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Tenth Meeting of the Clinical Center Research Hospital Board

October 19, 2018

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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

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Executive Summary

The tenth meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on October 19, 2018, on the main campus of NIH. The meeting was open to the public and was webcast live.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:02 a.m. and welcomed everyone in attendance.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, highlighted progress in filling the position of chief of the Department of Laboratory Medicine. He also showcased 16 Clinical Center employees who recently received NIH Director's Awards. A variety of projects were undertaken in 2018 to improve safety and ensure good patient experiences at the Clinical Center. Dr. Gilman presented data on the average daily census in the Clinical Center and remarked on trends in research that could influence the use of space in the building. Other topics included updates on projects undertaken in 2018, increased participation in the federal employee viewpoint survey, and the strategic planning effort, which should be completed in early 2019.

Pius Aiyelawo, FACHE, the chief operating officer of the Clinical Center, discussed the fiscal year (FY) 2018 and 2019 capital investments. He outlined the process by which projects are vetted and prioritized. In 2018, 10 projects were funded at a cost of $18,380,000.

The results of the Joint Commission survey conducted in July 2018 was the topic of a presentation by Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality. She briefed the CCRHB on the 18 exceptional leading practices and the 28 deficiencies identified by the surveyors. Regarding a finding about "high-risk, widespread" ligature risks in the behavioral health units, NIH leaders engaged with the Joint Commission, explained the special nature of the Clinical Center's patient population, and proposed a plan for risk mitigation based on furniture modifications and close monitoring. The Joint Commission accepted the plan.

A series of presentations by several NIH clinical directors and some of their colleagues highlighted some of the impacts of the Red Team's findings on several Institutes and Centers (ICs) of NIH. Despite some negative effects, on the whole, the Clinical Center has a heightened sense of awareness of patient and employee safety and clinical quality. Some ICs have implemented programs that build upon and complement the overall safety-oriented infrastructure of the Clinical Center.

Dr. Forese thanked the board members for attending and sharing their insights. Dr. Forese adjourned the meeting at 3:00 p.m.

The next face-to-face CCRHB meeting is scheduled for February 1, 2019.

Meeting Summary
Friday, October 19, 2018

Welcome and Board Chair's Overview

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

The tenth meeting of the CCRHB took place on October 19, 2018, 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 9:02 a.m. and welcomed all present. She announced that Ruth Brinkley, M.S.N./Adm., Carolyn Clancy, M.D., Jeanette Erickson, D.N.P., RN, and Richard Shannon, M.D., were participating via teleconference.

Dr. Forese introduced the agenda for the meeting.

NIH Principal Deputy Director's Remarks

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

Dr. Tabak did not deliver any remarks.

NIH Clinical Center CEO: Update

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

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

Clinical Center Census

Dr. Gilman presented hospital census data, which he described as a bit concerning. Fiscal year (FY) 2018 ended at about the same level as FY 2017 in terms of average daily census (ADC). The 3-year ADC is slightly lower than it has been for a few years. Recently, however, the ADC was up to about 150.

Nevertheless, outpatient visits and day hospital usage are up. Going forward, Dr. Gilman said that strategic planning will have to consider the amount of space allocated to the inpatient unit in relation to anticipated increases in activity in the outpatient areas.

Staffing and Awards

Dr. Gilman announced that Karen Frank, M.D., Ph.D., D(ABMM), is now the chief of the Department of Laboratory Medicine. She was formerly the acting chief. Efforts are under way to recruit additional staff for the department. Dr. Frank is also completing leadership training at Drexel University.

Sixteen Clinical Center (CC) employees received NIH Director's Awards on August 29. The Clinical Center team that assisted with the creation of the documentary film *First in Human* received an award for administration, and the technical award went to the Clinical Center's Radiology and Imaging Sciences film library. The film library has hundreds of thousands of de-identified images with interpretations, all of which are available to researchers around the country. Other Clinical Center employees were recognized for the NIH Distressed Trainee Working Group, the Pediatric Exoskeleton Development Team, the Medical Rehabilitation

Research Coordinating Committee, and the team leading the Optimize NIH Point-of-Care team. The 2018 Equity, Diversity and Inclusion Award of the Year went to Tricia Coffey, Chief, CC Health Information Management Department.

Dr. Gilman announced the recipients of the first annual trans-NIH clinical excellence awards: staff clinician of the year (Colleen Hadigan, M.D., M.P.H.) and nurse practitioners/physician assistants of the year (Victoria Anderson, B.S., M.S., N.P., and Karen Baker, RN, M.S.N., CRNP). There were more than 40 nominees for these awards, which were presented at a town hall meeting.

Joint Commission Survey

Three surveyors with the Joint Commission conducted a four day survey of the Clinical Center in July. More than 280 staff attended the closing summary presentation of findings and leading practices by the lead surveyor. (This was the first time a debriefing at the Clinical Center was conducted in a public forum.) Dr. Gilman found it heartening that so many people turned out. The surveyors commended the Clinical Center for its journey of the past 2 years focused on patient safety.

Morbidity & Mortality (M&M) Rounds

According to Dr. Gilman, M&M Rounds occur quarterly. In September, the subject was "The balancing act of bleeding and thrombosis in the era of new oral anticoagulants: A devastating consequence in a high-risk patient."

2018 Projects

Dr. Gilman updated the CCRHB on the status of 2018 projects:

- Protocol Resource Impact Assessment: The tool has been finalized and is being implemented now.
- Implicit Bias Training: The training has been launched.
- Outpatient Clinics and Day Hospitals: NIH staff strive to streamline outpatient research visits by coordinating nursing services, phlebotomy, clinic visits, and pharmacy services. Efforts to improve coordination and communication are in progress. Some technologies will also be applied. The steps taken thus far have been successful and, consequently, fewer research participants are experiencing delays during their Clinical Center visits.
- Clinical Center Space: This project is experiencing delays as strategic decisions need to be made about requirements for inpatient space vs. the need for outpatient space or office use.
- Clinical Center Fundamentals of Leadership: Dr. Gilman said NIH has excellent leaders at the senior level, mostly because of their natural abilities. More needs to be done to develop young leaders. The Office of Workforce Management has put together a leadership development course for new leaders that will start early next year.
- Anti-sexual Harassment Campaign: This new campaign is designed to combat harassment in all its forms, not just sexual and aligns with NIH's focus on anti-harassment in the workplace Sometimes the perpetrators are patients or family members. Responses to harassment by patients should go beyond changing nursing assignments. NIH needs a series of graduated responses based on severity and frequency of harassment

inflicted on employees by patients. The National Academies recently issued a report on sexual harassment in academia, engineering, and medicine.

Clinical Center Strategic Planning

The strategic planning process was set in motion during the summer of 2017, Dr. Gilman said. Version 2.0 is under review by senior staff. This fall and winter, senior Clinical Center and NIH leaders will meet four times to ensure that the strategic plan aligns with the NIH Strategic Plan and to submit the plan to the Clinical Center Governing Board (CCGB). Dr. Gilman hopes the plan will be completed early in 2019, when it will be presented to the CCRHB.

Federal Employee Viewpoint Survey

The response rate for Clinical Center employees was 61% in 2017, up from 40% in 2016. The responses show that people now are happier and feel more engaged working in the Clinical Center. One important finding was the number of people who believed that changes would be made in response to the survey findings.

Upcoming Events

Dr. Gilman mentioned that the keynote address for NIH Veterans Day on November 7 will be delivered by Pius Aiyelawo, FACHE, the Clinical Center's chief operating officer (COO) and a retired naval officer. Also, Trinity Health's upcoming 2018 Clinical Summit will include a presentation by Dr. Gilman on the Clinical Center's journey to high reliability as well as resources available to patients and how to access these resources.

Discussion

Dr. Tuckson asked whether the trend toward less research activity in the Clinical Center reflects a shift toward a different portfolio of research that requires no hospitalization or a decreased length of stay due to improved quality of care. Dr. Gilman said that the length of stay has remained about the same, and the number of protocols (1,600) has not changed. The inpatient ADC is only one indicator of research activity in the Clinical Center. In terms of sustaining very expensive infrastructure, NIH leaders need to think and plan.

Dr. Tuckson said that the ADC is an important indicator. Is NIH missing the mark in terms of the type of research that the nation wants? Dr. Tabak said that this topic is under discussion by the leaders of NIH. The inpatient infrastructure that supports groundbreaking research costs a great deal of money, and NIH leaders want to ensure that it is used optimally and maximally. Nevertheless, there is a trend toward protocols that require more outpatient, rather than inpatient, interventions.

Dr. Gallin added that NIH is coming to the end of an important transition: recovery from the findings of the 2016 report of the Clinical Center Working Group of the Advisory Committee to the Director (the Red Team). NIH continues to attract young investigators, especially at the National Cancer Institute (NCI). Researchers are using the Clinical Center's new facility for cell products, including CAR T cell-based therapy. Dr. Gallin is optimistic that critical research opportunities are moving in a very positive way.

Dr. Forese said the CCRHB intended to continue monitoring data on the Clinical Center's ADC and other indicators of usage. The trend around the world is toward outpatient care, although inpatient care is expanding in certain clinical areas. Discussions about optimal use of space are occurring everywhere. Dr. Tuckson also said that, regarding the fixed-cost infrastructure, the

CCRHB would not want to see a decision to diminish the Clinical Center in response to data from a single point in time.

Dr. Gilman spoke of the need for greater flexibility and agility to respond to the demands of clinical research.

Dr. Tuckson asked whether NIH has a health services research portfolio and whether NIH interacts with entities in this space, such as the Agency for Healthcare Research and Quality (AHRQ). Dr. Gilman said that NIH has connections with that community, but the Clinical Center's improvements in patient safety and clinical quality have not been driven by health services research design. The Clinical Center is a small hospital with low volume; it would not be easy to conduct health systems research in an institution whose strength lies in first-in-human projects. Laura M. Lee, M.S., RN, is connected with AHRQ and the Department of Health and Human Services community.

Ms. Erickson said that sexual harassment and disruptive behavior are universal issues in hospitals. Nurses are the ones who are usually the targets of harassment and violence abuse in any form cannot be tolerated. She lauded NIH for starting a thoughtful program to deal with this important and pervasive problem.

Follow-Up Item:

Continue to update the CCRHB on the Clinical Center's ADC and other indicators of usage.

2019 Capital Improvement Fund

Pius Aiyelawo, FACHE, COO, NIH Clinical Center

Mr. Aiyelawo discussed the fiscal year (FY) 2018 and 2019 capital investments.

Background

The Clinical Center's Capital Investment Fund was established in FY 2018 to meet crucial programmatic and infrastructure modernization needs. The fund is capped at $50 million per year for a 5-year period. In FY 2018, the Clinical Center received $19.4 million for capital improvements.

The Clinical Center Governing Board (CCGB) manages the fund and reviews projects submitted for consideration. Projects are selected based on their potential to improve patient safety and patients' experience by upgrading infrastructure, facilities, or clinical and information technology.

FY 2018 Approved/Funded Projects

Mr. Aiyelawo listed the 10 projects funded in 2018. The total cost came to $18,380,000. Investments included $2 million to implement Allscripts Mobile Care and purchase smartphones and iPads. Another example was the renovation of 174 inpatient bathrooms and 87 common-area bathrooms at a cost of $3.62 million.

Action Plan

Mr. Aiyelawo outlined the action plan for FY 2019 capital investment fund projects. In August, a data call was issued to all Clinical Center department and service chiefs asking them to identify their capital investment needs. Next, a series of individual meetings was held with clinical

directors of ICs that are heavy users of the Clinical Center to learn about their requirements and priorities.

In consultation with the Clinical Center's service chiefs, the C-suite, and the Office of Research Facilities, Mr. Aiyelawo will prioritize requests and provide a list of recommendations to the Clinical Center CEO and others. After the CEO approves the final package, Mr. Aiyelawo will prepare a presentation for the CCGB's review and approval. This step is scheduled for November 2018. The approved projects and equipment will be submitted to the appropriate acquisition offices for procurement.

Discussion

A CCRHB member asked about the pace of expenditures. Dr. Gilman said that the fund provides $50 million a year for 5 years. Originally, the fund was supposed to start in 2019, but the ICs asked for a ramp-up. Because federal monies have to be spent by the end of the fiscal year, in May the ICs requested that NIH leaders find good uses for the FY 2018 money. Therefore, $20 million was allocated for projects that could be implemented rapidly before the end of FY 2018.

Dr. Shannon said that this is a very positive step given what the CCRHB has heard from staff about the need for capital investments in the Clinical Center. Regarding the computed tomography scanner installed in the Critical Care Medicine Department, Dr. Shannon asked about potential duplication of labor. Dr. Gilman said that the new scanner will be run by the same staff who are in Radiology; there is no need for additional staff. Most scans will still be done with the larger scanners in Radiology and Imaging Sciences.

Dr. Tuckson asked about competing priorities (i.e., projects that did not make the cut). The cutline for 2019 has not been established yet, according to Dr. Gilman. In FY 2018, some projects in laboratory medicine were not funded because major renovations are anticipated. Also, replacing the revolving door at the main entrance to the Clinical Center did not make the cutline.

Dr. Forese asked about the lifecycle of Clinical Center equipment. Dr. Gilman said the planning factor for replacement of equipment—everything from an endoscope to a CT scanner—is 8–10 years. When calculating expected life, one must also consider repair and maintenance history. In general, equipment in the Clinical Center has lasted longer than industry averages because the budget was too low, meaning that some equipment had to be sustained longer than it should have. NIH keeps good maintenance records.

Dr. Forese asked about projecting equipment needs for the future. Dr. Gilman said that anticipated needs are taken into account in the planning process.

If a project might take several years, how does that fit into the budget? Does the entire cost accrue in the first year? Dr. Gilman said that it is sometimes necessary to find a way to spread costs over more than one year. Mr. Aiyelawo explained how 3- to 5-year projects can be designed.

Brig. Gen. James Burks discussed some distinctive features of federal budgeting.

Follow-Up Items:

- The CCRHB is interested in hearing from IC directors about their capital investment needs. More background information and ideas about their philosophical directions would be helpful.
- For a future meeting, the CCRHB would appreciate a presentation on equipment lifecycles and maintenance.

Patient Safety and Clinical Quality Update

Laura M. Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality

Ms. Lee reviewed the results of the Joint Commission Accreditation Survey results and updated the CCRHB on efforts to sustain patient safety and clinical quality performance.

Joint Commission Accreditation Survey Results

The survey was conducted over 4 days by three surveyors: a physician (lead surveyor), a nurse, and a life safety engineer. They focused on ligature risk, high-level disinfection and sterilization, operative venue, performance improvement, environment of care, and provision of care.

Ms. Lee listed the 18 exceptional leading practices identified by the surveyors, several of which centered on sterilization and disinfection. Until recently, the Clinical Center had 11 sites where sterilization and disinfection processes were carried out. By the time of the survey, however, these functions had been consolidated in two sites in the hospital by synching policies and procedures, evaluation of the NIH CC's high level disinfection and sterilization program by an external subject matter expert, and assuring expert oversight of the high level disinfection and sterilization enterprise .

Survey Findings

The surveyors cited 28 deficiencies as survey findings.

Ms. Lee presented the Survey Analysis for Evaluating Risk (SAFER) metrics in a chart form, that categorizes findings according to degree of risk (high, medium, and low) and frequency (limited, pattern, or widespread). With two exceptions, all findings clustered in the low to moderate risk range with frequencies designated as limited or pattern. Ligature risk for all behavioral health units was characterized as being high risk and widespread. Also, disinfection practices during transportation of ultrasound probes was characterized as a moderate but widespread risk.

Regarding the finding on disinfection, Ms. Lee said that the Clinical Center did not have a reliable way to track transvaginal and transrectal probes between patients and sterilization. The finding was based on a lack of documentation and administrative processes. Also, staff were not transporting the equipment in a moist environment. A product was purchased and deployed to resolve this defiency.

Regarding ligature risks, Ms. Lee said that the behavioral health units had purchased ligature-resistant beds, but because of their clearance from the floor the surveyors deemed them risky. The door handles in patient rooms are ligature resistant, but the ones in the common areas were

not. Desks were cited because of the drawers, as were the doors on the armoires and the bathroom doors.

Ms. Lee said that NIH responded to the Joint Commission survey findings on ligature risk by providing some context about the Clinical Center and its unique patient population. There are three behavioral health units in the Clinical Center: Pediatric Behavioral Health, Adult Behavioral Health, and the Alcohol and Addictions unit. Clinical Center patients are typically chronic, not acute, cases who are participating in research through planned admissions. The investigators are able to select patients to be research participants based on strict eligibility requirements. If acute problems arise, they occur in the context of research, meaning that the patients are carefully monitored. The nurse-to-patient staffing ratio is 3:1. Rigorous assessment and intervention practices are in place, including one-to-one monitoring. Many of the behavioral health patients are in the Clinical Center for long periods of time.

After the survey, Ms. Lee said that Clinical Center representatives reached out to the Joint Commission leaders, who were highly responsive and collaborative. NIH submitted its evidence of compliance based on the Clinical Center population and the research orientation of the hospital. In response to the findings, NIH is removing armoire doors and desk drawers to reduce ligature risk, but it proposed keeping the bathroom doors and the existing beds and instead relying on careful monitoring to minimize risk.

Dr. Tuckson reinforced the Joint Commission's acceptance of the Clinical Center's plan for risk mitigation, which includes a rigorous monitoring component.

Sustaining Patient Safety and Quality Performance

Ms. Lee highlighted progress on two fronts:

- Hand hygiene: Adherence is now up to 90%. The epidemiology team is taking the lead with three main interventions designed to sustain and improve adherence: awareness raising, training and competence building, and staff observations.
- STAT antibiotics: Any antibiotic ordered is deemed STAT and should be infused within 60 minutes. In January through May of 2018, adherence was 53%. The maximum (85%) was achieved in July, but since then, it has dropped to about 70%. To improve timeliness of infusions, some antibiotics are now available in the automated dispensing cabinets on the patient care units. Also, each instance of an overdue antibiotic was analyzed in near real time by a patient safety specialist. Weekly meetings are held with key stakeholders to review all instances of nonadherence, identify ongoing or recurring systems issues, and engage in problem solving and intervention deployment. Challenges include communication gaps, ordering of nonstandard doses, preparation and delivery, limited IV access, and patient care issues.

The executive dashboard presenting clinical and safety performance metrics was included in the CCRHB's binders.

Discussion

Dr. Tuckson recommended creating separate lists of the Joint Commission findings, based on whether they were related to research or to clinical care. An example would be the finding of lapses in physicians' documentation of conscious sedation. The whole point of the Clinical

Center is research; if problems with clinical care introduce confounding variables, then they need to be addressed, because they could compromise the mission.

Dr. Shannon said that ligature risk is a near-universal finding in Joint Commission surveys. Mitigating such risks in a short period of time is challenging.

Ellen Berty suggested pocket doors for the patients' bathrooms.

Dr. Tuckson asked about ligature risk for patients who are not in the behavioral health units but who may have a triggered depressive response to serious illness or futility of care. Also, a screening tool is available to assess risk of acute suicidality. If a patient is at elevated risk, Clinical Center staff respond accordingly to reduce risk.

Ms. Berty observed that curtains in the day hospital and patient rooms have a shelf life. Ms. Lee concurred, noting that the curtains have an expiration date for infection control reasons.

Dr. Shannon noted that timeliness of antibiotic administration is a process measure among very important clinical outcomes associated with sepsis. He asked about outcomes data in sepsis. If sepsis mortality is coming down, 90 minutes from order to administration might be acceptable. What is important is knowing the front-end triggers and the back-end outcomes. More information is needed to understand the importance of getting to 100% when it comes to administering an antibiotic within 60 minutes.

Ms. Lee added that cytokine storm would be a critical risk of cell therapy. Dr. Shannon suggested expanding the project to preventing end-organ damage from cytokine storm and preventing mortality from sepsis. He suggested emphasizing clinical outcomes that are of greatest importance. In addition, he mentioned that cell-based therapies can trigger syndromes that are similar to systemic inflammatory response syndrome.

David Henderson, M.D., Deputy Director for Clinical Care, agreed with Dr. Shannon's comments. Despite the availability of about 15 different lifesaving processes to prevent death from septic shock, the national mortality rate for sepsis has remained constant for years at 35%.

Follow-Up Items:

- Dr. Shannon requested more information about the triggers (e.g., sepsis alert) for STAT antibiotics and outcomes data for sepsis. The CCRHB would like more information about front-end triggers and back-end outcomes to understand the importance of achieving the stated goal of administering all antibiotics within 60 minutes of the order.
- The CCRHB would like to review and discuss the executive dashboard at each meeting.

Patient Safety at the CC—Right Path?

Forbes D. Porter, M.D., Ph.D., Clinical Director, Eunice Kennedy Shriver *National Institute of Child Health and Human Development (NICHD), NIH*

Deena Y. Zeltser, M.D., Pediatric Ward Chief, Office of the Clinical Director, NICHD, NIH

Dr. Gilman said that this part of the meeting would be devoted to a series of presentations on patient safety at the Clinical Center. Clinical directors and their colleagues who represent Institutes that are primary users of the Clinical Center delivered the presentations.

Background

Dr. Porter provided an overview of NICHD, its commitment to patient safety, and the impacts of patient safety and clinical quality initiatives. The Institute's organizational chart is a flat structure consisting of research affinity groups that report directly to the research director. Traditionally, research groups are organized by laboratory or branch. NICHD has its own Data Safety and Monitoring Committee. The Institute's three consultation services handle about 500 consultations each year in the Clinical Center.

NICHD underwent reorganization of its Intramural Research Program in 2014–2015 to consolidate clinical research support in the office of the NICHD clinical director. Previously, clinical support was associated with particular laboratories or groups. The reorganization helped ensure uniform coverage for research programs. In response to the May 2015 CRC sentinel event that led to the Red Team's findings and because an NICHD research participant died due to a postoperative bleed in August 2015, NICHD decided to develop a new system called the Ward Chief Safety Net to improve safety for NICHD patients.

The Ward Chief System

Dr. Zeltser explained that the new system was created to oversee and enhance the safety and quality of clinical care provided to all NICHD inpatients and to provide clinical support for research protocols. NICHD now has four ward chiefs and is planning to hire a fifth. Their clinical duties include the following:

- Attend daily rounds with NICHD protocol teams.
- Provide clinical support for general pediatric issues.
- Serve as a liaison among patients, families, protocol teams, and other NIH clinicians.
- Establish rounding times for multiple protocol teams to enhance each team's overall workflow efficiency.
- Be a point of contact and provide clinical backup if the primary team cannot be reached.

On a macro level, Dr. Zeltser explained that the ward chiefs are responsible for the three *C*s: catches, consultation, and communication.

- *Catches:* Pediatric Ward chiefs review the medical charts of all NICHD pediatric inpatients and catch safety errors involving, for example, medications, intravenous fluid rates or composition, and documentation. When a ward chief catches an error, he or she discusses it with the provider and enters a Safety Tracking and Reporting System (STARS) report.
- *Consultation:* As a pediatrician, Dr. Zeltser provides general pediatric consultations for NICHD principal investigators who are not pediatricians. Similarly, the adult ward chief conducts internal medicine consultation for NICHD principal investigators who are not internists. The ward chief also provides medical clearance for surgical candidates.
- *Communication:* The ward chiefs improve and facilitate communication among research teams, clinical providers, and patients and their families. They bring key stakeholders together to discuss patient safety concerns.

Other duties of the ward chiefs include professional development. This includes education, serving on multiple NIH-wide committees, and clinical research. Increasingly, ward chiefs are getting involved in clinical research, primarily as principal or associate investigators on research protocols related to endocrinologic and/or genetic disorders.

Impact on NICHD of the Red Team's Findings

Dr. Porter explained how the Red Team's findings affected NICHD. The closure of the Pharmacy Development Service (PDS) resulted in studies being canceled or not developed at all, increased costs, and a lack of placebos for trials. There was also heightened concern about medical care available for pediatric research participants, which led to decreased admissions and increased referrals. The impacts had downstream effects by hindering progress of studies of rare disorders with childhood onset, slowing the development of novel therapies, hindering delivery of therapeutic interventions before significant disease burden develops, and decelerating investigations into developmental origins of health and disease.

In terms of positives, Dr. Porter said that the ward chief system complements what is being done across the Clinical Center. It has increased safety for NICHD patients. Oral agent compounding is being considered for placebos and active agents. This is important and will facilitate many studies but limited in its impact on Pediatrics because many children cannot take pills. Getting suspension formulations is more complex. The Intermediate Care Unit is very important to NICHD research; it facilitates sedation of research participants who are in the pediatric age range or are cognitively impaired. The Pediatric Anesthesia and Critical Care Unit provides monitored beds with 24/7 in-house pediatric coverage. Increasingly, collaborations are being established with extramural institutions.

Dr. Porter concluded by presenting a Venn diagram to illustrate that high-impact research occurs where safe and high-quality clinical care intersects with unique, high-risk clinical science. He said that since the Red Team issued its findings, people in the Clinical Center have been thinking and talking more about safety.

Discussion

Dr. Tuckson pointed out that a fundamental core infrastructure of support exists across the Institutes and Centers (ICs). The NICHD Ward Chief Safety Net bolts onto that infrastructure. What has changed in that infrastructure since the Red Team issued its findings? To what extent does NICHD have to supplement the core competencies and infrastructure in the Clinical Center? Dr. Zeltser said that for trainees in general, a certain level of safety is added with their supervision by an attending physician. The attending physicians oversee trainees, and there is redundancy to minimize gaps, but those measures are not consistent across the ICs. The ward chiefs are another set of clinical eyes watching for gaps and errors. The ward chiefs have stopped procedures that could have been problematic, and they help balance research needs with the clinical needs of the patient. Dr. Porter said that the ward chief system complements the Clinical Center's infrastructure. Every IC makes efforts to improve patient safety and clinical quality. The Ward Chief Safety Net is NICHD's contribution.

Regarding the findings of the Red Team, are the negative impacts on NICHD research all related to the PDS closure? Dr. Zeltser said that the Red Team's findings triggered an overall concern about the capabilities in the Clinical Center to comprehensively care for sick pediatric patients.

Dr. Tuckson thought that ICs that are adding their own safety programs to the clinical infrastructure would be well positioned to identify problems that should be solved by common

infrastructure and core competencies. Dr. Porter said that this is why the ward chiefs are highly engaged in NIH committees: Their observations might help other ICs and could provide insights about the core infrastructure.

Dr. Gilman said that all of the presentations today by Clinical Center users demonstrate that more time and effort are put into planning and thinking ahead. The Clinical Center staff are certainly more risk aware, and they are probably more risk averse now. They have become well versed in individual risk-based assessments. Staff are more comfortable in deciding not to bring certain patients to NIH because the Clinical Center is not equipped to handle some patients. Also, some patients are not up to the rigors of traveling many miles to come here. Staff go through a failure mode and effects analysis (FMEA) to help plan and prevent problems.

Dr. Shannon commented that NICHD's development of a specialist hospitalist model suggests a new culture of safety and quality. He was impressed that the ward chiefs are now learning to do research. Pediatric research is underemphasized at many research institutes; therefore, making pediatric research front and center at the Clinical Center is very important in terms of developing new therapies. Dr. Shannon also supported the idea of collaborating with outside organizations. Many academic centers and hospitals would be amenable to engaging in research and adding to the capabilities available at the Clinical Center.

Patient Safety at the CC—Right Path?

William L. Dahut, M.D., Clinical Director and Scientific Director for Clinical Research, Center for Cancer Research (CCR), National Cancer Institute (NCI)

Dr. Dahut provided an overview of the NCI intramural program and the impact of the Red Team's findings. The CCR is part of the Intramural Research Program at NIH. Overall, CCR represents only 8% of the NCI budget, but it is the primary user of the Clinical Center, representing about 35% of usage in terms of adjusted patient days and financial consumption (37%). CCR has 235 principal investigators, 58 tenure-track investigators, a total staff of about 2,900, and approximately 900 postdoctoral and clinical fellows. CCR investigators publish about 2,500 papers a year. The intramural program focuses on areas of need and potential impact.

About 54% of CCR activity involves clinical or translational research, and 46% is in basic science. CCR research has supported the development of many cancer drugs now approved by the Food and Drug Administration. Examples include selumetinib for neurofibromatosis type 1, moxetumomab for hairy cell leukemia, and avelumab for treating Merkel cell carcinoma. CCR investigators, including Steven Rosenberg, M.D., Ph.D., Douglas Lowy, M.D., and John Schiller, Ph.D., have been recognized for their groundbreaking research.

Safety Following the NIH Red Team's Findings

CCR hired three full-time hospitalists and contracted with two local hospitals to hire a pool of hospitalists who provide coverage for two of CCR's three inpatient services—the Medical Oncology Service and the Urologic Oncology Service. Five advanced practitioners were replaced. In FY 2018, 928 patients were admitted for work-ups, treatment, pharmacokinetics studies, or adverse events related to their cancer or treatment toxicities.

To improve safety, a series of fellow-led quality improvement/quality assurance projects was carried out focusing on sign-outs and transitions in care; outpatient clinic flow; documentation, notes, and new patient records; a standard operating procedure for clinic admissions; a sepsis

algorithm; improved admission process and enhanced access to radiology services; addition of an oncology tab in CRIS medical records; restricted access to investigational agent order sets; patient-centered workflow in the day hospital; pilot test of a manual process for order verification; and a chemotherapy competency program. A future project will develop standard order sets for common cancer regimens to reduce the potential for medication errors.

10-Year Anniversary of the Prostate Cancer Multidisciplinary Clinic

The clinic was established in 2008 to provide highly specialized care for prostate cancer. The prostate is the only organ in the body that is biopsied blindly. The lack of precision in biopsy procedures led to misdiagnoses and a general reluctance for patients to undergo active surveillance. A system for image-guided biopsy was needed to ensure that cancerous areas in the prostate were sampled.

CCR investigators developed a biopsy procedure based on multi-parametric prostate magnetic resonance imaging (MRI) registered with transrectal 3D ultrasound to facilitate real-time targeted biopsy. Dr. Dahut showed several images from patients who underwent the procedure. The technology became commercially available in 2013, and image-guided prostate biopsy is available at a few dozen sites in the United States, the EU, and elsewhere. One patient's story was featured in the *Washington Post.*

Dr. Dahut described another project investigating the sensitivity of computer-aided diagnosis for local recurrences of prostate cancer.

The Clinical Center is an excellent environment to drive the science and patient care.

Impact of the Red Team Findings

After the findings of the Red Team report were issued, the Clinical Center is on the right path. NCI, as the largest user of the Clinical Center, has a responsibility to lead the charge by affirming patient safety as our top priority. NCI continues to focus on process improvement, education and training at all levels, transparency from leadership, and collaboration across disciplines and organizations to carry out co-sponsored improvement projects.

Discussion

Dr. Tuckson appreciated Dr. Dahut's comments on integration of activities across ICs.

Dr. Tuckson inquired about the availability of neurosurgery services in the Clinical Center. Dr. Dahut said that surgeons in the Clinical Center are mostly affiliated with NCI, except head-and-neck surgeons and neurosurgeons. If a patient had an intracranial bleed, for example, CCR staff would reach out to their neurosurgical colleagues, who would determine if the case could be safely handled in the Clinical Center. They might transfer the patient to another hospital to get the best care, regardless of the patient's insurance status. If treatment could be safely delivered in the Clinical Center, attending physicians and trainees would perform the surgery. The Clinical Center is responsible for all privileging and credentialing.

In response to another question from the CCRHB, Dr. Dahut explained that line placements are done in the dedicated Vascular Access Clinic. The clinic staff do not do 100% of line placements because of occasional emergency situations. Dr. Tuckson favored this centralized approach, as it would allow problems to be addressed in a straightforward way.

Patient Safety at the CC—Right Path?

Suzanne Wingate, Ph.D., RN, ANP-BC, Clinical Director, National Institute of Nursing Research (NINR)

Brian Walitt, M.D., M.P.H., Medical Officer, NINR

Dr. Wingate provided an overview of NINR, NINR's intramural science program development, and commitment to patient safety. She is a nurse practitioner and is the vice-chair of the Medical Executive Committee.

NINR is a smaller Institute with one tenured investigator, three tenure-track investigators, one assistant clinical investigator, one staff clinician, one staff scientist, and multiple trainees. NINR has 12 clinical protocols; two more are in IRB review. All current studies are outpatient protocols.

NINR is currently in transition because the Institute Director recently retired and an acting Director is in place.

Dr. Wingate explained that Dr. Walitt is the medical officer of NINR. His expertise is in chronic symptoms. He is the medically accountable investigator for many NINR research protocols and serves as a shared resource with the National Institute of Neurological Disorders and Stroke, the National Institute of Dental and Craniofacial Research, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases. He is a member of the NINR Scientific Review Committee and the Combined Neuroscience Institutional Review Board (IRB).

NINR Intramural Science

According to Dr. Walitt, NINR's research portfolio emphasizes symptom science (fatigue and physical symptoms that occur inpost-traumatic stress disorder, traumatic brain injury, congenital muscle disorders, digestive disorders, and post-solid organ transplants). NINR investigators explore the biologic mechanisms that play a role in generating chronic symptoms that exist in the absence of gross pathologic change, using disease models such as traumatic brain injury, post-cancer treatment fatigue, and myalgic encephalomyelitis/chronic fatigue syndrome. NINR researchers engage in translational science aimed at developing clinical interventions, biomarkers, and bioassays; 67% of NINR's clinical research focuses on natural history studies, with the remainder being screening studies and clinical trials.

Dr. Walitt explained that NINR is organized into three branches: the Biobehavioral Branch, the Symptom Management Branch, and the Tissue Injury Branch. Two new branches are coming to NINR: the Symptom Science Center and the Advanced Visualization Branch.

Program Development and Patient Safety

Dr. Wingate reported that in 2014–2015, NINR performed a program assessment that found that great science is being done in isolation and identified several areas to address, including patient safety, protocol navigation, and protocol monitoring. The release of the Red Team's report coincided with ongoing infrastructure development at NINR.

To improve patient safety, NINR hired a quality management specialist who is also the safety liaison. The safety liaison attends daily Clinical Center huddles, and summarizes the safety issues for staff. In addition, NINR has a safety and quality meeting that is combined with a

biweekly research nurse meeting. Those meetings serve as a forum for sharing across teams. NINR also has appointed a protocol safety monitor for selected protocols.

Dr. Wingate said that for the first time, NINR set up a contract with an outside contract research organization. The additional research support for protocol navigation frees up team members, allowing them to focus on other areas, and also provides external monitoring support for selected protocols.

Although the missions of NINR and the Clinical Center Nursing Department are different, they do share many common purposes. These groups have combined their Intramural Scientific Review Committees and have also developed an affiliate faculty position for Dr. Gwen Wallen, the Clinical Center Chief Nurse Officer, in NINR.

NINR has taken advantage of the Clinical Center Office of Research Support and Compliance for general regulatory support. According to Dr. Wingate, NINR also developed an internal quality monitoring and auditing system which includes checks on CRIS documentation and event reporting.

NINR has many trainees. Dr. Wingate conducts orientation sessions to ensure that trainees understand Clinical Center and NINR policies, patient safety, and confidentiality requirements. A competency program was developed to assure appropriate competency and supervision of trainees in the clinical setting. Research nurse training helps nurses make the transition from bedside nursing to a research role.

In terms of credentialing, the plan is for nurse practitioners (NPs) to practice to the full extent allowed in Maryland, which allows NPs to have fully independent practice. The Medical Executive Committee at the Clinical Center recently approved full NP practice privileges which includes admission privileges and no need for co-signature on documentation.

Impact of PDS Closure

Regarding the PDS closure, two NINR protocols were affected. One was a sleep study that had to be closed because the study drug was no longer available. Another study used a sugar solution that could no longer be made by the Pharmacy and the close of PDS caused delays with obtaining internal and external availability of this product. In summary, since the Red Team issued its findings, there has been significant improvement in protocol resources and study oversight and patient safety. The culture has become one that supports asking questions and sharing ideas to support safe clinical research.

Discussion

In response to a comment from the CCRHB, Dr. Wingate confirmed that NINR has benefited from the new structure and resources of the Clinical Center.

Dr. Shannon said that all the presentations thus far have demonstrated that the ICs have embraced the new orientation emphasizing quality and safety. It is powerful to hear about the science and the horizontal integration of care and science in prostate cancer care.

Patient Safety at the CC—Right Path?

David Goldman, M.D., Clinical Director, National Institute on Alcohol Abuse and Alcoholism (NIAAA), and Chief, Lab of Neurogenetics, NIAAA

Nancy Diazgranados, M.D., Deputy Clinical Director, NIAAA

Dr. Goldman spoke about clinical care, safety, and addictions research in a multi-principal investigator environment.

Research at NIAAA

Dr. Goldman reported that NIAAA is among the smaller ICs with 13 basic science laboratories doing research on the brain, synapses, circuits, behavior, and genetics. NIAAA also investigates the effects of alcohol, cannabinoids, and other drugs on the cardiovascular system, liver, and metabolism. Several basic labs are engaged in clinical research, rolling out new drugs and probes and making neuronal models with induced pluripotent stem cells, and genomics studies.

NIAAA has a diverse portfolio of clinical research carried out in six clinical laboratories where scientists are investigating the neurocircuitry of addiction, the gut-brain axis, the gut microbiome, and hepatotoxicity. NIAAA is currently conducting 31 clinical protocols, 19 of which are overseen by the Addictions IRB and 10 by the Combined NeuroScience IRB. The protocols are transitioning to the central IRB of NIH.

Dr. Goldman explained the many ways that NIAAA is different from other ICs, mostly because its patients are different, the physical environment is different, and patient activities are different. He also highlighted the accomplishments of two "superstar" researchers at NIAAA.

Impacts of the Red Team's Findings

Dr. Goldman reported to the CCRHB on organizational changes that were put in place to enhance patient care and safety. The Red Team report has been a powerful tool to motivate change and obtain resources to support change.

NIAAA leaders replaced the single clinical lab with the Office of the Clinical Director and six laboratories. The clinical director reports to the scientific director and the director of NIAAA. The clinical director is responsible for the clinical research budget, staffing, and space, which allows for long-range planning and use of central resources. All patients enroll in one natural history protocol as a baseline for diagnosis, eligibility, treatment, and genomic studies. The cores include the Database Core, Neuroimaging Core, Regulatory Core, and Clinical Core Laboratory for assessment of patients.

To improve NIAAA patient care and safety, all protocols now have a monitoring plan, and principal investigators are annually audited. Event reporting is emphasized and monitored. All principal investigators know it is their responsibility to maintain safety, comply with regulatory standards, and deliver optimal care. Clinical care is better documented and monitored. Right now, NIAAA units are at capacity.

In terms of reporting unanticipated problems, Dr. Goldman said that potential breaches of personally identifiable information (PII) are recurring problems. NIAAA repeatedly trains staff

to use email properly and works with the Clinical Center and NIAAA to minimize these problems.

Needs of NIAAA

Dr. Goldman highlighted several needs:

- 503A/B capacity is needed to formulate oral drugs and placebos required for multiple studies following the closure of the PDS. Multiple studies were suspended, stopped, or never initiated because of lack of access to placebos and drugs.
- Systemwide solutions are needed to prevent transmission of unencrypted electronic PII.
- Office space is needed outside of the Clinical Center to move some research staff outside of clinical and laboratory areas. This would allow better use of clinical space.
- Improve the utilization of the addictions consult service.
- More Clinical Center medical/surgical nurses are needed, along with enhanced training of nurses in behavioral health.

Discussion

A member of the CCRHB asked about the unique set-up of the NIAAA–National Institute on Drug Abuse (NIDA) scientific review committee. Because of shared neuroscience across all addictive agents, these committees were merged functionally, Dr. Goldman said. NIAAA and NIDA are linked by close communication, coordination, and cross-funding. There is a great deal of interaction between laboratories.

Dr. Tuckson asked how high-quality care could be documented. Dr. Goldman said that NIAAA uses a comprehensive psychiatric rating scale that collects information on patient anxiety and depression. The Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar) scale is used to collect information on alcohol withdrawal. Patients' scores on the Comprehensive Psychopathological Rating Scale are often high initially, and then the scores come down to acceptable levels by week 3 or 4. The goal is to retain patients in a setting where they cannot access their drug of choice and provide a safe detoxification of alcohol.

Dr. Tuckson asked about metrics for patients who are more medically complex. Is there a timeline to indicate when these metrics should come down? Dr. Goldman said that medications may be administered for managing withdrawal and detoxification. Medication receipt history is tracked, although NIAAA has not monitored for changes year over year. Dr. Tuckson asked about best practices insofar as how medications are prescribed and received.

Dr. Diazgranados said that medically acute patients are not brought to the Clinical Center because they need to be part of research. NIAAA participants are not as severe as some community cases. Telephone screenings are done, as a method for screening incoming study participants but most patients come to NIH in acute alcohol withdrawal. We use the CIWA scale, which is symptom based. Patients are given medications (e.g., benzodiazepine, thiamine) as needed as determined by their symptoms. Dr. Tuckson said that inpatients who present with certain clinical syndromes need certain medications administered per a timeline, but he thought

that more solid metrics are needed to ensure high quality of care. Dr. Goldman agreed, saying that all patients are enrolled in one natural history protocol; it would be possible to look at CIWA-Ar scores and other outcomes (e.g., dental care outcomes, severe withdrawal). That approach could be used to aggregate outcomes over a year. There are efforts to measure rates of recidivism at 6 months and 1 year, but with alcoholism, there are very high recidivism rates. Many patients are homeless and hard to reach, making it a challenge to obtain information on everyone. Insofar as recidivism rates, Dr. Goldman speculated that the rates for the NIAAA program are probably similar to other programs'.

Dr. Goldman further noted that NIAAA has many studies recruiting people who are heavy drinkers but are not seeking care. Nearly 30% of the general population has a lifetime history of heavy usage. Most are working and functional in many ways. Those who are seeking care for alcoholism generally are not functioning well. Instead of just looking at crude clinical outcomes in a binomial way (i.e., relapse or not), NIAAA investigators look at what is happening with harm reduction. Some domains are likely to improve even though patients do not achieve abstinence. For heavy drinkers not seeking treatment, NIAAA uses interventions to decrease their drinking.

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 tenth meeting of the CCRHB by thanking the presenters and CCRHB members for their insights and thoughtful input. Dr. Tuckson also appreciated the series of presentations that demonstrate culture change within the Clinical Center. Everyone on the team should be proud of what has been accomplished in a short time.

The next face-to-face CCRHB meeting is scheduled for February 1, 2019.

Dr. Forese adjourned the meeting at 3:00 p.m.

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

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

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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
AHRQ	Agency for Healthcare Research and Quality
CCGB	Clinical Center Governing Board
CCR	Center for Cancer Research
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CIWA-Ar	Clinical Institute Withdrawal Assessment for Alcohol
COO	chief operating officer
FMEA	failure mode and effects analysis
FY	fiscal year
ICs	Institutes and Centers
IRB	institutional review board
MEC	Medical Executive Committee
M&M	Morbidity & Mortality (Conference)
MRI	magnetic resonance imaging

NCI	National Cancer Institute
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIDA	National Institute on Drug Abuse
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIH	National Institutes of Health
NINR	National Institute of Nursing Research
NP	nurse practitioner
PDS	Pharmacy Development Service
PII	personally identifiable information
SAFER	Survey Analysis for Evaluating Risk
STARS	Safety Tracking and Reporting System