U.S. Department of Health and Human Services

National Institutes of Health

Eleventh Meeting of the Clinical Center Research Hospital Board

February 1, 2019

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Clinical Center Research Hospital Board

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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

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

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

Carolyn Clancy, M.D., Deputy Under Secretary for Discovery, Education and Affiliate Networks (10X), Veterans Health Administration, U.S. Department of Veterans Affairs

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

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

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

Executive Summary

The eleventh meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on February 1, 2019, on the main campus of NIH. The meeting was open to the public and 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. Dr. Forese introduced Stephanie Reel, M.B.A., the Chief Information Officer of Johns Hopkins University and Health System, who is a new member of the CCRHB.

Francis Collins, M.D., Ph.D., Director, NIH, extended a welcome and spent a few minutes remembering the accomplishments of Stephen Katz, M.D., Ph.D., Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) for 22 years. Dr. Katz, who recently passed away, was a strong supporter of the Clinical Center and the CCRHB.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, updated the Board on various capital improvements planned and ongoing in the Clinical Center, the status of the Clinical Center's strategic plan, several projects completed in 2018, and results of the Federal Employee Viewpoint Survey (FEVS). He also announced that the Clinical Center Governing Board had approved a revised version of the Capital Investment Fund (CIF) proposal.

Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality, briefed the CCRHB on the results of a survey on patient perceptions of the Clinical Center, as well as various safety and performance metrics, and she asked the CCRHB for additional ideas about metrics to monitor in the Clinical Center.

Improvements in pharmacy facilities and processes were the topic of a presentation by Majid Tanas, Pharm.D., M.H.A, M.S., Chief, Department of Pharmacy. He outlined the medication use process in the Clinical Center and introduced a roadmap to improved care based on changes in pharmacy facilities, updated processes in the pharmacy and elsewhere in the Clinical Center, greater use of automation, and increased capacity in the pharmacy. Dachelle Johnson, Pharm.D., BCPS, Medication Safety Officer, spoke about the dual challenge of meeting clinically significant needs with customized medicines while increasing standardization. The pharmacy is continuing to establish controls within the system to manage the safety portfolio of the Clinical Center's medication use process.

Naomi O'Grady, M.D., Chief, Internal Medicine Service, and Attending Staff, Critical Care Medicine, and Tara Palmore, M.D., Hospital Epidemiologist, spoke about sepsis and cytokine release syndrome (CRS) events in the Clinical Center. They provided statistics on sepsis-related mortality, as requested by the CCRHB.

The meeting concluded with a presentation by Ronald Summers, M.D., Ph.D., Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, Radiology and Imaging Sciences. He spoke about advances made possible through the application of artificial intelligence in radiology and explained how data generated in the Clinical Center were advancing the entire field of clinical image analysis.

Dr. Forese thanked the Board members for attending and sharing their insights. Dr. Forese adjourned the meeting at 1:13 p.m.

The next face-to-face CCRHB meeting is scheduled for April 12, 2019.

Meeting Summary
Friday, February 1, 2019

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 eleventh meeting of the CCRHB took place on February 1, 2019, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and webcast live. Dr. Forese called the meeting to order at 9:02 a.m. and welcomed all present. She announced that Beatrice Bowie and Reed Tuckson, M.D., were participating via teleconference.

Dr. Forese welcomed Stephanie Reel, M.B.A., the Chief Information Officer of Johns Hopkins University and Health System, who is a new member of the CCRHB.

NIH Director's Remarks

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

Dr. Collins eulogized Stephen Katz, M.D., Ph.D., who was the director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) for 22 years. Dr. Katz played key roles in many NIH initiatives and was devoted to the Clinical Center. He had an incredible mind, with a memory for budget numbers and an institutional memory that were unmatched. Dr. Collins called for a moment of silence in recognition of this great leader, scientist, and friend of the CCRHB.

Dr. Collins announced that a major Clinical Center accomplishment will be highlighted on the CBS program *60 Minutes.* The topic will be gene therapy research for treating sickle cell disease.

Dr. Collins introduced the agenda for the day's meeting.

Discussion

Dr. Forese asked Dr. Collins about the outlook for NIH's budget in light of the government shutdown. Dr. Collins said that medical research has largely stayed out of the political fray. NIH enjoys strong bipartisan support in Congress. NIH leaders and staff are now gearing up for the hearing season, and Dr. Collins will speak with the Senate Appropriations Committee.

Dr. Collins clarified that NIH is still operating under a budget cap due to sequestration, which remains in force. He envisions a tumultuous year, with the possibility of another shutdown in September. However, Dr. Collins noted that for fiscal year (FY) 2019, NIH (along with most of the Department of Health and Human Services) received an approved budget in place on October 1, 2018. Rather than following the pattern of the previous 22 years, when final budgets were not in place until halfway through the year, for FY 2019 it has been possible to plan earlier how to best invest research dollars.

NIH Clinical Center CEO: Update

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

Dr. Gilman greeted the CCRHB members and updated them on developments in the Clinical Center.

Clinical Center Census

Dr. Gilman presented hospital census data as of December 31, 2018. He said the average daily census (ADC) is of concern, noting that the census is down by about 10 patients per day compared with the same time last year. In January, things ticked upward a bit, matching the ADC of January 2018. He reported that Clinical Center surgery programs have been very busy and that the pediatric oncology service has a new transplant program for immunodeficiencies. However, both the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI) have been performing fewer bone marrow transplants, which is affecting the ADC.

Dr. Gilman pointed out that outpatient activity has been increasing, perhaps reflecting national trends toward more ambulatory care and less inpatient care. In 2018, 6% more patients were seen in the day hospital than during 2017.

Maximizing the Utility of the Clinical Center

Dr. Gilman spoke of the need to consider further whether 200 inpatient beds is the right number for the Clinical Center in light of the shift away from inpatient research.

A new subcommittee of the Clinical Center Governing Board (CCGB) is studying ways to take maximum advantage of the Clinical Center. Walter Koroshetz, M.D., Director of the National Institute of Neurological Diseases and Stroke (NINDS), chairs the committee, which includes Dr. Gilman and three other directors of NIH Institutes and Centers (ICs).

Dr. Gilman highlighted several trends and future developments that are likely to affect Clinical Center operations. The list includes expansion of the Center for Cellular Engineering (CCE) and new research programs focusing on Alzheimer's disease and other forms of dementia, opioid use disorders, and pain management. The National Center for Complementary and Integrative Health (NCCIH), for example, started an important new program for pain management in outpatients who have sickle cell disease. Dr. Gilman mentioned a meeting scheduled in February 2019 during which he will make the case for expanding outpatient operations.

The Clinical Center hospice suites are being utilized, and plans are underway to expand the facilities to include pediatric patients.

Recent Appointments

Dr. Gilman announced that Norman Sharpless, M.D., Director of NCI, is now the chair of the CCGB. He also introduced Suzanne Wingate, Ph.D., RN, ANP-B, |Clinical Director of the National Institute of Nursing Research (NINR)who was appointed as the new Chair of the Medical Executive Committee. Jonathan Green, M.D., M.B.A., the new Director of the Office of Human Subjects Research Protections, is setting up the central NIH institutional review board (IRB).

Closeout of 2018 Projects

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

- **Protocol resource impact assessment:** The assessment tool was finalized and is being implemented now. Every department has an opportunity to provide input about the availability of resources to handle new protocols that are coming online.
- **Implicit bias training:** More than 2,000 NIH staff have completed training.
- **Outpatient clinics and day hospitals:** Workflow is much improved, with far fewer delays being reported for infusions and other procedures. On some days, hood capacity in the pharmacy is insufficient, but pharmacy staff are starting to prepare infusions earlier in the morning, and patient appointments are being staggered to minimize delays. This effort has required significant cooperation among nurses, NCI, and pharmacy staff. Further automation will help manage workflow even more effectively.
- **Clinical Center space:** Dr. Gilman acknowledged that space continues to be a major challenge in the Clinical Center, but some progress has been made. Staff completed a 100% inventory of space, resulting in the identification of a few new spaces, but reducing the number of beds could free up more room. Dr. Gilman spoke about the need to make some strategic decisions to balance the requirements for inpatient space with the need for outpatient space and offices.
- **Leadership development:** Dr. Gilman said the first class focusing on CC leadership fundamentals began on January 11, 2019. Developing the curriculum took a year and the class has been very well-received by participants thus far. Dr. Gilman listed other leadership development classes and a host of other training opportunities.
- **Patient online access to medical records:** This trend in health care reflects the importance of empowering patients and encouraging their engagement in care. It also helps encourage medical staff to write good chart notes. The Medical Executive Committee (MEC) endorsed the new practice of allowing patients full electronic access to progress notes starting on July 1, 2019. Dr. Gilman said that there will be a special accommodation for behavioral health studies. Patients will be able to access their progress notes through their existing patient portal accounts.
- **Federal Employee Viewpoint Survey (FEVS):** Participation in the FEVS has greatly increased. The response rate for the 2018 FEVS was 61%, compared with 40% in 2016 and 56% in 2017. For 2018, 48 of the 71 survey items were considered strengths (more above 65%). Eight items showed an improvement since 2017. One item was considered a challenge (rating below 40%). Dr. Gilman said that only 34% of respondents gave a positive rating to the statement “Pay raises depend on how well employees perform their jobs.” This challenge has been identified in FEVS results for the past 5 years, reflective of restrictions and regulations on pay raises in the federal employment system. Dr. Gilman said that he reviews the FEVS results with NIH leaders in one-on-one meetings.

2019 Priorities

Dr. Gilman highlighted several activities and initiatives in the Clinical Center:

- **Violence in the workplace:** The only two reported incidents in 2018 involved patients who did not have control over their movements, due to seizures in one case and

encephalopathy in the other, resulting in repeated striking of an employee and a needlestick with body fluid exposure, respectively. Very few violent episodes occur in the Clinical Center, and a report about nighttime safety is in development.

- **Anti-harassment campaign:** In addition to the NIH-wide anti-harassment efforts underway, Dr. Gilman described a CC campaign targeting mainly gender and sexual harassment of employees by patients and family members. Harassment is a ubiquitous problem, according to the National Academy of Sciences. Dr. Gilman reported that a multidisciplinary anti-harassment work group composed of NIH and Clinical Center staff is developing a multifaceted program to foster an organizational culture that promotes safety of staff, patients, and visitors in the Clinical Center.
- **Property accountability:** Dr. Gilman said that a a review is needed to evaluate whether a problem exists with managing property at the Clinical Center. Plans are in the works to assess the situation.
- **Unprofessional behavior:** In July 2019, Jo Shapiro, M.D., Director, Center for Professionalism and Peer Support, Brigham & Women's Hospital, Harvard Medical School, who has written extensively on professionalism in the workplace, will meet with the MEC and patient safety leaders and then speak at Medical Grand Rounds on this topic.
- **Clinical Center Strategic Planning Reboot, v2.0:** Current strategic planning efforts include a series of four meetings with senior Clinical Center and NIH leaders to review organization priorities in terms of people, hospital census, space, and capabilities. Once the strategic plan is formalized, it will be reviewed and approved by the CCGB and then presented to the CCRHB.
- **Opening of the CCE:** A ribbon-cutting ceremony was held on January 22, 2019. ADM Brett P. Giroir, M.D., Assistant Secretary for the Department of Health and Human Services, delivered the keynote address. Dr. Gilman reported that there are enough staff to have all the CCE rooms functioning.
- **International Rare Disease Day:** This event, a collaboration with the National Center for Advancing Translational Sciences (NCATS), will be held at the end of February.

Discussion

Dr. Forese asked about the scope and outcomes of the strategic planning process. Dr. Gilman said that the process will result in a 5-year roadmap. The timeline for certain activities, such as the pharmacy project, will extend beyond the 5-year horizon. The strategic planning process will include discussions about space needed to accommodate new programs and the Capital Investment Fund (CIF).

Ruth Brinkley, M.S.N./Adm., said she was impressed by the training opportunities in the Clinical Center, and she spoke about how training is essential in a highly effective clinical environment. Dr. Gilman said that staffing will be covered in the strategic plan. Many long-term organizational leaders in the Clinical Center will have to be replaced in the next few years with pending retirements and reduced clinical activities. Questions to be answered include the following: What is an NIH-er? What should we look for in the next generation of NIH-ers?

Regarding census analysis, Richard Shannon, M.D., suggested looking at ADC statistics and clinical volumes as lagging indicators, but the number of protocols might be a leading indicator. Dr. Gilman said that the number of protocols remains around 1,600, although some protocols just involve data analysis, and some are just using outpatient clinics, rather than inpatient beds. Dr. Shannon said that protocol activity and numbers may be ways to stress-test the Clinical Center in terms of volume.

Dr. Shannon asked about the ability to shift staff from the inpatient side to the outpatient side if current trends persist. Dr. Gilman said that although ADC trends affect the nursing service more than any other entity, this service has shown that it has the capability and flexibility to respond.

Gwenyth R. Wallen, Ph.D., RN, the Chief Nurse Officer in the Clinical Center, reported on trends in the ADCs of various patient units and explained how some nurses can be detailed from one unit to another to fill needs.

Dr. Tuckson commented on implications of the shift toward outpatient research at the Clinical Center and suggested that changes in care during transition from inpatient to outpatient should be considered as co-variables in studies. Dr. Tuckson also remarked on the role of unstructured data in electronic medical records for use in research. He recommended that the strategic plan reflect the shift toward ambulatory care and the need to capture unstructured data for use in research. It is important to understand any co-variables that would affect the science.

2019 Capital Investment Fund (CIF) Approval Process

Dr. Gilman said that Pius Aiyelawo, M.P.A., FACHE, the Clinical Center's Chief Operating Officer, described the CIF approval process during the last CCRHB meeting. That process resulted in a priority list that was presented to the CCGB. For 2019, the IC directors on the CCGB wanted to see strategic investments as exemplified by a few major projects rather than many small projects. The resulting strategy for 2019 included upgrading and leveraging the network, upgrading capabilities for trans-NIH research efforts, and modest facility investments. Dr. Gilman presented the costs for eight projects for 2019, a total of $28.9 million. The separately listed "tail" cost for each project covers maintenance, service contracts, and supplies.

Three projects will be deferred until 2020: installation of new magnetic resonance imaging equipment in the operating room, installation of new Intravenous Admixture Unit (IVAU) equipment, and the final phase of the Department of Laboratory Medicine project.

Dr. Gilman also spoke about the need to develop telemedicine capability. Dr. Gilman said that the CCGB accepted the CIF proposal.

Discussion

Beatrice Bowie mentioned a recent article in *The New York Times* on gene therapy for sickle cell disease. She also reported that the new beds in the day hospital are a great improvement from a patient's standpoint.

Dr. Forese asked whether telemedicine will be included in the strategic planning process. Dr. Forese encouraged Dr. Gilman and other Clinical Center leaders to consider the potential impact of telehealth in their strategic planning. Some hospitals have become "technology companies that have beds." Telehealth capability can decrease the need for inpatient beds and maximize utility

of capital. Dr. Gilman said telemedicine has become more user-friendly and less idiosyncratic in recent years. Such technology would be especially helpful for pediatric patients and other patients and families who want to communicate with the Clinical Center staff. Dr. Forese said that once telemedicine is in place, more research could be done.

Dr. Tuckson agreed, saying that the setting of care has an impact on many future research studies. He referred to an article he wrote on telehealth for *The New England Journal of Medicine* and said that the lack of data to support telehealth applications is of concern. The Clinical Center would have the capacity to study telehealth and its applicability to research and health care to answer important questions.

Carolyn Clancy, M.D., said she would like to see the Clinical Center take a leading role in telehealth. In the area of precision oncology, many patients in remote locations could benefit from telemedicine.

John Gallin, M.D., said that NIH has explored telemedicine to some extent, and NCI made a major investment in technology. One challenge is color fidelity of transmitted images, such as photographs of skin or pathology slides. A good example of successful telemedicine is the National Institute of Allergy and Infectious Diseases (NIAID) research on Ebola virus and malaria that relies heavily on video- and teleconferencing.

Ms. Reel encouraged greater emphasis on developing telemedicine at the Clinical Center by investing in infrastructure and establishing a starting point. She said that telemedicine can involve a separate technology space, but existing technology can also be adapted for medical applications. She recommended embedding telemedicine in the network infrastructure and application space to serve patients where they are.

Follow-Up Item

- The CCRHB recommended incorporating telemedicine into the strategic plan and/or related CIF projects, and collecting data on the safety and effectiveness of telemedicine.

Clinical and Safety Performance Metrics: Executive Dashboard

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

Ms. Lee conducted a review of NIH performance metrics covering two calendar years, 2017 and 2018. Ms. Lee pointed out that the executive dashboard presenting clinical and safety performance metrics was included in the CCRHB's binders. She highlighted the results of the review for both inpatients and outpatients.

- **Patient perception:** On patient surveys, the Clinical Center scored well above the average in terms of overall hospital rating and in terms of patients' willingness to recommend the Clinical Center to others.
- **Infection control metrics:** Ms. Lee highlighted results on several fronts: hand hygiene, central line-associated bloodstream infections (CLABSIs), catheter-associated urinary tract infections (CAUTIs), and surgical site infections. Hand hygiene compliance

continues to improve. Three thousand staff members were trained to observe and report on compliance. The hospital-wide CLABSI rate had shown a consistent downward trend, but there was an uptick in the third quarter of 2018 involving six patients. In-depth analysis implicated factors such as line manipulation and multiple line accesses. No CLABSIs have occurred among patients in the intensive care unit (ICU) since the first quarter of 2018. The CAUTI rate in the ICU is below the national benchmark. In surgical oncology, the CAUTI rate has usually remained below the national benchmark, but there was a spike in the last half of 2018 due to a couple of patients who had complicated surgical courses.

- **Nursing quality metrics:** According to Ms. Lee, key metrics include falls, pressure injuries, and medication administration barcode use. The inpatient fall rate (both with and without injury) in the Clinical Center is below the national benchmark. Very few falls result in injury. The prevalence of pressure injury (all grades) remains above the national benchmark but has been trending downward since peaking in the first quarter of 2018. Ms. Lee hopes to reach the benchmark over the next couple of quarters. The Nursing Department has initiated an aggressive risk mitigation strategy for pressure injuries in the Clinical Center. In response to a question from Dr. Shannon, Dr. Wallen said that data are tracked on grade 3 and 4 pressure injuries as well as community-acquired pressure injuries versus those acquired during Clinical Center hospitalization. Dr. Wallen also said that a contractor has been hired to supplement the NIH Clinical Center's wound, ostomy, and continence nurse (WOCN). In addition, skin integrity competency is being added across all nursing units, including behavioral health. Dr. Gilman said that the Clinical Center inpatient population is younger than the national average; the patients seen here are not at high risk for pressure injury. For medication administration barcode use, the target is 100%, and the rate of use has remained at about 99%. Reasons cited for bypassing the scanning process include a compromised or damaged wristband and, in some instances, when special medicines are being administered

- **Emergency response**: Ms. Lee reminded the CCRHB that the Clinical Center does not have an emergency room; rather, the code team provides emergency care to staff and visitors as well as to inpatients and outpatients. The total number of code blue responses has ranged between 40 and 55 per quarter for the past 2 years. Rapid response teams address issues as patients decompensate. A team consists of critical care medicine fellows and nurses. Affected patients stay on the same unit most of the time, but they may also be transferred to another unit or the ICU. Ms. Lee said that sometimes staff are reluctant to call a rapid response because they think they can manage the situation. Ms. Lee said that only Clinical Center staff can request a rapid response, but Dr. Forese said that the current standard is to allow patients and family members to call for a rapid response. Dr. Shannon observed that the number of codes in the Clinical Center is about 1.5 times higher than the number of rapid responses. Most hospitals report about twice as many rapid responses as codes. Dr. Forese asked about the recent increase in patients transferred to another unit after a rapid response. Ms. Lee indicated that most of these patients were transferred to a telemetry unit for closer monitoring.

- **Blood and blood product use:** Ms. Lee presented data on crossmatch-to-transfusion (C/T) ratio, transfusion reactions, and unacceptable blood bank specimens (due to hemolysis or mislabeling). The Clinical Center goal is to have a C/T ratio of 2.0 to ensure that blood products are maximally available to all patients. Over the past two years, the C/T ratio has remained at or below 1.5. The rate of transfusion reactions is well below the national average. No anaphylactic reactions have occurred in years. Ms. Lee pointed out the downward trend in use of transfused blood is probably the result of a decrease in the number of transplants performed in the Clinical Center in the last two to three years and a reflection of national trends. The percentage of unacceptable blood bank specimens has remained below the target of 3% for the entire 2-year review period.
- **Employee safety:** Ms. Lee presented data on occupational injury and illness, and she mentioned efforts to reduce employee injuries by training staff on body mechanics and use of equipment. The total number of occupational injuries and illness ranges between 22 and 35 per quarter; the most common complaints relate to musculoskeletal injuries and wounds, mainly injuries with sharp medical devices.
- **Clinical documentation:** These data are assembled by health information management department. In terms of delinquent records, Ms. Lee said that the Clinical Center's records are delinquent (more than 30 days post-discharge) less than 10% of the time, well below the Joint Commission's 50% benchmark. Countersignature compliance remains between 90% and 95%. Abbreviation avoidance is successful about 95% of the time, and records are accurately coded about 90% of the time. Dr. Forese said that the goals for countersignature compliance, abbreviation avoidance, and accuracy of record coding should be 100%. Ms. Lee said that use of electronic health records has eliminated nearly all use of abbreviations, except when the system is down, requiring that people make manual notes. Dr. Shannon said that if 100% is achieved except during downtime, then that should be clarified in a footnote. Dr. Forese asked for data on unplanned downtime.

Future State

Ms. Lee spoke about reviewing the portfolio of metrics in 2019, and she asked the CCRHB members whether they would like to see any additional metrics. She plans to add medication management metrics and some outcome measures (e.g., sepsis mortality, cytokine release syndrome outcomes). In addition, public displays of clinical metrics are going to be posted on patient care units and in other public spaces to engage patients and staff. Right now, data on clinical metrics are available in binders.

Discussion

Dr. Shannon pointed out that in terms of patients' perceptions, only 10% of academic health centers score as highly as the Clinical Center, which "is outperforming even the best."

Dr. Forese remarked that seeing 2 years' worth of data allows the Board to see improvements and sustainability of metrics.

Dr. Gallin inquired about using data from Biomedical Translational Research Information System (BTRIS). Ms. Lee said that BTRIS will be used for such metrics as sepsis mortality.

Ms. Brinkley said that the Clinical Center is transforming into a culture of safety.

Dr. Shannon asked about the morale of Clinical Center staff. Ms. Lee said that people are seeking data during safety huddles. Nursing is using data to drive decision making.

Follow-Up Items

- For future presentations, the CCRHB asked Ms. Lee to present data on the rates of all inpatient falls, along with data categorized as (a) falls with injury and (b) falls without injury.
- For future presentations, the CCRHB asked Ms. Lee to present data on total prevalence of pressure injuries, as well as of grade 3/4 pressure injuries.
- The CCRHB recommended revising the procedures for rapid responses to allow family members or patients to call for a rapid response.
- The CCRHB would like more information about the trend over the past three quarters indicating that more patients are transferring to different units after a rapid response.
- For future presentations of data on transfusion reactions, the CCRHB asked that data on anaphylactic reactions be separate from data on "other" types of reactions.
- The CCRHB asked that goals for countersignature compliance and avoidance of abbreviations be set at 100%. For abbreviation data, a footnote should be added to clarify how much of noncompliance is attributable to unplanned system downtime.

Department of Pharmacy Updates and Future Developments

Majid Tanas, Pharm.D., M.H.A., M.S., Chief, Department of Pharmacy, NIH

Dr. Tanas said that the Clinical Center pharmacy is a unique entity with unique challenges. Every patient is involved in research, and nearly every treatment is individualized. How does the pharmacy overcome challenges and adhere to regulations while maintaining its commitment to safety and quality?

For every product and for every research protocol, the pharmacy staff consider whether the product is commercially available or whether it is to be provided under an investigational new drug (IND) application or manufactured by the pharmacy.

Drug fact sheets are provided to care providers on the floor. Principal investigators define the screens in the pharmacy's electronic health record system. The screens include safety parameters and guidance for product use in the Clinical Center. The information goes to the pharmacists who prepare and dispense the product, deliver it to the nursing station, and then undertake clinical review and monitoring of outcomes.

Dr. Tanas presented the organizational chart for the NIH Department of Pharmacy. The leadership team is second to none; many of the leaders were recruited from around the country.

A Shift in Course

The Pharmaceutical Development Section (PDS) shut down after a visit from the U.S. Food and Drug Administration (FDA) in May of 2015 because of its failure to keep up with regulations. Dr. Tanas came on board as the new chief in August 2016. For more than a year, pharmacy staff worked on remediating the PDS with input from FDA. Once the clean room was qualified, FDA

urged the pharmacy to move into the new facility with all speed. In April 2017, the new interim IVAU was opened.

Dr. Tanas said that the FDA team has been very helpful, especially in terms of informing pharmacy leaders about the future of pharmacy practice and compounding procedures in hospitals.

Closing the Gap Between Care Models

Dr. Tanas spoke about the need to close the gap between Current Good Manufacturing Practice (CGMP) regulations and patient care. The pharmacy needs to ensure sterility of products and withhold products until all boxes have been checked. Because each product is for caring for one patient, medications are usually used within 24 hours. This means that the pharmacy must produce on demand instead of batching, as is the practice in most hospitals.

Roadmap to Improved Care

Dr. Tanas introduced the four Ps: plant, process, personnel, and patient.

Starting with the **plant,** Dr. Tanas explained that the original PDS operated as an open-air clean room without positive pressure. Now the facility has made the transition to pharmaceutical-grade operations, using pass-throughs, aseptic processing areas, and careful monitoring. The processing area includes separate hazardous and nonhazardous preparation hoods. The blueprint of the pharmacy showed scrubbing areas and an immunotherapy room for preparing biologics and vaccines.

Dr. Tanas presented data on workload compared with capacity of the three hoods in the interim IVAU. Capacity is regularly exceeded between 7:00 a.m. and 10:00 a.m., resulting in delays. The pharmacy has been working with NCI and the day hospital to prepare medications earlier in the day to prevent backlogs. The interim IVAU cannot meet patient care demands; the expanded IVAU will be set up on the north side of the existing pharmacy space. Construction will begin in the fall of 2019. Plans for a permanent IVAU room are coming together. The permanent IVAU will make a total of 12 hoods available, and 60% of the floor plan will be dedicated to the clean room. (The current facility is 20% clean room.)

Dr. Tanas then focused on **process**. Pharmacy staff are solidifying processes and identifying areas for improvement. Several external audits have checked progress. Pharmacy staff established a quality management system and are moving from an oral to a written and an electronic culture.

The final step in improving patient care is **personnel.** Some vacancies remain because of staff departures. People are being asked to work with greater efficiency while embracing a culture of safety. The pharmacy is empowering staff to halt operations if problems arise. Previously, staff felt that they could not come forward about their concerns. Leaders now have open-door policies. FEVS scores have improved dramatically.

Other efforts are aimed at standardizing work to achieve safer and more reliable outcomes.

Dr. Tanas spoke about relationships between the pharmacy, investigators, and nurses as being the key to improving care for **patients.** The vision is to increase flexibility for researchers to interact

with the pharmacy while increasing the pharmacy's commitment to accountability and process improvement. The pharmacy is striving to become a high-reliability organization by trying to predict how failures might occur and then taking steps to prevent them.

In terms of accomplishments, Dr. Tanas reported that remediation of the 483 items originally flagged by the FDA has been completed. The pharmacy has also condensed the formulary resource from four databases to one that is available on a handheld device. Implementation of wireless infusion pumps allows use of Guardrails Medication Safety software to ensure proper dosing. To enhance safety, automated medication dispensing cabinets are going to be rolled out in the operating room and patient care areas. Other accomplishments include:

- Establishment of a medication safety committee
- A Joint Commission survey with no findings
- Proposals for eight major system installation/upgrades
- Publication of 18 journal publications and 13 abstracts in a single year

Dr. Tanas spoke of an increased emphasis on automation as a way to improve safety.

At the direction of FDA, the pharmacy is working toward a higher level of care. Aseptic areas are expanding to meet patient care demands and new standards for hazardous medications. A rigorous cleaning schedule is better maintaining the pharmacy facility. Efforts are also ongoing to help educate patients about their medications.

Medication Safety Trends

Dachelle Johnson, Pharm.D., BCPS, Medication Safety Officer, Clinical Center, NIH

Dr. Johnson spoke about the dual challenge of meeting clinically significant needs with customized medicines while increasing standardization. Despite these challenges, the pharmacy is continuing to establish controls within the system to manage the safety portfolio of the Clinical Center's medication use process.

Institute for Safe Medication Practices (ISMP) Visit in 2018

The ISMP performed a review of medication use in the Clinical Center and provided the pharmacy with a comprehensive report on risks and recommendations to mitigate those risks. The report was reviewed with Clinical Center departmental leadership, which then identified project leads to deal with the observations from the report.

Major themes in the report dealt with fostering a culture of safety; educating staff using more simulations and observation, especially for error-prone procedures; improving drug storage, stock, standardization, and distribution; and increasing automation to reduce reliance on manual processes and to verify physician orders.

Dispensing Error Trends

Dr. Johnson presented data on dispensing errors, noting that they spiked in mid-2017, mostly due to look-alike and sound-alike errors. This is a particular challenge in the Clinical Center, because IND drugs have numbers, not names. Barcode technology is helping to reduce errors.

During the first quarter of FY 2019, 205 medication-related events occurred. In some cases, medications were unavailable or delayed. Administration errors are sometimes user errors with patient-controlled pain medications. With regard to prescribing/ordering errors, the dosing regimen may not match what was prescribed. Storage issues include temperature excursions. For the monitoring error category, monitoring might not have been done per protocol. Dr. Johnson also discussed 130 pharmacy-related events during the quarter, including delays, labeling issues, delivery problems, and barcoding problems. Capacity challenges and staffing issues continue to cause bottlenecks in the intravenous drug area. Most hospitals can avoid this problem because they can batch and store IV drugs on the units.

Central pharmacy issues include delays, incorrect diluents, cart exchanges, and timing and volume of nonsterile compounding. The sooner the pharmacy can start using more automated dispensing cabinets, the sooner the number of dispensing errors is likely to decline. Some events were related to informatics issues (e.g., barcoding).

On the outpatient side, events included shipping problems, failure to verify orders, and lack of orders. To overcome drug shipment problems, the pharmacy is increasing its use of FedEx.

Dr. Johnson also discussed knowledge-based medication administration. If a nurse has trouble with a medication on the unit, the pharmacy is notified to help with troubleshooting to improve patient safety and reduce the chance of medication error.

Discussion

Dr. Shannon spoke of the many chances for error in product preparation and administration because each Clinical Center's patient regimen is unique. He said that Dr. Tanas has a good command of potential sources of error, including human error and systems factors.

Dr. Shannon also asked whether the ADC is likely to rise as pharmacy capacity increases. Dr. Gilman said he was not sure whether pharmacy issues have affected ADC, because the pharmacy has been able to keep up with demand for products even as work is proceeding in a suboptimal facility. The expanded IVAU should be ready in a year.

Follow-Up Item

- The Board asked Dr. Tanas to develop a dashboard focusing on a few metrics tagged with red, yellow, and green status indicators. The dashboard should be presented at a meeting in 2020 to help inform the CCRHB about progress.

Sepsis Mortality at the NIH Clinical Center

Naomi O'Grady M.D., Chief, Internal Medicine Service, and Attending Staff, Critical Care Medicine, Clinical Center, NIH; Tara Palmore, M.D., Hospital Epidemiologist, Clinical Center, NIH

Dr. O'Grady defined sepsis and explained that the 30-day mortality rate ranges from 35% to 50% in the literature. She described the signs and symptoms of severe sepsis. Hypotension leads to reduced organ perfusion, elevated lactate, acute lung injury, kidney injury, shocked liver, and thrombocytopenia. Globally, sepsis is the most common cause of death in people who have been hospitalized.

Dr. Palmore explained that cytokine release syndrome can mimic sepsis. CRS is a known side effect of CAR (chimeric antigen receptor) T-cell therapy, which is now an FDA-approved immunotherapy. When the body's immune response is extremely vigorous, cytokine release can be overwhelming, resulting in high fever and hypotension.

During a previous meeting, the CCRHB had asked about the 30-day crude mortality rate for severe sepsis in the NIH Clinical Center. Dr. O'Grady said that, using BTRIS as a data source and using vasopressor requirement as a surrogate marker for severe hypotension, she and Dr. Palmore determined that 21 cases of severe sepsis occurred in 2018, resulting in a 23% all-cause 30-day mortality rate. Dr. O'Grady reviewed the five cases that resulted in death. All had significant comorbidities: Four had lymphoma or metastatic cancer, and one had HIV/AIDS and AIDS-related malignancies.

Dr. Palmore presented data on CRS. At the Clinical Center, no CRS was observed in 2018 until July, when there was one case, followed by one case per month for the next four months, for a total of five cases in 2018. None of these cases were fatal. The specific treatment is tocilizumab, which blocks IL-6, a cytokine that is abundant in CRS. Dr. Palmore thought it likely that the number of cases of CRS would increase as use of cell therapy expands; however, the mortality rate associated with sepsis in the Clinical Center is lower than rates published in the literature. The ICU is skilled at handling CRS and sepsis.

Discussion

Dr. Forese thanked the presenters for the data. She appreciated the point about distinguishing between sepsis and CRS.

Dr. Shannon said that sepsis rates in the Clinical Center approach the level of best in class. He suggested that the Clinical Center could be a leader in sharing information about CRS as more patients are exposed to cell-based therapies. Data on clinical outcomes from the Clinical Center can establish it as a home for expertise with these novel cell-based therapies.

Dr. Shannon asked to see data on *Clostridium difficile* infections and their complications. Dr. Palmore said that the Clinical Center has few cases of complicated *C. difficile* infection.

The Board observed that the focus of CCRHB meetings appears to be moving beyond process measures toward clinical outcomes. Dr. Shannon suggested "weaving a narrative that takes us away from the Red Team report and more toward a shining star."

Follow-Up Items

- The CCRHB asked that data on *C. difficile* incidence and complications related to *C. difficile* be presented during a future meeting to the CCRHB.
- The Board asked that the NIH staff think about other areas where the Clinical Center has developed a specialized focus and share information about these during future meetings. The CCRHB would also appreciate learning about areas where challenges exist.

The Impact of Artificial Intelligence on Radiology

Ronald M. Summers, M.D., Ph.D., Senior Investigator, Imaging Biomarkers and Computer-Aided Diagnosis Laboratory, Radiology and Imaging Sciences, Clinical Center, NIH

Dr. Summers defined artificial intelligence (AI) and explained that in medical imaging, AI can be applied for diagnosis, prediction, opportunistic screening, quantitation, and treatment planning.

According to Dr. Summers, a series of computer science developments has allowed development of deep neural networks for solving difficult problems such as object recognition in natural-world images. Also, graphic processing units can accelerate deep neural network training. This ability carries over to clinical image analysis. With machine learning or AI tools, data from images can be converted into predictions. After realizing the great potential of AI, Dr. Summers started a team for applying the technology on radiology images. Deep learning can detect pathological conditions, such as osteoporosis, prostate cancer, and colitis; a deep learning system for detecting colitis achieved 94% sensitivity and 95% specificity—similar to physician-level performance. It is also being used for organ segmentation (delineation of organs or organ segments in three dimensions). AI can also model and predict tumor growth.

Dr. Summers explained that deep learning algorithms are "hungry" for data, so, with IRB approval, NIH is contributing data sets to the community.

Dr. Summers provided an example showing how a computed tomography dataset was used to develop a system for pancreas segmentation. This was a noteworthy accomplishment because the pancreas is challenging to measure. A different deep learning technique is capable of complete segmentation of the lungs. Moreover, a deep learning system is capable of detection and segmentation of atherosclerosis, yielding a system for whole-body calcium scoring.

A deep learning system for detecting prostate cancer was able to detect some tumors that were missed by human observers. For interstitial lung diseases, an AI approach was used for label propagation for disease patterns in lungs, enabling Clinical Center clinicians to conduct accurate quantitative assessments of these diseases.

Dr. Summers described how AI can be used for opportunistic screening when a scan is performed for another purpose. For example, large populations can be screened for obesity using scans done to diagnose some other condition.

In conclusion, Dr. Summers said that the Clinical Center is a leader in AI in medical imaging. The AI community appreciates the Clinical Center's contributions, particularly its large publicly available datasets, which are propelling the field forward.

Discussion

In response to a question from Dr. Forese about what is next in this field, Dr. Summers spoke about ongoing work to integrate imaging data and nonimaging data, such as from clinical reports, genomic analysis, and laboratory data. BTRIS is an enabling technology that allows data amalgamation from diverse sources.

Dr. Shannon said that it would be interesting to think in terms of cost-effectiveness, such as screening smokers and then coming up with incidental findings. Dr. Summers said that the challenge of incidental findings is an important issue. The radiology community is developing guidelines on handling of incidental findings, such as lung nodules and ground glass opacities. Right now, the field is relying largely on expert opinion about reporting of incidental findings.

Ms. Reel spoke of collaboration and growth of datasets, but reliance on different tools and approaches is creating barriers to data sharing.

Dr. Summers said that greater access to genomic data could lead to discoveries. The AI field is characterized by its openness; much of the software is open-access. He also spoke about the need to attract more data scientists to NIH. A special interest group has set up hackathons to attract more interest from data scientists. Dr. Gallin agreed that data dissemination is a ubiquitous challenge; Dr. Summers has figured out how to share data and let the world work with the data.

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 eleventh meeting of the CCRHB by thanking the presenters and the CCRHB members for their insights and thoughtful input. The presentations gave the Board a sense of meaningful progress with Clinical Center facilities and the strategic planning process.

The next face-to-face CCRHB meeting is scheduled for April 12, 2019.

Dr. Forese adjourned the meeting at 1:13 p.m.

/ Laura Forese /

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

Chair, NIH Clinical Center Research Hospital Board

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

/ Lawrence A. Tabak /

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/ Francis S. Collins /

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

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

ADC	average daily census
AI	artificial intelligence
BTRIS	Biomedical Translational Research Information System
CAR	chimeric antigen receptor
CAUTI	catheter-associated urinary tract infection
CCGB	Clinical Center Governing Board
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CGMP	Current Good Manufacturing Practice
CIF	Capital Investment Fund
CLABSI	central line–associated bloodstream infection
CRS	cytokine release syndrome
C/T	crossmatch-to-transfusion [ratio]
FDA	U.S. Food and Drug Administration
FEVS	Federal Employee Viewpoint Survey (FEVS)

FY	fiscal year
ICs	Institutes and Centers
ICU	intensive care unit
IND	investigational new drug [application]
IRB	institutional review board
ISMP	Institute for Safe Medication Practices
IVAU	Intravenous Admixture Unit
MEC	Medical Executive Committee
NCATS	National Center for Advancing Translational Sciences
NCCIH	National Center for Complementary and Integrative Health
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIH	National Institutes of Health
NINDS	National Institute of Neurological Diseases and Stroke
NINR	National Institute of Nursing Research

PDS	Pharmaceutical Development Service
WOCN	wound, ostomy, and continence nurse