

Second Meeting of the Clinical Center Research Hospital Board

October 21, 2016

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Clinical Center Research Hospital Board

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Ruth Brinkley, RN, M.S.N., FACHE, Senior Vice President, Catholic Health Initiatives, President and CEO, KentuckyOne Health (by telephone)

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

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Executive Summary

The second meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on October 21, 2016, on the NIH main campus. 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, and Chair, CCRHB, welcomed all those in attendance. She also updated the CCRHB on the search for a Clinical Center chief executive officer (CEO). Some outstanding candidates have been brought forward to Dr. Collins and other NIH leaders.

Francis S. Collins, M.D., Ph.D., Director, NIH, thanked the CCRHB members for their useful advice and for their service on the CEO search committee.

John Gallin, M.D., Director and Chief Scientific Officer (CSO), Clinical Center, and Associate Director of Clinical Research, NIH, explained his duties in his new role as the CSO and ADCR, and presented

metrics on Clinical Center admissions for fiscal years (FYs) 2015 and 2016. Dr. Gallin highlighted many recent accomplishments aimed at ensuring patient safety and clinical quality in the Clinical Center, including the implementation of a new patient safety event reporting system, the Occurrence Reporting System (ORS), and an anonymous reporting system for safety issues.

The focus of a presentation by Laura Lee, RN, M.S., Chief, Patient Safety and Clinical Quality, Clinical Center, was on measurement challenges and opportunities, including the problem of the small statistical *N* in the Clinical Center's research environment. She discussed reports received through the ORS and the anonymous reporting hotline and presented key metrics tracked at the Clinical Center.

Worker safety at the Clinical Center was addressed by Michele R. Evans, Dr.P.H., Environmental Safety Officer, NIH Clinical Center, and Jim Schmitt, M.D., Medical Director, NIH Occupational Medical Service. They presented data on types and rates of work-related injuries in the Clinical Center and discussed the processes in place to proactively identify and mitigate risks and respond to occupational injuries and illnesses.

Francis S. Collins, M.D., Ph.D., Director, NIH, Douglas Lowy, M.D., Director, National Cancer Institute (NCI), and William L. Dahut, M.D., Scientific Director for Clinical Research, Center for Cancer Research, NCI, reported to the CCRHB about a reporting deficiency that occurred in the context of an intramural NCI trial. The principal investigator failed to report serious adverse events to the sponsor and the institutional review board in a timely manner. Drs. Collins, Lowy, and Dahut explained the activities being undertaken to identify and correct any problems that might have contributed to the reporting deficiency, both within NCI and across NIH, and to ensure that this event serves as an opportunity for learning and demonstrating the Clinical Center's commitment to transparency and patient safety.

Great clinical science requires great clinical infrastructure in terms of governance, personnel, infrastructure, and equipment. Three Clinical Center department heads—Henry Masur, M.D., Chief, Critical Care Medicine Department, Clinical Center; Thomas Fleisher, M.D., Chief, Department of Laboratory Medicine, Clinical Center; and Tara Palmore, M.D., Chief, Hospital Epidemiology Service, Clinical Center—responded to a CCRHB request for specific recommendations about what the CCRHB could do to help ensure that the Clinical Center can continue to conduct excellent research, provide exceptional care, and train the next generation of experts.

To garner feedback from clinical staff, in September 2016, Stewart Simonson, J.D. began facilitating a series of focus groups, in which several hundred staff have participated thus far. Michael Gottesman, M.D., Deputy Director for Intramural Research, and Andrew Griffith, M.D., Ph.D., Scientific Director, National Institute on Deafness and Other Communication Disorders, Deputy Director for Intramural Clinical Research, and Engagement Group Chair, summarized some of the concerns and ideas the staff brought to light and also presented the rosters of the recently constituted Clinical Center Steering Committee and the Clinical Center Engagement Group. Mr. Simonson explained the structure and implementation of the focus groups. Of note, evening and weekend sessions were convened to garner input of housekeeping, nutrition, and hospitality staff. He presented the themes emerging from the focus groups convened to date.

Lawrence Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, provided the CCRHB with an update on NIH's sterile and non-sterile processing facilities. Following the sentinel event that resulted in the

closure of the Pharmaceutical Development Section, inspection and assessment of facilities were conducted by outside firms with requisite expertise. All the production facilities currently are deemed “in control.” He reviewed the function and status of each facility and summarized all remediation and construction activities either under way or planned.

Drs. Forese and Collins thanked the board members for their thoughtful input. Dr. Forese adjourned the open session at 3:38 p.m.

The next face-to-face CCRHB meeting is scheduled for January 13, 2017.

Meeting Summary

Friday, October 21, 2016

Welcome and Overview of the Board Chair

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, New York-Presbyterian, and Chair, CCRHB

The second meeting of the NIH Clinical Center Research Hospital Board (CCRHB) took place on October 21, 2016, on the NIH main campus. The meeting was open to the public and was webcast live. Dr. Forese called the meeting to order at 9:03 a.m.

Dr. Forese welcomed the members and others present. Two members, Peter Pronovost, M.D., Ph.D., and Brig Gen James Burks, M.B.A., M.M.A.O.S., introduced themselves.

Dr. Forese clarified that the CCRHB is not a management team; rather, the board assists the Clinical Center management team toward achieving its goals targeted at improving the outstanding institution.

Francis S. Collins, M.D., Ph.D., Director, NIH, thanked the CCRHB members for their useful advice and participation on the chief executive officer (CEO) search committee. Remarkable skills and dedication are evident among the board members.

NIH Clinical Center: Clinical Quality and Safety of Patients and Employees

NIH Clinical Center: Overview and Recent Accomplishments

John Gallin, M.D., Director and Chief Scientific Officer, Clinical Center, and Associate Director of Clinical Research, NIH

Dr. Gallin has a new role as chief scientific officer (CSO) of the NIH Clinical Center, and Associate Director of Clinical Research, NIH. In these positions, he reports directly to the NIH Director and has extensive interactions with the Institutes and Centers (ICs), as well as the Intramural Research Program (IRP). He will take a major role in developing a systematic approach to distribute the scarce resources of the Clinical Center, and he will work closely with the Clinical Center CEO and the NIH deputy director for intramural research.

Among the seven duties associated with the CSO position are the scientific review of clinical protocols and the setting of priorities for use of Clinical Center resources. The latter will begin with a pilot for the cell products facility to address the demand for the facility's services, which exceeds its capacity. A fair process is needed to provide access to this resource. Dr. Gallin commented on clinical research training, noting that 6,000 international students are trained each year through Clinical Center courses.

Dr. Gallin presented metrics on hospital admissions for fiscal years (FYs) 2015 and 2016. Inpatient admissions have declined as has the average length of stay. The nationwide average for length of stay is in the range of 4.0 and 4.5 days, whereas the length of stay at the Clinical Center

is about twice that, most likely because of research activities. The number of outpatient visits remained stable. The number of new patients decreased slightly.

Clinical Center Admissions Data

	Fiscal Year End 2015	Fiscal Year End 2016	Percent Change (from 2015 to 2016)
Inpatient Admissions	5,448	5,275	-3%
Average Length of Stay	8.9	8.7	-2%
Inpatient Days	47,847	46,394	-3%
Average Daily Census (7-Day)	131	126.8	-3%
Outpatient Total Visits	100,507	100,141	0%
Clinic Visits	81,471	81,210	0%
Day Hospital Visits	19,036	18,931	-1%
New Patients	10,761	10,498	-2%

Dr. Gallin presented a graph of the average daily census (ADC) by month, showing a drop in the ADC in April and May of 2016 following the release of the Red Team report on April 21. Dr. Gallin postulated that important factors probably were the temporary closure of some production facilities, the loss of some key staff, and patients’ concerns about the safety of the Clinical Center. It will be important to make the public aware that the Clinical Center is a safe facility.

Recent Accomplishments in Patient Safety and Clinical Quality. Dr. Gallin highlighted progress in many areas:

- New patient safety event reporting system, the Occurrence Reporting System (ORS)
- Anonymous reporting system for safety issues
- Morbidity and mortality rounds (fully implemented in surgery but still to be expanded to other services)
- New Institute-based Patient Safety/Quality Liaison positions
- Addition of cascading patient safety elements in personnel reviews
- New hires, including staff for the new pediatrics observation unit and a new chief of pharmacy (recruitment is under way for a new chief of pediatric anesthesia and critical care)
- Physical infrastructure upgrades for sterile manufacturing
- Visits to academic medical centers (Johns Hopkins Medicine, Sibley Memorial Hospital, Brigham and Women’s Hospital). Future visits will occur at New York-Presbyterian, University of Virginia Medical Center, and Massachusetts General Hospital.

Performance Metrics Dashboard. Dr. Gallin noted that many metrics are tracked for regulatory purposes and measurement of patient perceptions, and some are collected for research protocols (e.g., adverse events, unanticipated problems) and high-risk processes (e.g., medications, infection control, blood use). He asked the CCRHB members about how often they would like to receive reports on metrics and sought their advice on the best options for presenting data and capturing clinical research metrics that interface with the metrics on the risks of patient care. The discussion was deferred to a later time in the meeting.

Patient Safety and Quality Performance Metrics

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

Ms. Lee focused on issues requiring the CCRHB's advice and counsel. She reported on measurement challenges and opportunities, including the problem of the small statistical N in the Clinical Center's research environment. She also discussed the new patient safety event reporting system, the ORS, as well as the anonymous reporting hotline. A report on metrics was distributed to the CCRHB members in advance of this meeting.

Ms. Lee presented data on surgical site infections, perioperative antibiotic delivery, discontinuation of post-operative antibiotics within 24 hours, and days between count discrepancies, by quarter, for the 2014–2016 period. Each service collects data on its own procedures. Complications are sometimes forwarded for morbidity and mortality rounds. The duration of cases is considered a quality and efficiency measure. Many surgical cases at the Clinical Center are complicated. Returns to the operating room are captured by the Trigger Tool system. The Department of Transfusion Medicine tracks blood use; the data are available but not widely used to drive performance in the operating room.

Ms. Lee asked the Board about other measures that should be tracked for the dashboard.

The Conundrum of the Small N. Many small hospitals face this challenge, which complicates the task of generating metrics that are useful assessments of safety and quality. For example, the NIH peripheral blood stem cell transplant program began in 1993 to serve research participants enrolled in studies done by several Institutes, primarily the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute, and the National Institute of Allergy and Infectious Diseases (NIAID). The focus is on innovative therapies for reducing graft-versus-host disease, transplant mortality, and relapse. NIH outcomes are comparable to those of other medical centers and often exceed national and international metrics in terms of survival. During the period 2012–2013, 88 transplants were performed at the Clinical Center. The total number of transplant centers was 207. The majority of centers (52 percent) performed fewer than 50 transplants, and nearly 30 percent of centers performed more than 101. Nineteen percent of centers performed between 51 and 100 transplants—the category that includes the Clinical Center.

The indications for stem cell transplants done at the Clinical Center differ greatly from most centers, however. Very few transplants at the Clinical Center are for acute myeloid leukemia (AML). The Clinical Center has a strong emphasis on transplantation for DOCK8 deficiency, chronic granulomatous disease, and sickle cell disease.

For transplants for AML, the Clinical Center exceeds national benchmarks for survival. Three-year survival rates at the Clinical Center for transplants performed between 2010 and 2014 were 67 percent, compared to 55 percent nationwide. Three-year survival for transplants using matched, unrelated donors for severe aplastic anemia was 86 percent at the Clinical Center, compared to the national benchmark of 52 percent.

The small N for Clinical Center metrics is the consequence of the type of research (mostly phase 1 and 2 clinical trials), the fact that many surgeries are incidental to larger cases, and the complexity of cases seen in the Center. In all of 2015, just four appendectomies were done at the Clinical Center. Therefore, in terms of metrics, it is impossible to divorce those procedures from the primary procedures. In this environment, how does one measure and maintain competence? What is the trigger for changing privileges? How can the Clinical Center sustain clinical investigators' participation in clinical care?

Safety Event Reporting. According to Ms. Lee, 22 reports were received via the telephone hotline and 1,200 via the ORS. Five people provided identifying information for follow-up. Follow-up took from 1 day to 23 days, depending on the nature of the concern. The concerns fell into five main categories: clinical care, communication, leadership/culture, ethics/human subjects protections, and facilities/security.

The new ORS serves as an effective tool to capture safety event reports, and it provides robust data analytics capacity.

Discussion

Richard Shannon, M.D., recommended embracing the small N , as it provides the opportunity to learn from every event. The Clinical Center can go beyond reporting to focus on response to and resolution of events. For example, the 3 percent mortality in the intensive care unit would allow one to answer questions about the person who died, the cause of death, and whether the death was expected. For the surgical service, one could look at who died in the first 30 days following surgery and try to reduce the number of deaths. Ms. Lee said that the Trigger Tool team is doing just that by focusing on preventable harm.

Jeannette Erickson, RN, D.N.P., noticed a 30 percent swing in the ADC over the past few months. N will become even smaller if the ADC keeps declining. She recommended meeting with clinicians to hear their narratives on a qualitative level and solicit their input on key questions: What is the impact of events on staff? Have staff experienced similar clinical situations before? Is it a new clinical situation? Were they trained for it? What was the reaction of staff to the event?

Reed Tuckson, M.D., thought that surgical complications appear to be isolated in silos. Some departments get together and talk; some do not. The common infrastructure should support opportunities to surface issues and address them. He also spoke of the importance of surgeon training: Are the surgeons who are handling the few complex cases considered the "best in class," making it possible to learn from events? Dr. Gallin clarified that the only transplants undertaken at the Clinical Center are bone marrow transplants, not surgical transplants. Nevertheless, surgical cases at the NIH are complicated and require greatly skilled surgeons. Generally, surgeons are hired from busy clinical centers, but as they get immersed in their

research portfolios, they tend to focus on particular problems and do fewer cases. Surgeons—and all care providers in the Clinical Center—face a risk that their skills will diminish. In critical care medicine, the staff rotate to other centers to build and maintain their skills, but the situation is complex because the receiving hospital wants to be paid for the procedures. The CCRHB discussed use of simulation exercises to enhance surgeons' and clinicians' skills.

Dr. Tuckson commented on the difficulty of distinguishing the effects of a research intervention from the variable of poor proceduralists.

Ms. Lee clarified that Institute-level reviews include checks of staff qualifications.

Brig Gen Burks recommended investigating open-practice models and affiliation agreements, and taking a strategic approach to developing external partnerships to increase and maintain competence.

Paul O'Neill, M.P.A., encouraged the NIH representatives to delve into each safety event. With so few patients, getting to perfect should be the goal.

Dr. Pronovost remarked that the health care field has been held to averages as benchmarks. Whether comparing to benchmarks or aiming for perfection, NIH should not be complacent. NIH must be clear about which events are appropriately reported as rates (a numerator and a denominator) and which events should simply be counted. Surgical volume is a key issue. One of the most critical measures is the volume of cases done by the surgeon and in the hospital. He suggested clustering cases to help overcome the small *N*. For example, one could look at events for all lung cancer surgeries as opposed to very specific types of lung surgeries. Patients might well decide that the benefit of coming to the Clinical Center outweighs the risk of low-volume procures. Dr. Gallin said that volume review is fragmented, divided among IC Directors, and does not lie within the domain of the Clinical Center Director; that might need to change.

Carolyn Clancy, M.D., asked whether the staff looking into patient safety and clinical quality have the requisite skills and expertise for this function. Ms. Lee said that generally these duties are collateral; there is a need to build more capacity around clinical quality. Meetings occur monthly.

In response to a question from Ms. Beatrice Bowie about the process of deciding which procedures are done in the Clinical Center, Dr. Forese said that communicating with the staff and patients about whether a procedure would be done at the NIH or at another hospital is very important and should be covered in the agenda for a future meeting. Also, breaking down siloes would be another good topic.

Brig Gen Burks referred to data on medication bar code use, which seems to hover around 95 percent. This means that 5 percent of the time, staff are bypassing an important, built-in safety mechanism. Is that acceptable? In terms of organizational culture, what would cause a staff member to bypass this step? He also underscored the importance of staff being assured that they are in a safe place for reporting. They need to know that the culture encourages and celebrates reporting. He recommended further study of the culture at the Clinical Center.

Dr. Pronovost suggested coupling retrospective reporting with proactive assessments in an effort to try to predict how the next patient might be harmed and find a way to mitigate risks. There has been too much focus on reporting and too little on learning. Some solutions might be best on the level of the IC, but others should be systemic. Dr. Forese said that the default position is that solutions should be cross-cutting when it comes to reducing risk.

Dr. Shannon suggested convening some patient forums to learn what is important to them in terms of data. Do those measures align with the measures of safety and quality? He continued, saying, “You are early in this journey. Compare yourself to yourself. Are you improving each year? The Clinical Center is doing unique things, but you can prove that the organization is improving.” Dr. Tuckson agreed and recommended measuring things that are actionable and events that could confound the outcomes of clinical research (e.g., medication errors). He also spoke about holding people accountable for fundamental measures.

Ms. Ellen Berty suggested consulting with patient/disease advocates regarding communications about patient safety. Advocates could be a source of reporting about incidents.

Dr. Clancy spoke about the potential for the Clinical Center to achieve very high reliability and recommended setting aspirational goals instead of meeting external benchmarks.

Mr. O’Neill made a point about organizations being either habitually excellent or not. Every person needs to be an action taker instead of waiting for someone else. The Clinical Center should compare itself to perfection rather than national averages. Dr. Shannon agreed, saying that aspiring to habitual excellence would be key, bearing in mind the needs to build confidence and seek aspirational leadership.

Occupational Illness and Injury

Michele R. Evans, Dr.P.H., Environmental Safety Officer, NIH Clinical Center, and Jim Schmitt, M.D., Medical Director, NIH Occupational Medical Service

Dr. Evans explained the Occupational Safety and Health Administration’s criteria for recordable and reportable occupational illness or injury. *Recordable* cases require first aid but do not entail reasonable accommodations or time away from work. Examples include injuries resulting in death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness.

Reportable events (work-related fatalities or inpatient hospitalizations, amputations, losses of an eye) are rare. No reportable events have occurred in the Clinical Center for decades. The number of recordable injuries at the Clinical Center is lower than the national average, and the number has declined by 31 percent since 2011, compared with an 8.8 percent drop nationally. In terms of days away from work, the Clinical Center rates are comparable to the national averages, and rates of job transfers or restrictions are somewhat greater than the national average.

Combining job restrictions and transfers and days away from work yields a statistic termed DART (days away, restrictions, and transfers). The DART rate at NIH (2.8 per 100 full-time equivalents [FTEs]) is slightly higher than national average (2.4 per 100 FTEs). The incidence of nonfatal occupational illness and injury is lower than the national average, but these events are more serious, hence, the need to apply more resources to reduce the problem.

Dr. Evans said that the data are not generally used to reduce injuries in the hospital. Instead, she reviews every case to see where and how the injury occurred and the type of personnel involved. She presents the information to the Medical Executive Committee. Musculoskeletal trauma is the most common recordable injury, and special attention is given to wounds, as well as ergonomic issues, allergies, mental health concerns, and burns. Half of recordable injuries occur in health care areas, although two thirds of cases had no patient contact. A third of injuries involved patient transfers. A particular focus is on radiology, where special restrictions and space restraints may increase risk of occupational injury. Dr. Evans and her staff are going through each imaging modality, staff concern, and ergonomic issue. Many injuries involve outpatients, who generally are not well characterized in terms of their mobility challenges. Some improvements to the grounds and walkways have been made to try to reduce staff injuries.

In 2015, 19 wounds involving human blood and body fluids were reported among staff, mostly among physicians. Two involved recapping of needles during medical procedures.

Regarding influenza immunization rates, in 2015, 95 percent of staff were vaccinated. The national average among adults is 60 percent. If they are not vaccinated, staff must wear masks during flu season.

Discussion

Brig Gen Burks spoke about worker safety and its correlation with patient safety, and he asked about the Clinical Center's safety goal and how it is messaged to staff. Dr. Evans remarked on proactive risk assessments, explaining that she leads a team through each department to identify risks. Using that information, she looks at ways to reduce risks (e.g., hazardous drugs, musculoskeletal injury). She looks for common themes and then communicates them broadly with the involvement of hospital epidemiologists, the Office of Research Services, and others as needed.

Dr. Schmitt said that the Clinical Center is exemplary in that services are tailored to the individual worker. Injured workers are seen within 4 minutes after arrival, on average. Emergencies are seen immediately. Two staff are on call at all times. The aim is to learn from each case, with a particular focus on high-risk injuries.

Dr. O'Neill recommended that Dr. Collins articulate the goal of making NIH an injury-free workplace. If anyone has a reason why the goal is unattainable, he or she should contact Dr. Collins so he can take action to remedy the situation. Dr. O'Neill also said the injury rate among health care workers is 40 percent more than any other industry. The incident rate is 12 times higher than dangerous industrial environments.

Dr. Erickson noted that at least one report of employee fatigue was captured via the reporting system; fatigue can increase the risk of workarounds and potential harm to patients. Dr. Evans shared concern on this point and reported that production stress occurred in some NIH departments.

Dr. Shannon observed that injuries leading to days away from work can waste large amounts of scarce resources in terms of direct and accrued costs. Eliminating harm to workers could help NIH recoup resources that could be directed to activities that provide value. Another member

said that focusing on financial aspects of worker safety can erode moral authority; the focus should be on doing right by our fellow human beings.

Follow-Up Items:

- The Board requested information about specific interventions (e.g., work redesign) aimed at reducing high-risk exposures occurring during medical procedures.
- The Board requested updates on worker safety in the Clinical Center during each meeting.
- The Board asked for the NIH to provide more details about how information—especially on patient safety issues—is flowing throughout the Clinical Center organization.
- The Board recommended reading about [worker safety at Alcoa](#).

Reporting Delays Documented in a Clinical Trial: Planned Remediation

Francis S. Collins, M.D., Ph.D., Director, NIH, Douglas Lowy, M.D., Director, NCI, and William L. Dahut, M.D., Scientific Director for Clinical Research, Center for Cancer Research, NCI

Dr. Collins introduced the presentation about a reporting deficiency that provides an opportunity for learning and for demonstrating the Clinical Center’s commitment to transparency. Some trans-NIH actions have been taken already, but he asked the CCRHB members to weigh in with their advice.

Dr. Lowy underscored the importance of ensuring that NIH has a culture of safety and compliance and provided background on significant delays in reporting serious adverse events that occurred in a phase 1 intramural trial of the NCI. These delays led the U.S. Food and Drug Administration (FDA) to issue a Form 483 report to the principal investigator (PI) who had failed to report serious adverse events (SAEs) to the sponsor within 24 hours. The median time of late reporting was 40 days with a range of 4 to 456 days. SAEs were supposed to be reported to the institutional review board (IRB) within 7 days, but the median was 18 days with a range of 8 to 56 days.

The investigator was testing a combination therapy for primary central nervous system lymphoma (PCNSL), a rare subtype of diffuse large B-cell lymphoma (DLBCL) that presents in the central nervous system. In the United States, 1,900 cases occur per year, representing 3 percent of brain tumors. The median age at diagnosis is 62. Current treatment is based on methotrexate and radiotherapy. Survival rates are poor for patients with refractory or relapsed disease.

The drug regimen used in the [trial](#) consisted of ibrutinib (an inhibitor of Bruton’s tyrosine kinase [BTK]—a key driver of DLBCL) given with dose-adjusted temozolomide, etoposide, doxil, dexamethasone, ibrutinib, rituximab (DA-TEDDI-R). A published trial by NCI had shown that ibrutinib is clinically effective in relapsed/refractory DLBCL, leading to registration of the drug. The trial participants were patients with refractory/relapsed PCNSL.

Among the 18 patients enrolled in the trial, four developed invasive aspergillosis (IA). Two patient deaths in 2015 were attributed to IA. A hospital epidemiologist confirmed that no outbreaks were occurring among participants on other trials, suggesting a causative relationship between IA and the ibrutinib (given with steroids). The experimental regimen showed anti-tumor activity; nevertheless, the study was halted when the reporting deficiencies came to light.

Dr. Lowy explained the remediation in progress at NCI:

- This trial and others under way or planned by the lymphoma team have suspended recruitment until a complete audit and training have been completed.
- The PI designation for the trial was shifted to the chief of the Medical Oncology Service.
- All patients and families in the PCNSL trial were notified of the delayed reporting.
- The PI was suspended from clinical research in the Clinical Center.
- All PIs throughout the NCI Intramural Center for Cancer Research (CCR) were instructed on proper procedures for reporting safety and regulatory information on all therapeutic Investigational New Drug (IND) trials.
- An audit of all informed consents within the CCR was conducted.

Future actions include the following:

- Review all sponsor audits within the past 3 years.
- Develop a formal quality assurance plan for all NCI clinical trials.
- Complete a 100 percent source documentation audit by an outside contractor for all lymphoma trials open for the past 3 years.
- Require all members of the lymphoma team to take part in an external Good Clinical Practices training course.

Dr. Collins said that all IC Directors, Clinical and Scientific Directors, and principal and associate investigators have been reminded about the critical importance of timely reporting of SAEs, unanticipated problems, and changes to or deviations from research protocols.

The newly established Office of Research Support and Compliance (ORSC) is leading the effort to identify any other instances of delayed reporting of SAEs to IRBs. The ORSC will initiate an audit of a sample of clinical protocols in all ICs that use the Clinical Center, prioritizing those that are regulated by the FDA.

Dr. Lowy said that this experience underscores the importance of respecting patient safety while improving health care. The event also serves as a dramatic example of patients achieving long-term remission despite having poor prognoses and being at increased risk of IA. Dr. Lowy said that it would be incorrect to say that the failure to report SAEs in a timely manner had a role in the deaths of those two patients. Nevertheless, reports need to go to the IRB, the sponsor, and the FDA as part of the contract with patients.

Discussion

Dr. Lowy said that the patients were on oral steroids as part of their treatment for refractory cancer. Most likely, the patients were colonized by *Aspergillus* sp. before they started on the trial, and the treatment led to an immunocompromised state, leaving the patients susceptible to IA. Different species of *Aspergillus* caused the infections.

Dr. Lowy pointed out that thousands of patients around the world have been treated with ibrutinib, but the problem of IA has not emerged in other settings; therefore, the thinking is that the IA was the result of combining ibrutinib with steroids. NIAID investigators developed a mouse model of reduced BTK expression that shows increased susceptibility to *Aspergillus* infection.

Dr. Shannon said that deaths at the Clinical Center are relatively rare, but by examining every death, the ORSC would be able to look in a crosscutting way to detect opportunities for improvement. A centralized approach will provide a better way to observe trends. Dr. Lowy said that the second death prompted a discussion between the investigators and infectious disease experts at the Clinical Center, leading to a decision to increase the number of scans to catch IA before it became symptomatic. That was done, but there were reporting deficiencies related to those decisions.

Dr. O'Neill asked whether the reporting requirements were well-known and understood. Dr. Dahut said that events were reported to the IRB and the sponsor, but the pattern and the relationship to the research was missed. It is the responsibility of the PI and his or her team to know the regulations and comply with them. The reporting requirements are included in the protocol, and the PI is the author of the protocol. Dr. Pronovost referred to the substitution effect: If a similar investigator were in the same position, would the same thing happen? If the answer is yes, then training is the likely answer. If the answer is no, then the PI is likely culpable. Dr. Collins said that the audit likely will answer these questions. If the audit reveals further evidence of this problem, then the Clinical Center probably has a leadership problem.

Dr. Gallin explained the surveillance system for *Aspergillus* infections. The hospital epidemiology team detected the cases of IA and contacted the PI. After the second death was attributed to IA, the PI instituted more frequent scans among the participants.

Dr. Forese commended the team for shedding light on this reporting deficiency and the rapid, layered approach to investigating and remediating the problem once it was discovered. However, this incident is deeply troubling. At every level, the NIH needs to internalize that such events can and do happen here. However, we owe it to our patients to learn and fix such problems.

Chief Executive Officer Search

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, New York-Presbyterian, and Chair, CCRHB

Dr. Forese updated the CCRHB on the effort to hire a Clinical Center CEO and acknowledged the many individuals who have been helping with the search. Many outstanding candidates have been reviewed; some face-to-face meetings have occurred. The individuals' identities must remain confidential for now, but Dr. Collins said that the candidates possess vision and strong

skill sets and demonstrate talent and energy. The co-chairs of the search committee recently updated Dr. Collins on the “short list.” Drs. Collins and Tabak will carry out the next set of interviews. The candidates will meet with the IC Directors and the NIH Patient Advisory Group. The candidates will be vetted through due diligence. The hope is that the new CEO will be identified before the end of the calendar year.

What Can the CCRHB Do?: Follow-Up on Action Items Recommended by Department Heads

Henry Masur, M.D., Chief, Critical Care Medicine Department, Clinical Center; Thomas Fleisher, M.D., Chief, Department of Laboratory Medicine, Clinical Center; and Tara Palmore, M.D., Chief, Hospital Epidemiology Service, Clinical Center

Dr. Masur reminded the Board that the Clinical Center has an excellent group of department heads who are eager to participate in the change process to put the Clinical Center on the right course for the next few decades. The infrastructure of the Clinical Center is the envy of the research world and has contributed to major biomedical advances and health improvements for more than 50 years. What is needed to continue to conduct great research, provide excellent care, and train the next generation of experts?

Dr. Fleisher said that, first, the CCRHB could help fix the governance of the Clinical Center. The CEO must have authority over all intramural clinical staff, but it is not clear how the announced governance changes would align responsibility and authority for the fragmented enterprise to optimize patient safety. How will the CEO, chief medical officer, CSO, and the chief regulatory officer interact? What is needed is a system of governance that works well and will continue to do so into the future. Safety crosses all boundaries. Silos and fragmentation are not excuses for lapses in patient safety.

Second, Dr. Fleisher recommended that the CCRHB be aware of the the budget process and the gap between expectations and funding. Resources must match clinical expectations to ensure that NIH support can provide optimal quality of care while conducting high-impact research and training future academic leaders. A rational process is needed to match resources with clinical expectations. NIH’s budget for the Clinical Center has not provided adequate support for workforce compensation consistent with federal guidelines (which would be sufficient to attract the best candidates for open positions or to retain key employees), for replacement of necessary capital equipment, or for facility upgrades. All these issues relate to the quality of the hospital, to clinical and research productivity, and to patient safety.

The sentinel event resulting in the closure of the Pharmaceutical Development Section (PDS) is an example of response exceeding capacity. The chief of pharmacy did not feel empowered to refuse a request for additional PDS services despite a very heavy workload relative to the level of staffing and the physical facility. In addition, intermediate facilities are required to support services and laboratories while new facilities are constructed. The budget process does not reflect the special requirements of a clinical enterprise for ensuring patient safety and effective operation in a competitive academic environment.

Third, Dr. Palmore said that the CCRHB should be aware of potential solutions that could fix the lines of authority for the hospital's facilities. Accountability and authority for facility maintenance should reside with Clinical Center management. Real accountability is central to patient safety. Critical needs include ensuring the purity of the water supply and repair of water leaks and defects in electrical, plumbing, and air-handling systems. Dr. Palmore reported that of 10 leaks occurred in the operating rooms and post-operative area in the past year. Each individual problem has been fixed promptly, but there is no system-wide management program to resolve these permanently. In another example, Dr. Palmore spoke about an incident that resulted in brown, particulate-laden water affecting patient equipment and ice machines. A couple of months earlier, a major WSSC water main break occurred, and in response, a nearby hospital in the area flushed its system but NIH facility staff did not appear to understand the downstream consequences of the event to a hospital and its sensitive equipment.

Fourth, Dr. Palmore called upon the CCRHB to help develop strategies to improve the morale of the hospital staff. The only engagement to date has been via a series of focus groups, but staff should be meaningfully involved in the process of organizational change. NIH leaders need to communicate to the public their confidence in the quality and safety of care at the Clinical Center to boost patient recruitment and restore the ADC to institutional targets.

Fifth, Dr. Palmore recommended that the CCRHB initiate management reform based on an in-depth analysis of the Clinical Center and lessons learned from other academic centers. Dr. Masur noted that the organizational structure proposed as a "straw man" at the first meeting of the CCRHB now seems to be the operational plan but there had been no communication to the staff as to how the CEO, CSO, DIR Regulatory group, and department heads would interact. .

In closing, Dr. Masur said that great clinical science requires excellent governance, personnel, infrastructure, and equipment. He said that the intramural staff and department heads look forward to reading the Stewart Simonson report summarizing the findings of the focus groups. Moreover, the Clinical Center department heads look forward to being partners in this historic opportunity to enhance the clinical care, research, and training that occur in the Clinical Center.

Follow-Up Item:

- Invite other Clinical Center department heads to present at future meetings of the CCRHB.

Discussion

Dr. Collins said that a plan is in the works for engaging department heads, but input from the new CEO would be required. With regard to the budget, Dr. Collins said that the budget dilemma is chronic and severe, but the only part of NIH that has had any significant increases in recent years has been the Clinical Center, and these have come at the expense of other programs. The Clinical Center cannot simply change its room rates. The Clinical Center Governing Board (CCGB) continues to wrestle with the budget problem. The CCRHB, unlike every other hospital board in the country, does not have budget authority.

Dr. Masur asked about solutions to make the Clinical Center a more viable community with the existing budget: one option would be to limit the number or size of programs and protocols, or to

perform real time cost monitoring to determine when costs exceeded funds allotted to specific projects. One possibility is establishing different kinds of partnerships with other hospitals. Dr. Fleisher spoke about the tension between basic and clinical research and the process of setting priorities. More direct discussions of priorities would be helpful, in his view.

Dr. Tuckson said that issues of morale are very important to the Board, but some things are not within the CCRHB's purview. Nevertheless, the Board members are all advocates for the NIH budget.

Brig Gen Burks said that, as chief resourcer for the Air Force health system, he looks across three time periods for budgeting: the execution year, the next year, and then 2-plus years out. Facilities investments tend to get pushed off to the future. He suggested using similar frames of reference to develop a strategy to guide investment decisions. Dr. Gallin said that the NIH uses a similar process by looking at the prior year to see how money was spent, and then stakeholder input is sought to create a strategic plan aligned to the budget. A complex review process, including dialogs with the Scientific and Clinical Directors, the CCGB, and the IC Directors. The NIH Director adjudicates the budget. The situation is a complex and dynamic one. For example, last year, the Clinical Center had to deal with an unanticipated challenge when the cost of drugs increased by 24 percent.

Mr. O'Neill said that his reading of earlier reports revealed that many of the problems related to facilities go back to 1996. He said that the CCRHB would appreciate not just an articulation of what is needed, but also a costing-out of what is needed to be a first-rate place. The chance of procuring funds for a one-time, big fix of facilities and adjustment of federal compensation would be better if you make a strong case and include sound estimates of cost. For example, how much would it cost to replace a 30- or 50-year-old building? Dr. Forese recommended that NIH leaders start thinking about such budgetary matters while they wait for the new CEO to come on board.

Dr. Pronovost said that the examples of infrastructure deficiencies are very troubling but predictable. He said that most hospitals have a 4 percent margin per year to fund capital expenditures for infrastructure. Regarding complex government structures, he said that he hopes the new CEO will create structures for conversations to ensure that solutions are developed with input from the directors.

Dr. Collins explained that Dr. Gallin's job as CSO is to identify scientific priorities. The CEO will take charge of establishing the governance structure and discovering opportunities for efficiencies.

Dr. Forese added that no institution has enough money. The CCRHB wants to be realistic but aspirational for Clinical Center. The CCRHB asked the department heads to think in terms of priorities when the new CEO seeks input. The Red Team report seemed negative, but much has been accomplished already! She suggested thinking in a positive way in terms of initiating a dialogs with the CEO. Dr. Fleisher agreed, saying that working at the Clinical Center provides remarkable opportunities. For the next few decades, progress must be amplified because the new research tools are extraordinary.

Dr. Tabak reported that he represented NIH at the Department of Health and Human Services (HHS) Secretary's Budget Council Meeting on the FY 2018 budget request. At the meeting, Dr. Tabak presented NIH's budget exercise, noting that repair and replacement comes to \$1.8 billion. The NIH condition index is 71 of 100—one of the worst in the federal government. To replace everything would be \$9.8 billion. The acting Deputy Secretary seemed sympathetic, but there is a tension between the Congress supporting building and facility funds versus other potential approaches to apply on a one-time basis.

Dr. Shannon said he was struck by the timing of the Red Team report and the ensuing decline in patient volume. He noted that inpatient volumes are down 3 percent across the country. Although the ADC has decreased, budgets for staffing, equipment, and supplies are probably unchanged. Perhaps some of those funds could be diverted to deal with some of the facility problems.

Follow-Up Items:

- The CCRHB recommended that NIH leaders develop estimates of the costs of a one-time, major fix of facilities and a comprehensive adjustment of federal compensation for Clinical Center providers. This cost information should be made available to the new CEO.
- Time should be set aside during the next meeting of the CCRHB to hear about the Clinical Center's department heads' plans for working with the new CEO as well as their priorities.
- Explore the idea of diverting funds that may have been freed up by recent declines in the ADS to pay for fixing some facility problems.

Clinical Center Staff Outreach and Engagement

Staff Responses to the Red Team Report

Michael Gottesman, M.D., Deputy Director for Intramural Research; and Andrew Griffith, M.D., Ph.D., Scientific Director, National Institute on Deafness and Other Communication Disorders; Deputy Director for Intramural Clinical Research, and Chair, Clinical Center Engagement Group

Dr. Gottesman reminded the Board that the Red Team issued a strong recommendation to rapidly and completely engage all NIH staff in improving the quality of patient care. He presented a timeline of events related to engaging staff in improving patient care and safety. Most recently, (September and October of 2016), volunteer facilitator Stewart Simonson, J.D., began facilitating a series of focus groups.

During June 2016, Steve Holland, M.D., facilitated six feedback sessions on the Red Team report. The participants included staff clinicians, tenured/tenure-track investigators, clinical fellows, and nursing staff. Participants were most interested in discussing patient safety and good patient care. They were upset about the PDS problems and had a sense that a better way was needed to report complaints. They emphasized that the findings of the Red Team do not reflect a lack of dedication or caring among Clinical Center staff for patients. Participants also stated that employee complaints require prompt action and feedback, and they highlighted a concern that

authority and responsibility for patient care need to be aligned through the CEO rather than fragmented across ICs.

Dr. Gottesman presented a list of members of the Clinical Center Steering Committee, which he chairs and includes three Clinical Directors.

Dr. Griffith identified the members of the Clinical Center Engagement Group, which he chairs. Mr. Simonson serves as the facilitator. Dr. Griffith pointed out that engaging practitioners is important because they are on the front lines and also are proximal to training. The Clinical Center Engagement Group is a forum where people are encouraged to speak candidly.

Update: Clinical Center Engagement Project

Stewart Simonson, J.D., Facilitator, Clinical Center Engagement Group

Dr. Griffith introduced Mr. Simonson, noting that Mr. Simonson has a long history of working closely with NIH on matters of public health interest. From 2001 to 2006, Mr. Simonson served as the first Assistant Secretary for Public Health Emergency Preparedness in HHS. More recently, he initiated efforts to set up the Special Clinical Studies Unit in the Clinical Center.

Mr. Simonson gave an overview of the focus group process and its purpose, which is twofold: to learn from stakeholders (staff of the IRP and the Clinical Center) how to improve quality of care in the Clinical Center and to provide the staff with an opportunity to air their concerns. More than 600 people have registered for 31 focus group sessions thus far. About 300 have already attended.

Mr. Simonson explained how the focus groups were structured and conducted. Notes were taken, but comments were not attributed. Off-hour sessions were convened to garner input of specific role groups (e.g., housekeeping, nutrition, hospitality).

Several themes have emerged from the focus group discussions:

- The Clinical Center is a fragmented enterprise, comprising not one hospital but 17.
- The Clinical Center Director and staff control only a portion of what occurs at the hospital; the ICs have more responsibility for clinical care than the Clinical Center Director and staff.
- Holding Clinical Center and IRP staff accountable is difficult.
- Patient care practices and procedures in the Clinical Center are not sufficiently consistent.
- Communications lapses are commonplace and affect patient care.
- The Clinical Center is not a full-service hospital, meaning that standard of care excursions occur when capabilities are needed that are not resident at the Clinical Center.
- More transparency is needed about misadventures or unexpected events at the Clinical Center.
- Resources, capabilities, and expertise for pediatric patients are lacking in the Clinical Center.

- There is no clear system for adjudicating and addressing ORS submissions.
- Improvements are necessary in the extant approach to resourcing protocols; insufficient attention is given to complications and outcomes adjacent to the protocol.
- Clinical Center facilities are maintained just like other buildings on campus, rather than being maintained specifically as a hospital.
- Non-tenured staff do not feel valued to the same degree as tenured or tenure-track staff.

Mr. Simonson listed some of the interim recommendations and steps to build confidence of the Clinical Center staff:

- Establish a risk management mechanism to develop and enforce Clinical Center mandatory policies and procedures related to high-risk patients and protocols.
- Establish a clinical care and standards mechanism to review deaths, misadventures, and unusual occurrences at the Clinical Center every month.
- Institute monthly morbidity and mortality conferences for the Clinical Center.
- Establish a mandatory email distribution system (e.g., LISTSERV®) to communicate to the staff important directives from Clinical Center director and CEO.
- Recognize and tangibly reward staff clinicians, nurse practitioners, and other non-tenured staff for excellence in clinical care.

In terms of next steps, Mr. Simonson said that he anticipates facilitating 30 more focus groups for a total of 700 participants, representing 10 percent of the total staff. Following the final session, he will meet with the Clinical Center Engagement Group to draft a summary. He will brief the Medical Executive Committee on the findings and then present the report to the Clinical Center Steering Committee.

Discussion

Mr. Simonson said that the sessions often started with the participants feeling defensive, but many of them said that they would want a family member to be treated here. Building participants' confidence is key.

Dr. Forese asked about what communications are shared with staff in writing. Dr. Gallin said that communications about specific actions and events are distributed, for example, about morbidity and mortality conferences. Now, communications are being sent out in a more systematic way. He acknowledged the need to improve communications, especially on impending transitions in governance and so forth.

Mr. O'Neill observed that many issues identified in the Red Team report were also acknowledged by the staff. That is a strength to build on. People feel demoralized now, but it would help for the staff to know that everyone is coming together to take on these challenges.

Dr. Forese said that the new CEO certainly would want to understand staff concerns. She suggested sharing some of the emerging themes sooner rather than later. Dr. Collins expressed

support for the idea of a monthly newsletter to encourage people in the Clinical Center to start thinking about the themes. Ms. Berty suggested a weekly newsletter.

Dr. Forese commended Mr. Simonson for engaging staff who work nights and weekends. Referring to the Commission on Magnet[®] Recognition, Dr. Erickson suggested convening an open session for anyone on campus who wants to meet with the facilitator. Information about the session should be widely posted. Several members of the CCRHB suggested other people to include in focus groups and committees.

Follow-Up Items:

- Develop a monthly (or weekly) newsletter targeted to IRP/Clinical Center staff highlighting the emerging themes from the focus groups.
- Set up a focus group for the facilities staff.
- Add a patient and a member of the facilities staff to the Clinical Center Engagement Group.
- Set up a widely advertised, open session for anyone on campus who wants to meet with the facilitator.
- Convene a focus group of patients and staff.
- Reach out to suppliers to elicit their feedback about working with the Clinical Center.

Update: NIH Sterile and Non-Sterile Processing Facilities

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

Following the sentinel event, an inspection and assessment of facilities were conducted by outside firms with requisite expertise. Dr. Tabak reported that, given tools and instructions, NIH facilities staff perform superbly. Nevertheless, the functioning of the Clinical Center continues to be a challenge because of antiquated facilities, particularly in Building 10. Nevertheless, all the facilities currently are deemed “in control.”

Dr. Tabak said that the Intravenous Admixture Unit (IVAU), which provides sterile pharmaceuticals by prescription, is operating under a moderate level of control. An interim IVAU is under construction in the former PDS space. Once it is operational, the current IVAU will be closed for renovation that is anticipated to take about 2 years. After renovations are completed, IVAU operations will be returned to the renovated facility, and the intermediate space will be used for additional cell processing. He said that facilities staff are in constant communication with the FDA, which has provided guidance.

The Department of Transfusion Medicine is essential for supplying materials for cell-based therapies. It is operating under minimum physical control with robust administrative controls. An unannounced FDA inspection in June 2016 generated no formal findings. A new facility is under construction. Once it is completed, the current facility will be renovated.

Dr. Tabak reported that the positron emission tomography (PET) facilities produce sterile PET radiopharmaceuticals. The facility located in the Clinical Center continues to be monitored; most

physical concerns have been resolved. The National Institute of Mental Health's PET facility is consolidating its manufacturing activities within the Clinical Center's PET Department.

Regarding the Nuclear Medicine Department's Radiopharmacy, Dr. Tabak said that it provides only commercially available nuclear medicine radiopharmaceuticals purchased from local sources. Construction is under way to enable future manufacturing on site.

The NCI's Surgery Branch Cell Processing Laboratory, according to Dr. Tabak, generates investigational cell and gene therapy products. The space is under renovation, and administrative updates are being made in terms of standard operating practices and equipment. The laboratory was reopened for restructured manufacturing with moderate facility control. The laboratory's capacity will be expanded in a new space in Building 53. The space will house a Good Manufacturing Practices (GMP) facility constructed with prefabricated modular components to significantly increase the volume of cell processing.

The NCI's Surgery Branch Vector Production Laboratory produces vectors for use in manufacture of engineered cells, and the Thoracic Epigenetics Laboratory produces experimental cancer vaccines. Due to concerns about physical plant and layout, two trailers were purchased to enable work to continue. Two other researchers were added to the Thoracic Epigenetics Laboratory.

Dr. Tabak said that remediation is ongoing at the NCI Biopharmaceutical Development Program facilities, where production of monoclonal antibodies, recombinant proteins, and so forth continues. The Leidos Radiopharmacy is operating at a high level of control. Very little is required in the way of remediation. The Radiopharmacy prepares short-lived PET agents.

Dr. Tabak reported that NIAID's vaccine stock manufacturing facility produces viral seed stock drug substance that is then sent to Charles River Laboratories for additional processing and release. Administrative controls were changed to allow continued operation until renovations are completed in early 2017. Also, NIAID's Vaccine Research Center is operating at an exceptionally high level of control. No remedial actions were recommended. The Centers for Disease Control and Prevention was consulted with regard to NIAID's planned Malaria Vaccine Laboratory. The laboratory will be housed off campus.

Follow-Up Item:

- All CCRHB members are encouraged to tour the Clinical Center's facilities. Interested members should [send a note to Dr. Tabak](#).

Discussion

Dr. Tuckson asked about the interaction between the FDA and the Clinical Center's pharmaceutical-type supply operations. Dr. Tabak said that the FDA oversees commercial production of such supplies, but in a research space, no formal mechanism exists for proactive engagement. If issues emerge, then the FDA has an obligation to step in. This situation has been a challenge. As a research hospital, the Clinical Center has to find outside experts, sometimes with the assistance of the FDA, to provide independent assessments. Some outside groups have turned out to be suboptimal.

Dr. Tuckson asked about generalizing processes and problems across the production facilities. Dr. Tabak said that some standard operating procedures are interoperable across all the production facilities. If a problem is observed in one facility, it could signal potential problems in the others.

Dr. Forese asked who is responsible for information technology (IT) and information security. Dr. Tabak said that NIH has an extensive cybersecurity program mandated by the Office of Management and Budget. Ms. Andrea Norris serves as the Director of the Center for Information Technology and the NIH Chief Information Officer (CIO). She reports directly to Dr. Collins through Dr. Tabak. Dr. Tabak said that NIH has made serious investments in its IT backbone; a whole series of monitoring sentinels help IT staff understand what is coming in and going out. In terms of security, two-factor authentication is required and strict guidelines are in place to require updates as flaws become apparent. Regarding the databases on genomics, NIH is ahead of the curve in terms of granting access only after authentication of credentials.

Dr. Shannon speculated that many ICs are working with complex data sets; there might be opportunities for economics of scale. He suggested thinking about ways to consolidate processes and systems in the future.

Regarding radiopharmaceutical production, Dr. Shannon asked whether a business proposition might exist for consolidating operations with Walter Reed or the Naval Hospital. Expertise at NIH could drive the field. Dr. Tabak said that NIH facilities are in stabilization mode right now, but there have been some early-stage conversations to gauge other institutions' capacities and levels of interest in creating partnerships.

Dr. Tabak remarked that in the past, if an IC wanted to go forward with a cell-based therapy, it did so, with little regard to the capacity of the PDS to handle the production. Now, there will have to be an adjudication with regard to priorities. Developing linkages to other facilities could help meet demand and provide some surge capacity.

Mr. O'Neill asked about control of IT hardware and testing of the systems. Dr. Tabak explained that two completely separate networks are maintained. One requires access through the virtual private network (VPN) – the intranet, and the other is for guest access. NIH has many outward-facing sites, but they are kept separate from the internal sites. NIH regularly contracts with companies that identify any vulnerabilities in the system so that they can be addressed. Staff cannot use a personal device to access any internal systems.

Mr. O'Neill asked whether NIH identification badges could compromise security. Dr. Tabak said that even if someone obtains an NIH badge, he or she would have to know the badge owner's password to enter the network.

Follow-Up Item:

- Invite CIO Andrea Norris, M.B.A. to present at the next CCRHB meeting.

Closing Statement and Adjournment of Open Session

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

The next face-to-face CCRHB meeting is scheduled for January 13, 2017. Drs. Forese and Collins thanked the board members for their thoughtful input. Dr. Forese adjourned the open session at 3:38 p.m.

Closed Session

This section of the meeting was closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 USC. The materials and discussion could disclose information on the internal personnel practices or rules of the National Institutes of Health as well as personal information associated with the individuals under consideration for leadership positions, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Adjournment of Closed Session

Dr. Forese adjourned the closed session at 4:15 p.m.

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

Chair, NIH Clinical Center Research Hospital Board

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

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

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

Ex-Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

ADC	average daily census
AML	acute myeloid lymphoma
BTK	Bruton's tyrosine kinase
CCGB	Clinical Center Governing Board
CCR	Center for Cancer Research
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CIO	chief information officer
CSO	chief science officer
DA-TEDDI-R	dose-adjusted temozolomide, etoposide, doxil, dexamethasone, ibrutinib, rituximab
DART	days away, restrictions, and transfers
DLBCL	diffuse large B cell lymphoma
FDA	U.S. Food and Drug Administration
FTE	full-time equivalent
FY	fiscal year

GMP	Good Manufacturing Practices
HHS	Department of Health and Human Services
IA	invasive aspergillosis
ICs	Institutes and Centers
IND	Investigational New Drug (application)
IRB	institutional review board
IRP	Intramural Research Program
IT	information technology
IVAU	Intravenous Admixture Unit
NCI	National Cancer Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
ORS	Occurrence Reporting System
ORSC	Office of Research Support and Compliance
PCNSL	primary central nervous system lymphoma

PDS Pharmaceutical Development Section

PET Positron Emission Tomography

PI principal investigator

SAE serious adverse event

VPN virtual private network