

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

**Ninth Meeting of the  
Clinical Center Research Hospital Board  
July 20, 2018**

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## **Clinical Center Research Hospital Board**

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

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

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

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

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

Ruth Brinkley, M.S.N./Adm., Kaiser Permanente Northwest

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

Carolyn Clancy, M.D., Deputy Under Secretary for Discovery and Advancement, Veterans Health Administration, U.S. Department of Veterans Affairs

Jeanette Erickson, D.N.P., M.S., RN, Senior Vice President for Patient Care Services and Chief Nurse Emerita, Massachusetts General Hospital

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

## Executive Summary

The ninth meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on July 20, 2018, 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 Hospital, and Chair, CCRHB, called the meeting to order at 9:01 a.m. and announced that Paul O'Neill, M.P.A., has stepped down from the CCRHB. Larry Tabak, D.D.S., Ph.D., Principal Deputy Director of NIH, welcomed CCRHB members to the meeting.

James Gilman, M.D., Chief Executive Officer of the NIH Clinical Center, reported that the Clinical Center's average daily census has been steady over the past few months and listed several staffing changes. With its recently opened hospice rooms, the Clinical Center now has a facility dedicated to patients at the end of life and their families. The magnetic resonance imaging area has been rezoned, and the Building 10 E wing will reopen after renovations in April 2021. Dr. Gilman summarized the recommendations of the Clinical Center Red Team in its 2016 report and listed the many Clinical Center activities that address these recommendations.

Laura M. Lee, M.S., RN, Director, Office of Patient Safety and Clinical Quality, Clinical Center, reported that the central line-associated bloodstream infection (CLABSI) rate has declined steadily since the first quarter of 2017, and the intensive care unit CLABSI rate dropped to 0 in the first quarter of 2018. The Office of Patient Safety and Clinical Quality is preparing for the Joint Commission accreditation process. In particular, the office is focusing on areas that the Joint Commission often identifies as problems: ligature risks, high-level disinfection and sterilization, and sterile compounding.

Janice Lee, D.D.S., M.D., M.S., Clinical Director, National Institute of Dental and Craniofacial Research, and chair of the Patient Safety, Clinical Practice, and Quality Committee, explained that the committee formed three subcommittees to address three high-priority areas. The Peer Review Subcommittee recommended to Dr. Gilman that the Clinical Center require employee cosignatures at the completion of all ongoing professional practice evaluations (OPPEs), use the OPPE and Performance Management Appraisal Program to enhance compliance with Joint Commission standards, and implement a standardized peer-review process to coincide with the OPPE every 2 years. The Quality of Consult Service Subcommittee is updating the roster of consult services, and it recommends that the Clinical Center develop a Clinical Research Information System consult service template and revise the bylaws for consult services to increase consistency. The High-Risk/Low-Volume Procedures Subcommittee plans to identify the areas of greatest risk and design methods to address these risks.

Representatives of three NIH Institutes and Centers gave presentations on their patient safety activities at the Clinical Center. James Balow, M.D., Clinical Director, National Institute of Diabetes and Digestive and Kidney Diseases, explained that the Institute has five consult services for Clinical Center patients, and the Metabolic Clinical Research Unit supports research on type 2 diabetes and obesity. The unit's 10 rooms are designed to accommodate adults and adolescents with severe obesity, and the unit has specialized equipment and a monitored

communal eating area for tightly controlled feeding studies. Metabolic Clinical Research Unit researchers have had difficulty finding alternate sources now that the Pharmaceutical Development Section (PDS) is closed. Partly for this reason, the development of new protocols was languishing, and existing protocol activity was slowing down. However, the unit's activity is rebounding, and the number of new protocols executed on the Metabolic Clinical Research Unit doubled between 2017 and 2018.

Maryland Pao, M.D., Clinical Director of the National Institute of Mental Health (NIMH), reported that NIMH research in the Clinical Center's outpatient clinics includes studies on the natural history of puberty, irritability, anxiety, autism, and psychiatric epidemiology. Since the Red Team published its report, NIMH promoted a team member, Lisa Horowitz, Ph.D., M.P.H., to the new role of Director of Patient Safety and Quality. Dr. Horowitz or Dr. Pao participates in the Clinical Center's daily huddles, and NIMH uses failure modes and effects analysis for new studies on the neurobiology of suicide and electroconvulsive shock therapy. NIMH recently developed a suicide screening tool for use by Clinical Center clinicians not specialized in mental health, a human research subjects protection toolkit, and an NIH distressed trainee toolkit.

Brian Brooks, M.D., Ph.D., Clinical Director of the National Eye Institute (NEI), reported that NEI has a long-standing relationship with a contract research organization, which assigns protocols appropriate levels of regulatory guidance and monitoring at scientific review. Clinical Center staff are invited to NEI-wide activation meetings for all intervention protocols, and Clinical Center nurses are invited to monitoring visits. NEI has an external data and safety monitoring board for large intervention trials and an internal serious adverse events review committee. Dr. Brooks listed several changes to planned clinical trials as a result of the PDS closure that have led to delays in or indefinite suspensions of these studies.

Elizabeth Wendell, B.S.N., M.S., Nurse Manager, 3NE, NIH Clinical Center, described efforts to create an environment of efficiency and safety in the ophthalmology clinic. These activities include weekly clinical operations planning meetings to evaluate clinical and research activities, daily staff-led nursing huddles to discuss daily clinical and research activities, and a mini-360 pilot project that allowed all staff to give feedback on the performance of all other staff members. Nurses have revised the protocol for intravitreal injections to maintain patient comfort, ensure that patients do not move during the procedure, and prevent infection.

The next face-to-face CCRHB meeting is scheduled for October 19, 2018.

## **Meeting Summary Friday, July 20, 2018**

### **Welcome and Board Chair's Overview**

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

The ninth meeting of the CCRHB took place on July 20, 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 9:01 a.m. and thanked those present for their attendance. She announced that Paul O'Neill, M.P.A., has stepped down from the CCRHB. Dr. Forese has assured Mr. O'Neill that the CCRHB will continue to focus on the issues for which he has advocated, especially the safety of all Clinical Center staff.

### **NIH Principal Deputy Director's Remarks**

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

Dr. Tabak welcomed CCRHB members to the meeting and thanked them for coming. He explained that Francis Collins, M.D., Ph.D., and John Gallin, M.D., were unable to attend the meeting.

### **NIH Clinical Center CEO's Update**

*James Gilman, M.D., Chief Operating Officer (CEO), Clinical Center*

#### ***Average Daily Census***

After reviewing the meeting agenda, Dr. Gilman reported that the Clinical Center's average daily census has been steady over the last few months. Although June was a busy month, the census dropped in late June and early July. However, Dr. Gilman predicted that the average daily census would soon rise.

#### ***Staffing***

Dr. Gilman announced the following staffing changes:

- Elizabeth Jones, M.D., M.P.H., M.B.A., is now Chief of Radiology and Imaging Sciences.
- Karen Frank, M.D., Ph.D., Acting Chief of the Department of Laboratory Medicine, will be a fellow of the Hedwig van Ameringen Executive Leadership in Academic Medicine<sup>®</sup> Program for Women at Drexel University in 2018-2019.
- Adam Politis, M.S., is now Chief of the Speech and Language Pathology Section in the Rehabilitation Medicine Department.
- Barbara Jordan, D.N.P, RN, is the new Service Chief of Nursing Operations.
- James Paterson, M.S., RN, is the Acting Service Chief of Neuroscience, Behavioral Health, and Pediatrics.

Dr. Gilman congratulated the NIH Clinical Center Clinical Research Nursing Residency Program staff for the program's recent accreditation with distinction for 3 years as a practice transition program by the American Nurses Credentialing Center's Commission on Accreditation.

### ***Facilities and Space***

The Clinical Center held a ribbon-cutting ceremony for its new hospice rooms on July 10. The ceremony was very moving because the Clinical Center now has a facility dedicated to patients at the end of life and their families. The CCRHB might be interested in hearing from Ann Berger, M.D., Chief of the Pain and Palliative Care Service, about the hospice rooms and her service's other activities.

The magnetic resonance imaging area has finally been rezoned to keep people who are in contact with metallic objects from coming too close to the equipment. Plans are being developed for the east terrace modular facility for the Center for Cellular Engineering. Work is ongoing to increase the capacity of the interim Intravenous Admixture Unit (IVAU) and construct the new IVAU. Four inpatient rooms in 5SWN are being reallocated to the National Eye Institute (NEI). The Building 10 E wing renovations, mostly to laboratory and office space, are continuing, and the wing is expected to reopen in April 2021. The Department of Transfusion Medicine will have renovated space in the new E wing.

NIH has established a capital investment fund to address deficits in equipment and facilities that have accumulated over the years. The Institute and Center (IC) directors were able to obligate \$18 million in fiscal year 2018 dollars for this purpose. The Clinical Center has identified several projects that can be initiated in the current fiscal year using these funds, including refreshing all inpatient rooms and common area restrooms, adding a computed tomography unit to the intensive care unit, and purchasing Allscripts Mobile Care. The full list of planned projects is available to CCRHB members upon request.

### ***Federal Employee Viewpoint Survey***

Early results for the 2018 Federal Employee Viewpoint Survey indicate a 57% response rate. This represents a substantial increase from 2 years ago.

### ***Two Years After the Red Team Report***

In its April 2016 report, [\*Reducing Risk and Promoting Patient Safety for NIH Intramural Clinical Research\*](#), the Clinical Center Red Team identified seven opportunities for improvement. Dr. Gilman was recently asked to give an update on responses to these opportunities to the IC directors. To prepare for this presentation, Dr. Gilman grouped these opportunities into three themes and identified Clinical Center activities over the last 2 years that addressed these themes. He has now presented his findings to the IC directors, scientific and clinical directors, and the Clinical Center staff at town hall sessions.

The themes and relevant activities are as follows.

Theme 1: Fortify a culture and practice of safety and quality

- Formed the Clinical Center Research Hospital Board
- Created a CEO position with a function that is separate from science and research

- Changed clinical directors' reporting so that they now report directly to Institute directors
- Closed the Pharmaceutical Development Section (PDS)
- Completed turnover of pharmacy leadership
- Constructed the interim IVAU, which opened in April 2017
- Expanded pharmacy staffing
- Provided additional resources to the Office of Patient Safety and Clinical Quality
- Initiated daily patient safety huddles
- Implemented the new Safety Tracking and Recording System (STARS)
- Empowered nurses and staff clinicians
- Provided additional resources for pediatric patient care and established a pediatrics observation unit
- Changed assignment process for Clinical Center leadership positions and search process for key positions
- Reinforced efforts to proactively assess clinical risk in research-related activities and the advisability of saying no
- Established the Patient Safety Clinical Practice and Quality (PSCPQ) Committee

Theme 2: Strengthen leadership for clinical care quality, oversight, and compliance

- Established a new CEO position with quality and compliance authority and assigned scientific responsibilities to the Chief Scientific Officer
- Formed the Office of Research Support and Compliance
- Made provisions in the 2018 Clinical Center budget for the Office of Research Support and Compliance to facilitate clinical research, including regulatory compliance
- Conducted trans-NIH reeducation on the importance of compliance and how to achieve and maintain it
- Conducted self-assessment and independent audits of compliance with all relevant laws, rules, regulations, and policies
- Purchased a unified information technology system to facilitate compliance and its oversight
- Began centralizing institutional review board operations to standardize processes across all ICs

Theme 3: Address sterile processing of all injectables and the specifics of the sentinel event

- Provided sterile manufacturing expertise via the Intergovernmental Personnel Act with Duke University
- Stopped PDS manufacturing
- Constructed interim IVAU to meet current good manufacturing practice (cGMP) requirements
- Revised operating procedures to meet cGMP standards
- Trained all staff to meet cGMP standards
- Maintained the new IVAU in strict environmental control, with careful microbiological monitoring to ensure quality compliance
- Applied cGMP standards, methods, and procedures outside the pharmacy and to such areas as cell processing facilities in the Department of Transfusion Medicine



- Established Sterile Products for Human Administration Committee to review the preparation of injectables in the intramural program and all products procured from external sources, to ensure patient safety
- Began reviewing all injectable products that lack documentation to ensure compliance with all standards before administration
- Began arranging for external subject matter experts to advise on, audit, and inspect facilities, standard operating procedures, documentation, and operations to ensure compliance with the highest industry standards

The Clinical Center has substantially addressed every recommendation in the Red Team report. However, many of these responses are ongoing with work that will continue.

### *Discussion*

Regarding facilities updates, Dr. Forese asked about the condition of “backstage” areas in the Clinical Center that are not patient-facing, such as locker room areas. Dr. Gilman replied that these facilities are need updates, but they are unlikely to be renovated in the near future. Dr. Forese suggested that these backstage spaces be given higher priority in the Clinical Center’s renovation plans and Dr. Gilman agreed that this recommendation should be considered.

Brig. Gen. James Burks, M.B.A., commended Dr. Gilman and his team for their phenomenal leadership, which is demonstrated in the progress that Dr. Gilman had described. He agreed with Dr. Forese about the need to consider renovating the backstage areas as well the message that postponing these renovations sends to staff who do not work in patient care but who have a critical impact on patients.

Brig. Gen. Burks inquired about the status of the Clinical Center in its journey toward a just culture. Dr. Gilman said that culture takes a long time to change, and the Clinical Center’s patient safety, according to the recent survey, does not yet reflect a complete transition to a just culture. Sometimes, the desire to conduct good science gets ahead of concern for the partners in this research. However, the Clinical Center’s culture has improved and is moving in the right direction.

Brig. Gen. Burks asked about potential risks to the accomplishments that Dr. Gilman had described. Dr. Gilman said that one concern of young staff investigators and clinicians is that if a problem arises in their work, they alone will be blamed. They are concerned that the Clinical Center might not investigate systems-related issues that contributed to the issue or hold those responsible for these issues accountable.

Carolyn Clancy, M.D., suggested that the Clinical Center develop a performance scorecard or learning report on the vulnerabilities identified in the Red Team report. Dr. Gilman said that the lessons that the Clinical Center has learned could be published on its website. He has been reluctant to disseminate lessons learned until the Clinical Center has actually completed many of the required steps. However, he is now preparing a presentation to a major health system in the fall because he believes he can tell a story that is worth sharing. Dr. Clancy expressed an interest in attending this event.

Dr. Clancy commented that external transparency is sometimes easier than internal transparency. Dr. Gilman said that internal transparency is easier when an institution has a single site. In addition, the NIH leadership encourages transparency which allows Dr. Gilman to be open and candid in communications with Clinical Center staff.

Dr. Forese encouraged Dr. Gilman to share the lessons that the Clinical Center has learned with organizations within and outside of health care. The fact that no major patient safety event prompted the formation of the Red Team is good news. Dr. Forese asked Dr. Gilman to share the CCRHB's thanks for the Clinical Center's accomplishments in response to the Red Team report with Drs. Collins and Gallin.

Jeanette Erickson, D.N.P., RN, commented that hospitals constantly struggle with ensuring that personnel speak up when they notice a broken system, before a patient is harmed. The Clinical Center is developing a communication strategy that others can use to identify broken systems. Dr. Erickson congratulated Dr. Gilman and his colleagues on the Clinical Center's responses to the Red Team report and on sharing this summary in a transparent way. Dr. Erickson also congratulated the Clinical Center's nursing staff for the Clinical Research Nursing Residency Program's recent accreditation by the American Nurses Credentialing Center's Commission on Accreditation. Obtaining this certification is very challenging.

Ellen Berty expressed her gratitude that no patient safety incident had led to the Red Team report. She encouraged Dr. Gilman to spread the word about the Clinical Center accomplishments in response to the Red Team report.

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

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

Ms. Lee highlighted a few recent performance metrics and noted that more data are in the report shared with the CCRHB. The central line-associated bloodstream infection (CLABSI) rate has declined steadily since the first quarter of 2017, and the intensive care unit (ICU) CLABSI rate dropped to 0 in the first quarter of 2018. This accomplishment is particularly remarkable because the ICU population is very sick. The area that needs more work is pressure injury prevalence, which is higher than the benchmark, and the Nursing Department has identified several interventions to address this issue. The Clinical Center has made substantial progress in increasing the hand hygiene compliance rate to greater than 80%. The entire organization is engaged in a robust implementation plan developed by the hospital's Epidemiology Service and an interdisciplinary team.

The Office of Patient Safety and Clinical Quality is preparing for the Joint Commission accreditation process, with a focus on three areas that the Joint Commission often identifies as problems: ligature risks, high-level disinfection and sterilization, and sterile compounding.

Like other academic medical centers, the Clinical Center has patients at risk of self-harm and suicide because of chronic diseases or new and life-threatening diagnoses. Leaders in this field at NIH have worked closely with clinical staff to design and validate a short suicide assessment

tool that the Clinical Center uses for medical patients. When a patient has an assessment result that raises concern, the patient is monitored continually and given one-on-one care.

Over the last year, the Clinical Center has made substantial advances in high-level disinfection and sterilization. Before last year, 10 sites were doing high-level disinfection and sterilization, and none was doing it the same way. After a thorough assessment, just three sites now perform these activities using standard operating procedures under new leaders. Ms. Lee thanked the CCRHB as well as NIH and Clinical Center leaders for making these advances possible, but she noted that sterile compounding is still a challenge.

Over the last few years, the Clinical Center has made major changes in its culture. To share this work more broadly, the Clinical Center recently held a 1-hour program on the risks associated with a novel cellular therapy. The program featured presentations by Richard Sherry, M.D., on the history of cellular therapy; Nirali Shah, M.D., on a pediatric patient treated with cellular therapies; and Dr. Gilman on managing risk and ensuring patient safety.

Two ICs, the National Cancer Institute and the National Heart, Lung, and Blood Institute, conduct adoptive T-cell therapy research. Currently, 23 protocols are active in three patient care units and one ICU at the Clinical Center. This research touches every aspect of the hospital and provides a nice example of how the Clinical Center provides safe and high-quality care.

Because the Clinical Center cannot always predict risks, it builds a preoccupation with failure into its daily work. The Center uses contingency planning to ensure that the highest quality supportive care is available and that unexpected complications are addressed meticulously by the research team through its regulatory bodies. Another priority is to share knowledge about care and complications with investigators and clinical staff to improve future care.

To ensure consistent approaches by the seven principal investigators in the 23 adoptive T-cell therapy protocols, the Clinical Center is considering the establishment of a cellular therapy consortium for investigators to discuss their protocols and complications and to standardize their approaches to managing patients. Other strategies are for ICs to review others' protocols and a forum to discuss case outcomes and Grade 3 and 4 toxicities. Standardized treatment protocols and algorithms are needed to recognize adverse events and intervene appropriately. This model could be applied to other types of research at the Clinical Center as well.

### *Discussion*

Dr. Forese said that the cell therapy activities Ms. Lee had described have the potential to benefit other facilities that do this type of research, and not only from a scientific perspective. Dr. Gilman noted that the cellular therapy consortium is a great idea that has not been implemented. He added that the activities Ms. Lee had described to improve the Clinical Center's high-level disinfection and sterilization are important steps in the right direction.

Brig. Gen. Burks asked how the ICU succeeded in having no CLABSIs. Ms. Lee gave credit to the hospital's nursing and epidemiology staff for developing an evidence-based program that includes patients reporting nurses who do not scrub the hub for enough seconds. Gwenyth Wallen, Ph.D., RN, Chief Nurse Officer at the Clinical Center, added that these efforts began

with a two-person approach to dressing changes in pediatric units. For adult units, a concern was that not enough staff might be available, so this approach is required only for complicated situations.

In response to a request from Ms. Berty, Ms. Lee agreed to send the CCRHB a summary of the Joint Commission's findings once they are available.

### **Patient Safety, Clinical Practice, and Quality Committee**

*Janice Lee, D.D.S., M.D., M.S., Clinical Director, National Institute of Dental and Craniofacial Research; Chair, Patient Safety, Clinical Practice, and Quality Committee*

The 17 PSCPQ Committee members include representatives from throughout the Clinical Center as well as several ICs. The committee works with the Medical Executive Committee (MEC) to promote patient safety and clinical quality. The committee has compiled a list of 29 areas that it might need to address based on Red Team, NIH Office of Research Service, and STARS reports, as well as issues identified by committee members. The committee combined these 29 issues into three areas that are important to clinical staff and are not addressed by any other committee, and it formed three subcommittees to address each of these areas.

The Peer Review Subcommittee focuses on how to assess clinical care quality. Although almost all ICs use some form of peer review for this purpose, each uses a different peer review process. Only two ICs routinely share performance review results with clinicians. In a 2016 survey, half of respondents said that their peers can best assess their clinical skills, but almost 20% did not know who conducts these assessments.

Based on its findings, the subcommittee recommended to Dr. Gilman that the Clinical Center:

- Require employee cosignatures at the completion of all ongoing professional practice evaluations (OPPEs)
- Use the OPPE and Performance Management Appraisal Program to enhance compliance with Joint Commission standards and provide guaranteed direct feedback to employees about OPPE findings
- Implement a standardized peer-review process to coincide with the OPPE every 2 years, when recredentialing is required

These recommendations will allow the Clinical Center's performance evaluation system to account for the unique clinical skills and practice in the Clinical Center, where standard performance metrics might not be applicable.

The Quality of Consult Service Subcommittee reviewed 239 randomly chosen charts from seven consult services. More than 80% of the time, the reviewer was able to identify a consult question, a consult note was completed, the primary team implemented the recommendations, and follow-up was evident. However, direct communication from the consult service to the primary team was documented in less than 35% of charts, and Clinical Research Information System (CRIS) orders were finalized less than 50% of the time. The subcommittee is updating the roster of consult services and recommends that the Clinical Center develop a CRIS consult service template that can be linked to consult orders and that it revise the bylaws for consult services to increase consistency.

The High-Risk/Low-Volume Procedures Subcommittee plans to identify the areas of greatest risk and design methods to address these risks.

### ***Discussion***

Ms. Berty recommended that the PSCPQ Committee collect patient input, including whether interactions with a clinician were satisfactory. Dr. Gilman pointed out that the PSCPQ Committee includes a patient representative. Dr. Lee suggested that the Clinical Center incorporate patient satisfaction surveys into the OPPE.

Dr. Forese suggested that the Peer Review Subcommittee consider use of the OPPE in combination with the focused professional practice evaluation (FPPE) when something goes wrong or the Clinical Center has reason to focus on a given clinician. Dr. Lee replied that the subcommittee hopes to minimize the rare cases requiring an FPPE by, for example, making staff clinicians aware of the evaluations. Dr. Gilman noted that FPPEs are time consuming, difficult, and contentious. The MEC, not the PSCPQ Committee, has primary responsibility for FPPEs.

## **Patient Safety at the Clinical Center—Right Path?**

### ***National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Perspective***

*James Balow, M.D., Clinical Director, NIDDK*

NIDDK's research spans theoretical physics, mathematical models, and more traditional clinical specialties (including diabetes, endocrinology, gastroenterology, and liver and kidney diseases). The Institute has five consult services for Clinical Center patients: blood glucose management, adult endocrinology, gastroenterology, hepatology, and nephrology. The Blood Glucose Management Service includes clinicians with expertise in medicine, nursing, pharmacy, and nutrition.

The Metabolic Clinical Research Unit supports research on type 2 diabetes and obesity. Its 10 rooms can accommodate adults and adolescents with severe obesity, and it has specialized equipment (including metabolic chambers and body composition scanners) and a monitored communal eating area for tightly controlled feeding studies. The unit's main purpose is to conduct small, scientifically rigorous pilot studies that inform new approaches to definitive population-based studies. Protocols from eight ICs on a broad range of topics (e.g., energy changes associated with changes in the human microbiome, metabolic benefits of brown fat induction, complex effects of artificial sweeteners on caloric balance) are ongoing in the unit.

The Metabolic Clinical Research Unit depended on the PDS for isotopes and analytes and has had difficulty finding alternate sources now that the PDS is closed. Partly for this reason, the development of new protocols was languishing, and existing protocol activity was slowing down. However, the unit's activity is rebounding, and the number of new protocols executed on that unit doubled between 2017 and 2018.

Communication through the electronic medical record (EMR) is challenging. Although EMRs offer easy ways to create progress notes, this information is often of questionable quality or not

in the right part of the EMR. The nationwide problem of poor communications threatens patient safety. New investigators need to understand the importance of documenting their thoughts on patient care in the EMR to improve quality and safety.

### ***Discussion***

Dr. Forese asked whether the Blood Glucose Management Service is activated only when a physician requests it, or whether the service can be activated by EMR notices. Dr. Balow said that the service can be activated in different ways, and he was not sure whether a laboratory value could trigger this service. Dr. Forese explained that some clinicians believe that they can manage well without consulting an expert team until something goes wrong. Dr. Balow pointed out that many different services need to understand how to best manage glucose and insulin, given the controversy over whether tight glucose control is always advisable because of its association with more adverse events and longer hospital stays.

Dr. Forese asked whether the Metabolic Clinical Research Unit has a standardized process for referrals. Dr. Balow supported standardized approaches, but they must reflect consultants' thought processes about diagnoses and treatments. Medical records have too much irrelevant information, diluting their impact and making people reluctant to read them. Standardized reporting can be useful, but it is not sufficient. Dr. Forese pointed out that consultant notes can be in different places in the EMR, which is why standardization (possibly using artificial intelligence) could be helpful. Dr. Balow encourages staff to critique one another, including through reviews of EMRs completed by their peers, to identify what clinicians could have done better.

Brig. Gen. Burks pointed out that Dr. Lee, like Dr. Balow, had mentioned the unintended consequences of the PDS closure. Dr. Gilman explained that the Clinical Center is still developing consensus on how to address the issues mentioned at this meeting. Sometimes commercial products are available but too costly, or they are affordable but have the same quality concerns as the Clinical Center's PDS did. Brig. Gen. Burks asked Dr. Gilman to keep the CCRHB posted on the approaches it ultimately chooses.

Dr. Balow pointed out that many companies have quality control issues from time to time. He recommended that the Clinical Center choose a pragmatic approach over an ideal but unrealistic approach. Dr. Tabak agreed that the Clinical Center needs practical solutions, but it must be careful about the important concerns in this area.

### ***National Institute of Mental Health (NIMH) Perspective*** *Maryland Pao, M.D., Clinical Director, NIMH*

Dr. Pao reported that 18% of adults and 20% of children in the United States have a mental illness, and half of all lifetime cases of mental illness begin by age 14. The NIMH mission is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure; NIMH supports more than 3,000 research grants and contracts. Dr. Pao listed the objectives in the current NIMH strategic plan for research; the NIMH Intramural Program goals; and the short-, medium-, and long-term research

priorities of the NIMH director, Joshua A. Gordon, M.D., Ph.D. The NIMH Intramural Research Program (IRP) funds 41 research groups, of which 19 do clinical research, and it shares 11 shared core resources with the rest of NIH.

NIMH IRP uses 20 adult inpatient beds for studies of treatment-resistant depression, the neurobiology of suicide, and schizophrenia. The Clinical Center's four child and adolescent psychiatry inpatient and two-day hospital beds are used for research on adolescent depression and severe mood dysregulation disorder. NIMH research in the Clinical Center's outpatient clinics includes studies of the natural history of puberty, behavioral endocrine disorders, irritability, anxiety, autism, and psychiatric epidemiology.

Clinical efficacy trials are very important. For example, an NIMH-sponsored clinical trial showed that fluoxetine is effective for premenstrual dysphoric disorder and was one of two studies used to obtain Food and Drug Administration (FDA) approval for fluoxetine for this indication, leading to insurance coverage for this treatment. Other clinical trials have shown that many treatments are not effective for mental health disorders. Placebo-controlled studies, in particular, are critical in mental health because simply giving a medication causes physiologic and psychological effects. Placebos can help researchers determine whether the medication, and not its administration, is responsible for the observed effects.

Before the Red Team issued its report in April 2016, NIMH had established monthly patient safety and quality meetings. Since the report came out, NIMH promoted Lisa Horowitz, Ph.D., M.P.H., to the new role of Director of Patient Safety and Quality. Dr. Horowitz, Dr. Pao or other members of the Patient Safety and Quality team participate in the Clinical Center's daily huddles. The Institute with the Clinical Center employed failure modes and effects analyses for new studies on the neurobiology of suicide and electroconvulsive shock therapy. Since the report's publication, NIMH has also done the following:

- Integrated the NIMH positron emission tomography (PET) laboratory into the Clinical Center's cGMP PET facility
- Worked with the Office of Research Support and Compliance to Transfer Investigational New Drug certificates to the Clinical Center
- Developed a suicide screening tool for use by clinicians not specialized in mental health in Clinical Center adult and pediatric patients
- Continued to improve human subjects protections, including development of a human research subjects protections toolkit
- Developed an NIH distressed trainee toolkit

Since the PDS closed, NIMH has struggled to obtain the placebos it needs. Contracting with vendors is complex and time consuming, and many external pharmacy sources are too expensive. It is difficult to find sources for some products, such as syringes and hormone patches, and an external pharmacy that NIMH selected failed FDA GMP inspections. The products NIMH has purchased have had quality issues, such as lack of a necessary FDA-mandated analytics or drug inconsistencies. Some NIMH investigators have stopped designing placebo-controlled trials. This issue has had a particularly strong effect on junior investigators trying to establish their careers who do not know how to navigate the challenging contracting system.

## ***Discussion***

Beatrice Bowie asked whether the Clinical Center now provides pain management to patients with sickle cell disease. Dr. Pao replied that NIH Clinical Center offers this service in addition to the NIMH Psychiatric Consultation Liaison Service.

Dr. Forese noted that the PDS closure does not explain all of the challenges with pharmaceutical products in behavioral health. Some of the issues raised by the day's presentations were common to all facilities that deliver health care, but others are unique to the Clinical Center.

## ***National Eye Institute (NEI) Perspective***

*Brian Brooks, M.D., Clinical Director, NEI*

*Elizabeth Wendell, B.S.N., M.S., Nurse Manager, 3NE, NIH Clinical Center*

Dr. Brooks explained that the mission of NEI's clinical research program is to conduct high-quality research on the pathogenesis and treatment of blinding diseases in adults and children while providing expert clinical care in a safe environment. Like most ophthalmology departments, the Clinical Center's ophthalmology services are provided almost exclusively in outpatient clinics. Of more than 9,000 visits per year, almost 3,000 are consultations to other ICs on the clinical care of patients at the Clinical Center or for research collaborations. NEI is small, with only six principal investigators conducting clinical research, seven staff clinicians, and one staff scientist.

NEI's clinical program is a matrix organization, allowing the program to nimbly manage limited resources across multiple investigators in real time, functional redundancy, and subspecialization of support staff. However, the Red Team's report pointed out that fragmented authority and responsibility for clinical operations is a potential concern. The NEI and CC staff have sought to address this potential problem via regular clinical NEI staff meetings as well as weekly planning meetings between NEI operations personnel and Clinical Center Nursing.

The Red Team's report cited two opportunities for improvement: insufficient expertise in regulatory affairs as well as regular monitoring and metrics. NEI has a long-standing relationship with Emmes, a contract research organization. At scientific review, an appropriate level of regulatory guidance and monitoring is assigned. Clinical Center staff are invited to NEI-wide activation meetings for all intervention protocols, and Clinical Center nurses are invited to monitoring visit summary meetings. In addition, NEI has an external Data and Safety Monitoring Board for large intervention trials and an internal Serious Adverse Events Review Committee for smaller studies.

Dr. Brooks described some of NEI's clinical research projects. These studies are exploring the role of the gut microbiome in the pathogenesis of uveitis (intraocular inflammation); use of minocycline, a common antibiotic, or transplantation of a retinal pigment epithelium patch to treat geographic atrophy (the dry form of age-related macular degeneration); and a gene replacement strategy to treat X-linked retinoschisis. An NEI bioengineer has built one of the nation's only custom adaptive optics machines, which can noninvasively examine individual rod, cone, and retinal pigment epithelium cells in living humans.



### Effects of PDS Closure

NEI has had to make several changes to its clinical trial plans as a result of the PDS closure. For example, the clinical trial of oral minocycline on geographic atrophy was originally a randomized controlled trial. Because the investigators could not obtain a matched placebo, the study now has an untreated run-in phase followed by an open-label treatment phase. This change delayed the study's start by almost a year. An investigator had planned to use oral minocycline in two other diseases that cause blindness (branch retinal vein occlusions and central retinal vein occlusions). Because of the nature of these diseases, run-in and open-label phases were not possible. The investigator had to outsource the manufacture of the investigational agent, resulting in a 2-year delay and much higher costs than expected. To pay for this investigational agent, NEI had to delay two other projects. Another study that could not outsource the manufacture of an agent because of cost has been suspended indefinitely.

Several research projects have probably not been pursued because there was no path forward, and this has affected morale. However, morale is improving with the leadership of Majid Tanas, Pharm.D., M.H.A., M.S., Chief of the Clinical Center's Pharmacy Department. The NEI and Dr. Tanas have established a monthly operations meeting for pharmacy and NEI staff. If the Clinical Center could again offer the ability to create a matched oral placebo in house, this would be a major step forward for the NEI clinical research program.

### Creating an Environment of Efficiency and Safety

Ms. Wendell explained that NEI has weekly clinical operations planning meetings to evaluate clinical and research activities in the ophthalmology clinic for participants from all facets of NEI and the Clinical Center. These meetings escalate quality and safety concerns quickly, check in with each discipline, facilitate group decision-making, and build consensus around NEI's clinical research mission. The meetings are used to evaluate the plan for each patient over the next week for safety and to determine whether the needed resources are in place.

Daily staff-led nursing huddles focus on daily clinical and research activities. These huddles include reviews of plans of care for high-risk patients (e.g., those with mobility or behavioral health issues, those who need to be isolated) and of the resources they might need. The huddles also include just-in-time education, announcements, and morale boosts.

Dr. Brooks implemented a mini-360 pilot project, in which each staff member (including nurses, physicians, and technicians) gave feedback on everyone else's performance; Clinical Center nursing and NEI staff both participated. These reviews offered opportunities to recognize strengths and opportunities in the program of care, and all supervisors received the mini-360 results for those they supervise. The NEI plans to repeat these assessments toward the end of 2018.

Participants in the interdisciplinary planning meetings preview the upcoming clinic schedule to ensure that resources are sufficient to handle the testing and predicted patient flow. Ongoing participation in protocol activation meetings has increased, and interdisciplinary monitoring visits with Emmes are ongoing. The standards of care for procedures performed in the clinics have been revised, and primary nursing is used for high-risk patients and those with special needs. The NEI team and Clinical Center staff lead joint education programs, and a pharmacy

collaborative sends group emails whenever a drug is in short supply or its manufacture changes. Town hall meetings give NEI and nursing staff opportunities to agree on decisions and address concerns. The clinic is being redesigned to bring all nurses and technicians into a central workspace to facilitate communications.

Clinic staff do approximately 60 to 80 intravitreal injections, which carry a small risk of infection, every month. The nurses have revised the standards for these injections with the ophthalmologist. The staff focuses on comfort during the procedures, and one staff member uses guided imagery to help anxious patients stay comfortable and avoid moving their eyes during the procedure. The clinic does everything it can to control patients' pain. In a survey from the second quarter of 2018, 88% of patients indicated that their pain was managed, 91% said that nurses listen carefully, and 94% had confidence and trust in the physicians.

### ***Discussion***

Ms. Berty was pleased to hear that patients had been surveyed about their ophthalmology clinic experiences. She suggested asking them which stretchers and chairs are most comfortable.

Dr. Forese asked about challenges unique to small ICs. Ms. Wendell reported that four clinics have many nurses with cross-training in ophthalmology who can help when a staffing shortage arises. NIH offers many resources and people willing to help small ICs. Dr. Brooks added that teamwork might be simpler for smaller ICs because everyone knows each other. The main limitation for NEI is its budget (which it also uses to support 3,000 consults) and space. Also, NEI has not found a simple answer to the hurdles caused by the PDS closure.

## **Adjournment**

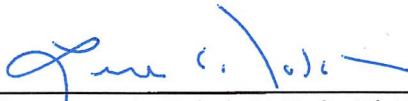
*Laura Forese, M.D., Executive Vice President and COO, NewYork-Presbyterian Hospital, and Chair, CCRHB*

Dr. Forese closed the ninth meeting of the CCRHB at 1:43 p.m. by thanking NIH staff and the CCRHB members. The next face-to-face CCRHB meeting is scheduled for October 19, 2018.



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Laura Forese, M.D., M.P.H.  
Chair, NIH Clinical Center Research Hospital Board  
Executive Vice President and COO, 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

CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
cGMP	current good manufacturing practice
CLABSI	central line–associated bloodstream infection
CRIS	Clinical Research Information System
EMR	electronic medical record
FDA	Food and Drug Administration
FPPE	focused professional practice evaluation
ICs	Institutes and Centers
ICU	intensive care unit
IVAU	Intravenous Admixture Unit
MEC	Medical Executive Committee
NEI	National Eye Institute
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
OPPE	ongoing professional practice evaluation
PDS	Pharmaceutical Development Section
PET	positron emission tomography
PSCPQ	Patient Safety, Clinical Practice, and Quality
STARS	Safety Tracking and Reporting System