U.S. Department of Health and Human Services

National Institutes of Health

# Sixth Meeting of the Clinical Center Research Hospital Board

## October 20, 2017

## Table of Contents

## Clinical Center Research Hospital Board

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, NewYork-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

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 (by telephone)

Paul O'Neill, M.P.A., Non-Executive Chairman, Value Capture, LLC

Peter Pronovost, M.D., Ph.D., Director, Armstrong Institute for Patient Safety and Quality, and Senior Vice President, Patient Safety and Quality, Johns Hopkins University

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

## Executive Summary

The sixth meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on October 20, 2017, 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, NewYork-Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:08 a.m. and welcomed all those in attendance. She reviewed the highlights of the last meeting and introduced the agenda for this meeting.

Francis S. Collins, M.D., Ph.D., NIH Director, welcomed the CCRHB members and highlighted a few activities, including his recent visit to the University of Virginia Medical Center to learn about opportunities for building capacity in data science to identify unusual genotypes. He also participated in a recent meeting of the American Society of Human Genetics, where Bill Gates and renowned medical experts articulated a goal of using new gene-editing technology to cure sickle cell disease.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, referred to various data points provided in a report entitled *Clinical Performance and Employee Safety Metrics: Executive Dashboard,* which was distributed to the CCRHB. He remarked on an uptick in pressure injuries, which appeared to be related to a particular procedure in the operating room, and outlined various corrective actions. He also informed the CCRHB about an event in September that arose when antibiotics were not delivered in a timely manner to a patient with febrile neutropenia.

Dr. Gilman reported on the success of employee recognition programs and progress with filling vacant leadership positions in the Clinical Center. Discovery Channel's documentary *First in Human,* which followed several Clinical Center patients, was very well received and generated a slight increase in telephone calls and email inquiries. The social media impact of the series was substantial.

In addition, a series of leadership sessions focused on developing a list of top strategic priorities to serve as a foundation for a full strategic plan. Dr. Gilman highlighted progress with expanding and renovating facilities for the Center for Cellular Engineering.

Recent data from the Safety Tracking and Reporting System was the focus of a presentation by Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality. She also presented STARS data collected by the NIH patient representative, based on an average of 60 to 85 encounters with patients in the Clinical Center each month. Ms. Lee discussed an upcoming employee survey and new educational initiatives, including Lean Six Sigma training.

Virginia Guptill, Ph.D., Acting Director, Office of Research Support and Compliance, Clinical Center, presented the results of the Quality Improvement Assessment conducted by an outside organization. A sample of participant records from a subset of intramural protocols were reviewed for compliance with consent procedures, eligibility criteria, and problem reporting. The audit revealed a few critical findings and identified some concerning trends. Corrective actions are already being put in place.

Michael Gottesman, M.D., Deputy Director for Intramural Research, briefed the CCRHB on the consolidation and centralization of institutional review boards (IRBs) across the NIH intramural program. The goal is to create about six IRB panels with 7 to 13 members each (plus alternates). The six panels would be generic and thematic, with possible special panels as needed. All the legacy protocol management systems are being migrated to the Integrated Research Information System. A pilot IRB panel will be launched in the next couple of months.

The meeting included a closed session.

The next face-to-face CCRHB meeting is scheduled for February 2, 2018.

# Meeting Summary

# Friday, October 20, 2017

## 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 sixth meeting of the CCRHB took place on October 20, 2017, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and was webcast live. Dr. Forese called the meeting to order at 9:08 a.m. and welcomed all present. She announced that Carolyn Clancy, M.D., and Peter Pronovost, M.D., Ph.D., were unable to attend. Reed Tuckson, M.D., participated via teleconference.

Dr. Forese reviewed the topics covered during the last meeting and then introduced the agenda for this meeting.

## NIH Director's Remarks

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

Dr. Collins acknowledged the hard work of the CCRHB members as he recalled past meetings and accomplishments. The CCRHB is ensuring that the NIH Clinical Center retains its reputation as a remarkable facility—a jewel in the federal government's crown—thanks to the hopes and visions of patients and staff.

Dr. Collins mentioned NIH's contributions to efforts to ameliorate the opioid crisis gripping the nation. He emphasized the importance of using a scientific approach to develop strategies for preventing and treating addiction.

Regarding the Clinical Center, some new developments are taking shape in terms of building regional network capabilities with nearby medical centers. Dr. Collins spoke of his recent visit to the University of Virginia Medical Center to learn about opportunities for building capacity in data science to identify unusual genotypes.

Dr. Collins participated in a recent meeting of the American Society of Human Genetics in Orlando, Florida, that was attended by about 8,000 people. The presidential symposium included Microsoft founder Bill Gates and Dr. Collins. One session included not only Bill Gates, but also Stuart Orkin, M.D., of Boston Children's Hospital, and NIH's John Tisdale, M.D., who pioneered the use of bone marrow transplantation in sickle cell disease. The experts spoke about the possibility of curing sickle cell disease, possibly within 5 or 6 years, by using gene editing. The Clinical Center's capabilities could put this goal within reach.

Dr. Collins closed his remarks by thanking the CCRHB members for their oversight and advice.

Dr. Forese thanked Dr. Collins and remarked that the Discovery Channel program about the Clinical Center, *First in Human,* was very well done.

## NIH Clinical Center Chief Executive Officer (CEO): Update

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

Dr. Gilman thanked the CCRHB members for their hard work and dedication to the Clinical Center.

***Safety Data***

Referring to a report entitled *Clinical Performance and Employee Safety Metrics: Executive Dashboard,* which was distributed to the CCRHB, Dr. Gilman explained that the spike in pressure ulcers was related to a particular type of complex surgery that required keeping patients in one position in the operating room for an extended period. Multidisciplinary efforts are being put in place to reduce the prevalence of these injuries.

Dr. Gilman reported that some hand, finger, and wrist injuries occurred in the pharmacy's new Intravenous Admixture Unit (IVAU). Staff from Hospital Safety and Occupational Medicine are working with IVAU staff to address ergonomic issues to reduce injuries and maintain effective operations. Dr. Gilman said that more information on employee safety will be forthcoming.

***Employee Recognitions***

Dr. Gilman highlighted several Clinical Center programs for recognizing scientific and research excellence, clinical and administrative excellence, and length of service. Recent recipients of length of service awards have included Harvey Alter, M.D., the discoverer of the hepatitis C virus, and Clara Chen, M.D., a nuclear medicine physician. About 20 individuals were recognized in the first round of Town Hall meetings and 40 people in the second round. Dr. Gilman said that these recognitions have boosted staff morale.

The Clinical Center fared well at the 2017 Director's Awards ceremony on Sept. 1. Sixty-two employees were recognized, along with Team Ebola, the STARS team, the Nutrition Care team, and Justin Cohen, M.S., M.A., who led the Office of Communications and Media Relations in providing support for *First in Human*.

The NIH Clinical Center received NRC Health's Dimension Award for Emotional Support because the Clinical Center was ranked first in the country in overall satisfaction by patients and their families. Several hundred Clinical Center employees had their photo taken with the award as it "toured" the Clinical Center. The photos will be posted in the Clinical Center.

***Filling Vacant Positions***

Dr. Gilman provided an update on openings for key positions on the Clinical Center's organization chart:

- Chief nursing officer/chief nursing executive: The final interview for the position is being scheduled after having been delayed due to a family illness for one of the job candidates.
- Chief operating officer: 51 applications were received from highly qualified people. The field has been narrowed to one candidate, who will soon undergo a series of interviews.
- Radiology and imaging science chief: The hiring process is entering its final stages.
- Director of the Medical Research Scholars Program and pediatric cardiologist (dual appointment): An individual has been recruited for this high-visibility position. The

candidate plans to remain clinically active and staff who are involved in setting up the new pediatric observation unit welcome this individual's experience and expertise.

Several clinical positions remain open at this time:

- New surgeon-in-chief
- Tenured or senior investigator for the immunology service within the Department of Laboratory Medicine
- Two assistant clinical investigators for the Clinical Center

***Pharmacy Update***

Dr. Gilman said that the new IVAU is now open, and pharmacy leadership positions are being filled. Majid Tanas, Pharm.D. is the new pharmacy chief, and Barry Goldspiel, Pharm.D. continues as deputy chief. Wafa Samara, Pharm.D. is in charge of pharmacy operations, and Jeff Carrico, Pharm.D., leads the research and clinical pharmacy. According to Dr. Gilman, the pharmacy is now staffed with enough people who know what "right" looks like in pharmacy leadership. With the additional staff, Dr. Tanas can focus on strategic and operational issues concerning the pharmacy. Dr. Gilman explained that no statistics are available yet on any effects of the new staffing on measures such as medication errors.

Dr. Gilman said that the pharmacy has about 35 more staff members than a year ago.

**First in Human *Documentary Series***

The Discovery Channel production led to better morale because the documentary showed in a very public way how Clinical Center and IC staff work together to contribute to scientific progress while providing excellent, compassionate patient care. The narrator, Jim Parsons, spoke about the program on late night talk shows. Screenings were held at the Clinical Center and other venues.

The Clinical Center leaders anticipated a spike in the volume of calls and emails to the patient recruitment center. They assembled a plan for adding staff and training them to handle inquiries. Dr. Gilman reported an increase in communications, mostly during the weeks when the series was aired. Email inquiries increased and remained somewhat higher than baseline. Little increase was seen in calls except during the first two weeks. Dr. Gilman also presented data on social media impacts of the program, including nearly 1.5 billion Twitter impressions.

***Strategic-Thinking Summer Sessions***

A series of leadership sessions were held to develop a list of top strategic priorities to serve as a foundation for a full strategic plan. The plan will be a living document that can be adjusted as major organizational influences change over the next 6 to 12 months.

The proposed priorities are as follows:

1. Balance of clinical research with clinical research support
2. Fostering team science
3. Talent management
4. Patient safety and clinical quality
5. Compliance and regulatory requirements

6. Business expertise
7. Metrics
8. Learning environment
9. Branding

The priorities apply to the Clinical Center. Some target the level of the Institutes and Centers (ICs), whereas others aim at the level of central leadership. Work on the priorities and the full strategic plan will start following the IC Directors' Leadership Forum this fall which will include several discussions on strategic Clinical Center priorities.

***Response to Focus Group Recommendations***

Fifty recommendations were presented in the *NIH Clinical Center Engagement Project Report* delivered in July 2017. Each recommendation is assigned to one lead Clinical Center senior staff member; reports are presented at Town Hall meetings. About 10 responses to the recommendations are completed or nearly so.

***Looking Ahead***

Much work has been accomplished on the Center for Cellular Engineering (CCE). The concept has been approved, and priorities have been assigned to projects. The Department of Transfusion Medicine has completed the full business plan. Dr. Gilman anticipates that the 2J facility will be online by January 2018.

One room was set aside to test linings and coatings. Facilities managers have been very cooperative. The rooms are now being commissioned, and equipment is being moved in. The rooms will go live in January 2018.

Dr. Gilman spoke about increasing capacity by purchasing a modular facility to be located on the east terrace. Harvey Klein, M.D., is the head of the Department of Transfusion Medicine, which recently received safety recognition. The CCE facility in the Clinical Center's Magnuson wing is also scheduled for renovations, which will probably be complete in 2021.

The pediatric observation unit is slated to open in November 2017. Pediatric hospitalists have been hired, but additional nursing staff are still needed.

***An Event Report***

During the night of August 17 and early on August 18, a young patient with bone marrow failure (aplastic anemia) who was receiving conditioning chemotherapy for bone marrow transplantation developed febrile neutropenia. Dr. Gilman said that the Clinical Center staff were well prepared for this eventuality. They knew that the patient was colonized with antibiotic-resistant microorganisms, and they had planned in advance to ensure that the right antibiotics would be on hand. Yet, it took far too long to administer the antibiotics for Gram-negative coverage.

Dr. Gilman explained that although this event did not cause any harm, it caught the attention of many staff. The Clinical Center does not have an emergency room, and while staff are accustomed to handling clinical research emergencies, when serious events occur, opportunities for improvement result. According to Dr. Gilman, more skilled clinicians tend to work during the day shift, and a resulting priority from this event is to assure processes are in place to assure Clinical Center patients receive the highest quality of care day or night.

This event was the subject of a recent Morbidity & Mortality (M&M) conference. This patient's experience gave Clinical Center staff some profound insights into the systems in need of work.

***Discussion***

Referring to the proposed strategic priorities, Ruth Brinkley, M.S.N./Adm., asked about the meaning of "team science." Dr. Gilman said that the days of scientists working solo in a laboratory are gone. Modern science requires putting together teams of scientists with diverse backgrounds, ranging from the life sciences to physics to engineering. Team science also includes cross-institute and cross-institution collaborations. The NIH Clinical Center could serve as the hub for a number of such activities and collaborations.

Richard Shannon, M.D., asked about the possibility of setting up emergency teams who are always available. Dr. Gilman said that such teams are already available for around-the-clock emergency coverage. He pointed out, however, that Clinical Center staff—physicians, nurses, pharmacists—need much emphasis on the essential importance of asking for help. Mechanisms exist to cross-link those groups across the Clinical Center during any shift.

Dr. Forese asked about the management structure in place nights and weekends. Dr. Gilman said that managers include a nursing coordinator who is a nursing asset, a senior administrator who is on call 24/7 (the position is shared by six people). In addition, either David Henderson, M.D., or Dr. Gilman is in town at all times.

Dr. Collins said he was glad that Dr. Gilman brought this event to the attention of the CCRHB. He asked how the event came to light and whether the system for flagging problems is working. Dr. Gilman said he was on a cross-country flight, but when the aircraft landed he had messages from Dr. Henderson, the principal investigator, the Critical Care Medicine staff, and others. There was some finger-pointing initially, but the focus quickly shifted to identifying the root cause and taking corrective action in order to prevent similar events in the future.

Dr. Shannon said that this event creates an opportunity to develop a measure for the processes relating to outcomes (e.g., sepsis events). He suggested following all deaths, especially sepsis-related deaths, to learn about patterns of meaningful clinical outcomes that might be affected by processes in the Clinical Center. Dr. Gilman said that because deaths are quite rare events in the Clinical Center, process metrics likely would be more meaningful. Following this event, staff conducted a review of STAT antibiotic orders that showed that delays in starting antibiotics are not always attributable to the pharmacy. The review suggested three or four actions to take; the data will be rechecked later to see whether these actions influence process measures. The Clinical Center is too small to observe any statistically valid changes in outcomes data, however. Dr. Shannon thought that once the CCE is operating, the Clinical Center might have 1,000 febrile neutropenia/sepsis events per year; that level of activity could support analyses of outcomes data.

Although the Clinical Center does not deal with the same sorts of emergencies as typical hospitals, emergent situations do arise, and the Clinical Center needs to be ready to manage these events appropriately and effectively. The CCRHB recommended working up a list of emergencies that Clinical Center staff need to be prepared for; the list could include febrile neutropenia and cytokine storms. Dr. Forese suggested running drills or simulations to hone responses to these emergencies.

Paul O'Neill, M.P.A., recommended adding a strategic priority aimed at achieving an injury-free workplace. Dr. Gilman thought this idea merited further consideration.

Dr. Forese inquired about the survey process for employees. Dr. Gilman said that results of the Federal Employee Viewpoint Survey are pending. Last year, 40% of NIH employees participated in that survey; this year, the figure was up to 56%, with the largest gains occurring in the larger ICs. That input is very important for making decisions and setting priorities. The Agency for Healthcare Research and Quality (AHRQ) developed the Hospital Survey on Patient Safety Culture, which is designed to help hospitals assess the culture of safety in their institutions. That survey will be coming up, according to Dr. Gilman.

Dr. Forese acknowledged that caring for pediatric patients is challenging in any hospital. How are decisions made about procedures that are safe to do in the Clinical Center? Dr. Gilman said that the Clinical Center has a Pediatric Care Committee. About 150 or 160 pediatric specialists are on staff. Intervening at younger ages can enable more normal development, so investigators would like to be able to enroll younger and smaller patients at the Clinical Center. The Pediatric Care Committee is very involved in establishing the pediatric observation unit. Some investigators want to recruit younger and smaller patients, but it is important not to proceed more quickly than the Pediatric Care Committee recommends. The current minimums are age 3 years and a weight of 20 pounds.

Brig Gen James Burks, M.B.A., M.M.A.O.S., voiced support for the efforts of Clinical Center staff to identify the root cause of the event involving delayed administration of antibiotics. He also encouraged increasing preparedness. Regarding the employee awards, he noted that the photos of staff seem to reveal a sense of joy in their work. He also suggested further efforts to build a culture of support for employees, because they are the greatest strategic asset.

Brig Gen Burks asked about the strategic priorities, in particular where capital improvement and facilities planning appears in the listed priorities. Dr. Gilman said that these are embodied in the eighth priority (learning environment). The top capital improvement priority for the campus is a new surgery, radiology, and laboratory medicine wing. Dr. Gilman underscored the importance of planning ahead to anticipate needs 10 or 20 years hence. Capital improvements should be sufficiently flexible to adapt to changes that will occur in the future.

Beatrice Bowie was grateful that the story of a patient with sickle cell disease was included in *First in Human.*

Ms. Bowie asked about setting aside a couple of rooms in the day hospital to serve as an emergency room. Dr. Gilman said that if patients have an emergency, Clinical Center staff generally advise them to go to their local hospital; however, processes are in place to handle cases that come to the Clinical Center.

Mr. O'Neill spoke about opportunities for cross-organizational learning. Giving people more tasks without additional resources can lead to patterns and practices that increase risk. He suggested doing walk-arounds to ask people about practices that have become embedded but should be avoided because of potential risks. Dr. Gilman said that the challenge used to be a lack of information, but now people have to deal with the cognitive burden of having too much data. Ongoing patient safety rounds highlight areas where staff may have become accustomed to doing things in a way that could compromise safety.

Brig Gen Burks spoke about people's reluctance to say no when asked to do something even if they are already overloaded. Dr. Gilman recalled the example of the Pharmaceutical

Development Section to demonstrate why having a fair, credible process for adjudicating priorities is required.

**Follow-Up Items:**

- Consider adding "zero-injury workplace" as a strategic priority to be incorporated into the strategic plan.
- Work a list of the most common types of emergencies (e.g., febrile neutropenia, cytokine storm) that Clinical Center staff need to be prepared for.

## Provide the results of federal employee surveys and the AHRQ's Hospital Survey on Patient Safety Tracking and Reporting System (STARS)

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

Ms. Lee discussed event data collected in STARS, which has been in place for 6 months. As of last week, 3,135 reports have been entered in STARS. Most ($n$ = 2,996) are considered STARS events, but the system also accepts high-quality service events ($n$ = 139). The most frequently reported event types involve clinical care/treatment services, medications/fluids, and laboratory specimens. The top contributing causes are human factors (38%), communications (27%), equipment (18%), policies and procedures (9%), and other causes (8%). Events involving human factors are followed up to obtain additional details.

The number of STARS events has been holding steady at slightly more than 500 reports per month. The number of anonymous submissions has been trending downward.

Ms. Lee presented an infographic based on the 6 months of STARS data. This sort of information is sent to staff.

Delays in medication administration have become a point of emphasis. Data reviews often focus primarily on events that cause patient harm, but Ms. Lee's team delves into near misses that could have snowballed into actual harm. The top five no-harm, near-miss events were medications unavailable or delayed, other events, communication issues, unscheduled visits, and code blue events.

Ms. Lee reported that most of the medication events involved delays in medication delivery ; no external supply chain issues exist presently. Other medication events include incorrect doses or timing, prescribing/orders management, and incorrect medication or fluid.

***Data from the NIH Patient Representative***

Ms. Lee presented STARS data collected by CAPT Antoinette L. Jones, M.S.O.D., RN, the Clinical Center Patient Representative, based on her encounters with patients in the Clinical Center. The number of encounters averages between 60 and 85 per month. Most encounters are with patients, but the patient representative also interacts with family members and significant others, potential research volunteers, NIH staff, external health care facilities, and the general public. Most encounters relate to protocol participation and recruitment, but some focus on hospital operations, clinical care, and customer service. The patient representative deals with issues, primarily by contacting NIH staff or providing information.

Ms. Lee said that patient encounter events can be linked to the TARS database to determine if events cluster around certain patients. Complex patients often experience systems-related lapses

and event; in such cases, it is possible to examine their care to understand how these events occurred.

***Critical Event: Delayed Administration of Antibiotics***

Regarding the failure to administer antibiotics in a timely way to a patient with febrile neutropenia, Ms. Lee said that the Clinical Center staff must do a better job of getting the right antibiotics into patients quickly—day or night. The Clinical Center staff need to be prepared to take care of more of these patients as the CCE ramps up activities. It is critical that high-quality, experienced staff be available on every shift.

Some comments reflected the thinking that NIH seems to operate in a 4-day-per-week mode much of the time. That way of thinking has become more embedded in the hospital culture than is healthy.

***Clinical Emergencies***

Although the Clinical Center does not have an emergency department, emergencies do arise. Typical emergencies include febrile neutropenia/sepsis, cytokine storm, difficult airway, myocardial infarction, perioperative hemorrhage, unplanned admissions, in-hospital suicide attempts, and neurologic codes (e.g., stroke, spinal cord problems).

When scored on frequency, severity, and readiness, the top three clinical emergencies were febrile neutropenia/sepsis, perioperative hemorrhage, and cytokine storm. Ms. Lee said that the scores are being used to set priorities.

***Culture of Patient Safety Survey***

The AHRQ's instrument for assessing hospital culture of patient safety will be launched later this month. The survey is used all over the United States to assess communication/handoffs, teamwork, nonpunitive response to errors, reporting, organizational learning, and leadership support. The Clinical Center has implemented the survey in 2012 and 2009.

Results from previous surveys indicated that the NIH CC had room for improvement in a variety of patient safety domains. Some process improvements have been implemented in response to the survey findings. She anticipates that staff will be enthusiastic about implementing changes given the organization's current commitment to patient safety.

***Training and Education***

A recent Grand Rounds featured Rollin (Terry) Fairbanks, M.D., M.S., speaking about human factors engineering and the science of safety in health care. Ms. Lee also highlighted the recent M&M on the timeliness of STAT antibiotics and communication lapses and the potential for patient harm.

I-PASS, a standardized communication initiative designed to facilitate patient handoffs, will be launched later in October. High-reliability training and Lean Six Sigma training will come to the Clinical Center in the fall and winter of 2017–18 to increase the number of Clinical Center staff who know about process improvement and organizational learning.

***Discussion***

Dr. Forese asked about events related to unscheduled appointments. Dr. Gilman said that most patients who come to the Clinical Center have scheduled visits on a protocol. Resources and staff are set aside for their visit, and laboratory and imaging orders are readied. Sometimes patients come in unexpectedly, and it is not possible to conduct the visit expeditiously if, for example, the

right member of the team is not available. Dr. Gilman suggested that there are no actions to take to reduce these statistics, so he suggested not tracking it anymore. If the problem seemed to be associated with a particular staff member or clinic, then there may be some action to take.

In response to a question from Dr. Forese, Dr. Gilman said that the STARS data elements are not standardized. Although there are no inclusion and exclusion criteria, STARS is a tool to engage everyone in the Clinical Center who is concerned about patient safety.

However, individuals have differing thresholds for reporting. Dr. Forese suggested continuing to track data on unscheduled appointments but not present them to the CCRHB. Walk-ins are disruptive to clinic operations, but they are not safety issues. Because they occur frequently, they are skewing the data. Dr. Gilman said that the data on walk-ins (121 events in 6 months) show how well scheduled the Clinical Center clinics are.

Ms. Brinkley agreed with the idea of checking to see whether walk-ins are occurring with certain protocols, investigators, or clinics. Dr. Gilman said that the problem is more of an internal communication issue than a management issue. Most Clinical Center patients are handled by groups, not individual clinicians.

Mr. O'Neill thought that the goal should be to drive the number of reported events to zero. Ms. Lee agreed, saying that zero events would be ideal. Mr. O'Neill also emphasized focusing on clinical performance and worker safety to eliminate those events. Worker safety data drive the outcomes data. Ms. Lee said that worker safety is an important piece of the puzzle.

Regarding the reports related to medications/fluids, Mr. O'Neill said the number of reports would not go to zero unless a system were put in place to analyze each event and take corrective actions. Dr. Gilman said that the number of reports would be unlikely to drop to zero because people who are making STARS entries when a medication is 30 minutes late likely would start reporting delays of 15 minutes when delivery within 30 minutes becomes routine. Ms. Lee added that each event is investigated, leading to corrective actions. Mr. O'Neill recommended that future meeting presentations include examples of investigations that led to actionable findings and how corrective actions are impacting numbers of reports. Ms. Lee said that every medication use issue and fall results in a patient-safety huddle discussion or, in the event of a serious safety lapses or patient harm, a root-cause analysis. She outlined measures taken to prevent falls, both in the care unit and during transport. The fall rate is decreasing, but it is unlikely to reach zero, because some patients are very independent and keep getting up without assistance.

Brig Gen Burks spoke about high reliability, continuous performance improvement, and leadership development and asked whether training opportunities are targeted to specific audiences or are a voluntary basis. Strategically, training would apply to everyone from the front line to the C-suite, but most likely it would be necessary to target certain audiences. Ms. Lee spoke about the Maryland Patient Safety Center's course offerings. So far, senior-level people and some key clinical leaders within their areas have participated in 5-day trainings at the center to earn their Lean Six Sigma Green Belts. The training will probably be brought to the Clinical Center. Because the training program is new for the Clinical Center, Ms. Lee said she would appreciate suggestions and ideas from the CCRHB.

Dr. Shannon pointed out that 150 medication errors (dose or timing) per year means that an error is occurring every second or third day. Those are not infrequent events, in his view. If those data are combined with medication delays, 800 medication/fluid events occur each year. He asked for

more information to help the CCRHB understand structures and work processes to reduce those numbers. Dr. Shannon recommended focusing efforts to drive down these rates and then highlighting how rates were reduced. He also asked for information about how numbers of pressure ulcers were reduced and requested that future meetings include a presentation on a couple of events to explain actions taken and show movement in the numbers of events.

Dr. Gilman clarified that "incorrect dose" does not mean that the improper dose was actually administered. Errors are usually caught by the pharmacy or nursing staff.

Mr. O'Neill recommended focusing on hand hygiene to achieve 100% compliance (currently at 60%).

Dr. Shannon underscored the importance of freeing up people's time to learn and implement what they learn from Lean Six Sigma and continuing improvement training. If these tasks add to their daily work, that is a real problem. People need to be able to carve out time with management's support. Also, Ms. Lee pointed out that management needs to give people a chance to apply their new skills.

John Gallin, M.D., associate director for clinical research and chief scientific officer of the NIH Clinical Center, amplified Dr. Shannon's point. Some clinical investigators have reported that this has an enormous impact on their time and that they feel discouraged because it seems that they do not have time to carry out their science. Some investigators are feeling discouraged. There needs to be a way to track what this cultural revolution is doing to the scientific mission; if it is having a negative impact, then action is needed.

Dr. Forese said that sounds very concerning. Referring to the Red Team report, many people had concerns that science was taking precedence over patient safety. Both are critical; there was a concern that there is a trade-off. If the concern is that there could be an impact on research, then progress on patient safety would be reversed. The federal survey and the Culture of Patient Safety survey will be important inputs to assess staff concerns. Maintaining the highest standards of safety will require selecting the right people and making safety part of their job and their evaluation. Leaders are in the best position to know who the critical influencers are.

Dr. Shannon spoke about ensuring that the data have integrity and are informative, by investigating medication delays, for example. If patients do not receive their medications properly, research validity could be affected. Clinical investigators need to understand the importance of connecting the dots between scientific progress and patient safety. Also, the results of "deep dives" would help CCRHB envision systematic changes that could lead to improvements. He suggested that Dr. Gallin would be in a position to help select some measures to focus on to improve safety and thereby advance science.

Mr. O'Neill pointed out that resources can be freed up when an organization goes from typical numbers of events to perfection. He suggested selecting a process (e.g., the medication pathway) and conducting an analysis of the current time synchronization related to the medication pathway to understand potential time savings by, for example, avoiding just-in-time workarounds.

Dr. Tuckson underscored the importance of taking into account ethical considerations in research. He also mentioned infrastructure, assets, and accountabilities being in place to support all research. Dr. Tuckson suggested having a conversation about the relationship between iatrogenic incidents and the conduct of first-rate clinical research. Iatrogenic events could confound the interpretation of clinical research outcomes. Dr. Forese said that this point had been

raised during prior meetings, and she agreed that it would be important to consider this point further.

Dr. Shannon expressed concern about the future of the scientific workforce. The role of the clinician scientist is in jeopardy in many ways. The workforce is at risk of burnout and disaffection. The daily burden of imperfect processes takes a toll. Improving care can make a big difference in the quality of research.

Dr. Tabak reinforced NIH leadership's commitment to patient safety and exemplary care. If the Clinical Center, where so many variables can be controlled, cannot achieve the highest standards, then no institution can. The CCRHB's input will help the Clinical Center improve and succeed.

Dr. Forese spoke about shortages in intravenous fluids and medications affecting all U.S. hospitals. The situation has become much worse since the closure of facilities in Puerto Rico. Deliveries are occurring in new ways. She recommended vigilance with regard to medication errors and delays if the Clinical Center is affected.

**Follow-Up Items:**

- Provide the safety metrics report and an updated infographic to the CCRHB in advance of every meeting.
- Have future safety data presentations include in-depth analysis of two or three events that captured the attention of senior leadership. The presentation should explain the investigation, root cause, actions taken, and any resulting changes in metrics.

Continue to track data on unscheduled appointments; however, there is no need to present the information or include it in analyses unless problems are associated with certain groups or investigators.

- Patient Safety Culture to the CCRHB for review and discussion at future meetings.

## Quality Improvement Assessment (QIA) Results

*Virginia Guptill, Ph.D., Acting Director, Office of Research Support and Compliance, Clinical Center*

Dr. Guptill reported on a recently completed assessment of how well the Clinical Center is doing in terms of protecting the health, welfare, and safety of patients.

The NIH Intramural Program has more than 2,000 research protocols. The QIA assessed a sample of participant records from 80 protocols that were actively enrolling as of January 1, 2017. The QIA focused on the informed consent process, eligibility, and problem reporting.

Training, screening, and repository protocols were excluded from the analysis. There were 810 protocols that met the inclusion and exclusion criteria for QIA. A sample of 80 (10%) randomly selected protocols from all the ICs was included in the analysis. For each protocol, the records of up to 10 participants were examined, for a total of 468 participant records evaluated.

NIH contracted with an outside research organization for the QIA. Dr. Guptill explained that many ICs audit and monitor protocols, but NIH engaged Pharmaceutical Product Development, LLC, a global contract research organization, to carry out the QIA. The organization was chosen using a competitive process.

Protocols included trials regulated by the U.S. Food and Drug Administration (FDA), observational studies, natural history studies, clinical trials (not FDA-regulated), and thematic protocols (e.g., multiple sclerosis). Not all the protocols were being conducted at the Clinical Center; some were based in Phoenix, Arizona; Detroit, Michigan; Baltimore, Maryland; and Research Triangle Park, N.C.

Dr. Guptill reported that critical findings with a potential for harm were identified for each area (informed consent, eligibility, and problem reporting).

***Informed Consent Findings***

For informed consent, two critical findings were discovered out of 468 records. For one protocol, a participant was consented with the wrong consent based on their participation type (donor vs. recipient). For another protocol, an individual not listed on the delegation log administered consent.

The QIA also revealed some concerning trends. For example, documentation of the informed consent process in the medical record was sometimes incomplete or missing. The proposed solution is to develop a policy to ensure that the consent process will be supplemented by a complete and accurate informed consent note in the medical record, in keeping with Good Clinical Practice (GCP) guidelines.

***Eligibility Findings***

A total of three critical findings resulted from the QIA. Two related to the failure to perform tests to determine eligibility, or the tests were performed after enrollment. The third was for a protocol with a required 4-week washout period, but the participant was enrolled before the washout period was completed.

The QIA assessors also identified trends; in some cases, eligibility could not be verified due to inadequate or missing documentation in the medical record. The proposed solution is to develop a policy to ensure that eligibility criteria checklist data are documented in the medical record.

***Problem Reporting Findings***

Two critical findings were identified among the 468 records examined. One problem report was classified incorrectly after submission, but the institutional review board (IRB) corrected the problem report after it was submitted. In addition, one serious protocol deviation was not reported to the IRB. The principal investigator submitted the problem report when notified by the QIA reviewers.

***Positive Findings***

Using an outside auditor revealed some processes that work well. The QIA reviewers said that health, safety, and welfare of human research participants is a clear priority among Clinical Center staff. Very few safety and critical events were identified. Also, staff were collaborative and receptive to the reviewers' feedback and are formulating plans to implement best practices.

***Areas for Improvement***

The QIA reviewers recommended the following:

- Have one centralized NIH IRB with standardized policies and procedures.

- Implement role-based training on GCP guidelines training to promote improved study practices.

Dr. Guptill spoke of future plans to expand current committees to address areas that need improvement (i.e., NIH Training Advisory Committee, Quality Assurance Professionals Advisory Committee). She suggested continuing the QIA to include annual deep dive audits of protocols. Other recommendations included establishing some common guidelines for best practices (e.g., delegation logs) and adjusting the ICs' monitoring plans for 2018 using the results from QIA.

***Discussion***

Dr. Forese suggested using technology to help ensure that informed consent is properly documented in the medical record, perhaps by providing a link or inserting a hard stop in the consent process. Technological solutions could also ensure that all eligibility criteria are met. Proper documentation could reduce the number of critical findings to zero.

Ellen Berty asked whether the audit collected data from patients. Dr. Guptill said that patient input will be sought in future audits.

In response to a question from Dr. Forese, Dr. Guptill said she would like the audits to show no critical findings, but the data do reveal areas that can be improved to help investigators.

Dr. Forese thought it was an excellent idea to bring in an outside group to conduct the QIA.

Dr. Shannon appreciated the report and said he felt assured that Dr. Guptill understands the opportunities for improvement. He recalled a prior report about failures to report adverse events in a timely fashion. He asked for an update next year as a marker of progress. Dr. Guptill said that since last spring, each IC has a standard operating procedure (SOP) in place for problem reporting. Because there is now 6 months of data available, a plan is being put in place to collect the data and return the findings to the ICs.

**Follow-Up Items:**

- The CCRHB would appreciate an update on adverse event reporting as a marker of progress.

## Closed Session

Dr. Forese adjourned the open session at 11:50 a.m. and called the closed session to order at 11:56 a.m.

As described in 82 FR 18660, a portion of the meeting will be closed to the public in accordance with section 10(d) of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App), and provisions set forth in sections 552b(c)(6) and 55b(c)(9)(B), 5 U.S.C.

## Adjournment of Closed Session

Dr. Forese adjourned the closed session at 12:43 p.m.

## IRB Consolidation and Centralization

*Michael Gottesman, M.D., Deputy Director for Intramural Research*

Dr. Gottesman recalled that the first IRBs were developed at NIH in 1953. Currently, NIH has 12 IRB panels; the three neuroscience panels are administratively consolidated. Three different document repository systems exist for protocols. The time for processing and approving protocols varies and, in some cases, is lengthy. IRB processes vary among the ICs; the extent of the IRBs' deliberations varies widely, and sometimes too much time is spent dealing with minor stipulations. Inconsistent practices cause concerns about a lack of efficiency and variable follow-up for some compliance issues, despite full accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

Several groups have recommended centralizing and consolidating the IRBs. Information was sought from institutions outside NIH, including Johns Hopkins University, Partners HealthCare, and Washington University in St. Louis, all of which have very different IRB systems. These institutions were asked about their systems and what they would change. Various NIH leaders and groups weighed in as well. The process of defining goals and collecting input was open and transparent, with the goal of reorganizing the IRB system within the coming year.

The resulting proposal included several elements to migrate all the legacy protocol management systems to the Integrated Research Information System (iRIS): Use standard protocol templates, clarify that scientific review and review of conflicts of interest are not the IRBs' primary responsibilities, create a central IRB Operations Office to assign protocols to panels and track performance metrics, and create about six IRB panels with 7 to 13 members each with supporting alternates. The six panels would be generic and thematic, with possible special panels as needed.

A pilot panel was created to review all protocols of leaders within the National Heart, Lung, and Blood Institute (NHLBI), the National Cancer Institute, and the National Institute of Allergy and Infectious Diseases, as well as protocols of staff of the National Human Genome Research Institute and NHLBI. After a period of evaluation of the pilot panel, SOPs will be developed for running the new IRBs.

In terms of consolidation, Dr. Gottesman said that two thematic IRBs will oversee oncology and epidemiology studies; there will also be four general medicine IRBs. Pursuant to the new Common Rule, a dedicated IRB might be needed to deal with multisite studies.

Each IRB will be constituted with a new IRB chair, vice-chair, and members. The chair and vice chair will be paid, members will be supported through their ICs, and nonaffiliated members will receive expenses and an honorarium. The panels will meet weekly to ensure that protocols are reviewed soon after submission. All investigators will have access to protocol navigators to help write protocols and ensure that they meet regulatory requirements. Staff at the IRB level will also review the protocol to take care of minor problems that could bog down the IRB. Medical writers will take minutes at all meetings, edit protocols, and draft stipulations with the benefit of electronic tools to the extent possible.

Everything will be handled via electronic systems to the extent possible. Submissions for expedited review would be evaluated and approved by IRB operations staff and chairs/vice chairs (or their designees). Problem reports would be assigned to the panels that reviewed the

original protocols. Chairs and vice-chairs would meet monthly with officials. An annual retreat and ongoing evaluation and education would also be features of the new system.

Dr. Gottesman said that much progress has been achieved. Already, protocols are beginning to be imported into a single IT system (iRIS); IRB consolidations will take place over the next few months.

A search for a director of IRB operations is about to get underway.

***Discussion***

Dr. Forese asked about sources of resistance to the IRB reorganization. Dr. Gottesman said that the main concern seems to be the development of nonthematic IRBs. The thinking is that only people from the same IC can make informed decisions about that IC's protocols. Dr. Gottesman said that getting input from people outside of the IC could inject more objectivity into the reviews. Another source of resistance stems from relinquishing control.

Ms. Berty asked about having someone from the IC be present as a guest member of the nonthematic IRB. Dr. Gottesman said that the panels will have an abundance of experts, possibly including people with expertise in human subjects protections. The science will be assessed separately through the scientific review process, and then the IRB will assess the risk to human subjects.

Dr. Shannon asked whether this new model would be "best in class" compared with other institutions' IRBs. Dr. Gottesman said that several of the outside experts consulted would like to implement a system similar to the one envisioned for the Clinical Center. He also said that positive aspects of the current system are being retained.

## Future Meetings

*Laura Forese, M.D.*

Dr. Forese reviewed the meeting dates for 2018.

- Friday, February 2
- Friday, April 20
- Friday, July 20
- Friday, October 19

## Closing Statement and Adjournment

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

Dr. Forese closed the sixth meeting of the CCRHB by thanking NIH staff and the CCRHB members.

The next face-to-face CCRHB meeting is scheduled for February 2, 2018.

Dr. Forese adjourned the meeting at 1:50 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, NewYork-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

| | |
|---|---|
| AAHRPP | Association for the Accreditation of Human Research Protection Programs, Inc. |
| AHRQ | Agency for Healthcare Research and Quality |
| CCE | Center for Cellular Engineering |
| CCRHB | Clinical Center Research Hospital Board |
| CEO | chief executive officer |
| FACA | Federal Advisory Committee Act |
| FDA | U.S. Food and Drug Administration |
| GCP | Good Clinical Practice |
| ICs | Institutes and Centers |
| I-PASS | I – Illness severity; P – Patient summary; A – Action list for the next team; S – Situation awareness and contingency plans; S – Synthesis |
| IRB | institutional review board |
| iRIS | Integrated Research Information System |
| IVAU | Intravenous Admixture Unit |
| M&M | Morbidity & Mortality (Conference) |
| NHLBI | National Heart, Lung, and Blood Institute |

| | |
|---|---|
| NIH | National Institutes of Health |
| QIA | Quality Improvement Assessment |
| SOP | standard operating procedure |
| STARS | Safety Tracking and Reporting System |