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Twelfth Meeting of the Clinical Center Research Hospital Board

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Clinical Center Research Hospital Board

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Stephanie Reel, M.B.A., Chief Information Officer, Johns Hopkins University and Health System

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Executive Summary

The 12th meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on April 12, 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.

Francis Collins, M.D., Ph.D., NIH Director, greeted the CCRHB members and highlighted several leadership changes, including the departure of National Cancer Institute (NCI) Director Norman Sharpless, M.D., who was tapped to become Acting Commissioner of the Food and Drug Administration. Douglas Lowy, M.D., is stepping in as Acting Director of NCI and also Acting Chair of the Clinical Center Governing Board. Dr. Collins also presented a clip from a CBS *60 Minutes* segment on gene therapy for sickle cell disease.

James Gilman, M.D., Clinical Center Chief Executive Officer, updated the Board on the hospital's average daily census, which remains somewhat below the 3-year average. He announced that the first cohort of 16 participants completed the six-session leadership course for nonphysicians. Dr. Gilman also highlighted progress with the strategic plan, various external reviews of the Clinical Center's information technology systems, a recent meeting with Institute leaders for the purpose of Clinical Center planning, Rare Disease Day, and the Clinical Center's anti-harassment campaign.

Dr. Gilman also provided details about a March 2019 steam pipe failure that resulted in a 2-day closure of the operating room and the loss of many medical supplies. He explained steps being taken to mitigate the risk of such events in the future.

Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality, briefed the CCRHB on patient safety data requested during the last meeting. She also presented data on clinical outcomes, including complicated *Clostridium difficile* infections and blood glucose control among Clinical Center inpatients.

Jose Galvez, M.D., Chief, Office of Biomedical Translational Research Informatics, presented information on the Biomedical Translational Research Information System (BTRIS), outlining the types of data housed in BTRIS and highlighting the system's capabilities. Because not all Institutes and Centers deposit their research data in BTRIS, an NIH-wide policy is needed to ensure that research participants' data are used to the maximum extent. In response, the CCRHB issued a resolution to support such a policy.

For the surgical services update, Andrew Mannes, M.D., M.E., M.B.A., Chief, Clinical Center Department of Perioperative Medicine, presented data on the main operating room activities and demographic data. Over the past decade, there has been a slight upward trend in numbers of surgical cases. Demographic data indicate that the NIH surgical population tends to be younger and sicker than the general surgical population and more likely to be inpatients than outpatients—a reflection of the Clinical Center being a research hospital.

Jeremy Davis, M.D., FACS, Clinical Center Surgeon-in-Chief, Staff Clinician, NCI, Surgical Oncology Program, advised the CCRHB on surgical quality initiatives of the Surgical Administrative Committee. The Surgical Outcomes Data Project is nearly completed, with phased implementation set to begin this summer. The surgical complications database can reveal

how patients are faring under a given service or be used to examine specific surgeons' performance.

The meeting concluded with a presentation by Nilka Schulman, M.S.N., Post-Anesthesia Care Unit Nurse Manager, Clinical Center Nursing Department, Nursing Operations. She explained how the shared governance model was used to create a collaborative decision-making model for optimizing data use, increasing standardization, and improving the patient experience. Results included the installation of real-time tracking boards in strategic areas throughout the Department of Perioperative Medicine and the integration of the tracking system with a database to analyze and visualize data on surgical cases.

Dr. Forese thanked the Board members for attending and sharing their insights. She adjourned the meeting at 2:16 p.m.

The next face-to-face CCRHB meeting is scheduled for July 19, 2019.

Meeting Summary
Friday, April 12, 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 12th meeting of the CCRHB took place on April 12, 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. ET and welcomed all present.

NIH Director's Remarks

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

Dr. Collins introduced Douglas Lowy, M.D., Acting Director of the National Cancer Institute. Norman (Ned) Sharpless, M.D., the former NCI Director, was tapped to become the Acting Commissioner of the U.S. Food and Drug Administration (FDA). Dr. Collins said that Dr. Lowy is an accomplished scientist, having led the effort to develop preventive vaccines for human papillomavirus, as well as the Cancer Moonshot. Dr. Lowy is also taking on the role of Chair the Clinical Center Governing Board (CCGB), which interacts closely with the CCRHB.

Dr. Collins commented on two major congressional hearings that occurred over the past 10 days regarding the fiscal year 2020 budget. For the past 4 years, with bipartisan and bicameral support, the NIH budget has increased by 30%, representing a $9 billion increase. The current budget is $39 billion. According to Dr. Collins, Congress has signaled its intention to support steady, predictable growth of NIH in the future. Dr. Collins expressed his gratitude to the appropriators for recognizing the importance of having a financial trajectory to support thoughtful planning.

Dr. Collins noted, however, that it is not clear what will happen with the 2020 budget, nor is there a solution for the sequestration threat. Stringent budget caps might remain in place for some years to come.

At both hearings, Dr. Collins had a few minutes to present the stories of three individuals who have participated in clinical trials at the Clinical Center. Dr. Collins also ran a short clip from the *60 Minutes* program on sickle cell advances made possible by NIH research.

Dr. Collins closed by saying, "We are in an exciting place scientifically. We are on the edge of what is possible. Not all our stories have happy endings, but the sense of promise, excitement, and high morale is tangible. It is a privilege to be part of this noble enterprise."

Introduction of Douglas R. Lowy, M.D.

Dr. Lowy greeted the Board members and acknowledged that serving as Acting Chair of the CCGB is a big job. He previously served as the Acting Chair for 2½ years. Trained in internal medicine and dermatology, Dr. Lowy has admitting privileges at the Clinical Center. He is aware not only of the amazing research carried out in the Clinical Center but also of the challenges with patient and employee safety, infrastructure, and more.

Dr. Lowy said that he welcomes the opportunity to work with Dr. Gilman and with the CCRHB. He thanked Dr. Collins and Lawrence Tabak, D.D.S., Ph.D., for their strong commitment, support, and follow-through. Dr. Lowy noted that he had served on the search committee that selected Dr. Gilman for the position of hospital chief executive officer (CEO).

In conclusion, Dr. Lowy thanked the CCRHB for its good work. He plans to complement and reinforce what the board is doing.

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.

Hospital Census

Dr. Gilman presented hospital census data as of March 31, 2019. The average daily census (ADC) in March 2019 was above the ADC in March 2018, but this statistic still remains below the 3-year average. Dr. Gilman reported that frank discussions are occurring among the clinical and scientific directors about clinical research and execution. Clinical Center utilization will be a topic included in the strategic plan, which will likely be presented to the CCRHB during its July meeting.

Leadership Changes

In addition to the departure of Dr. Sharpless, the appointment of Dr. Lowy as Acting Director of NCI, Dr. Gilman announced that Colleen McGowan, Clinical Center Executive Officer, has left that post to become to the Director of the NIH Office of Research Services. Eric Cole, M.S., FACHE, is the acting Clinical Center Executive Officer. Dr. Gilman explained that the main functions of the Clinical Center Executive Officer involve hospital administration, workforce management, and materials management; this position does not deal with financial matters. A search is underway for a replacement for Ms. McGowan.

First Graduates of Clinical Center (CC) Leadership Training Course

Sixteen individuals completed a new course put on by the CC Office of Workforce Management and Development between January and March 2019. The course, entitled "Clinical Center Fundamentals in Leadership Training," focuses on leadership rather than supervision of government employees. The program is designed to support ongoing leadership development, deepen individual capacity, and strengthen a collective leadership culture in the Clinical Center. Class size is limited to 20. There will be a call for nominations for upcoming cohorts soon.

The graduates are now connected via an email distribution list, and they were provided with a reading list to continue their professional development.

External Reviews

Dr. Gilman reported on several external reviews of information technology (IT) systems in the Clinical Center:

- The Department of Homeland Security (DHS) conducted high-value asset review focusing on the Clinical Research Information System (CRIS) only. DHS will present its draft review on April 15 followed by the final report in May.

- An audit by the Office of the Inspector General also focused on CRIS. The initial technical reviews were completed, and documentation requests were submitted to the NIH Office of the Chief Information Officer.
- An audit by the Government Accounting Office covered all of NIH. The Office is now initiating documentation requests.

The FDA carried out an unannounced review of the Clinical Center Pharmacy in February and March 2019 and made 7 observations. Dr. Gilman remarked that the prior FDA review, in May and June of 2015, led to 17 observations of a serious nature and a suspension of sterile activities in the Pharmaceutical Development Section (PDS).

Dr. Gilman said that the seven observations have been posted on the Clinical Center website:

- Aseptic manipulations are performed in an area where the unidirectional movement of air in the ISO 5 area is disrupted.
- Deficiencies were noted with aseptic processing performed within the ISO 5 areas.
- Cleaning pads used in the ISO 5 classified aseptic processing areas were not sterile.
- Media fills that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations were not performed.
- The facility design allowed the influx of poor-quality air into a higher classified area.
- The material of construction of the clean room walls is not suitable for the intended use.
- The facility was designed and/or operated in a way that permits poor flow of personnel.

Dr. Gilman reported that the CCRHB, as well as all pharmacy staff, was notified of the observations on March 22. An email message was sent to all Clinical Center staff emphasizing progress achieved since 2015.

Strategic Planning

Dr. Gilman said that Clinical Center planning meetings are being transformed into a cross-Institute effort with all Institutes and centers (ICs) assembled at one meeting, rather than individual meetings with each institute. The first meeting in this new format brought together more than 50 IC and Clinical Center leaders, who reviewed Clinical Center priorities, the status of the capital investment fund, protocol and census data, and activity in the Center for Cellular Engineering. The planning meeting underscored the importance of patient safety and clinical quality, the need to get the new Surgery, Radiology and Laboratory Medicine (SRLM) building started, and the need to increase utilization of the Clinical Center.

Other Activities and Initiatives

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

- **Clinical Center strategic plan preview:** Dr. Gilman hopes to present the Strategic Plan to the CCRHB in July, with the goal of completing the plan this year.
- **Campus security:** Dr. Gilman spoke about security provisions at the main NIH campus, including fences, guards, and the NIH Police Department. Risk is mitigated by not having an emergency department, but the campus is pretty desolate after hours.
- **Anti-harassment update:** Dr. Gilman spoke of efforts to curtail harassment in the clinical environment. A multidisciplinary effort is underway focused on inappropriate behavior and harassment of staff by patients and visitors. Since Ms. McGowan's

departure, CAPT Antoinette L. Jones, M.S.O.D., RN, the Clinical Center's Patient Representative, will lead the anti-harassment campaign. Training on evaluation of complaints is available. Dr. Gilman recommends that a plan be developed to deal with problems, based on frequency and severity.

- **Rare Disease Day:** The Clinical Centers partners with the National Center for Advancing Translational Sciences each year for NIH Rare Disease Day to promote awareness about rare diseases and to honor patients who have rare diseases.[1] On February 28, 2018, in commemoration of this international celebration, the Empire State Building was lit up in Rare Disease Day–themed colors. The Office of Patient Recruitment was highlighted at the NIH event.
- **Feature media story:** On March 10, 2019, the CBS television program *60 Minutes* ran a segment on the successful treatment of sickle cell disease with gene therapy.
- ***First in Human* mural:** A large, eye-catching mural was installed in the Clinical Center. It depicts researchers, patients, and actor Jim Parsons, all of whom were featured in the documentary produced by Discovery Communications.

Discussion

Dr. Forese asked about the follow-up plan for the FDA inspection and whether this would be considered an interim inspection. Dr. Gilman said that the FDA can conduct an inspection at any time. NIH staff had 15 working days to write a response to the FDA's observations, as well as other items that did not rise to the level of observations. The response has already been submitted and under review by the FDA now.

With regard to the DHS IT review, Reed Tuckson, M.D., remarked that one challenge with the *All of Us* Research Program has been the public's concern about privacy of information. The DHS review should allay some concerns about data privacy.

Dr. Tuckson asked about the morale of Clinical Center employees. Dr. Gilman said that the responses to the Federal Employee Viewpoint Survey (FEVS) have been trending upward since 2016. He said that the 2019 FEVS will start in May. The Clinical Center typically scores slightly lower than the NIH average, but it has made gains over the past 2 years.

Dr. Tuckson asked whether the clinicians think that they are receiving good support from the Clinical Center for their research. Dr. Gilman said that the clinicians believe that their patients are getting good and safe care. It is the nature of researchers to push the science and safety envelope. For example, there is interest in admitting younger children to the Clinical Center, and NIH leadership is seriously evaluating whether to include them in research safely. Clinical researchers also understand that pharmacy care is much better, despite the current constraints of the interim facility. Nevertheless, many researchers would like to see the PDS return.

Brig Gen James Burks, FACHE, asked about the severity and prevalence of the FDA's observations. Dr. Gilman said that he considered the observations to be low-risk, minor problems.

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[1] In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. This definition was created by Congress in the Orphan Drug Act of 1983. Other countries have their own official definitions of a rare disease. In the European Union, a disease is deemed rare when it affects fewer than 1 in 2,000 people. There may be as many as 7,000 rare diseases. The total number of Americans living with a rare disease is estimated to be between 25 million and 30 million. (Genetic and Rare Diseases Information Center, National Center for Advancing Translational Sciences, NIH)

Brig Gen Burks asked about a similar course for physician leadership development. Dr. Gilman said that all too often, having physicians in the room can inhibit open discussions. For the first course, the focus was on non-physicians. There will be a course for physicians in the future, but the course will be adapted accordingly.

Steam Pipe Incident

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

Dr. Gilman reported on a steam pipe failure that occurred on March 11, 2019, in the Ambulatory Care Research Facility.

The Event

A steam pipe in a utility tunnel in the basement of the Clinical Center burst, resulting in a loss of steam and hot water. The outside temperatures were mild, so it was not necessary to interrupt operations in the clinics on the first day. Surgeries had to be halted for 2 days due to sterilization limitations. NIH worked with the staff of Walter Reed National Military Medical Center to transport equipment back and forth for sterilization. After the second day, operations returned to normal for the most part, although the clinics had to be displaced that day.

Because the steam leak could not be isolated for several hours, steam rose and condensed, and nearly all the items stored in the medical warehouse were ruined by the moisture. Dr. Gilman estimated that between $1.5 million and $2.0 million in supplies were lost due to the incident. In addition, areas of ceilings in the affected areas were damaged. The offices for the Materials Management and Environmental Services Department (MMESD) had to be closed and relocated. Automated systems had to be manualized for all supplies.

The failure occurred in a gasket at a flange in a steam pipe. The steam had to be turned off to let everything cool down. Even after the flange was fixed, new leaks developed due to cooling and reheating.

Dr. Gilman praised the work of the MMESD staff, who did a heroic job. Surgical procedures had to be postponed but not cancelled, and no patients had to be transferred.

In terms of lessons learned, Dr. Gilman said that the new SRLM will be much more robust, with greater redundancy of steam provision. Had it been in place, surgeries likely would not have been cancelled, although the loss of supplies would not have been prevented. Clinical Center leaders are reevaluating how many supplies are on site at any one time. From here on, supplies will be staged in an NIH-controlled warehouse in Gaithersburg, Maryland.

Dr. Gilman also reported on two more water leaks this week, including one affecting the cell processing facility, which will have to be shut down for a couple of weeks. The second incident involved a mishap caused by a contractor working in an area under renovation.

Discussion

The CCRHB extended its gratitude to the MMESD team.

Carolyn Clancy, M.D., inquired whether the Clinical Center has sufficient staff in place at night to detect problems. Dr. Gilman said that the steam leak was detected quickly; isolating it was the challenge.

Dr. Tuckson asked whether the Clinical Center has a special capital budget for government building infrastructure so that operational funds do not have to be used. Dr. Gilman said that the backlog of maintenance and repair on the campus is enormous. Additional funds for constructing new NIH buildings are needed. He mentioned plans to seek funds for a new CC wing in 2020 to avoid impacts on the operating budget. The National Academies of Sciences, Engineering, and Medicine has been studying infrastructure on NIH's Bethesda campus. The report is expected soon; it will likely support the construction of a new wing, a new animal facility, and some infrastructure. Dr. Collins discussed a strategy to attract support from Congress, although members of Congress are less excited about bricks and mortar than about a cure for cancer. The backlog to maintain and repair NIH facilities is about $1 billion. Dr. Collins said he has discussed the need for a new wing with congressional supporters.

Follow-Up Item

- The CCRHB recommended convening the next meeting in the Clinical Center and including a 1-hour tour.

Patient Safety and Clinical Quality Update and Clinical Performance Metrics Report

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

Ms. Lee recalled the recommendations that the Board issued during its last meeting regarding data that it would like to review on patient safety, including inpatient falls with or without injury, prevalence of pressure injuries, unit transfers after a rapid response, countersignature compliance, and anaphylactic transfusion reactions. The CCRHB had also recommended that the Clinical Center allow patients or family members to call for rapid responses. Ms. Lee read the existing policy and responded that key stakeholders have discussed the logistics of making this change. She thought that the change would be implemented by the next CCRHB meeting.

Process-Related Metrics

Ms. Lee updated the Board on various performance metrics:

- Hand hygiene compliance is holding steady at 85% to 90%. In 2017, compliance hovered around 60%.
- The quarterly rate of inpatient falls in the Clinical Center has been in the range of 1.0 to 1.5 per 1,000 patient days; the rate of falls with injuries is about 0.1 per 1,000 patient days. The National Database of Nursing Quality Indicators (NDNQI) benchmark is about 2.5.
- The quarterly prevalence rate for pressure injuries in the Clinical Center has been steadily declining; no stage 3 or 4 pressure injuries have occurred.
- Mediation administration barcode use is steady, around 99%. Noncompliance events have been due to damaged wristbands and the lack of barcodes on some investigational medications.

Ms. Lee said that because of the Clinical Center's population and the nature of protocol-driven care, few outcome metrics apply. However, some data on *Clostridium difficile* infections and on blood glucose control have been assembled.

Clostridium difficile *Infections*

Tara Palmore, M.D., Hospital Epidemiologist for the Clinical Center, developed data on *C. difficile* infections. From January 2017 through April 2019, one complicated *C. difficile* infection occurred. The patient had metastatic cancer and was admitted to the intensive care unit (ICU) with bleeding from duodenal ulcers, pneumonia, and fulminant *C. difficile* with ileus. *C. difficile* responded to aggressive medical management, but the patient did not recover from multiorgan failure and transitioned to comfort care.

Four patients with recurrent or refractory *C. difficile* injection underwent fecal microbiota transplantation. All four responded.

Dr. Palmore said that the Clinical Center has a younger patient population; most complex cases of *C. difficile* occur among the elderly. Ms. Lee added that the housekeeping and nursing services deserve praise for their infection control efforts.

Inpatient Diabetes Program

Based on discussions with Dr Gilman and other NIH CC leadership, blood glucose management was identified as the next critical clinical outcome to track organizationally. According to Ms. Lee, the goals of the inpatient glucose management program are twofold:

1. Provide rational, safe, and high-quality care to inpatients who have diabetes mellitus.
2. Provide comprehensive training in diabetes care to endocrinology fellows.

A well-rounded glucose management program rests on four pillars: a clinical team, a hyperglycemia committee, administrative support, and organizational priority. Generating inpatient glucometrics data starts with point-of-care (POC) testing, POC data transfer to CRIS, transfer of data to the Biomedical Translational Research Information System (BTRIS), and the generation of glucometrics reports.

Glucometrics domains include glycemic exposure, efficacy of control, and adverse events. Ms. Lee defined the "patient day" and "patient stay" metrics. For 2018, nearly 13,000 data points were generated. Glucometrics data based on patient day in the Clinical Center indicated a median glucose level of 140 mg/dL and a mean of 152 mg/dL. The benchmark is "top quartile < 156 mg/dL." For patient stay, the median was 130 mg/dL and the mean was 142 mg/dL. The benchmark is "top decile < 146 mg/dL." Ms. Lee said that no benchmarks were available for some data points, because the Clinical Center does not yet belong to the body that produces the benchmarks.

Ranganath Muniyappa, M.D., Ph.D., of the National Institute of Diabetes and Digestive and Kidney Diseases, clarified that the tests are random from any point of care. In response to a question from Ellen Berty, Dr. Muniyappa explained that the data were from any patient who had an inpatient stay in the Clinical Center. He added that BTRIS could be used to see what treatments the patients were on.

Ms. Lee reported that 66% of the POC patient samples were within the target range of 70 to 180 mg/dL. A total of 5.5% of patient samples were in the hyperglycemic range (> 300 mg/dL). About 3.4% of patient samples were in the hypoglycemic range (< 70 mg/dL).

Ms. Lee presented data on glycemic exposure by patient care unit, as well as adverse event rates. A scatter diagram helps identify units that may need more focus on glycemic control. Ms. Lee

clarified that data from the ICU were not included in the analysis, because ICU targets are unique.

Ms. Lee said that the hope is to expand use of glucometrics to conduct unit-specific and data-informed staff education, implement an active surveillance program, work with investigators to identify high-risk protocols, set up triggers in CRIS to mitigate any lapses in care, and standardize glycemic management order sets.

Discussion

Richard Shannon, M.D., said that, population aside, *C. difficile* infection is at the interface of appropriate testing, antibiotic stewardship, and the environment. He said that it is a very compelling outcome that the Clinical Center is managing all three factors very effectively. Dr. Shannon suggested not minimizing this outcome in an immunocompromised population that is using broad-spectrum antibiotics.

To reduce the incidence of pressure injuries, Gwyneth Wallen, Ph.D., RN, Chief Nurse Officer at the Clinical Center, said that pressure injury prevention was instituted as a competency across all clinical areas. Originally, the focus was only on high-risk areas; however, additional resources have been allocated to expand the program's scope. Plans are being readied to implement an evidence-based project in the ICU, because vasopressors put patients at higher risk.

Regarding the data on inpatient falls, Dr. Gilman said that the Clinical Center does not have any active Alzheimer's disease or dementia inpatient protocols. The intramural research program of the National Institute on Aging is in Baltimore. Some patients in the neurology unit of the Clinical Center are at high risk for falls, however. Dr. Gilman noted that Congress has provided funds for Alzheimer's disease and dementia research for the Bethesda campus, so a clinical program will be established. Dr. Gilman anticipates that some research participants might be inpatients, but most would be outpatients, since intervention needs to occur early in the disease. He also pointed out that informed consent is a challenge with cognitively impaired populations.

Dr. Gilman said that the patient population in the Clinical Center does not include very elderly people. Falls are most prevalent in the "fiercely independent population," who are reluctant to summon help when arising from a bed or chair.

Regarding the glucometrics program, Dr. Tuckson asked whether this line of research will find its way into the health services literature. He thought that the data could be useful to the clinical care community. Dr. Muniyappa plans to publish the findings.

Dr. Shannon asked about zeroing in on some populations, such as ICU patients and patients who are frankly diabetic. With these datasets, it might be possible to identify best practices to drive outcomes (e.g., management of excursions in glucose levels). Having the ability to do this type of research and show that the Clinical Center is best in its class would be very important. Ms. Lee said that she plans to look at various populations in the Clinical Center, and another goal is to investigate anticoagulation.

John I. Gallin, M.D., NIH Associate Director for Clinical Research and Chief Scientific Officer of the Clinical Center, asked about the frequency of glucose testing in patient care units. Dr. Muniyappa replied that testing is done much more frequently in some units, especially infectious disease units and areas where patients with Cushing syndrome receive care. The dataset based on random POC tests is complex but can facilitate analysis. Dr. Forese said that the data are not truly random; it is just a collection of data points, but the dataset gives important information.

Dr. Forese remarked on the power of being able to pull data from BTRIS. She thanked Ms. Lee for implementing the Board's recommendations so quickly and pulling together some compelling data.

Biomedical Translational Research Information System

Jose Galvez, M.D., Chief, Office of Biomedical Translational Research Informatics

Dr. Galvez said that the BTRIS is an enabling platform for research and patient care, accessible to the NIH intramural community. It brings together clinical research data from the Clinical Center and other NIH ICs. BTRIS gives clinical investigators access to identifiable data for subjects on their own active protocols, while providing all NIH investigators access to data without personal identifiers across all protocols. Data are available from 1976 to the present.

Nearly 40% of active clinical protocols use BTRIS. Electronic health record (EHR) data from CRIS comprise the largest dataset. Some BTRIS data came from the legacy Medical Information System. The ICs submit select data, including data from case report forms, certain genomics data from CRIMSON (the Clinical Research Information Management System (CRIMSON) of the National Institute of Allergy and Infectious Diseases), and death data from the Social Security Administration.

Dr. Galvez pointed out that not all data are in BTRIS. The excluded data fall into two main categories:

- **Data that are not in a format useful to research (e.g., PDF reports sent to CRIS).** The solution is to work with the ICs to obtain raw data. Dr. Galvez and colleagues work with the ICs and vendors to gain access to back-end systems, with varying levels of success. In some cases, data are extracted from PDFs, but the resulting data are less reliable.
- **Gaps in data submissions.** There is no requirement to deposit all clinical research data into BTRIS. Some ICs have their own systems, meaning that all data sources must be individually negotiated, due to a lack of uniform policy. The solution would be to have an NIH policy regarding 100% data submission to BTRIS.

According to Dr. Galvez, BTRIS supports intramural clinical research, primarily protocol-based research but also data reuse, artificial intelligence (AI), and machine learning. Data use does not require approval of an institutional review board; because the data are deidentified, the data use is not considered human subject research. BTRIS data can also support quality assurance/quality control (QA/QC) programs, as well as hospital-level efforts that affect everyone in the Clinical Center.

Dr. Galvez said he is often asked what the difference between CRIS and BTRIS is. He explained that CRIS is for support of patient care at an individual patient level; BTRIS supports data use across patients. CRIS data are downloaded daily to BTRIS as identified and deidentified data. CRIS data are fully identified; BTRIS restricts access to identified data to the Principal Investigator on whose protocol the patient is enrolled.

Dr. Galvez enumerated data sources from 1976 to the present. BTRIS holds data from 11,000 protocols, 500,000 patients, 15 million observations, and semi-structured documents such as pathology and radiology reports. Data are held indefinitely and are available online.

In addition, BTRIS services are available to help researchers manage phenotypic elements across their patients. Assistance is available to help researchers with analysis and data visualization. The Office has informaticists to aid investigators. Helping junior investigators organize their large raw datasets is very helpful in those investigators' research.

Other BTRIS functions include tracking participant consents. Paper-based consents are hard for investigators to track and manage, but researchers cannot access participant data until they have a proper consent. BTRIS can also help with regulatory submissions, such as those to clinicaltrials.gov.

BTRIS is a perfect platform for data QA/QC. Dr. Galvez presented an example of a QA/QC project with stem cell transplants. Multiple protocols were collated into a single view to allow investigators to assess how they were doing in terms of treating their patients. The resulting spreadsheets are delivered weekly, allowing the investigators to sort and identify problem spots. The tabulations are also helpful for regulatory submissions.

Another project focused on graft-versus-host disease (GvHD). The researchers wanted visualizations of key data elements (e.g., stool volume, skin rash, direct bilirubin) for every patient on a mixture of protocols. Data points represent selected patients; the researchers can see trends and can highlight individual patients to see their GvHD grading.

Dr. Galvez listed some of the challenges:

- Not all clinical or research data are included in BTRIS.
- Not all the data are in a standard structure.
- Protocol objectives are not provided
- IC-specific care summary is not discrete data.
- There is no comprehensive research data policy.

Dr. Galvez observed that BTRIS is a homegrown system, but efforts are underway to build a business case for possibly using a commercial or academic system to ensure that NIH has the "best of breed" among available systems. Natural language processing is cutting-edge research and could be a way to extract data from nonstandard documents.

Discussion

Dr. Forese asked about barriers to implementing a policy requiring that data be deposited in BTRIS. What is going on with the policy needed? Michael Gottesman, M.D., Deputy Director for Intramural Research, said that there is active resistance in some cases, but some ICs also have their own analytical systems and do not want to transfer their data to BTRIS. He agreed with Dr. Galvez about the importance of getting all data into BTRIS. Dr. Forese asked about a path forward to drive a policy. Dr. Tabak acknowledged the need for change and said that there had been a concern about a lack of a "home" for the data. Efforts are being directed toward identifying cloud providers that intramural and extramural researchers could use. Intransigent researchers who want to be buried with their datasets pose a more complicated problem. Because they are employees of the Intramural Research Program, it should be possible for them to exert greater control. Dr. Tabak said that, absent a uniform approach, intramural research will never realize its full potential. He thought that a system of "carrots and sticks" would help get researchers on board.

Brig Gen Burks commented on the need for a data governance strategy, which would be beyond the scope of the Clinical Center; it would have to be an NIH-wide policy. The data belong to

NIH, not to the researcher. Dr. Tabak suggested that the Board underscore the importance of making data sharing a priority.

Dr. Galvez said that the real issues are around governance and policy. Security and database issues are solvable.

This is a universal challenge, according to Dr. Shannon. He thought that it would be hard to implement a punitive approach and suggested figuring out incentives. Given this organization's mission and the Clinical Center's being the world's largest hospital dedicated to research, especially with its focus on rare diseases, data sharing is essential. Dr. Shannon also mentioned concerns about data governance. Greater clarity on governance would help individual researchers could feel confident about data access and use. NIH could help research everywhere by convening an organization around the issue of data governance, because everyone is facing this challenge.

Dr. Tabak said that, regarding data governance, the NIH Scientific Data Council deals with extramural research. There is also an internal structure for these discussions, but intramural researchers are NIH employees, which means that a policy could be implemented to require the deposition of data into BTRIS.

Stephanie Reel, M.B.A., spoke on the topic of data governance. Some years ago, the Johns Hopkins University trustees worried about security of assets. That provided an opportunity to think innovatively about the assets, their management, and research programs. The mission is to support investigators and patients. About 7 years ago, the focus turned to creating a data trust. More than 200 people have contributed to the effort. Ms. Reel recommended describing and defining what is expected from investigators when it comes to data. Data need to be available and useful and have integrity. Johns Hopkins has 10 working groups associated with the data trust governance structure. Ms. Reel offered to share the policy; some pieces may fit with the NIH environment.

Dr. Clancy asked whether BTRIS collects information on adverse events. Dr. Galvez said that the supporting information is in the system, but it is up to the investigator to decide whether a finding is an adverse event.

Dr. Gallin pointed out, with regard to data governance and policy, that the BTRIS steering committee is made up of researchers. The major barrier is the lack of a policy. Dr. Gallin pointed out that genomics data are not deposited in BTRIS; four other databases house genomics data.

Beatrice Bowie noted that the National Heart, Lung, and Blood Institute (NHLBI) was not listed among the ICs that deposit their data in BTRIS. Dr. Galvez said that NHLBI is among the ICs that do not deposit their research data in BTRIS.

In response to a question from Ruth Brinkley, RN, Dr. Galvez said that although NIH researchers are brilliant, security of data is not foremost in their minds. BTRIS can manage data security for them. It is important, however, to avoid encumbering scientists' ability to analyze data and conduct research. The individual researcher is not really capable of managing data security. If the data are housed in BTRIS, the fear is that anyone can use them. Investigators need assurance that they will retain appropriate control over their data. Investigators should not be able to hoard their data, but no one wants to hinder researchers' career goals. Once a policy is in place, safeguards can be enacted. Dr. Galvez said he wants to see that patients' gifts of data are utilized to the maximum extent. Some trials can be done completely *in silico*.

Dr. Forese summarized the CCRHB's position thus:

> RESOLVED: The Board strongly supports a single NIH-wide policy for data submission to BTRIS; there needs to be a mechanism to take maximum advantage of the data generated by world's largest hospital dedicated to research that sits atop an incredible intramural system of research.

Follow-Up Items

- Dr. Reel volunteered to share the Data Trust Policy of Johns Hopkins University and Health System with NIH leaders and the CCRHB in the hope that some elements could be adapted to create NIH policy or guidance regarding data sharing among intramural researchers.
- Dr. Clancy suggested that Dr. Galvez could add to his slide presentation the inpatient glucose management project as another example of a QA/QC project made possible through BTRIS.

Clinical Center Electronic Health Record (EHR) Business Case

Maria D. Joyce, M.B.A., CPA, Chief Financial Officer, NIH Clinical Center

Over the past 5 months, Ms. Joyce has been leading a business case evaluation of the Clinical Center's EHR system. CRIS, which is based on Allscripts, has been in place since 2004. Since then, many upgrades and enhancements have been applied to meet NIH's unique research needs.

Much has changed since CRIS was implemented. Many competitors have entered the EHR market. New systems may include capabilities such as interoperability, machine learning, and virtual health. The systems also emphasize patient safety and reflect the emergence of personalized medicine, as well as advances in cloud and mobile technology.

Market Analysis

Ms. Joyce outlined the scope and methodology for the analysis. The analysis underpinning the business case began by identifying viable commercial off-the-shelf products. Ms. Joyce and the team:

- Conducted site visits to the Department of Defense and academic medical centers, including the Mayo Clinic, the Johns Hopkins Hospital, the Memorial Sloan Kettering Cancer Center, and St. Jude Children's Research Hospital (also a research facility that does bill insurance providers but never charges patients for their care,)
- Engaged Clinical Center stakeholders to identify current and future functionality needs and elucidate critical gaps in current CRIS capabilities
- Met with representatives of Allscripts, Cerner, and Epic to understand their 5- to 10-year roadmaps

An analysis of the EHR data and market trends revealed a major movement toward virtual care and remote patient monitoring, capabilities that could be transformative for intramural research, since study participants live all over the world. Cloud-based technology will be increasingly important as the Intramural Research Program scales up with genomics data, AI, and voice recognition.

The market research narrowed the field to three suites that might meet NIH's needs: Allscripts, Cerner, and Epic. Epic and Cerner dominate the market for acute care and ambulatory care.

Recently, Allscripts has been losing market share in acute care because several large hospitals and acute care facilities changed systems. Top academic medical centers all use Epic. Cerner is the EHR solution for the Department of Defense and the Department of Veterans Affairs (VA). Allscripts is oriented more toward private practice, international markets, and acute care.

All three companies have strong revenue streams. Net income is a different story, however. Epic is privately held, so no information on its net income is available. Allscripts had endured losses because of aggressive acquisitions and mergers. All three seem to be financially viable for the foreseeable future.

The EHR platforms are differentiating factors. For example, Epic is rigid and does not allow much customization. Cerner and Allscripts have a base platform plus modules for more flexibility. Epic also has strict training requirements: All users must have 16 hours of training before they get access to the platform. Ms. Joyce said that this training requirement was not considered a disadvantage, however.

Comparing NIH Requirements with the Systems' Capabilities

The next step involved mapping NIH requirements to the capabilities of the EHR suites. This exercise yielded several key insights:

- There was very little distinction between suites, but the VA's Cerner product seems to be the most aligned with Department of Clinical Research Informatics (DCRI) requirements. However, the VA product as envisioned will not start deploying until 2020.
- All vendors offer operational/analytical reporting to support development of business intelligence and data warehousing as part of their base suites.
- Each vendor has a unique definition of "base suite"; a formal request for information may result in more accurate representations.

Ms. Joyce said that no clear winner emerged among the three EHR systems.

Ms. Joyce also reported that Memorial Sloan Kettering Cancer Center decided to stick with Allscripts. Given the cost, distraction, and loss of technological advancement during a lengthy implementation of a new system, the institution's leaders did not see enough value to justify a change. All of the institutions they met with recommended that NIH get its workflows, processes and infrastructure in order first and make sure that everything is aligned to make the best use of any new system and avoid downtime.

Ms. Joyce also emphasized the importance of viewing a new EHR suite as an improvement in clinical care, not an IT project. To ensure a smooth transition, change management processes need to be put in place alongside training. The recommendation is to have a 5:1 ratio in terms of the support staff–to-user ratio to boost user satisfaction after the go-live date.

Feedback on CRIS

Stakeholder feedback sessions with Clinical Center and IC staff led to some valuable insights about CRIS:

- CRIS is a great option for a clinically focused research medical center, and it meets the majority of Clinical Center functional needs, but there is room for improvement.
- The lack of a cross-organizational governance structure for clinical processes across protocols impairs knowledge exchange between the Clinical Center and the ICs. The existing framework should be optimized to reduce inefficiencies and safety concerns.

- Clinicians recognize that harmonization of clinical workflows is needed to improve business processes and that a training enforcement mechanism is needed to ensure proper levels of knowledge.

Recommendations

1. Maintain and upgrade the current CRIS platform and improve key processes to ensure full system functionality and deploy important new functions. There is a need for a strategic plan that aligns with the overall Clinical Center strategic plan. System governance of CRIS and other relevant NIH systems needs to be reformed, including the elimination of duplicate systems to improve accountability, clinical documentation, and patient safety. A better training model is needed to ensure that people know how to use CRIS.
2. Start the procurement process now for a new EHR platform or undertake a significant modernization effort within 3–6 years. The procurement process would likely take 3 years, and implementation another 2 years.

Ms. Joyce underscored the need for cross-governance between clinical care and research at NIH. A lack of standardization persists because there is no governance group to set standards for all.

In addition to this presentation to the CCRHB, the socialization process for improving the existing CRIS platform and implementing a new EHR system in the future has begun with the Medical Executive Committee and the CCGB.

Discussion

Dr. Tuckson said that one of the companies is not good at sharing data and that its platform is more of a "black box." He hoped that, with NIH clout, it might be possible to push for changes to ensure data flow between NIH and academic centers.

Dr. Tuckson also underscored the importance of patient centeredness as a selection criterion, and he recommended seeking the capability to handle unstructured data access.

Dr. Tuckson was also interested in learning more about how NIH uses AI. NIH could be a real leader in this area.

Brig Gen Burks said that his institution just went through an EHR implementation. He thought that 3 years was an ambitious timeline. He said that requirement identification is critical; that is where most of the heavy lifting with partners has to occur. The interfaces with radiology, the clinical laboratory, and other ancillary departments are also key. Brig Gen Burks also recommended considering user-centeredness when selecting an EHR provider.

Jeanette Erickson, D.N.P., RN, said that the decision making should involve patients in every step, starting immediately. Many of the vendors are similar, but some cannot provide what patients want.

Follow-Up Items

- The Board requested regular updates on the processes and decisions involved in the procurement and implementation of a new EHR system for the Clinical Center.
- The Board recommended querying EHR providers about unstructured data access.
- The Board recommended including patient centeredness as a selection criterion. How will the tool support putting people at the center of research?

- The Board recommended considering user centeredness as a selection criterion, identifying classes of users, and ensuring that they can access information to advance clinical services as well as research.

Surgical Services Update

Main Operating Room (OR) Activity and Demographic Data

Andrew Mannes, M.D., M.E., M.B.A., Chief, Clinical Center Department of Perioperative Medicine

Dr. Mannes said that the Clinical Center has 11 ORs. Most are general surgical suites, but some are more specific (e.g., laparoscopic suites, robotic surgery). Twelve surgical services use the ORs. Most cases are from the urology, surgical oncology, and gastrointestinal services. The caseload runs about 150 to 200 cases per month, but the trend has been slightly upward over the past 10 years. Since 2016, some cases have been handled in the intermediate care (IMC) unit, which offers less intensive services than the OR.

Dr. Mannes anticipates that new incoming protocols will likely increase the surgical caseload. The need for different surgical services fluctuates as investigators come and go.

Dr. Mannes reported that for the main OR:

- The large majority (70%) of surgical patients are between the ages of 19 and 65.
- General anesthesia is used for 48% of cases; monitored anesthesia care for 29%; and local anesthesia for 19%.
- Fifty-six percent of cases are inpatients (because of the research setting), and 44% are outpatients.
- Sixty-two percent of cases have an American Society of Anaesthesiologists (ASA) severity score of III (patients with severe systemic disease).
- Most surgeries are planned, but some are emergent cases.
- Some patients go to the ICU for recovery.

NIH Surgical Services Update: 2019

Jeremy Davis, M.D., FACS, Clinical Center Surgeon-in-Chief, Staff Clinician, Surgical Oncology Program, NCI

Dr. Davis said that the Surgical Administrative Committee (SAC) is a subcommittee of the Medical Executive Committee. In 2017, Dr. Davis presented the SAC's vision for 2018 to the CCRHB. The vision rededicated the SAC as the primary NIH body responsible for:

- Surgical (perioperative) quality
- Efficiency and utilization
- Contingency planning

In his presentation, Dr. Davis focused on surgical quality. The SAC formed the quality working group, which meets biweekly to discuss cases in a structured way for peer review. The group members discuss near misses and adverse events in near real-time. Quarterly NIH-wide surgery conferences cover thematic issues; they are not focused on a particular case or adverse event. Themes have included the massive transfusion protocol, best practices for monitoring intravenous patient-controlled anesthesia, and uniform management of obstructive sleep apnea. In addition, surgery planning meetings focus on planned operative cases.

Current methods for capturing surgical outcomes are not centralized or standardized. The goal is to use outcomes data to demonstrate quality of care, improve patient outcomes, identify positive and negative outliers, identify areas for standardization, and support peer review. The Surgical Outcomes Data Project is nearly completed, with phased implementation scheduled to begin this summer.

Dr. Davis clarified that surgical outcomes differ from medical outcomes. The focus in surgical outcomes is on the event and its severity. The surgical event, or complication, can be analyzed by patient, procedure, operation (encounter), and surgeon. The severity grading system was adopted and validated by surgeons.

Dr. Davis presented examples from the surgical complications database. Using a condensed format, he can see how patients are faring under a given service or examine specific surgeons' performance with regard to quality indicators or to organ-specific or procedure-related complications. The data can be used for clinical purposes or for research.

Dr. Davis showed an example of an outcomes report covering a 12-month period and drilled down to show the number of gastrectomy-specific, major adverse events.

Discussion

In response to a question from Ms. Berty about the system that generates the surgical outcomes reports, Dr. Davis said that the reports come through the CRIS interface. Surgery staff spend most of their time documenting things in the medical record in CRIS. In the same interface, they can document and grade the event.

Department of Perioperative Medicine (DPM) and Interprofessional Total Quality Management for Maximizing Patient Safety and Quality

Nilka Schulman, M.S.N., Post-Anesthesia Care Unit Nurse Manager, Department of Nursing Operations, Clinical Center Nursing Department

Ms. Schulman spoke about efforts aimed at:

- Data optimization and utilization
- Greater standardization across DPM, Procedure Services, and Interventional Radiology
- Improved patient experience

Ms. Schulman explained that the Perioperative Information System (POIS) houses a large body of data, but there has been no way to use the data or translate them into practice.

Before doing a deep dive into the data, Ms. Schulman focused on creating an infrastructure that would fit with existing initiatives and practice. After consideration of the Balanced Scorecard model, it became clear that the shared governance model was superior because of some key features: stakeholder involvement, accountability, transparency, and a focus on learning, sharing, and improving quality of care. Input was sought from clinicians who "were stripped of their titles but not their knowledge."

One solid deliverable from the process involved setting up a real-time tracking board, a tracking and communication tool used to display perioperative information on dashboards. The tracking board included OR staff workflows, patient surgical navigation, procedures, times, and locations. The first board was so popular that 10 have now been installed in strategic areas throughout DPM.

Ms. Schulman also reported on a collaborative effort with Clinical Center Nursing Department to integrate the tracking system with POIS to collect and analyze data by case volume, day of the week, time of day, patient characteristics, and type of anesthesia. The system can also compare annual surgical volumes for different years and analyze length of stay in the post-anesthesia care unit.

Future plans include integration with special procedures units, and early discussions are underway with sterile processing and inpatient units. In addition, more real-time tracking boards will be installed to optimize support services, including in the waiting room for patients and families. In 2018, an analysis showed that more than 300 people passed through the waiting room each day, but the area was inconsistently staffed with volunteers. Now, a full-time employee works in the waiting room to process patients and enter their tracking information.

Discussion

Dr. Erickson congratulated Ms. Schulman for thinking outside the box and translating a nursing model to a whole-system, collaborative, decision-making model. Dr. Erickson encouraged her to publish the model as it could help people work together to solve problems.

Dr. Forese agreed that this is very impressive and is achieving demonstrable results for the team.

Follow-Up Item

- The CCRHB encouraged Ms. Schulman to publish the decision-making model and to consider joining the Clinical Center leadership training program.

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 12th meeting of the CCRHB by thanking the presenters and the CCRHB members for their insights and thoughtful input. She remarked on the richness of the data presented during the meeting.

This meeting was the 12th meeting of the CCRHB in its 3 years of existence. Dr. Forese said that the progress over this period has been remarkable. She congratulated the NIH leaders in attendance and thanked the Clinical Center employees who are on the front lines.

The next face-to-face CCRHB meeting is scheduled for July 19, 2019.

Dr. Forese adjourned the meeting at 2:16 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
ASA	American Society of Anesthesiologists
BTRIS	Biomedical Translational Research Information System
CCGB	Clinical Center Governing Board
CCRHB	Clinical Center Research Hospital Board
CEO	chief executive officer
CRIMSON	Clinical Research Information Management System of the National Institute of Allergy and Infectious Diseases
CRIS	Clinical Research Information System
DCRI	Department of Clinical Research Informatics
DHS	Department of Homeland Security
DPM	Department of Perioperative Medicine
EHR	electronic health record
FDA	U.S. Food and Drug Administration
FEVS	Federal Employee Viewpoint Survey
GvHD	graft-versus-host disease
ICs	Institutes and Centers
ICU	intensive care unit
IT	information technology
MMESD	Materials Management and Environmental Services Department
NCI	National Cancer Institute
NDNQI	National Database of Nursing Quality Indicators
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
OR	operating room
PDS	Pharmaceutical Development Section
POC	point of care
POIS	Perioperative Information System
QA/QC	quality assurance/quality control
SAC	Surgical Administrative Committee
SRLM	Surgery, Radiology and Laboratory Medicine
VA	Department of Veterans Affairs