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Seventeenth Meeting of the Clinical Center Research Hospital Board

April 23, 2021

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Clinical Center Research Hospital Board

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

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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

James J. Burks, FACHE, Vice President and Chief Operating Officer, Centra Lynchburg Hospitals

*Julie Freischlag, M.D., Dean, Wake Forest University School of Medicine

Steven I. Goldstein, M.H.A., President and Chief Executive Officer, University of Rochester Medical Center

William Hait, M.D., Ph.D., Global Head of External Innovation, Johnson & Johnson

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

Richard P. Shannon, M.D., Chief Quality Officer, Duke Health

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*Absent

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 17th meeting via videoconference on April 23, 2021. The meeting was webcast live and open to the public. A video recording of the meeting is available online.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital; and Chair, CCRHB, called the meeting to order at 9:00 a.m. ET. Board members Julie Freischlag, M.D., and Ruth Williams-Brinkley, M.S.N.-Adm., were unable to attend the meeting.

Francis S. Collins, M.D., Ph.D., NIH Director, spoke of the national outlook for the coronavirus disease 2019 (COVID-19) pandemic and the remarkable pace of scientific progress that has led to development of vaccines, diagnostics, and treatments. He highlighted NIH research activities that have contributed to this rapid progress. Dr. Collins reported on NIH's unparalleled employee testing program, which has completed 141,000 tests.

James Gilman, M.D., Chief Executive Officer (CEO), NIH Clinical Center, announced the recipients of several Clinical Center awards that recognize exemplary performance and length of service. He also noted several changes in Clinical Center leadership and observed that the hospital census is still lagging after being severely curtailed in 2020 because of the pandemic. Approximately 25% of the Clinical Center's outpatient volume is now in the form of telehealth visits. NIH is committed to continuing telehealth even after the pandemic wanes.

According to Dr. Gilman, nearly 60% of Clinical Center employees participated in the 2020 Federal Employee Viewpoint Survey (FEVS). For this iteration, the original portion of FEVS was shortened from 78 items to 38 questions in order to accommodate 29 new COVID-19-focused items. Of note, more than 90% of respondents believe that senior leaders have demonstrated commitment to their health and safety during the pandemic.

Pediatric research is a 2021 strategic focus area. Dr. Gilman reported that discussions are underway to decide upon the sorts of research that could be done at the Clinical Center, the types of patients that might be enrolled, and potential partners who could help maximize the safety of pediatric research.

Dr. Gilman updated the board on screening and testing of staff and patients for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). As of March 30, 2021, nearly 1.2 million screenings have occurred at the building entrances. A total of 97,016 tests have been done on 12,126 employees—an average of 350 per day. About 0.1% to 0.2% of samples have tested positive for the virus.

The Clinical Center has been a safe place to work throughout the pandemic. No spread of SARS-CoV-2 from staff to patients has occurred, and there has been no spread from patients to staff since the spring of 2020. More than 1,900 staff have received at least one dose of COVID-19 vaccine.

Mary Sparks, RN, Acting Director, Clinical Center Office of Patient Safety and Clinical Quality, said that the Joint Commission review is expected to occur this year. To prepare for the review,

the Clinical Center uses a self-evaluation tool to help ensure adherence to standards of compliance. Chapter leaders have been reviewing each area for weaknesses and identifying data to demonstrate compliance throughout the entire hospital. Staff are practicing for the Joint Commission review to ensure that everyone is comfortable with online meetings and sharing documents over the platform.

Michele R. Evans, DrPH, Environmental Safety Officer, NIH Clinical Center, briefed the board on worker safety at the Clinical Center. Dr. Evans presented data on recordable and reportable occupational injuries and illnesses at the Clinical Center and compared the data to other U.S. hospitals. She also provided information on injuries among Clinical Center workers and discussed ways to reduce those injuries. The data demonstrate reductions in human blood and body fluid exposure injuries over time.

H. Clifford Lane, M.D., Deputy Director for Clinical Research and Special Projects, Division of Clinical Research and Clinical Director, National Institute of Allergy and Infectious Diseases (NIAID), said that NIH's role in COVID-19 research has led to important successes, including demonstration of remdesivir's effectiveness, the launch of coordinated therapeutic and diagnostic research protocols, and involvement in three of the four ongoing phase 3 vaccine trials. The Rapid Acceleration of Diagnostics (RADx) initiative has boosted the nation's testing capability to around 2 million tests per day. Dr. Lane noted that the first release of the NIH Treatment Guidelines occurred about a year ago. The guidelines have received more than 14 million page views.

Gwenyth Wallen, Ph.D., RN, Chief Nurse and Senior Investigator, Clinical Center Nursing Department, updated the board on progress with the Clinical Center's Magnet® Designation Journey. Magnet Recognition sends a strong message about commitment to patient safety and excellence in practice. Data are being collected to support the Clinical Center's submission, which is likely to occur in the spring or summer of 2022.

David Stroncek, M.D., Director, Center for Cellular Engineering (CCE), said that the CCE provides cell and gene services for Clinical Center investigators and their patients. The CCE has 43 active protocols, and 14 new protocols are in the product development stage. In 2019, 76 hematopoietic stem cell transplants were processed, and 71 were processed in 2020.

Several construction and renovation projects have been completed in the Clinical Center, and others are planned or underway. Daniel Wheeland, P.E., Director, Office of Research Facilities, described progress on projects intended to increase patient safety and expand research facilities. Funding has been secured for the planned Surgery, Radiology, and Laboratory Medicine facility.

Meeting Summary
Friday, April 23, 2021

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 17th meeting of the National Institutes of Health (NIH) CCRHB took place on April 23, 2021. The meeting participants convened via videoconference. The meeting was open to the public and webcast live. A video recording of the meeting is available online.

Dr. Forese called the meeting to order at 9:00 a.m. ET. She announced that board members Julie Freischlag, M.D., and Ruth Williams-Brinkley, M.S.N.-Adm., were unable to take part in the meeting.

NIH Director's Remarks

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

Dr. Collins thanked Dr. Forese for her willingness to continue as chair of the CCRHB. He also expressed his gratitude to Richard P. Shannon, M.D., who will be continuing as a board member.

COVID-19 Pandemic: National Outlook

Dr. Collins spoke about the remarkable pace of scientific progress that has led to development of vaccines and treatments for coronavirus disease 2019 (COVID-19). Nearly half of U.S. adults have received at least one dose of either the Pfizer or Moderna vaccine, and one-third are fully vaccinated. No worrisome safety signals have been reported for either of these products.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are meeting today, April 23, to review the data on six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the Johnson & Johnson (J&J) vaccine. Based on the number of doses given, the incidence rate is about one in a million. The clots occur with severe thrombocytopenia; the condition is similar to one associated with heparin treatment. Most cases have been in females, but one case developed in a male who was part of a vaccine clinical trial. The clots are salmon colored due to being largely composed of platelets. Dr. Collins noted the rapidity with which the mechanism was identified and the recognition that the condition can be prevented by avoiding use of heparin.

Dr. Collins thought it was reasonable to declare a pause to collect and analyze more data on the clotting events. The few events have heightened anxiety about vaccination, particularly among those who were already hesitant. He observed that the European Medicines Agency faced the same situation and decided to allow the J&J vaccinations to proceed. A key advantage of the J&J vaccine is that it is administered as a single injection; no booster shot is required.

The United States must be mindful of other countries that are stricken by the virus. A day before this meeting, India had 330,000 cases, overwhelming the country's health care system in some areas. Dr. Collins said that Israel, which has achieved about 60% seropositivity through

vaccination or illness, may be a forecast for the United States. Cases and deaths in Israel have plummeted even as the country is opening up.

Increasing Vaccine Confidence

To put vaccination in a more positive light, Dr. Collins encouraged use of the phrase "vaccine confidence" instead of "vaccine hesitancy." Many people are already benefitting from vaccination by being able to visit with vaccinated friends and family. Former president George W. Bush said that vaccination is "liberating."

The COVID-19 Community Corps (https://wecandothis.hhs.gov/covidcommunitycorps) is a rapidly growing initiative bringing together grassroots organizations to spread the word about vaccine safety and efficacy. The Corps was set up by the White House a couple of months ago. Now, hundreds of organizations are involved in the effort to disseminate consistent and accurate information about vaccines. Individuals, churches, and community groups can join the Corps.

NIH's COVID-19 Research

Dr. Collins reported that NIH continues to focus on making progress on diagnostic tests, therapeutics, and vaccine development for COVID-19.

NIH is involved in several clinical trials of potential therapeutic agents launched by the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership. The ACTIV-6 trial was just launched, which is testing repurposed oral agents as treatments for outpatients with COVID-19.

The Rapid Acceleration of Diagnostics (RADx℠) initiative aims to increase accessibility of COVID-19 testing. Thirty-two new technologies developed under the auspices of the program are contributing 2 million tests per day. Most are point-of-care tests, but a few are for home testing.

What would happen if home tests were distributed freely in communities? That is the question being addressed by the Say Yes! COVID Test study that is underway in Pitt County, North Carolina, and Hamilton, Tennessee. More than 2 million rapid home tests are being distributed to 80,000 households to see whether increased testing can drive down case numbers. Community monitoring is being done via wastewater testing for SARS-CoV-2. NIH is providing Quidel QuickVue antigen test kits through the RADx initiative. The test is easy to perform with an app that provides instructions and offers the option to send results to the user's doctor.

NIH Employee Testing

Dr. Collins reported findings from NIH employee testing. Over the past 15 months, 1,532 index cases among staff have been identified through NIH and community testing. People with symptoms are tested in the car line, so they do not enter any buildings. NIH has completed 141,000 tests. NIH is not only doing 100% screening of asymptomatic people, but also sequencing the virus to identify workplace clusters. In every instance but two, individuals were coincidentally infected by different sources in the community. In those cases, genome testing revealed that two people most likely became infected at work, probably because of their failure to observe safety measures.

Dr. Collins said that NIH has administered at least one dose of either the Moderna or Pfizer vaccine to nearly 15,000 staff members; another 11,000 reported being immunized elsewhere. NIH has 40,000 staff members, meaning that NIH staff members are not being vaccinated at projected rates. However, Dr. Collins pointed out that it is possible that many people have been vaccinated in the community or may not be reporting that they have been vaccinated. NIH surveillance studies are aimed at detecting vaccine breakthrough by vaccine-resistant variants. Three confirmed active infections have been found and are under study as possible breakthroughs.

The collected data provide a basis for discussions about returning to work at NIH. About half of the staff is now authorized to work on campus. Laboratories are working in shifts, but this is not a very effective way to get science done. Discussions are focusing on the question of whether laboratories or administrative units could reopen fully if a significant proportion of their personnel are vaccinated.

Dr. Collins discussed concerns about unvaccinated staff members having direct patient contact. One issue has to do with the ethics or legality of asking people whether they have been vaccinated or requiring vaccination—as is the case with influenza vaccine. Requiring vaccination is questionable because the COVID-19 vaccines are authorized under Emergency Use Authorization (EUA); they do not have final Biologics License Application (BLA) approvals. Some hospitals are requiring vaccination, but as of now, the federal government is not requiring vaccination of federal employees or the military.

Discussion

William Hait, M.D., Ph.D., asked about the status of sequencing variants around the country. Dr. Collins said that CDC has ramped up its sequencing capability. CDC's goal is to run 25,000 genome sequences per week; right now, they are testing about 15,000 samples from all the states. Dr. Collins said that as of the end of March 2021, the B.1.1.7 variant (identified first in the United Kingdom) had rapidly spread in the United States and comprised 44% of isolates. This is concerning because the variant is 50% to 70% more contagious and also more lethal. Vaccines appear to work well against the B.1.1.7 variant, indicating that the best defense is "shots in arms." The B.1.351 variant has decimated South Africa and is present in the United States, including one case at NIH. This is a worrisome development because the variant is more infectious and appears to be less responsive to vaccines. "Homegrown" variants have popped up in California and New York.

Dr. Collins said that the ACTIV public-private partnership, which is managed by the Foundation for the National Institutes of Health (FNIH), is running a project that aims to track resistant variants and learn about the consequences for the effectiveness of vaccines and treatments. The B.1.351 variant is the source of deep concern because some monoclonal antibodies are not effective against it.

Dr. Shannon said that the origins of these coronaviruses are animal reservoirs. Historical viral surveillance of bat and farm animals failed to detect the emergence of SARS-CoV-2. Are there better ways to understand how these viruses jump from animals to humans? Dr. Collins said that this needs to be the subject of a worldwide discussion, with the World Health Organization in a

critical role, but political tensions are complicating the situation. There have been efforts in the wake of SARS and MERS to collect coronaviruses from bats and other potential vectors. The emergence of a virus such as SARS-CoV-2 was anticipated to some extent. However, everyone needs to prepare better in terms of therapeutics and vaccines. NIH's Vaccine Research Center had been working on mRNA vaccines against MERS, and Barney Graham, M.D., Ph.D., of the National Institute of Allergy and Infectious Diseases (NIAID) had been working on spike-protein-directed vaccines. With the exception of the AstraZeneca vaccine, COVID-19 vaccines have been based on that body of work. The American Rescue Plan is a major push to prepare the nation for emerging infectious agents in the future. Especially important are novel antiviral drug therapies that are effective against many different viruses; COVID-19 treatments are all based on repurposed drugs.

Dr. Forese asked about differences between the current and past administrations in terms of their approaches to the pandemic. Dr. Collins said that the current administration is looking to science to solve important problems, including the pandemic and climate change. President Biden has chosen Eric Lander, Ph.D., as White House science advisor and director of the Office of Science and Technology Policy. If confirmed by the Senate, he will serve as a cabinet member—a first for this position and a sign of the level of confidence this administration has in science to provide answers.

The fight against COVID-19 has been an amazing story of scientific triumph in the midst of tragedy. Science has produced a huge output of safe and efficacious drugs and treatments that have received emergency authorization on a very short timetable—almost beyond what anyone dared to hope.

Dr. Forese expressed the board's appreciation to Dr. Collins and other NIH leaders. The board looks forward to hearing about NIH's future achievements.

Action Item

- For the next CCRHB meeting, Dr. Collins recommended having a session on UNITE, NIH's diversity initiative. The UNITE initiative was established to identify and address structural racism within the NIH-supported and greater scientific community.

NIH Clinical Center Chief Executive Officer Update

James Gilman, M.D., Chief Executive Officer (CEO), NIH Clinical Center

Dr. Gilman said that the Clinical Center has been busy despite variations in the patient census.

Average Daily Census

Dr. Gilman reported that the average daily census (ADC) of inpatients has been well below 2020 levels and the 3-year average. On the morning of this meeting (April 23), 87 inpatients are in the hospital—about two-thirds of the usual ADC for a Friday in a normal year. However, the ADC indicates that the number of patients is trending upward.

Referring to the ADC drop from 2020 to 2021, Dr. Gilman said that the most concerning statistic is the 42% decrease in new patients. (This statistic does not include telehealth visits.) Between March 2020 and March 2021, the number of telehealth visits rose from about zero to more than

1,200. The telehealth platform can be somewhat awkward with required privacy and security controls, but the Health Information Management Department (HIMD) ,often called the telehealth concierge service, works with patients and providers to facilitate telehealth visits. The service has been well accepted and well regarded. NIH is committed to continuing telehealth even after the pandemic wanes. Approximately 25% of the Clinical Center's outpatient volume is now in the form of telehealth. The chief of HIMD, Patricia S. Coffey, RHIA, CPHIMS, CPHI, BS, along with many coauthors, published an article about NIH's telehealth service.

Employee Recognition

Dr. Gilman announced the following awards honoring Clinical Center personnel:

- SuperSTARS awards recognize staff for high-quality services and "good catches." Seven Clinical Center employees from nursing, maintenance, the Department of Laboratory Medicine, and housekeeping received awards in December 2020.
- The clinician-scientists who comprise the hematology consultation service received the Team SuperSTAR award.

The Clinical Center instituted Length-of-Service awards about 4 years ago. Employees are recognized during quarterly Town Hall meetings. Presenting awards in a largely virtual environment presented some challenges, but a bit of detective work helped with the logistics of locating the award recipients and giving the awards during their work shifts. Recent honorees were Kerry Bruton, with 20 years of service, and Letitia Johnson, with 35 years of service.

Dr. Gilman said his experience in the military was that when health care providers and others returned from battleground theaters, they came back somewhat changed, and their families also changed while they were away. Those types of deployments and the winding down of this pandemic are cues for reflection and decisions about life priorities. These events may also lead to transitions in the workplace. He promised a more complete update at the board's July meeting.

Rare Disease Day

The Clinical Center partnered with the National Center for Advancing Translational Sciences to take part in the 10th NIH Rare Disease Day and the 13th international Rare Disease Day on March 1, 2021. More people were able to participate this year due to the virtual meeting format; as a result, there were twice as many attendees.

Staffing Updates

Dr. Gilman announced three new hires:

- Genevieve Mbamalu, M.D., is the new service chief for neuroscience, behavioral health, and pediatrics.
- Barbara Bryant, M.D., FCAP, FASCP, was hired as the chief of the Department of Transfusion Medicine. Dr. Bryant will attend the next CCRHB meeting and introduce Dr. Harvey Alter, who will discuss his career in the Clinical Center and highlight the hepatitis C research that led to his Nobel Prize.
- Michael Bell, M.D., M.P.H., now serves as the director of the Occupational Medical Service (OMS).

Active searches are underway for a chief medical officer and a chief of the Office of Patient Safety and Quality Control.

Educational Lecture Series

Dr. Gilman announced that Excellence through Clinical Education Lectureship (ExCEL) launched in October 2020. The lectures, sponsored by the Patient Safety, Clinical Practice, and Quality Committee, take place each month. They are led by clinical specialists or consultation services. ExCEL is designed for all frontline clinical staff and provides continuing medical education credits.

2020 Federal Employee Viewpoint Survey (FEVS)

FEVS is an annual employee survey administered by the Office of Personnel Management across the federal government. Clinical Center participation in 2020 (59%) dropped slightly compared to 2019 (62%), but the participation rate in 2012 was only 17%.

For 2020, the original portion of FEVS was shortened from 78 items to 38 questions in order to accommodate 29 new COVID-19-focused items.

Three key measures for the Clinical Center have been fairly consistent but have trended upward for the past 3 years:

- Belief in Action is up 7%, reaching 63% in 2020.
- Global Satisfaction increased by 8%, reaching 74% in 2020.
- Employee Engagement is up 6%, reaching 78% in 2020.

Dr. Gilman reported that 32 of 37 items were considered Clinical Center strengths, as they had more than 65% positive ratings. Ratings for all items improved, but 28 improved by more than 5%, compared to 2019 results. Lowest ratings were for items on dealing with poor performers and with compensation.

Regarding Clinical Center responses to COVID-related items, just over half of the staff reported working onsite at least 75% of the time during the pandemic. Before the pandemic, 19% teleworked regularly, but this jumped to 55% at the time of the survey. More than 90% of respondents believed that senior leaders demonstrated commitment to their health and safety.

2021 Strategic Priorities: "People" Initiative

Dr. Gilman said that a key priority for 2021 is improving the employee onboarding process. Studies confirm that successful onboarding will improve role clarity, performance, job satisfaction, and engagement. Peer sponsors, who are trusted, motivated colleagues, will help new staff members feel welcome and connected and give them a better sense of the organization's culture and helpful resources. The Clinical Center has a new onboarding website.

Dr. Gilman reported excellent progress on establishing individual development plans (IDPs), another key part of the "people" initiative. IDPs are required for all federal employees working in the Clinical Center. Supervisors must set aside time to discuss and understand employees' professional goals and find out how NIH can help employees prepare to meet those goals.

UNITE is a new NIH initiative to support diversity, equity, and inclusion while dismantling any policies or practices that may harm the NIH workforce and impede science. Five committees were formed with representation from all 27 Institutes and Centers. Daryl Holder, M.S., and Bernard Harper, M.A., are Clinical Center representatives on two committees.

2021 Strategic Focus Area: Pediatrics

In 2018, senior nursing staff and Drs. D. Merke, Chief, Pediatric Service and Z. Quezado, Chief, Pediatric Anesthesia & Critical Care, spoke to the CCRHB about the Clinical Center's capabilities for conducting pediatric research. To ensure that research activities can be done safely, there are cutoffs for pediatric participants based on their size and age. Younger patients are screened before they come to the Clinical Center.

The gene therapy community is interested in enrolling younger, smaller patients. If a child is born with a genetic defect and an effective gene therapy exists, early intervention offers the greatest chance of success. Further discussions are planned to decide upon the types of research that could be done at the Clinical Center, the types of patients that might be enrolled, and potential partners who could help ensure the safety of pediatric research. The Clinical Center Governing Board will take up this topic in June 2021.

CEO Emails

Dr. Gilman sends emails to more than 3,000 Clinical Center and Building 10 occupants at least weekly to stay in touch with staff and maintain a sense of community. Usually, he distributes emails once per week, but during the pandemic, he has been sending them almost daily. Some messages are informational (e.g., reminders of public health measures), and others are exhortations. An example of the latter includes messages saying that seeking help is a sign of strength, not weakness. The emails usually include contact information for the employee assistance program. To encourage audience participation, the emails may include questions such as "What have you done because of the pandemic that you never thought you would do?" Usually, 70 or 80 people will respond.

COVID-19 Screening and Testing in Building 10

Dr. Gilman reported that as of March 30, 2021, nearly 1.2 million screenings have occurred at the building entrances. On March 23, 5,841 individuals were screened—the most to date. A total of 97,016 tests have been done on 12,126 employees—an average of 350 tests per day. The positivity rate is around 0.1% to 0.2%. Both nasal swabs and saliva samples are acceptable for testing.

Vaccinating NIH Staff

It took just 2 weeks to set up a vaccination clinic in a cafeteria. A kickoff event was held in the Clinical Center in December 2020. Dr. Gilman reported that, as of April 13, 2021, all NIH staff, including teleworkers, are eligible to receive vaccines; more than 1,900 staff members have received at least one vaccine dose.

The staff is reminded regularly about the importance of wearing masks, screening, and maintaining a safe distance from others. Vaccination is strongly encouraged. The Clinical Center

has been a safe place to work throughout the pandemic. No spread from staff to patients has occurred, and there has been no spread from patients to staff since the spring of 2020.

Discussion

Dr. Shannon congratulated Dr. Gilman on the 90% approval rating for leadership performance during the pandemic. He asked whether FEVS includes any items on inclusion and sense of belonging that might be indicators of systemic racism. Dr. Gilman said that the items on the FEVS vary little from year to year. He thought that one or two items might be generally related to diversity and inclusion, but those topics are not the focus of FEVS.

Dr. Shannon inquired about the demographics of people who are served at the Clinical Center and comparing those data with staff demographics. A lack of alignment on these measures may influence cultural competency. Dr. Gilman said that patients come to the Clinical Center from all over the world. The Clinical Center tracks demographics of patients, and he offered to provide those data to the board along with data on staff demographics. Dr. Gilman thought that Dr. Collins would be able to provide data for NIH staff overall; that is an important measure because many interactions occur with institute staff outside of the Clinical Center. Cultural competence is addressed during onboarding and orientation.

Dr. Hait asked how new areas in drug development and gene editing and the possible expansion of pediatric research would affect the Clinical Center's infrastructure, capabilities, and personnel. Dr. Gilman said that the Center for Cellular Engineering (CCE) is the single largest initiative the Clinical Center has been pursuing. NIH has been invested in that effort for a long time, but going from early-stage development into manufacturing that approximates CGMP (Current Good Manufacturing Practice) standards has been the focus of much of the work. Dr. Gilman said that when he first became CEO of the Clinical Center in 2017, access to more cell processing was the top request of NIH directors. Excellent progress has been made in meeting that demand.

Dr. Hait asked about interactions between NIH and biopharma and whether some areas of interaction could be improved. He noted that biopharma now has more interest in rare disease indications—a major shift for industry—and that rare diseases could be an area where NIH and industry could have fruitful interactions. Dr. Gilman said that interactions with biopharma are controlled and somewhat challenging, but this is by policy. A third-party fiscal intermediary is necessary to serve as a firewall between pharma and NIH investigators; the FNIH usually facilitates such interactions. Dr. Gilman offered to discuss the topic further at another time.

Stephanie Reel, M.B.A., observed that much of the nation is emphasizing vaccination over testing, but it seems that the Clinical Center is underscoring the importance of testing in overcoming the pandemic. Dr. Gilman said that the Clinical Center is conducting surveillance testing for two main reasons: (1) Vaccination protects against clinical illness, but it does not necessarily prevent people from carrying SARS-CoV-2 asymptomatically and possibly transmitting it to others. The evidence is incomplete. (2) The Clinical Center, along with NIAID, is concerned about the emergence of variants. Testing is the best way to detect variants.

Dr. Bell provided the following information in the online chat session: Five SARS-CoV-2 infections have been detected in fully vaccinated employees since March 2021. Of those, four

employees had received the Moderna vaccine, and one had received the Pfizer vaccine. These numbers are in the expected range based on the efficacy of the vaccines and the number of people who have been vaccinated. The higher number of infections in Moderna recipients is also expected since the Clinical Center started with the Moderna vaccine; more than twice the number of staff have completed the Moderna series than the Pfizer series. Sequencing showed that two cases were due to the U.K. variant, one was the original genotype (not a variant), sequencing results are still pending in one case, and one case was detected through community testing and a sample was not available for sequencing. No workplace transmission was associated with any of the cases. All affected individuals have fully recovered except one whose infection was just detected in the past few days.

Action Items

- At the July meeting, Dr. Gilman will update the board about employee transitions.
- Include a session on NIH's UNITE initiative on the agenda for the July meeting. The board requested that the session include information on staff and patient demographics as well as cultural competence.
- Dr. Gilman will provide demographic data on Clinical Center patients and staff.
- Dr. Collins will provide demographic data on NIH staff overall.
- NIH will arrange further discussions with the board about NIH's interactions with biopharma.

Joint Commission Readiness

Mary Sparks, RN, Acting Director, Clinical Center Office of Patient Safety and Clinical Quality

Ms. Sparks said that the Joint Commission review is expected to occur this year. Every year, the Clinical Center conducts a focused standards assessment (FSA), a self-evaluation tool to help sustain standards of compliance. It covers 18 different areas of focus that cover the whole hospital. Chapter leaders review each area for weaknesses and identify data to demonstrate compliance throughout the entire hospital. Each standard statement has a scoreable element of performance, yielding a total of more than 1,400 elements of performance. The standards assessment depends on organization-wide multidisciplinary collaboration. Ms. Sparks reported that every department in the Clinical Center responded robustly to deal with COVID-19 while providing care to patients and keeping staff and patients safe. Staff members have readily adapted to these changes while collecting more than 40 performance improvement projects.

Ms. Sparks reported on FSA gains. For example, chapter champions have become familiar with the standards. In terms of the environment of care, building egress is clear, and staff are familiar with fire safety protocols. The staff are also doing well with "virtual" practice tracers. Ms. Sparks acknowledged the help of her nursing colleagues in helping with these tracers by ensuring that everyone, from leaders to frontline staff, is comfortable with online meetings and sharing documents over the platform. Those skills will be important when the Joint Commission surveyors come.

In terms of opportunities for improvement, Ms. Sparks noted the following:

- *Policies:* Maintain periodic review and revisions.
- *Medication reconciliation:* Develop electronic medical record system to upgrade current process.
- *Verbal orders:* Analyze utilization of verbal orders to look for trends, such as certain services relying more than others on verbal order.
- *Interpreter services:* Assess quality of documentation when interpreter services are used.
- *Pain management:* Develop new process to monitor pain assessment and management throughout the Clinical Center.
- *Emergency management:* Plan update and communicate to staff.
- *Environment of care:* This standard includes constructive aspects of the building. The Joint Commission requires 100% compliance, but the Clinical Center had a few areas that were not fully compliant. A plan is in place to improve processes to ensure that the 100% standard is met. A work plan has been developed to improve cleanliness in certain areas and address needs for repainting and for replacement of ceiling tiles, for example.

Ms. Sparks said that Joint Commission surveys occur unannounced, usually in the summer. Some area hospitals are reporting more regular surveys than has been the historic norm.

Worker Safety at the NIH Clinical Center

Michele R. Evans, DrPH, Environmental Safety Officer, NIH Clinical Center

Dr. Evans presented data on *recordable* and *reportable* occupational injuries and illnesses at the Clinical Center to other U.S. hospitals. She also provided more detail on serious injuries among Clinical Center workers and discussed ways to reduce those injuries.

Occupational Injuries and Illnesses

The Occupational Safety and Health Administration (OSHA) defines a *recordable* event as any event that results in work-related death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. In addition, employers must record a significant injury or illness diagnosed by licensed health professional even if it does not result in any of these events. At NIH, the Occupational Medical Service evaluates and treats individuals with an occupational an injury or illness. Some cases may necessitate transporting a worker to emergency departments of local hospitals.

As of January 1, 2015, OSHA requires that all employers *report* occupational illnesses or injuries for the following: all work-related fatalities within 8 hours and all work-related inpatient hospitalization, amputation, or loss of an eye within 24 hours.

Dr. Evans reviewed data on nonfatal *recordable* workplace injuries at the Clinical Center, noting that the NIH Clinical Center's dynamic environment differentiates it from other hospitals and affects worker risk levels. For the years 2017–2019, the Clinical Center had slightly more total

recordable case incidence rates than 50% of hospitals nationwide. However, the Clinical Center's incidence rate of "other recordable cases" (about 3 per 100 full-time equivalents [FTE]) was lower than the median for all U.S. hospitals.

The U.S. median incidence rate for job transfer or days restricted has been stable during 2017–2019, hovering around 1 per FTE. The incidence of these events at the Clinical Center was higher, ranging between 1.1 and a peak of 2.5 per FTE during 2017–2018. About 75% of U.S. hospitals had lower rates than the Clinical Center for 2017–2019. For days away from work, the Clinical Center's rates have also been higher than the U.S. median.

A key statistic, according to Dr. Evans, is the days away, restricted, or job transfer (DART) incidence rate. The Clinical Center's rates peaked at 4 cases per 100 FTE in 2018, when the median for U.S. hospitals was 2.2. About 75% of U.S. hospitals had lower DART rates than the Clinical Center for 2017–2019.

For nonfatal, recordable injuries and illnesses, the Clinical Center's rates have been pretty consistent from year to year, except for a slight increase in days away from work since 2017 and a significant drop in 2020 due to the pandemic, when the ADC has been low.

Select Occupational Risks for Health Care Personnel in the Clinical Center

Dr. Evans said that the Clinical Center has work to do to reduce injuries and illnesses. The main risks are musculoskeletal trauma and syndromes, and exposure to human blood and body fluids. Musculoskeletal trauma and syndromes account for up to 60% of cases reported at the Clinical Center—a statistic that is similar to data from many other industries and health care facilities nationwide.

In 2020, DART accounted for 32 (54%) of the 59 total recordable cases. The majority of injuries were sprains, strains, and ergonomic injuries. One DART case was a burn, and another was an allergic reaction.

Some DART cases arose from required activities (indispensable tasks) and others were unrelated to job activities (e.g., fall from chair, striking a wall or door when walking). Repetitive injuries accounted for 20% of DART that occurred during required activities, and hands-on patient care accounted for 30%. The remaining musculoskeletal injuries occurred while ambulating or reaching for an item.

Reducing Risks in the Clinical Center

Reducing the risk of injury in the Clinical Center requires a multifactorial approach:

- Proactive job risk assessment includes preplacement assessments by the OMS to verify immunizations and provide medical clearance.
- Administrative controls include safe patient handling and mobility programs, specific consultations by a physical therapist who reviews procedures and identifies risks, employee orientation, and staff huddles when events occur.
- Engineering controls are key for worker safety in the Clinical Center's highly dynamic environment.
- Medical management allows some injuries that occur among federal and contract staff and visitors to be treated at the Clinical Center.

- Worker accommodations allow injured staff to continue working rather than staying at home to recover.

Dr. Evans highlighted a few engineering controls for reducing the risk of musculoskeletal injury:

- *High-energy medical equipment:* The docking station for the magnetic resonance imaging (MRI) table moves up and down for transferring patients onto the table. The recently FDA-approved fluoroscopy setup also allows the table to move up and down to allow a more ergonomic position for the technician and physician, and the greater distance between the detector and the X-ray enhances management of patients of size.
- *Wheelchairs:* New wheelchair designs have a liftable arm to allow side entry. The brakes are on the back instead of the front, and the wheels travel smoothly on carpeted or smooth surfaces.
- *Hydraulic assist device for linen carts:* The device can handle linen carts that weigh up to 300 pounds.

Occupational Exposures to Human Blood and Body Fluids

Dr. Evans said that CDC breaks down data on activities associated with percutaneous injuries in health care settings. Nearly half of injuries occur during use of a device, 30% occur after use and before disposal, 13% occur during disposal, and 3% occur when workers recap needles. Injuries in Building 10 follow a similar pattern, with most injuries occurring during a procedure; one or two injuries are due to recapping each year.

Dr. Evans presented data demonstrating reductions in human blood and body fluid exposure injuries in the Clinical Center over time. In the 1980s, an average of 15–18 injuries per 1,000 hospital discharges occurred. From 2018–2020, the rate was in the range of 3–5. Targeted interventions include training, engineering controls, and mandated use of personal protective equipment.

Dr. Evans said that having a hospital-wide culture and commitment to prudent and effective practices and procedures is paramount for a stable and sustainable worker safety program.

Discussion

Dr. Shannon thanked Dr. Evans for presenting data with such fine-grained detail. He anticipated that there will be a great deal of "noise" in data of the comparator hospitals in the peri–COVID-19 period, especially at the national level. For example, hospitals that have cared for many COVID-19 patients likely have had to report employee quarantine or isolation as DART events. This means that data from other institutions may not be useful for the Clinical Center to use for comparison. However, by focusing on the 30 DART musculoskeletal injury events against the backdrop of interventions being implemented in the Clinical Center, it should be possible to assess the interventions' effectiveness based on changes in the number of musculoskeletal events. If the Clinical Center is able to move the needle on musculoskeletal events, that would show up in the data on total recordable events and DART events. This approach would reduce the need to rely on data from comparator hospitals for 2020. Dr. Evans said that discussions are already underway on this very issue.

Dr. Evans said that another topic under discussion relates to how OMS classifies certain incidents. Consistency in recording and reporting is needed for injury events. Dr. Bell said that, in terms of classification of events, the plan is to analyze injury care between first aid and recommendations for job restrictions. NIH has an excellent reporting culture, so OMS sees a good sampling of events that occur in the hospital. It is possible that many minor injuries could be handled at the level of first aid; perhaps some of these injuries do not warrant job restrictions. Dr. Evans added that employees are strongly urged to go to OMS with all work related medical concerns. OMS is convenient and readily available for Clinical Center staff, and that may not be true for other facilities. The focus should be on serious injuries and ways to reduce them.

Dr. Bell mentioned a plan to look at the distribution of injuries by workforce demographic characteristics. Because NIH is a highly specialized facility, the workforce may include more senior employees or staff members having other demographic characteristics that may raise the risk of occupational injuries compared with peer hospitals. After adjusting for demographic factors, there may be more to learn about Clinical Center injury patterns.

Action Item

- Dr. Shannon recommended that, during the COVID-19 period, the Clinical Center focus on musculoskeletal events as a measure of the effectiveness of interventions to reduce these injuries. Comparator DART data will be highly affected by "noise" from peri–COVID-19 events related to employee isolation/quarantine from caring for COVID-19 patients.

The NIH Response to COVID-19: An Update

H. Clifford Lane, M.D., Deputy Director for Clinical Research and Special Projects, Division of Clinical Research; and Clinical Director, National Institute of Allergy and Infectious Diseases (NIAID)

Dr. Lane presented information on COVID-19 case numbers for the period of January 22, 2020, to April 14, 2020. In terms of COVID-19 incidence, Dr. Lane said that the U.S. case numbers seem to be plateauing in the range of 60,000 to 70,000 per day. The 7-day case average is currently about 64,000, slightly less than the prior week, but the decreases do not reflect a strong downward deflection such as that seen in Israel.

To put the COVID-19 pandemic in perspective, Dr. Lane presented mortality data for wars and other pandemics. The number of deaths in the United States (470,110) is second only to the 1918 influenza pandemic (675,000). A total of 405,399 people died as a result of World War II.

Dr. Lane presented a membership list of the current administration's White House Coronavirus Task Force. He also recalled that on May 15, 2020, the Trump administration announced Operation Warp Speed. The operation is a national program to accelerate the development, manufacture, and distribution of COVID-19 vaccines, treatments, and diagnostics.

Diagnostics

Dr. Lane highlighted NIH's role in diagnostics research, particularly the RADx initiative. RADx has boosted the nation's testing capability to around 2 million tests per day. RADx is also rolling out home tests.

The ultrasensitive Quanterix Technology sandwich immunoassay developed with RADx support takes advantage of a nanotechnology approach to detect the virus's nucleoprotein antigen in plasma at levels as low as 0.02 pg/mL—a marked improvement in sensitivity.[1] Dr. Lane explained that blood testing is more reliable and reproducible compared with nasal swabs.

Therapeutics

Dr. Lane outlined the progressive stages of COVID-19 illness and overlaid the different therapies that are appropriate at different stages.

- Antiviral strategies apply in asymptomatic cases, outpatients with mild symptoms, and inpatients whether they are on oxygen or not. Antiviral drugs are not appropriate for patients on mechanical ventilation.
- Immunomodulatory strategies apply for inpatients.
- Anticoagulation therapies apply across the board.

With regard to long COVID-19 syndrome, Dr. Lane pointed out that a report from CDC in July 2020 indicated that about one-third of outpatients with a positive test for SARS-CoV-2 had not returned to baseline health 2 or 3 weeks after the positive test. Older age and comorbidities were associated with a failure to return to baseline health, but nearly 20% of young adults had not returned to baseline health. Michael Sneller, M.D., the medical officer for the NIAID Laboratory of Immunoregulation, is leading a Clinical Center study aimed at investigating the mechanisms behind long COVID-19.

Dr. Lane spoke about NIH's role in therapeutics research.[2] The U.S. National Academies of Sciences, Engineering, and Medicine has concluded that "randomized, controlled trials are the most reliable way to identify the relative benefits and risks of investigational products, and every effort should be made to implement them during epidemics.[3]

The intramural program is running at least seven protocols led by four Institutes and Centers. Extramural programs include the following:

- The Adaptive COVID-19 Treatment Trial (ACTT) led by John Beigel, M.D., of NIAID, is enrolling hospitalized patients. The first ACTT trial began in February 2020; four trials have been completed. ACTT-1 was the basis for licensure of remdesivir for treating COVID-19. ACTT-2 led to an EUA for baricitinib. ACTT-3 showed that remdesivir plus

[1] Su B, Yin J, Lin X, Zhang T, Yao X, Xu Y, Lu Y, Wang W, Liu K, Zhang J, Xie L, Jin R, Feng Y. Quantification of SARS-CoV-2 antigen levels in the blood of patients with COVID-19. Sci China Life Sci. 2020 Nov 26:1–4. doi: 10.1007/s11427-020-1830-8. Epub ahead of print. PMID: 33259038; PMCID: PMC7706695.

[2] Lane HC, Fauci AS. Research in the Context of a Pandemic. N Engl J Med. 2021 Feb 25;384(8):755-757. doi: 10.1056/NEJMe2024638. Epub 2020 Jul 17. PMID: 32678528; PMCID: PMC7383591.

[3] National Academies of Sciences, Engineering, and Medicine. Integrating clinical research into epidemic response: the Ebola experience. Washington, DC: National Academies Press, 2017.

interferon beta-1a was not superior to remdesivir alone. The recently completed ACTT-4 demonstrated that remdesivir plus baricitinib was not superior to remdesivir plus dexamethasone.

- The six ACTIV trials have led to several important therapeutic approaches for COVID-19 for outpatients and hospitalized patients, including immunomodulators, anticoagulation strategies, monoclonal antibodies, antivirals, and an inhaled beta interferon. ACTIV-5 is currently randomizing patients to lenzilumab. ACTIV-6 will be opening soon to randomize patients to ivermectin or other repurposed drugs, including antivirals, protease inhibitors, polymerase inhibitors, and entry inhibitors.

Prevention

Prevention measures fall into several categories:

- *Public health measures.* Dr. Lane said that public health measures (e.g., masks, social distancing, avoidance of travel and crowds) remain the most important way to get back to life as usual. For the vaccinated population, some of these restrictions can be relaxed. CDC is likely to issue less restrictive guidelines as more people are vaccinated.

- *Antibody prophylaxis.* Several phase 3, randomized, placebo-controlled trials are underway to test monoclonal antibodies as post-exposure prophylaxis. Bamlanivimab, for example, reduced symptomatic disease by 80% among nursing home residents. However, the government and Eli Lilly stopped distributing bamlanivimab alone on March 24, 2021, with the emergence of COVID-19 variants. Preliminary results of a study of the REGEN-COV antibody cocktail showed that the combination reduced transmission among household contacts by half and provided 100% protection against symptomatic infection.

- *Vaccines.* Dr. Lane spoke about the importance of tracking how variants change over time to predict what the next variant will be and how effective vaccines will be against it. He discussed SARS-CoV-2 variants of concern, their lineages, and characteristics. Most countermeasures are effective against the variants, although vaccine efficacy may provide less protection against certain variants. Some variants appear to be more easily spread and cause more severe disease. Dr. Lane also compared the vaccine protocols that demonstrated safety and efficacy of the Pfizer (mRNA), Moderna (mRNA), AstraZeneca (adenovirus vector), and Janssen/J&J (adenovirus vector) vaccines. The effectiveness of the AstraZeneca vaccine does appear to be reduced against the P.1 (South Africa) variant. FDA has authorized three vaccines. The AstraZeneca vaccine is still in testing. Incidence data show that the vaccines are very effective at reducing severe disease and mortality. A Merck viral-vectored vaccine is in phase 1/2 trials; the Novavax protein subunit vaccine is in phase 1/2 and 3 trials; and the GlaxoSmithKline/Sanofi vaccine, which is also directed against a protein subunit, is in phase 1/2 trials. As of February 10, 2021, the 7-day rolling average for vaccine doses administered in the United States had reached 1.6 million doses per day, for a total of 44.8 million overall. Globally, more than 151 doses have been administered. Questions have arisen about a possible association of the

adenovirus-based vaccines with cerebral venous thrombosis, a thrombocytopenic blood clotting problem that is seen with antibodies induced by heparin.

NIH Treatment Guidelines

Dr. Lane noted that the first release of the guidelines occurred about a year ago. The "living document" is updated often as new clinical data accrue; 24 releases came out over the first year. The guidelines have received more than 14 million page views.

Conclusion

Dr. Lane said that NIH's role in COVID-19 research has led to important successes, including demonstration of remdesivir's effectiveness, launch of coordinated therapeutic and diagnostic research protocols, and involvement in three of the four ongoing phase 3 vaccine trials. By coordinating research efforts and setting clear priorities, it is hoped that the most effective countermeasures will get to the greatest number of people in the shortest period of time.

Discussion

Dr. Forese asked how an EUA product would obtain full approval from FDA. Dr. Lane clarified that an EUA may be issued for an investigational product if a cabinet secretary declares a public health emergency. It is still an investigational product, but the company may apply for licensure as is the case for any product. A key point is that the U.S. government cannot require EUA products to be used by federal employees or the military.

Dr. Hait said that people want to know how long they will be protected after natural infection or vaccination. Dr. Lane said that no correlate of immunity has been identified; therefore, it is difficult to ascertain how long immunity lasts. He pointed out that COVID-19 is a brand-new disease; we have only one year of experience. Some reinfections have been observed. It appears that vaccines induce a greater antibody response than natural infection. Important factors include booster vaccinations and emergence of more variants.

Dr. Hait asked whether serology testing has been improved. Dr. Lane said that testing is pretty good. He hopes that vaccine trial follow-up will help identify correlates of immunity.

ANCC Magnet® Designation Journey Update

Gwenyth Wallen, Ph.D., RN, Chief Nurse and Senior Investigator, Clinical Center Nursing Department

Dr. Wallen thanked the board for its recommendation to continue the effort to gain Magnet designation for the Clinical Center despite the pandemic. Magnet Ambassadors, NIH leaders, and the NIH Patient Advisory Group expressed support for continuing the effort and help overcome some people's reluctance to initiate such an effort in this timeframe. Magnet Recognition sends a strong message about commitment to patient safety and excellence in practice. The Clinical Center application will likely be submitted in the spring or summer of 2022.

Dr. Wallen updated the board on the effort to collect data to support the Clinical Center's Magnet submission. The Magnet application focuses on three components:

- *Nurse satisfaction.* The response rate to the 2020 National Database of Nursing Quality Indicators survey was 89%, up 10% from the 2019 survey. Dr. Wallen said that with such a high response rate, people can be confident that the results are representative.
- *Patient outcomes.* This component focuses on nurse-sensitive clinical indicators for inpatient and ambulatory care.
- *Patient satisfaction.* In a setting such as the Clinical Center, patient satisfaction data from inpatients and ambulatory patients is of paramount importance.

Four categories have been selected for Magnet submission:

- *Professional development.* This category relates to educational resources and also corresponds to the Clinical Center strategic plan, which is focusing on people. The initiation of IDPs also contributed to this area. From conversations that Dr. Wallen has learned that the data for the Clinical Center Nursing Department shows diversity; however, more work is needed to ensure equity. Some nursing staff indicated that they did not have the same professional development opportunities that their white counterparts have. Dr. Wallen said that the Equity, Diversity, and Inclusion Council will be able to help ensure that all have opportunities. Additionally, more work needs to be done to support nurse managers as well.
- *Leadership access and responsiveness.* The nursing staff has communicated the need for more interaction with not only Dr. Wallen, but also the rest of the nurse executive team. Virtual interactions are not enough.
- *Fundamentals of quality nursing care.* Patient outcomes depend on good-quality nursing care. In a research hospital, high-quality inpatient and outpatient care is the baseline that is essential to the interpretation of research findings. In terms of patient outcomes, some indicators are required, including falls with injury and hospital-acquired pressure injuries (HAPI). The data show that the Clinical Center has improved care with regard to these indicators. Catheter-associated urinary tract infections and central-line blood stream infections are also important outcomes to track for inpatients. The Magnet Recognition Program is increasing emphasis on ambulatory care. Falls with injury is a key measure, and Dr. Wallen is working with leaders and the quality team to decide on other measures.
- *Adequacy of resources and staffing.* The responsibility of chief nurses and nurse executives is to ensure sufficient staffing while being good stewards of resources. The Clinical Center is slightly below the 50th percentile compared to Magnet hospitals. Having adequate staffing and resources is key to being able to carry out clinical trials while providing excellent care. Dr. Wallen said that some units need some attention in this regard to get the entire nursing department up to the benchmark.

Dr. Wallen explained that focusing on these four targets should help ensure success. These seem like realistic goals for the Clinical Center Magnet submission.

Dr. Wallen said that the budget for fiscal year (FY) 2021 reflects hiring a Magnet consultant. The Clinical Center's Magnet coordinator has also been working with a mentor.

One thing that is required to achieve Magnet designation is a clinical ladder. Dr. Wallen reported working closely with human resources colleagues and with Dr. Gilman to develop a clinical

ladder, which will take nurses who are new graduates from the residency program from GS7 up to GS12. Discussions with staff revealed that promotions were not always made in an unbiased way based on experience. Part of the clinical ladder will include a peer review process that involves a board made up of other nurses to evaluate nurses and make recommendations about advancement to the highest level (GS12). The clinical ladder will be similar to other academic settings, spanning from Clinical Research 1 to Clinical Research 4. The information could be included on nurses' ID badges to show their level of experience on the clinical ladder and the excellence they are trying to achieve.

Discussion

A board member asked how the nurses will receive the concept of a clinical ladder. Dr. Wallen said that they are excited about it. Dr. Wallen said that some nurses are asking when GS12 positions will be posted, but Dr. Wallen has been waiting to post them. Everyone wants to see how the process works. The goal is to have the first evaluation of portfolios in May 2021.

Dr. Shannon encouraged Dr. Wallen to hire a Magnet consultant to help close gaps. Because of the pandemic, many hospitals have had to withdraw from consideration for Magnet status. The Clinical Center has been very resilient, so the timing may provide an advantage.

Ms. Berty asked about patient involvement in the Magnet journey. Dr. Wallen clarified that patient involvement is required every step of the way. She plans to work with the Patient Advocacy Group to explore improvement areas. New data surveys are going to be implemented, and those data might underpin conversations with patients about areas for improvement.

Update: Center for Cellular Engineering

David Stroncek, M.D., Director, Center for Cellular Engineering

Dr. Stroncek said that the CCE's mission is to provide cell and gene services for Clinical Center investigators and their patients. The center manufactures early-phase (phase 1 and 2) cell and gene therapies and processes human stem cell grafts for transplantation. CCE also coordinates the collection and shipment of autologous cells to other facilities for manufacturing cell therapies and receiving, storing, and issuing the final products. Finally, the CCE also labels cells for in vivo trafficking and survival studies.

In 2017, the Cell Processing Section consisted of one section within the DTM with two supervisors and 50 staff. The section had one processing facility that was built in 1997.

A 2017 business plan was based on having five CCE sections: Cell Therapy Manufacturing, New Product Management, Research and Practice Development (organized in 2018), Product Assurance and Characterization Testing (PACT, organized in 2019), and an independent Quality Unit (organized in 2019). The Research and Practice Development Section includes three nurses who coordinate with physicians to schedule products and collections.

Dr. Stroncek said that some new staff were hired in late 2018, including a deputy director, quality unit director, PACT section chief, and a CMO for cell therapy manufacturing. The original projection was to have 182 staff by 2020, but hiring has been slower, mainly because of the need to develop new position descriptions and a shortage of leadership staff to hire people. Dr. Stroncek anticipates an uptick in hiring soon.

Dr. Stroncek reported that in mid-2019, an additional 2,500 square feet on the fifth floor of Building 10 provided rooms for cell culture, laboratory space, and office space which are being used for the development of new products by the New Product Management Section. New office space on the first floor was occupied in February 2020. The CCE opened the Molecular Quality Control Laboratory in 2018.

Existing cell processing laboratories are sufficient but have limitations. The new T10B cell processing laboratory will open in 2021. It will have a 21st century design, four culture rooms, separate entrance and exit corridors, and laminated walls. Each culture room has airlocks at the entrance and exit. In 2023, the new, state-of-the-art 12E facility will open. It will have seven culture rooms, two cell processing rooms, an assay laboratory, and office space.

In terms of cell processing activity, Dr. Stroncek reported that the CCE has 43 active protocols, and 14 new protocols are in the product development stage. In 2019, 76 hematopoietic stem cell transplants were processed and 71 were processed in 2020. Transplant activity has increased since 2020 and is approaching normal levels. An average of four to seven transplants are done per month. Transplants are used to treat leukemia and lymphoma patients, but also those with sickle cell disease, aplastic anemia and congenital immune deficiencies.

The CCE manufactures a number of gene cancer therapies, including chimeric antigen receptor T-cells (CAR-T cells). In addition, the CCE manufactures T-cell receptor engineered T-cells, dendritic cells, interferon-treated monocytes, virus-specific T-cells, and gene-corrected hematopoietic stem cells.

Recently, the CCE started to manufacture retinal pigmented epithelial cells for treating age-related macular degeneration. The project was 5 years in development, and FDA approved the Investigational New Device application in December 2019. Dr. Stroncek said that the first patient will be treated in June 2021.

CAR-T cell manufacturing has grown a great deal since 2012, when the first protocol began. In 2021, seven protocols are active. The CCE has manufactured most CAR-T cells for treating B-cell malignancies, including multiple myeloma.

The CCE is also acquiring new instruments for manufacturing. Because cell freezing/thawing technology is rapidly evolving, the CCE is purchasing cGMP devices.

Challenges include keeping up with the growing needs of the Institutes and Centers. Hiring of staff and increasing regulatory and quality expectations are also challenges. Dr. Stroncek spoke of the difficulties of developing quality systems for managing an emerging field that lacks clearly defined regulations. Building, commissioning, and validating new processing faculties are time-consuming activities. With the growth in facilities, the CCE needs better systems for maintenance.

Dr. Stroncek spoke about current development and future directions for the CCE. New protocols for cancer immunotherapies and for treating immune deficiencies are planned. Another new protocol will labeled RBCs with fluorescein and these cells be used to image the retina. The CCE will also implement a new vector integration site assay.

Discussion

Dr. Hait asked about sustainability in terms of environmental impact as more plastics are being used in laboratories, as glassware has been phased out. Has consideration been given to

minimizing use of plastics? NIH is a beacon for the rest of the country and, as such, could be a strong leader in this area. Dr. Stroncek said that sustainability is a critical issue. A great deal of plastic labware is consumed in cell manufacturing, plus CCE staff use many disposable items for gowning and gloving as they come and go from tissue culture rooms. Closed, automated processes still require plasticware, but only one disposable kit for the entire 10 days of cell culture. In addition, fewer gloves and less disposable clothing are required because automated processes are less reliant on people. Dr. Forese suggested that the topic of sustainability be included in the agenda for a future meeting.

Dr. Shannon asked how much production time could be saved by using automated bioreactors rather than manual transduction. Dr. Stroncek said that automatic processing requires two high-activity days, whereas manual transduction requires four to six high-activity days; however, it takes time to get automated systems in place.

Action Item

- The CCRHB requested a presentation on NIH's sustainability practices during a future meeting.

Clinical Facilities Projects Update

Daniel Wheeland, P.E., Director, Office of Research Facilities, NIH

Mr. Wheeland updated the board on completed projects, challenges with facilities, and sustainability strategies.

Completed Projects

Mr. Wheeland highlighted several recent positive developments since the last board meeting:

- The interim Intravenous Admixture Unit project was completed. Qualifications are underway.
- The CCE project was completed. Qualifications are underway.
- The balance of funding was provided in the 2021 Omnibus Appropriations Act for the Surgery, Radiology, and Laboratory Medicine (SRLM) project. Mr. Wheeland thanked the CCRHB for writing a letter supporting the funding request. The award will be made in the first quarter of 2022. No further external approvals are needed; therefore, the risk of further delays is minimal.
- Quarterly meetings with the staffs of Congressional Appropriations Committees were set up and will continue. The meetings demonstrate an interest in NIH facilities overall. Congressional support will be needed for future projects.

Challenges

Building 10 continues to show its age and vulnerability to flooding. Six major flood events have already occurred in 2021, although no major damage resulted. Mr. Wheeland spoke about demonstrating to Congress the need to consider the future of Building 10.

The design feature for the new SRLM building will reduce the likelihood and consequences of leaks and floods.

Arteries that carry high volumes of water will be located in two mechanical towers so any floods will not affect occupied space. There are capillaries over occupied space, but this design will provide much more resilience and safety for the Clinical Center.

Sustainability Strategies

Mr. Wheeland provided information requested by the CCRHB about sustainability strategies:

- The Office of Research Facilities is aiming for Leadership in Environmental and Energy Design (LEED) certification at the gold level.
- The area around the Clinical Center includes gravel and planting mixes to support micro-bioretention.
- Energy conservation features include chilled beams, heat recovery, building automation and control system, and metering.
- Lighting is with LED lights with no mercury and includes lighting controls.
- Efficient fixtures reduce water usage by 20%.
- Construction and demolition waste is managed and recycled when possible.
- Materials meet or exceed the Environmental Protection Agency's recommended recycled composition. No ozone-depleting compounds are used.

Other Projects

Mr. Wheeland described progress on other facilities projects:

- The CCE is the first such facility designed from the ground up to meet needs associated with cell engineering. Construction was completed in November 2020. Commissioning, qualification, and validation is scheduled for completion in May 2021. Performance qualification is scheduled for June 2021 to provide evidence that the area can meet specified levels for the proposed calculation.
- The National Cancer Institute's tumor infiltrating lymphocyte cell processing modular facility will support the institute's Surgery Branch. Construction was completed in September 2020, and commissioning and testing were completed in March 2021. The institute is completing the environmental monitoring performance qualification for the facility.
- Construction of the DLM's Sterility Laboratory is in progress and should be completed in May 2021.
- Construction and qualification of the expanded interim IVAU was completed in 2020. An occupancy permit was approved and the space turned over to the Pharmacy Department.
- The renovation of the pharmacy and permanent IVAU is underway. Most demolition work was completed in July 2020, and the final design was completed in December. The facility will have independent exhaust and supply air. The construction phase is scheduled for completion in November 2021.

- The E-Wing renovation is supporting the CCE. Construction is in progress and is anticipated to be completed in February 2022. The result will be a high-quality facility with dedicated facilities to support cutting-edge research.
- Turnkey upgrade for positron emission tomography (PET) and MRI: A single company was awarded the contract to provide the equipment and handle construction. Construction began in January 2021 and should be completed in June 2021.

Summary

Mr. Wheeland thanked the CCRHB for its advocacy on behalf of the Clinical Center. All the projects will improve patient care, patient safety, life safety, and the overall environment of care. NIH continues to work with the U.S. Department of Health and Human Services, the Office of Management and Budget, and Congress to build trust and enhance knowledge of future projects, including renovations for nuclear medicine, a solution for the outpatient clinics, and more.

Discussion

Dr. Forese was gratified that the board's advocacy was helpful. She looks forward to hearing more about the facilities projects at the next board meeting.

Adjournment

Dr. Forese congratulated Dr. Collins, Dr. Tabak, Dr. Wallen, Clinical Center leaders and clinicians, Institute and Center directors, and NIH staff for the amazing body of work described today. She said she feels proud when she tells people that she's affiliated with this national treasure. Dr. Forese thanked the board members, meeting organizers, and presenters.

The next CCRHB meeting is slated for July 23, 2021.

Dr. Forese adjourned the meeting at 12:46 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 Tabak /

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/ Francis Collins /

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

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ACTT	Adaptive COVID-19 Treatment Trial
ADC	average daily census
BLA	Biologics License Application
CAR-T (cells)	chimeric antigen receptor T-cells
CCE	Center for Cellular Engineering
CCRHB	Clinical Center Research Hospital Board
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CGMP	Current Good Manufacturing Practice [regulations]
CLABSI	central line–associated bloodstream infection
CMO	Chief Medical Officer
COVID-19	coronavirus disease 2019
DART	days away, restricted, or transferred
DLM	Department of Laboratory Medicine

DTM	Department of Transfusion Medicine
EUA	Emergency Use Authorization
FDA	U.S. Food and Drug Administration
FEVS	Federal Employee Viewpoint Survey
FNIH	Foundation for the National Institutes of Health
FSA	focused standards assessment
FTE	full time equivalent
FY	fiscal year
HIM	Health Information Management
IDP	individual development plan
IVAU	Intravenous Admixture Unit
J&J	Johnson & Johnson
LEED	Leadership in Energy and Environmental Design
MRI	magnetic resonance imaging
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health

OMS	Occupational Medical Service
OSHA	Occupational Safety and Health Administration
PACT	Product Assurance and Characterization Testing
PET	positron emission tomography
RADx	Rapid Acceleration of Diagnostics
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SRLM	Surgery, Radiology, and Laboratory Medicine