board Chair’s Overview ..... 1

NIH Clinical Center CEO: Update ..... 1

    Staff Changes..... 2

    Response to Challenges: Opioid Shortages, Unplanned Admissions, and Patient Stress ..... 2

    Improvements, Honors, and Milestones ..... 2

    Welcome Video ..... 3

    Hand Hygiene Campaign..... 3

    Discussion..... 3

    Follow-Up Items..... 4

NIH Director’s Remarks .....4

    Discussion..... 5

Patient Safety and Clinical Quality Update .....5

    Reducing Harm..... 6

    STAT Antibiotics ..... 6

    Hand Hygiene and Safety of Staff and Patients..... 7

    Opioids..... 7

    Discussion..... 7

    Patient Activation .....8

    Opioids..... 9

    Follow-Up Items..... 9

Pediatrics at the NIH Clinical Center ..... 9

    Pediatrics at the NIH Clinical Center ..... 10

    Pediatric Consult Service ..... 10

Pediatric Care Committee.....	10
Discussion.....	11
Creating High-Reliability Systems .....	11
Enhanced Preadmissions Process .....	11
Pediatric CLABSI Prevention Bundle.....	11
Discussion.....	12
Monitored Pediatric Care Unit in 1 Northwest.....	12
Care Details .....	13
Discussion.....	13
Follow-Up Items.....	14
Vision: Surgeon-in-Chief.....	14
2018 Goals.....	14
Problematic Outcomes Data Capture.....	15
Discussion.....	15
NIAID Update: Clinical Center Operations/Extramural Use of the Clinical Center.....	16
History: Impact of the AIDS Epidemic and Bioterrorism.....	16
Today’s Focus on Safety .....	17
Expanding Extramural Research Opportunities at the Clinical Center .....	17
Discussion.....	18
Patient Safety, Culture Change, and Staff Morale.....	18
Clinical Center Facilities Update.....	18
Infrastructure Outside of the Clinical Center .....	19
Clinical Center Projects .....	19
Discussion.....	20
Follow-Up Items.....	20
Adjournment .....	21
Abbreviations and Acronyms .....	22

## **Clinical Center Research Hospital Board**

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, New York-Presbyterian Hospital, and Chair, National Institutes of Health (NIH) Clinical Center Research Hospital Board (CCRHB)

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, and Executive Director, CCRHB

Francis S. Collins, M.D., Ph.D., Director, NIH, and Ex Officio Member, CCRHB

Ellen Berty, Special Education Teacher, Book Author, and Former NIH Research Participant

Beatrice Bowie, Facilitator, Sickle Cell Support Group, Adventist HealthCare Shady Grove Medical Center, and Board Member, NIH Patient Advisory Group

Ruth Brinkley, M.S.N./Adm., KentuckyOne Health

Brig Gen James Burks, M.B.A., M.M.A.O.S., Director, Manpower, Personnel, and Resources, and Chief, Medical Service Corps, U.S. Air Force (by telephone)

Carolyn Clancy, M.D., Deputy Under Secretary for Health for Organizational Excellence, Veterans Health Administration, U.S. Department of Veterans Affairs

Jeanette Erickson, D.N.P., RN, Senior Vice President for Patient Care Services and Chief Nurse, Massachusetts General Hospital (absent)

Paul O'Neill, M.P.A., Nonexecutive Chairman, Value Capture, LLC (by telephone)

Richard Shannon, M.D., Executive Vice President, Health Affairs, and Professor of Medicine, University of Virginia Health System

Reed Tuckson, M.D., Managing Partner, Tuckson Health Connections (by telephone)

## **Executive Summary**

The eighth meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on April 20, 2018, on the main campus of NIH. The meeting was open to the public and was webcast live.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, New York-Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:05 a.m. and welcomed all those in attendance.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, introduced the agenda for this meeting. He discussed a fiscal year (FY) 2018 average 5% increase in the seven-day patient daily census over the FY 2017 figure, staff changes, and responses to challenges including a shortage of opioids and unplanned admissions. Waiting room videos with relaxing music and images help alleviate patient stress, and a welcome video helps newcomers navigate the NIH campus. Joint Commission surveyors are expected soon. The Clinical Center is building on the early success of a new hand hygiene campaign.

Francis S. Collins, M.D., Ph.D., NIH Director, announced a \$3 billion boost in federal funding for NIH in FY 2019 and support from Congress, aided by members' ability to visit the Clinical Center and see its work.

Laura Lee, M.Sc., RN, Chief, Office of Patient Safety and Clinical Quality, described specific patient safety efforts. She noted that after some early success at improving timely delivery of STAT antibiotics, timeliness has diminished. Ms. Lee noted related factors. She also described a new hand hygiene campaign aimed at staff, patients, and families and the Clinical Center's response to an opioid shortage and societal concerns about opioid addiction.

Deborah Merke, M.D., M.S., Senior Investigator and Chief, Pediatric Services at the Clinical Center, gave an overview of the Pediatric Consult Service and the Pediatric Care Committee. The consult service cares for a growing number of children on protocols by many more pediatricians than have been available in the past. The committee drives improvements in drug administration, suicide-prevention screening, and transports to other hospitals when necessary.

Krista Cato, M.H.A., RN, Nurse Manager, Pediatric Program of Care in the Clinical Center Nursing Department, discussed an improved pediatric preadmissions process and efforts to curtail pediatric central line-associated bloodstream infections (CLABSIs). Recent improvements to an online preadmission form drive expanded user access and improved communication. Tactics that were successful in reducing pediatric CLABSIs are now being used in adult care.

Zenaide Quezado, M.D., Chief, Pediatric Anesthesiology and Critical Care at the Clinical Center, described how the monitored pediatric care unit in 1 Northwest addresses the complex care needs of children on high-risk protocols and makes care of younger, sicker children possible. She described the special expertise and equipment involved in unit care.

Jeremy Davis, M.D., Clinical Center Surgeon-in-Chief, Staff Clinician, National Cancer Institute, Thoracic and Gastrointestinal Oncology Branch, described Surgical Administrative

Committee 2018 goals, including increased surgical quality, greater efficiency, and contingency planning. Working groups address these areas. Dr. Davis said the committee will start a campaign to empower Clinical Center staff to advocate for patients and promote teamwork. He also described difficulties in obtaining surgical outcome data.

H. Clifford Lane, M.D., National Institute of Allergy and Infectious Diseases (NIAID) Deputy Director for Clinical Research and Special Projects, gave an overview of NIAID's history and work and how the AIDS epidemic and bioterrorism shaped it. More recently, NIAID has made changes that increase patient safety and instituted a new nurse case manager model that requires some adjustment.

Dr. Lane also reviewed a new funding opportunity that aims to provide extramural investigators access to both the Clinical Center and NIH research infrastructure. He explained how the funding opportunity emerged from a working group recommendation that more protocols use the hospital.

Dan Wheeland, Director, NIH Office of Research Facilities, updated the board about facilities improvements within and outside the Clinical Center that are being planned and implemented. He detailed challenges in expanding space for the Permanent Intravenous Admixture Unit within the Clinical Center. Dr. Wheeland also explained high-priority needs related to planned construction of a very expensive surgery, radiology, and laboratory medicine building at the Clinical Center complex.

Dr. Forese adjourned the meeting at 2:53 p.m.

The next face-to-face CCRHB meeting is scheduled for July 20, 2018.

# Meeting Summary

## Friday, April 20, 2018

### Welcome and Board Chair's Overview

*Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, Clinical Center Research Hospital Board (CCRHB)*

The eighth meeting of the CCRHB took place on April 20, 2018, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and webcast live. Dr. Forese called the meeting to order at 9:05 a.m. and welcomed all present. She noted that Francis S. Collins, M.D., Ph.D., would join the meeting later that morning. Reed Tuckson, M.D., Paul O'Neill, M.P.A., and Brig Gen James Burks, M.B.A., M.M.A.O.S., participated by telephone. Jeanette Erickson, D.N.P., RN, was absent.

### NIH Clinical Center CEO: Update

*James Gilman, M.D., CEO, Clinical Center*

Dr. Gilman greeted board members and introduced the agenda for the meeting.

Dr. Gilman discussed a chart that compared fiscal year (FY) 2018 patient activity with FY 2017 patient activity. As of April 11, the FY 2018 average seven-day daily census was 5% higher than the FY 2017 figure. The increase is largely related to National Cancer Institute (NCI) protocol patient stays—especially in the day hospital—and to patients on National Institute of Mental Health (NIMH) and pediatrics protocols. Stays at the day hospital are up 12% over FY 2017.

Dr. Forese asked why there has been a 2% decrease in new patients in FY 2018, compared with FY 2017. Dr. Gilman said that the decrease is larger than usual.

He added that long-term patients and their families report good experiences at the Clinical Center, but new patients do not always find the Clinical Center as welcoming.

FY 2018 funding makes possible some new Clinical Center programs, but space must be identified first. Colleen McGowan leads an ongoing inventory of available space, which should be finished within a month.

Dr. Gilman said that later in the morning, Norman “Ned” Sharpless, M.D., Director of the National Cancer Institute, would stop by to greet the board. Dr. Sharpless is an advocate for the Clinical Center and improving its facilities.

Other areas of focus in 2018 include leadership development and supervisory training, to include staff who have worked at the Clinical Center for a long time; review of the Protocol Resource Impact Assessment (PRIA) process, especially for imaging and laboratory technology; and operations in the outpatient clinics and day hospitals.

### ***Staff Changes***

Pius Aiyelawo, FACHE, was sworn in as the Clinical Center's new chief operating officer (COO) on April 2. His background is in resource management and health care administration and in medical research at the Department of Defense. Chosen in a national search that included more than 50 well-qualified applicants, Mr. Aiyelawo oversees all research and clinical domains, education, and fiscal and administrative operations, allowing Dr. Gilman to focus on strategic priorities.

Elizabeth Jones, M.D., M.P.H., M.B.A, is now Acting Chief of Radiology and Imaging Sciences. A Staff Senior Clinician, Dr. Jones is in her second rotation as Acting Chief and her department has the Clinical Center's largest budget and the most equipment.

Naomi O'Grady, M.D., is Chief of the Internal Medicine Consult Service. Her staff provides clinical and clinical research support service to NIH investigators and patients.

### ***Response to Challenges: Opioid Shortages, Unplanned Admissions, and Patient Stress***

Since the last meeting, the Clinical Center pharmacy has faced a shortage of fluids and opioids. Clinical Center leadership is speaking with the Food and Drug Administration (FDA) about ways to alleviate shortages. The shortages have driven respectful dialogue and cooperative efforts, with positive results. For example, positive changes to day hospital patient flow followed loss of one of the pharmacy's two hazardous drug doses and after physician, nurse, and pharmacy staff met to plan a response and communicated challenges to the entire Clinical Center. Some patient services were postponed.

A new process for managing unplanned admissions was introduced in response to patients who sometimes come in unexpectedly without scheduled CC visits, instead of seeking care with local providers or at local hospital emergency departments. The process allows identifying beds for these patients, quick workups, and treatment. The Clinical Fellows Committee identified the need for this new process as fellows frequently take care of patients who arrive off-hours or in the middle of the night, so the fellows' input resulted in a positive change.

Staff from the National Academy of Sciences visited the Clinical Center on one of the days of the federal government shutdown for a tour of the facility that resulted in discussions for replacing parts of the facility with anticipation of additional appropriated funds for building improvements

In response to Dr. Gilman's concern that both staff and patients could benefit from additional, carefully delivered spiritual care, the Department of Spiritual Care has developed the Continuous Ambient Relaxation Environment (C.A.R.E.<sup>®</sup>), relaxing images and music that can be shown on monitors in patient rooms and waiting rooms. C.A.R.E.<sup>®</sup> provides 84 hours of images and music as an alternative to news channels, which can be polarizing and upsetting to patients and families.

### ***Improvements, Honors, and Milestones***

The new Center for Cellular Engineering includes 11 cell-processing rooms, with seven new ones in 2J and four in 3T. Capacity is nearly tripled since last year and 18 rooms are projected by 2021. The medical staff will consider the implications of more patients getting engineered cells

and immunotherapy. For example, neurology consults and emergency brain scans may be needed, so critical care staff will need more neurological emergency training.

The Clinical Center's six-month Joint Commission window ends in September; therefore, it is likely the JC will visit the hospital soon. The CC is preparing for the survey with significant hospital improvements to share when the JC arrives.

The National Research Council gave the Clinical Center an award for providing top-in-the-nation emotional support to patients and families. Patients and families who come for long-term stays or return multiple times over years—especially in the long-standing sickle cell and HIV programs—give the Clinical Center very high survey marks.

### ***Welcome Video***

Despite the high marks from longtime patients and families, many newcomers find access to the Clinical Center intimidating. Justin Cohen, M.S., M.A., and the Offices of Communications and Media Relations and of Patient Recruitment made a welcome video at the suggestion of the Patient Advisory Group (PAG), which is celebrating its 20th anniversary..

Dr. Gilman showed the video. It acknowledges that NIH can be overwhelming and gives preparation tips, such as leaving extra time to go through security and park. The video shows a map noting the proper visitor entrance and its address and points out that GPS is not always reliable on campus. The video likens the NIH security procedures to airport inspections. It adds that The Children's Inn provides free lodging for parents of young patients and offers free parking and a valet service available during specific hours. The video also notes details about public transportation and campus shuttle buses and adds that families—who are always welcome—can apply for extended visitor passes.

The video is available on the NIH website. There is no Spanish version, but the site has instructions in Spanish. Dr. Forese encouraged board members who called in to the meeting to watch the video.

### ***Hand Hygiene Campaign***

The Clinical Center is in the third week of a new hand hygiene campaign. The hospital achieved a 75% rate of compliance with proper handwashing in the campaign's second week. A related video from the Offices of Communications and Media Relations and of Patient Recruitment emphasizes proper technique and the importance of hand hygiene, especially after caring for norovirus and *Clostridium difficile* patients. The video discusses educating patients about hand hygiene and empowering them to remind staff who forget to wash. It suggests saying “top 10” as a code phrase and respectful reminder to staff and visitors who do not wash their hands.

### ***Discussion***

Dr. Shannon said that Clinical Center leadership transitions represent an opportunity to commit to racial, ethnic, and gender diversity.

He noted that the Drug Enforcement Agency (DEA) is considering restrictions on manufacture of opioids, following a hypothesis that the manufacturing process drives the opioid addiction epidemic. Dr. Shannon characterized this logic as faulty and maintained that manufacturing does not result in oversubscribing of opioids.

#### *Joint Commission Survey*

Like the DEA, the Joint Commission is under considerable congressional scrutiny, so health care organizations, including the Clinical Center, must prepare well for Joint Commission surveys. The Joint Commission process is now more regulatory than the collaborative process to which hospitals are accustomed, said Dr. Shannon. After his experience with a recent Joint Commission survey of his institution, University of Virginia Health System (UVHS), he urged escalated preparation for the Clinical Center's upcoming Joint Commission survey. He suggested preparing for new, more stringent requirements by having a mock survey conducted according to the new standards.

Under the new Joint Commission scoring system, just one deficiency results in a major finding. Dr. Shannon emphasized that one survey area of focus is on ligature risks, so surveyors will scrutinize behavioral units for deficiencies such as beds that are not suitably bolted.

Dr. Shannon invited CC staff to interact with the UVHS team to learn more about its preparation for the survey and results and follow-up.

Dr. Clancy noted additional pressure from the Centers for Medicare & Medicaid Services (CMS), which published a report noting discrepancies between Joint Commission inspection findings and CMS's own, more stringent inspections.

#### *Hand Hygiene*

Mr. O'Neill asked why the hand hygiene compliance rate is only 75%. Mr. O'Neill noted his concern that the compliance rate is indicative of the general conditions at the Clinical Center and that staff "don't own the goal." Brig Gen Burks noted that executive dashboard figures from two years ago showed a poor rate of medication barcode use, which later rose to 99%.

Dr. Gilman provided context for the single data point on handwashing. The campaign began less than three weeks before data were gathered. The hospital is early in the intervention stage and is watching the handwashing rate mindfully. Brig Gen Burks said that the occupational incident case rate is an issue parallel to hand hygiene problems. Dr. Shannon said that at the board's next meeting, there will "be a moment of accountability" to see whether progress has been made on the handwashing rate.

#### ***Follow-Up Items:***

- At next meeting, provide an update on compliance with proper hand hygiene procedures.

### **NIH Director's Remarks**

*Francis S. Collins, M.D., Ph.D., Director, NIH*

Dr. Collins praised efforts to improve care and fight complacency at the Clinical Center. He noted recent challenges, especially shortages of saline and fentanyl. Fentanyl is not diverted from

legitimate manufacturers. Fentanyl becomes dangerous when mixed with other substances. Meanwhile, the Clinical Center has a legitimate, critical need for the drug. FDA Commissioner Scott Gottlieb has been responsive to Clinical Center needs. NIH can use its influence at the FDA to improve the national supply.

The Clinical Safety has made big strides in safety in the last couple of years. Dr. Collins credited the board for improvements to serious safety issues and warned against complacency. He pointed to handwashing as an example of a “job that’s never done.” Daily safety huddles are an example of new mechanisms that direct attention to specific patient safety problems.

In the last three weeks, the Clinical Center cared for “VIP” patients with complicated, serious medical problems. Dr. Collins said that he was able to assure these patients and their caregivers that the Clinical Center was positioned to diagnose problems and provide the best care possible. The entire staff is dedicated to this goal on behalf of all patients.

The Clinical Center’s proximity to Washington, D.C., allows the center to host visits by members of Congress, show how it helps the whole country, and inspire lawmakers. A reception attended by 28 members of Congress, held by Advancing Cures Today (ACT), led to a \$3 billion boost in federal funding for NIH in the coming year. Comments by key congressional committee chairs shows that they are well-informed about medical research and that research is poised to make breakthroughs. Significant increases in federal funding three years in a row are the result of enthusiasm for NIH’s work shared by both political parties and houses of Congress, following a period of flat funding.

NIH and the Clinical Center are in a good place, but the board and staff should not become complacent.

### ***Discussion***

Various board members congratulated Dr. Collins for securing increased funding.

Dr. Clancy asked whether most members of Congress have been strong supporters of the Clinical Center. Dr. Collins said Senator Roy Blunt and Representative Tom Cole, who head subcommittees with influence over the Department of Health and Human Services and other agencies, organized visits of their fellow subcommittee members. Dr. Clancy commented that lawmaker and policymaker visits to patient care sites are powerful, influential experiences.

Subcommittee members were especially moved by meeting Steven A. Rosenberg, M.D., Ph.D., who pioneered development of immunotherapy, learning about his work, and meeting his patients, Dr. Collins said.

### **Patient Safety and Clinical Quality Update**

*Laura M. Lee, M.Sc., RN, Chief, Patient Safety and Clinical Quality, Clinical Center*

Ms Lee thanked Dr. Shannon for details about the recent Joint Commission survey at his hospital. The NIH Clinical Center staff and leadership view the Joint Commission accreditation process as critical in assuring high quality and safe care.

### ***Reducing Harm***

In the last year, the Clinical Center had a major shift in the organizational culture regarding patient safety. She attributed the change to leadership from the board, Dr. Gilman, and investment by NIH leadership in patient safety resources and staff engagement.

The best evidence of staff engagement is the daily patient safety huddle. Each morning, approximately 60 staff members discuss patient safety events that occurred in the previous 24 hours, review current risks, and identify possible future risks. The huddle results in real-time engagement about, and accountability for, patient-related issues and events..

Ms. Lee highlighted several organizational performance improvement initiatives launched, or expanded, in the last year. These included: the implementation of a brain code algorithm and a massive transfusion protocol; the expansion of the ICU Trigger Tool program - a 10 person team (including fellows, physicians, and nurses) who review all intensive care unit admissions to identify instances of preventable harm; implementation of system-based mortality and morbidity rounds, the expansion of the Safety Tracking and Reporting System (STARS) and the implementation of Unit-based Patient Safety and Clinical Quality meetings.

Reducing preventable harm to patients is a major goal for 2018-2019. The majority of patient safety events are caused by communication lapses; therefore, the Clinical Center will expand the I-PASS communication program, a standardized communication handoff process, to the entire organization.

Another area of focus for 2018 will be patient engagement. Historically patients have been considered partners in research; however, they will now also be considered partners in safety. The Patient Advisory Group will assist in this effort.

Ms Lee shared that medical literature demonstrates that unprofessional and disruptive behavior can have a negative effect on patient safety. To address this issue, new efforts will focus on determining if these issues are a problem at the Clinical Center and empowering staff to “speak truth to power” when they see unsafe situations. Ms. Lee indicated that she would reach out to other organizations for new patient safety ideas.

Ms. Lee asked the board for its input on best practices regarding providing information about safety events to the frontline staff, creating a culture that supports the reporting errors, and patient activation regarding patient safety.

### ***STAT Antibiotics***

An analysis of August and September data revealed that patients received antibiotics within 60 minutes in only 53% of cases. After starting corrective interventions, that figure rose to 72% in November and December 2017. Despite expectations of achieving a 90% rate in the first quarter of 2018, during that period the proportion of patients receiving antibiotics within 60 minutes fell to 57%. Factors in the decrease include limited production capacity within the pharmacy department and a shortage of small-volume intravenous (IV) fluid bags. Another factor that contributed to late antibiotics was the inappropriate use STAT orders—driven by prescribers’ fear of getting drugs late—which resulted in an increased workload in the pharmacy IVAU.

More than 20% of antibiotics that were administered late were available in the automatic dispensing units on the patient care units. In an effort understand the etiology of these events, staff from the Office Patient Safety and Clinical Quality review each case of a late antibiotic administration and interact directly with the staff caring for the patient to understand precisely the factors that may have influenced the last administration.

### ***Hand Hygiene and Safety of Staff and Patients***

The Clinical Center has initiated a new Hand Hygiene program. A key aspect of the initiative is the active engagement of staff in encouraging their colleagues to adhere to hand-washing requirements. One strategy in this initiative has been to identify a hand hygiene code word– “TOP TEN” – that staff can use when they see someone who has not washed his/her hands. For instance, if a respiratory therapist observes a physician who does not wash her hands, the respiratory therapist can approach the physician and say: “TOP TEN” – this reminds the staff person to wash their hands. Using this code work may make staff more comfortable when approaching their colleagues. All staff are also encouraged to participate in the hand hygiene observation initiative in an effort to enhance our surveillance program. Patients will receive placards that look like red hands to hold up if they are uncomfortable asking Clinical Center staff about washing hands. The placards increase patient engagement.

A successful long-standing fall prevention program in the nursing department has been expanded to the entire hospital and educates staff that fall prevention is a shared responsibility.

A new task force is examining ways to handle patients that avoid ergonomic/musculoskeletal injuries to staff.

### ***Opioids***

In response to the national opioid crisis and new guidance from the Joint Commission regarding pain assessment and management, an interdisciplinary team has been charged with addressing opioid use and patient safety. Specifically the team is focusing on opioid prescribing, assessing patient’s opioid histories as well as their risk for mis-use, the use of adjuvant therapies, and the patient’s role opioid use.

An area of focus is assuring that Clinical Center prescribers have appropriate information regarding the opioid prescriptions that patients are receiving from other healthcare providers. Patients come to the Clinical Center from across the nation, however, Clinical Center practitioners do not have access to state medication databases. One of the areas of focus of the workgroup is to identifies strategies to provide Clinical Center practitioners access to these state databases

### ***Discussion***

#### ***Sexual Harassment***

Ms. Brinkley pointed out that Ms. Lee’s presentation did not address sexual harassment.

Dr. Gilman noted discussion that a previous board meeting discussion addressed this issue regarding an staff member. An incident resulted in a message to NIH staff about inappropriate behavior.

Feedback from staff noted that the message did not address inappropriate behavior by patients. Nursing and housekeeping staff have long dealt with this issue, which is a problem at NIH in part because of an international patient population with varying attitudes. NIH Deputy Director Lawrence A. Tabak is leading an effort to address sexual harassment, but creating a policy may take some time. In the meantime, NIH is trying to both make staff feel safe and be culturally sensitive to patients. Dr. Forese said sexual harassment is a common problem and noted the importance of reviewing employee survey data about it.

#### *STAT Transfusions, Antibiotics, and Facilities Issues*

Dr. Sharpless introduced himself and asked board members to tell him any concerns they have about patient care and safety. He thanked Ms. Lee for the forthright statistics about late antibiotic administration.

Dr. Sharpless asked for statistics about lapses in timely transfusions after STAT orders. Ms. Lee said that late transfusions have all been reported to STARS, and she can give related data to Dr. Sharpless almost immediately. He predicted that STAT transfusion figures will be better than those for STAT antibiotics, noting his suspicion that pharmacy capability may limit timely STAT antibiotics.

Dr. Gilman said that his analysis of 2018 quarter 1 data on late STAT antibiotics shows that about half were due to pharmacy deficiencies. The pattern of antibiotic use differed from the previous two quarters and needs more examination. Dr. Sharpless said he suspects that prescribers may be ordering more STAT antibiotics from procedure rooms because they worry they won't get the drugs in time.

Dr. Sharpless said that some of the STAT antibiotics and other Clinical Center problems may be related to facility deficiencies. Noting recent discussions about the capital fund, he argued that patient safety is its most important use. He asked the board to articulate needs related to devices, rooms, and physical structure that would make the hospital safer.

#### *Patient Activation*

Dr. Tuckson emphasized the importance of patient activation in safety. He suggested partnering with the Agency for Healthcare Research and Quality (AHRQ). Dr. Gilman related an instance when a peripheral IV was placed on the wrong patient despite the patient questioning the order. He noted that it is essential that patients feel empowered to speak up about their care.

Dr. Forese said that during the first week of a New York-Presbyterian Hospital program that allows patients to view medications, a patient spotted a mistake. The incident situation shows that patients understand more medical information than doctors and nurses predict. Ms. Berty said that she keeps track of her drugs and often knows her medication needs better than unit nurses do. Ms. Berty added that during a stay in a Clinical Center isolation room, staff never reminded her to wash her hands, and she never reminded her visiting family to do so. Ms. Berty emphasized the need to make patients aware of the "Top 10" campaign that reminds everyone to practice hand hygiene.

The Veterans Health Administration (VHA) shares a daily care plan with all patients, Dr. Clancy noted. Even though plans may change, they give patients a sense of control. Patients do catch mistakes. The VHA employs informed consent that details treatments' side effects and benefits, and is part of the electronic medical record. The VHA does not use patient contracts.

Ms. Bowie said that she is well aware of medications she takes and finds it helpful to communicate with hospital physicians and nurses if she spots a related problem. Dr. Lee praised this tactic.

### ***Opioids***

Dr. Clancy asked why the Clinical Center cannot check Joint Commission Prescription Drug Monitoring Program databases. She noted that scrutiny of opioid prescribing generally does not extend to cancer patients. Successful care at the Clinical Center means it has more long-term patients who can develop new medical problems for which opioids might be prescribed. Ms. Lee said that she needs to investigate how to access state databases to see who else prescribes opioids to Clinical Center patients. Dr. Collins noted that no national database tracks opioid prescriptions. Dr. Clancy commended Ms. Lee's daily dive on antibiotics, noting that quarterly reports are ineffective.

Dr. Shannon said that University of Virginia does not have opioid contracts but that the opioid shortage forced his hospital to examine surgery protocols focused on certain drugs. Following this process, pilots now focus on giving patients hydration until just before surgery. The hospital has seen an 80% reduction in perioperative and postoperative opioid use in these pilots and is considering building hydration into algorithms to avoid automatic perioperative administration of opioids. Dr. Forese suggested bringing up ways to diminish opioid use during a later presentation by Jeremy Davis, M.D., Clinical Center Surgeon-in-Chief.

Dr. Shannon noted that the Clinical Center's renewed focus on quality and safety is two years old and that the hospital is now stabilizing and improving systems to create predictable processes for doing work. At the same time, however, staff need training about the new systems. He urged Clinical Center leaders to engage staff in new systems with adequate training and time to learn.

### ***Follow-Up Items:***

- Provide Dr. Sharpless with STARS data about late STAT transfusions.
- Investigate strategies to access state databases to determine if patients are receiving opioid prescriptions from other practitioners.

## **Pediatrics at the NIH Clinical Center**

*Deborah Merke, M.D., M.S., Senior Investigator and Chief, Pediatric Service, Clinical Center  
Krista Cato, M.H.A., RN, Nurse Manager, Pediatric Program of Care, Clinical Center Nursing  
Department*

*Zenaide Quezado, M.D., Chief, Pediatric Anesthesiology and Critical Care, Clinical Center*

### ***Pediatrics at the NIH Clinical Center***

Dr. Merke gave an overview of pediatrics, the Pediatric Consult Service, the Pediatric Care Committee, and initiatives aimed at optimizing patient safety, including preadmission patient screening and protocol screening. She noted that pediatrics has always been an integral aspect of the intramural research program. In 1994, the Clinical Center opened its first multi-institute pediatrics unit. Today the Clinical Center has 1 Northwest, a multi-institute unit with 22 beds and 14 day hospital stations, a pediatric outpatient clinic with 21 patient care rooms, and a six-bed pediatric behavioral health inpatient unit.

### ***Pediatric Consult Service***

Dr. Merke made the following key points:

- Thirty-five percent of the Clinical Center's approximately 1,600 active protocols include children. About half are natural history studies, while the other half are studies of new treatments. Fourteen institutes admit children to the hospital. In FY 2017, 442 inpatient admissions involved children and 3,168 outpatients were children.
- Institutes are hiring more pediatricians. In 2018, 164 board-certified pediatricians practice at the Clinical Center. In 2014, there were just 116 pediatricians. Pediatrics accounts for about 13% of the hospital's patient activity. Before 2014, that figure was only about 10%.
- The Pediatric Consult Service, available to inpatients and outpatients, now includes two pediatricians and two pediatric nurse practitioners. The service provides one-time consults for acute pediatric problems, ongoing consults, and procedure consults.
- The service's total number of consults increased 143% from FY 2014 to FY 2017. The number of consult days increased 59% during the same period.

### ***Pediatric Care Committee***

The Pediatric Care Committee (PCC) provides interdisciplinary oversight, includes representations from Clinical Center departments and Senior Investigators from Institutes performing pediatric research, and advises the Medical Executive Committee (MEC) and CEO about pediatric problems, policies, and procedures. Dr. Merke made the following key points:

- In 2017-2018, the PCC worked to ensure prompt administration of antibiotics for febrile neutropenia or sepsis, suicide prevention screening, patient transports to Children's National Medical Center; partnered with Walter Reed National Medical Center to provide pediatric subspecialists; gave feedback to The Children's Inn about new problems; and reviewed a policy on pediatric visitors.
- The PCC is a subcommittee of the MEC and oversees the Medication Occurrence Report Evaluation Subcommittee, which looks for trends in medication occurrences and pharmacist interventions and compares pediatric and adult data to identify issues unique in pediatrics. PCC members are on several other committees throughout the hospital to ensure bidirectional communication
- Challenges related to pediatric clinical research include optimizing patient safety while doing cutting-edge research, involvement of multiple stakeholders and diverse protocols, and limited pediatric-specific subspecialty services.
- To mitigate risk, a new screening process begun in 2016 targets higher-risk patients to ensure proper resources are available for their care. The process involves research teams completing a form that identifies medical needs. . The process has increased communication among the research team, Pediatric Consult Service, and nursing staff

prior to patient visits; identified problems; and allowed staff to help plan patient visits prior to arrival.

- In 2017, the Protocol Resource Impact Assessment (PRIA) was established to allow Clinical Center departments to review protocols. Twenty-eight protocols were reviewed by the Pediatric Consult Service, and the process identified three with significant feedback involving other departments and one that had a failure mode and effects analysis.

### *Discussion*

Dr. Forese asked about the age range of patients seen at the Clinical Center. Dr. Merke said inpatients range from ages 3 to 18 and pediatric outpatients are of all ages.

Ms. Bowie asked whether there are any pediatric sickle cell anemia patients. Dr. Merke said there is currently a child with sickle cell anemia undergoing a bone marrow transplant at the Clinical Center. She added that with transplants, studies of new techniques generally include adults first. If those techniques succeed in adults, subsequent studies include children.

### *Creating High-Reliability Systems*

Ms. Cato discussed the enhanced pediatric preadmission process, the pediatric central line–associated bloodstream infections (CLABSIs) prevention bundle, and opportunities for growth.

### *Enhanced Preadmissions Process*

Ms. Cato said that early on, the enhanced preadmission process involved feedback from multiple departments, stakeholder forums, discussions with patients and families, and monitoring and reviewing patient safety reports from STARS and the Office of Research Services. Over time, she has identified trends that point to opportunities for improved care coordination, such as lack of standardization in the preadmission form.

A retrospective review of five days' preadmission forms by an interdisciplinary team revealed that the forms captured information about specific protocols and branches and suggested that standardizing the preadmission form could improve communication and care coordination. Specialty teams designed and enhanced three different forms to address care models in different settings. The new standardized forms had dropdown menus, smart logic, autopopulating fields, mandatory fields, alerts, and high-risk screening questions.

The November phase 1 launch of the standardized forms involved a switch from a manual paper process to an electronic one with enhanced reporting capabilities. The new process ensured proper staff were available for specialized care. Challenges during this phase included overly tight security settings and continued, albeit limited, reliance on paper forms.

An enhanced process went live in March 2018, along with expanded user access to allow consistent, efficient communication. Overwhelmingly positive feedback includes requests to expand the enhanced process to all pediatric care areas and the entire Clinical Center.

### *Pediatric CLABSI Prevention Bundle*

The 1 Northwest pediatrics unit in quarter 2 of 2016 saw a spike in CLABSIs. In response, a systematic approach to evaluating patient outcomes created improvement strategies that led to change, commitment to patient safety, and implementation of reliable care models.

Staff identified areas of vulnerabilities, performed a root cause analysis for all infections, sought epidemiologists' expertise about causative organisms, and explored best practices and evidence for prevention techniques. After choosing appropriate techniques and training staff about them, the team developed the pediatric CLABSI bundle and piloted it.

Best practices include appropriate handwashing, central line care and maintenance, patient and family education and engagement, cleaning of high-touch surfaces, and a deep clean of rooms where individual patients have been for 30 days. Family education and engagement has perhaps been most useful, while the two-person dressing change received the most staff complaints. However, in time staff came to appreciate the presence of a second nurse and the resulting diminished time needed for dressing changes. Cleaning became an opportunity to educate patients and families and make them aware of their environment.

After the CLABSI bundle's success, it is now being implemented in adult care areas. Pediatric staff are sustaining success by talking about it in daily safety huddles, with families, and in staff patient safety meetings. Pediatric staff have built on its success with new use of chlorhexidine bath wipes and discussion of central line removal at rounds.

### ***Discussion***

Mr. O'Neill said that Ms. Cato's pediatric patient safety efforts are a model for what needs to be done across the institution.

Brig Gen Burks said that Ms. Cato's presentation reminded him of a saying in his organization, "Every team member a problem solver every day." The saying, he said, relates to workforce development strategy and development of competencies. He asked how the approach described in the presentation could be scaled across the Clinical Center.

Dr. Gilman noted that Ms. Cato looked at benchmarking and best practices from outside the Clinical Center to develop new procedures. Her efforts and others related to pharmacy and cellular engineering overcome a tendency to ignore expertise from outside of NIH. To achieve a safer care environment, NIH leaders have been more receptive to advice from experts from outside of NIH.

Ms. Brinkley praised implementation of two-person dressing changes, noting that the procedure uses tactics long used by scrub nurses in an innovative way.

### ***Monitored Pediatric Care Unit in 1 Northwest***

Impetus for the unit, which opened in December 2017, was an understanding that earlier diagnosis and treatment prevent some adult diseases and care needs for children who receive interventions on high-risk protocols, Dr. Quezado said. In addition to improved safety, other goals include enriching the environment for studying rare, complex diseases and treating younger, sicker children.

The unit includes five beds equipped with cardiovascular, pulmonary, neurologic, and metabolic monitoring capabilities. The unit required an investment in personnel, so the Clinical Center created a Pediatric Anesthesia and Critical Care (PACC) team that includes anesthesiologists and hospitalists. Hospitalist coverage is continual, minimizes patient handoffs, and increases safety. The unit has a higher pediatric nurse/patient ratio than is usual for the Clinical Center.

### *Care Details*

The PACC team provides coverage 24 hours a day, seven days a week. The team covers for the pediatric consult team at night and on weekends, responds to pediatric emergencies and code calls, and stabilizes patients and oversees emergency transfer. The team also provides simulation training for low-volume, high-acuity pediatric scenarios and ensures that staff have pediatric advanced life support certification.

The unit's care model is multidisciplinary. The PACC team coordinates daily medical and supportive care, while a primary team provides protocol-required care. Patient admission to the unit is scheduled via preadmission form at the time of care escalation. Unit staff is available for consultations.

Unit patients frequently need bronchodilators, oxygen supplementation, and bilevel positive airway pressure or continuous positive airway pressure, or tracheostomy. Patients have chronic and stable neurological disorders and need monitoring after anesthesia. Patients who have protocol-directed therapy often need cardiac or respiratory monitoring and medications that require titration until a stable administration regimen is achieved. Often they also need opioids or sedatives, or investigational new drugs or therapies, such as cellular or immunotherapies.

If an escalation of care is required, patients may be admitted to the intensive care unit or, if the Clinical Center cannot provide required care, transferred to a partner institution. In collaboration with the Office of Patient Safety and Clinical Quality and the Pediatric Clinical Care Committee, the unit developed an algorithm for safe transfer.

Of the 3,000 anesthetics administered at the Clinical Center each year, 25% are for children. About 10% of anesthetics used in the operating room are for children. Outside of the operating room, more than 60% are for pediatrics. Forty percent of Clinical Center anesthesiology staff are trained to administer pediatric anesthesia.

Dr. Quezado's staff goes anywhere within the Clinical Center where there is need for pediatric anesthesiology and always abides by operating room standards.

### *Discussion*

Dr. Forese said many hospitals would love to have 40% of anesthesiology staff trained in pediatrics. Dr. Gilman said that while Dr. Quezado's staff provides pediatric anesthesiology care to all who need it, finding pediatric nurses and good hospitalists is a challenge. Dr. Gilman said that David Lang, M.D., has been dedicated to these and other pediatric care efforts. Dr. Forese praised all hospital staff involved in caring for children.

Noting that Clinical Center care processes have become very refined, Dr. Shannon asked whether data shows better clinical outcomes after cellular therapy. Such outcomes could be used

as a sales pitch to attract staff. Dr. Gilman said gathering data is a challenge because it involves so many institutes and protocols, which generally have few patients. Dr. Shannon asked for data on just a few protocols.

***Follow-Up Items:***

- Give Dr. Shannon data from few protocols in which cellular therapy has improved clinical outcomes.

**Vision: Surgeon-in-Chief**

*Jeremy Davis, M.D., Clinical Center Surgeon-in-Chief, Assistant Research Physician, NCI, Thoracic and Gastrointestinal Oncology Branch*

Dr. Davis said that the Surgical Administrative Committee's (SAC) many responsibilities include coordination of procedures in operating rooms (ORs), reviewing and approving new OR equipment, coordinating emergency surgical services for the Clinical Center, and coordinating surgical consultative services with Institutes and Centers (ICs) that lack surgeons. Other duties include reviewing justification for surgical procedures, interactions between the OR and lab of pathology, and the quality of pathology services. The SAC's real purpose, however, is to serve patients and ensure delivery of high surgical quality care to patients enrolled in trials at the Clinical Center.

***2018 Goals***

Dr. Davis said that his first step in defining SAC goals for the 2018 calendar year was to succinctly define the SAC mission. The first part is serving patients. The second part is redefining the SAC as the primary NIH body responsible for surgical and perioperative quality, efficiency, and utilization and for contingency planning.

Surgical quality is at the top of Dr. Davis's list. It includes critically reviewing adverse events and near misses; assessing clinical competency; maintaining skills of surgeons and any other staff who come near patients; and having outcomes and peer review processes to support professional development and organizational advancement.

Focus on efficiency and utilization includes the experiences of patients as they move through the perioperative world and how well the SAC and surgical staff act as stewards of its resources. The SAC must think about what it really needs and asks for. The SAC also aims to standardize supplies—including equipment and instruments—and processes for maximum efficiency.

The SAC's contingency planning role overlaps with duties of the Patient Safety, Clinical Practice and Quality Committee led by Ms. Lee. The SAC must plan for special procedures and staff with specific skills. Often the SAC assesses case practicality by asking what the Clinical Center can and should do.

Strategies for accomplishing SAC 2018 goals include having SAC members recommit to serving Clinical Center patients. On a practical level, SAC has established three working groups focused on surgical quality, efficiency, and utilization, and contingency planning. Since January, renewed focus on these areas resulted in the addition of a nurse anesthetist, physician assistant, and

surgical oncology fellow to the SAC. The SAC intends to start a campaign to empower Clinical Center staff to advocate for patients and promote teamwork. Working groups have been established and have met to establish priorities.

### ***Problematic Outcomes Data Capture***

The Surgical Quality Working Group has determined that surgical quality requires precise outcome data, but data capture in some parts of the Clinical Center is fragmented and inefficient. Individual departments and IC are responsible for collecting perioperative data, but it is not standardized or readily accessible. The working group also observed that current outcomes data are reliable but are not sufficiently comprehensive to advance surgical quality.

As corrective actions, the Surgical Quality Working Group suggests regular review of adverse events by a peer group able to provide immediate feedback. Currently this process takes weeks. The working group also wants a quarterly review of events that focuses on systemic issues. The Surgery Morbidity and Mortality Rounds have recently adopted a systems issue focus and examined unplanned after-hours admission to the Clinical Center. Conversations resulted in systemic changes that Dr. Davis hopes will drive a related policy change. The working group is also exploring the feasibility of a centralized documentation system for perioperative outcomes.

For the SAC to succeed, it needs buy-in from stakeholders including surgeons, anesthesiologists, nurses, techs, and transporters. Buy-in exists among surgical staff but must extend to staff in the rest of the Clinical Center who use operating room resources. Success also depends on staff trust that the hospital can capture data and will support continuous improvement in care.

### ***Discussion***

Noting that surgeons are known for rigorous examination of perioperative outcomes data, Dr. Shannon asked how data collection could be centralized. Dr. Shannon added such data is especially important for high-risk, low-volume procedures common at the Clinical Center. He said board members have data that shows an increase in surgical site infections and asked whether subsets of procedures are associated with greater risk of these infections. Is there existing data to work with as the Clinical Center builds more substantial systems?

Dr. Gilman said the Clinical Center is not waiting for a data system to respond to the six surgical site cases to which Dr. Shannon referred. Dr. Shannon said that he is pleased that Dr. Gilman has identified the trend and is acting on it. Dr. Davis said that surgical site infections are already well tracked. Infection data help institutes and clinicians reduce rates and improve care, he added.

Referring to earlier board discussion of challenges related to the opioid shortage at the Clinical Center, Dr. Shannon asked whether certain surgeries might benefit from protocols that aim to minimize the need for perioperative opioids. Dr. Davis said that discussion by small groups in each service identified procedures where IV opioid usage can be minimized. To avoid IV opioid use, Dr. Davis's own thoracic and gastrointestinal surgeries use regional anesthesia. He noted that diminished usage of these drugs requires a culture change, now aided by trainees being aware of enhanced recovery pathways that avoid narcotics.

Noting Dr. Davis's earlier comment that current outcomes data are reliable but sometimes difficult to access, Dr. Clancy asked how the SAC intersects with the Clinical Center and the

Office of Patient Safety. Dr. Davis said that interactions should be seamless. The SAC's efforts, he noted, align with those of Dr. Lee's patient safety activities.

Currently, specific outcomes data are available but difficult to obtain, because data are siloed in individual departments. However, data are available from the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) that allow the SAC to target surgical areas needing improvement. The NSQIP data don't help the Clinical Center benchmark itself against other institutions, however. Dr. Shannon added that NSQIP uses clinical risk adjustment, which will help level the playing field for complex Clinical Center surgeries.

Dr. Forese said that because the Clinical Center is so unlike other hospitals, its ability to benchmark against other institutions is questionable. However, the Clinical Center can benchmark against itself over time to improve. Dr. Davis's role, she added, is to look across pieces of surgical care. Dr. Forese praised Dr. Davis's work and noted that much more work remains.

## **NIAID Update: Clinical Center Operations/Extramural Use of the Clinical Center**

*H. Clifford Lane, M.D., NIAID Deputy Director for Clinical Research and Special Projects*

Dr. Lane gave an overview of the National Institute of Allergy and Infectious Diseases (NIAID), evolution of its clinical program, current operations and challenges, and an anticipated announcement for funding of extramural use of the Clinical Center. He said that HIV-related and biodefense needs have affected how NIAID runs its programs and builds infrastructure to support clinical work.

NIAID is the second largest IC, with a current annual budget of approximately \$5 billion. Charged with maintaining and increasing a robust and applied research portfolio, the Institute's mandate includes rapid response to new infectious diseases and as a result has an infrastructure that extends globally.

### ***History: Impact of the AIDS Epidemic and Bioterrorism***

The AIDS epidemic brought major changes to NIAID. During the early 1980s, median survival for AIDS patients was 8 to 15 months. The congressional omnibus appropriation to address the AIDS crisis included Clinical Center investment. The institute developed a model for clinical research that involved a nurse with primary responsibility for the patient ; and a nurse with a primary responsibility for the protocol. To facilitate the care fo inpatientns at the CC, NIAID established contracts with local medical schools brought in residents to deliver care under the supervision of NIAID fellows.

A second major change for NIAID was the establishment of their program in biodefense and emerging infectious diseases research. This included working with the CC to build the 5<sup>th</sup> floor Special Clinical Studies Unit that was used to care for Ebola patients during the 2014-16 West African outbreak

Another NIAID initiative has been to reduce the barriers to clinical research for its investigators through a series of activities oriented to provide support to its PIs. These include a protocol navigation program, the development of standards for clinical research modeled after those of the CC, and training and quality assurance programs.

Most recently, NIAID is working to build a partnership with Children's National Medical Center to expand its pediatric clinical research program to younger and more ill patients.

### ***Today's Focus on Safety***

For FY 2018, NIAID expects its Clinical Center activity to include 5,709 inpatient days, 15,319 outpatient visits, and 494 admissions, with an average stay of eight days.

Second- and third-year internal medicine residents provide inpatient care. Identifying a given patient's attending physician had been a challenge. In response, a board in the 5SEN Clinical Research Center lists names of all patients and their attending physicians. Ideally, this information could be conveyed electronically.

NIAID has several patient safety activities, including thrice-weekly formal rounds where fellows discuss patients for whom medical decisions are necessary. Twice-weekly minirounds insure attending physicians to engage with house staff. Medical grand rounds are held weekly. Once a month, grand rounds focus on quality assurance and patient safety.

A summary of STARS reports filed in March revealed one report of moderate harm from anaphylaxis during a food challenge in a peanut allergy protocol. The patient was not harmed by the challenge itself, but rather from eating something else that caused the allergic reaction. Four reports of mild harm include an instance of an IV line placed in the wrong patient, an incident for which Dr. Gilman delivered a personal apology. Poor communication was an issue in five near misses.

Recent patient safety activities, including the daily huddles, have been a positive addition and make it easier to quickly get multi-disciplinary action directed toward pressing issues. The "three things to know this week" emails and quarterly town hall meetings have been of benefit as well.

One critical gap that NIAID has repeatedly noted is a shortage of space for clinically active staff. The soon to be conducted inventory of space utilization may help with the allocation of space to insure those caring for the patients in the CC have offices in proximity to those patients. Another challenge has been obtaining reliance agreements for multi-site studies to be compliance with NIH policy.

### ***Expanding Extramural Research Opportunities at the Clinical Center***

In response to recommendations from a working group, a pending NIAID funding opportunity announcement aims to provide extramural investigators access to both the Clinical Center and the NIAID clinical research infrastructure. This pilot could prompt a new paradigm for how the Clinical Center supports extramural research.

The pilot's Request for Information (RFI) was released on March 13, 2018. The deadline for comments was May 18, 2018. None have been reported, so that deadline has been extended. Dr. Lane anticipates this proposal being discussed at the June 4, 2018 meeting of the NIAID Council. If approved by the council, the first awards could be made approximately a year later.

### ***Discussion***

Dr. Forese asked for examples of the types of studies that the pilot might fund. Dr. Lane said these studies might involve rare diseases and targeted therapies; neurological disease cohorts that need high-resolution magnetic resonance imaging (MRI) and; studies could benefit from physiologic monitoring in the metabolic unit.

Dr. Forese asked Dr. Lane how NIAID could draw on its position as a large institute, its resources, and its history of novel approaches to issues to connect elsewhere. She asked where other institutes could piggyback on NIAID's unique position. Dr. Lane recalled a non-NIAID investigator with a good research question who wanted to study NIAID subjects and was overwhelmed by the process of writing a protocol. Noting that NIAID had more resources than his own institute, the investigator asked for help. The conversation led to a report on the implications of similar situations and foresaw the protocol navigator role.

Dr. Gilman said that earlier this year, the Office of Research Support and Compliance gave the Clinical Center funds to startup a research support office to provide protocol navigators to small institutes. The effort is off to a slow start but has support from high-level NIH leadership. A related issue is the need to centralize NIH IRBs and have them function in a standardized, predictable fashion.

### ***Patient Safety, Culture Change, and Staff Morale***

Dr. Tuckson asked whether Clinical Center staff are receptive to changes being made to support patient safety and how culture has changed. He noted that when the board first met, there was tension across the NIH campus. Dr. Lane noted morale hit a low point then, but it has since improved. He identified one big difference: empowerment of staff clinicians who care for patients and spend the most time with them. More work must be done, especially with longtime staff, but the situation is improving.

Dr. Gilman attributed improved morale to an intramural research program and attention to written agreements between staff and supervisors that specify staff expectations about time set aside for research, as well as changes to handling of increased workloads following staff clinician departures. Staff clinicians know they can expect help with patient care. New titles created for staff clinicians enable them to advance professionally. Dr. Lane said that staff clinicians on the Ps and Qs Committee feel like they can influence how the hospital provides care.

## **Clinical Center Facilities Update**

*Dan Wheeland, Director, NIH Office of Research Facilities*

Mr. Wheeland noted that there had been two positive developments relative to NIH facilities. First is that the FY 2019 President's Budget request for the NIH Buildings & Facilities appropriation includes an increase from \$128.6 million to \$200 million. While the request is no guarantee of an increase, it is a recognition that there is a need to address the physical plant needs of NIH. The second development is that thanks to NIH and Congressional support, an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine was established to study the capital needs of the Bethesda campus. On March 16, 2018, the ad hoc committee toured portions of Building 10 with Clinical Center and ORF leaders in order to view the conditions in Surgery, Radiology and Laboratory Medicine. Mr. Wheeland is cautiously optimistic that the committee's efforts and suggestions will be helpful in improving physical conditions, especially those related to patient safety.

### ***Infrastructure Outside of the Clinical Center***

Mr. Wheeland described several critical infrastructure projects outside of the Clinical Center complex that enhance patient safety in cases of regional and local water and electrical power failure. Funded projects include an industrial water storage unit that would allow the central utility plant to generate steam and chilled water, a thermal energy storage system, black start generators, and a utility vault and a new patient parking garage that allows patients to walk to the Clinical Center without exposure to the elements. Infrastructure projects that are not yet funded include upgrades to normal and emergency power supply equipment in Buildings 59 and 59A and another utility vault and parking garage upgrade.

### ***Clinical Center Projects***

Critical projects within the Clinical Center Complex that have been funded include replacement of electrical equipment in Vault 11; new fire alarm control panels throughout the facility; installation of barriers in the atrium to prevent falls and suicides; replacement of preheat piping that failed and caused a January 2018 flood in several Outpatient Clinics; a new chemical-based effluent decontamination system for the Special Clinical Studies Unit that would enable NIH to safely treat patients exposed to infectious diseases such as Ebola; conversion of existing patient care unit space into a hospice family suite; construction of a Department of Laboratory Medicine Sterility Lab; and Tumor-Infiltrating Lymphocytes Cell Processing Modular Facility for Dr. Rosenberg. Additionally, two NCI modular trailers employing Current Good Manufacturing Practices will soon go into operation.

Mr. Wheeland described one of the most critical project under design, that of the expansion of space for the Permanent Intravenous Admixture Unit, which currently operates an interim facility with inadequate space and relies on existing infrastructure elsewhere. The challenge is that the unit's previous location relied on the infrastructure within its building, but current standards require dedicated infrastructure to achieve the right air exchange rates, humidity, and differential pressures. Therefore, the new Permanent Intravenous Admixture Unit will require a mechanical penthouse dedicated to this function. The project also involves fitting many pieces of sophisticated equipment into a tight space, and it must comply with standards and must be completed as soon as possible.

A funded Radiopharmacy project will ensure NIH meets regulations supporting patient and workforce safety. It will provide space to the Clinical Center's radiopharmaceutical work and cell labeling work associated with NCI. The facility will have secure access and properly pressurized rooms that provide increasing levels of cleanliness that will improve patient safety.

One of the critical unfunded needs, according to the Facilities Working Group, is a combination Utility Vault and Patient Parking Garage, which is also a key enabling project in support of the new Surgery, Radiology, and Laboratory Medicine Wing, which will include an NHLBI catheterization lab. Mr. Wheeland is working with stakeholders to make this project shovel-ready so that a design-build contract award can be made when funds are available.

### ***Discussion***

Dr. Forese asked for the price of the new wing of the surgery, radiology, and laboratory medicine building. Mr. Wheeland said the cost is about \$480 million, a figure that excludes scientific and medical equipment and is larger than a single year's Office of Research Facilities budget. Mr. Wheeland was hesitant to give a square footage figure, because some estimates account for interstitial space and the price tag includes renovation of some of the existing building to make Surgery contiguous on one floor. He added that members of the National Academies ad hoc committee commented to him after touring the Clinical Center that the plans appear to address current risks appropriately.

Mr. Wheeland noted that the amount of money budgeted for funded projects is about \$392 million. These projects affect patient safety and infrastructure resilience, allow safe biomedical research, and are most relevant to the board. The value of the unfunded projects is about \$550 million.

Dr. Forese asked how much the equipment for the surgery, radiology, and laboratory medicine building would add to the \$480 million cost. Dr. Gilman estimated that equipment would be about 20% of that figure, noting that not all equipment in the building will be new. Dr. Tabak said that funds for equipment and the building come from different sources.

Dr. Forese asked how long construction would take after funding has been secured. Dr. Gilman predicted that if funding were secured in May 2018, the building would be finished in 2025. Dr. Forese said that most Board members who toured current Clinical Center labs and post-anesthesia care units believe proposed surgery, radiology, and laboratory medicine building plans would drive an enormous upgrade in staff work environment and quality of patient care.

Dr. Forese thanked the board and speakers for their contributions to the meeting and recognized the efforts of everyone who cares for Clinical Center patients.

### ***Follow-Up Items:***

- Give Dr. Forese the surgery, radiology, and laboratory medicine building's cost-per-square-foot figure.

The next face-to-face CCRHB meeting is scheduled for July 20, 2018.

## **Adjournment**

*Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, CCRHB*

Dr. Forese adjourned the meeting at 2:53 p.m.

/Laura Forese/

Laura Forese, M.D., M.P.H.

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, New York-Presbyterian Hospital

/Lawrence A. Tabak/

Lawrence A. Tabak, D.D.S., Ph.D.

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/Francis S. Collins/

Francis S. Collins, M.D., Ph.D.

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

## **Abbreviations and Acronyms**

ACT	Advancing Cures Today
AHRQ	Agency for Healthcare Research and Quality
C.A.R.E. <sup>®</sup>	Continuous Ambient Relaxation Environment
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CLABSI	central line–associated bloodstream infection
CMS	Centers for Medicare & Medicaid Services
COO	chief operating officer
FDA	Food and Drug Administration
FY	fiscal year
ICs	Institutes and Centers
IRB	institutional review board
IV	intravenous
IVAU	Intravenous Admixture Unit
MEC	Medical Executive Committee
MRI	magnetic resonance imaging
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NSQIP	National Surgical Quality Improvement Program
PACC	Pediatric Anesthesia and Critical Care
PAG	Patient Advisory Group

PCC	Pediatric Care Committee
PRIA	Protocol Resource Impact Assessment
RFI	Request for Information
SAC	Surgical Administrative Committee
SARS	severe acute respiratory syndrome
STARS	Safety Tracking and Reporting System
VHA	Veterans Health Administration