

Fifteenth Meeting of the Clinical Center Research Hospital Board

July 17, 2020

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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)

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

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

Brig Gen James Burks, M.B.A., M.M.A.O.S., U.S. Air Force (Ret)

Jeanette Ives Erickson, D.N.P., RN, FAAN, Chief Nurse Emerita, Massachusetts General Hospital; and Executive Committee Chair, Commission on Magnet Recognition, American Nurses Credentialing Center

*Julie Freischlag, M.D., 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 Emerita, Johns Hopkins University and Health System

Richard Shannon, M.D., Executive Vice President for Quality and Transformation, Duke Health

Ruth Williams-Brinkley, M.S.N., President and Chief Executive Officer, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

*Absent

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 15th meeting via videoconference on July 17, 2020. The meeting was open to the public and was webcast live. 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. She welcomed new Board members Steven I. Goldstein, M.H.A., President and Chief Executive Officer (CEO) of the University of Rochester Medical Center; and William Hait, M.D., Ph.D., Johnson & Johnson’s Global Head of External Innovation. Julie Freischlag, M.D., Wake Forest University School of Medicine, was absent.

The Board and NIH staff honored two former Board members, Beatrice Bowie and Paul O’Neill, who recently passed away.

Francis Collins, M.D., Ph.D., NIH Director, greeted the CCRHB members and highlighted NIH and other agencies’ activities focused on the pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The [Accelerating COVID-19 Therapeutic Interventions and Vaccines](#) (ACTIV) public–private partnership aims to speed the development of the most promising treatments and vaccines for coronavirus disease 2019 (COVID-19). In addition to private firms and NIH, the Department of Veterans Affairs, the Department of Defense, the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, and other federal entities are collaborating within the framework of [Operation Warp Speed](#). Dr. Collins also outlined the many provisions aimed at keeping Clinical Center employees safe during the current pandemic.

James Gilman, M.D., CEO, NIH Clinical Center, announced several changes in Clinical Center leadership and noted the precipitous drop in the hospital census because of the pandemic. The phased approach for bringing NIH employees back to the Clinical Center was also discussed. Dr. Gilman announced the new [Blood and Immune Deficiency–Cellular Therapy Program](#) at NIH, which consolidates three or four separate inpatient services. New initiatives to improve employee safety have been launched. The Behavioral Emergency Response Team (BERT) responds to disruptive or violent behavior by providing verbal or physical crisis de-escalation. The Anti-Harassment Response Team (AHaRT) addresses inappropriate behavior and harassment by patients and visitors toward Clinical Center staff. The Clinical Center is improving the hospital’s simulation capabilities and establishing a clinical simulation center. Dr. Gilman also explained new Clinical Center systems to support telehealth visits. In closing, he spoke of the movement inside and outside NIH calling for social justice and rejecting racism in all its forms.

Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality, briefed the CCRHB on patient and employee safety data, noting several recent encouraging trends. She also explained the Trigger Tool, a qualitative peer review of factors that contribute to individual patient harm events. Madeleine Schuyler Deming, M.D., Staff Clinician and Assistant Research Physician, Clinical Center Internal Medicine Consult Service, presented three cases that were analyzed by the Trigger Tool team. These deep-dive peer reviews have highlighted some systems issues and led to several organizational changes.

Gwenyth Wallen, Ph.D., RN, Chief Nurse Officer, Clinical Center Nursing Department; and Rachel Coumes Perkins, M.S.N., RN, Nurse Consultant, Clinical Center Nursing Department, described the Clinical Center's journey to become a Magnet Recognition Program® hospital. Ms. Perkins is serving as the Magnet Recognition Program® manager, coordinating with nursing staff and an analyst as NIH develops a plan for achieving Magnet status.

Dr. Gilman; Ann Marie Matlock, D.N.P., RN, NE-BC, Chief, Medical–Surgical Specialties Clinic, and Captain, United States Public Health Service; Karen Frank, M.D., Chief, Clinical Center Department of Laboratory Medicine (DLM); and Tara Palmore, M.D., Chief, Clinical Center Hospital Epidemiology Service, outlined in detail the provisions in place for screening and testing staff and patients for SARS-CoV-2. They also provided information on the testing setup in the DLM as well as data on Clinical Center test results to date.

Meeting Summary

Friday, July 17, 2020

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 15th meeting of the National Institutes of Health (NIH) CCRHB took place on July 17, 2020. The meeting participants convened via videoconferencing. 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 and welcomed everyone. Dr. Forese announced that CCRHB member Julie Freischlag, M.D., Wake Forest University School of Medicine, was absent.

Dr. Forese asked the meeting participants to observe a moment of silence to honor one of the Board's first members, Beatrice Bowie, who passed away several weeks ago. Ms. Bowie was a vital participant. She never missed a meeting and took every opportunity to provide a patient's perspective on the NIH Clinical Center's efforts to ensure patient safety and provide top-notch care in the world's largest hospital dedicated to biomedical research.

The Board welcomed new members Steven I. Goldstein, M.H.A., President and Chief Executive Officer (CEO) of the University of Rochester Medical Center; and William Hait, M.D., Ph.D., Johnson & Johnson's Global Head of External Innovation.

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 continued service as leader of the Board and welcomed the new members.

The Clinical Center has experienced stresses during the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as has every other medical organization during recent months. Dr. Collins said that his days have been very long and packed with meetings and decisions. He also spoke of the enormous responsibility of bringing the best science forward to end the crisis in this nation and around the world.

Dr. Collins reflected on Ms. Bowie's contributions to the Board and to NIH as a whole. Ms. Bowie frequently reminded everyone that patients are the point behind this research enterprise. Dr. Collins acknowledged Ellen Berty, who now is assuming the sole responsibility for reminding the Board and others that patients should be front and center.

Dr. Collins also acknowledged the recent death of former Board member Paul O'Neill, M.P.A., who was a real force for patient and employee safety.

Dr. Collins also spoke about the role of Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases (NIAID), in promoting the science of SARS-CoV-2 while

communicating about what is known as well as knowledge gaps. Dr. Fauci is resilient and will continue to tell the stories of coronavirus disease 2019 (COVID-19) and scientific progress.

Clinical Center Activities Related to the Pandemic

Dr. Collins explained the [Accelerating COVID-19 Therapeutic Interventions and Vaccines](#) (ACTIV) public–private partnership with the goal of developing a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. This unprecedented public–private partnership involves private firms and NIH, the Department of Veterans Affairs, the Department of Defense, the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention (CDC), and other federal entities operating within the framework of [Operation Warp Speed](#) (OWS). The goal is to deliver 300 million doses of a safe, effective vaccine for SARS-CoV-2 and therapeutics for treating COVID-19. Such partnerships usually take 2 years to set up; OWS was assembled in just 2 weeks.

The ACTIV network already launched a clinical trial of Moderna’s mRNA vaccine in collaboration with NIAID’s Vaccine Research Center. All 45 participants in the Phase I trial demonstrated good responses to the vaccine. The 100-mcg dose produced high titers of neutralizing antibodies; the hope is that these will translate into immunity to COVID-19. A randomized clinical trial is slated to begin on July 27, 2020. The goal is to enroll participants in the West and Southeast—areas that are currently hit hard by the virus.

The ACTIV network is also facilitating a trial of a monoclonal antibody and another trial of anticoagulants among the sickest patients. The latter trial will test several anticoagulants at low and high doses.

More vaccine trials are slated to get under way in August and September of 2020. The federal government is investing in manufacturing capacity at its own risk, to allow an eventual vaccine to be distributed rapidly.

Dr. Collins stressed the importance of enrolling people in the trials who are at greater risk: minority groups and older people. To engage minority groups, significant community outreach will be necessary to build trust among populations that often distrust government for many legitimate reasons. The idea is to enroll people as partners, not research subjects.

Employee Safety at NIH

NIH is operating as well as possible given current circumstances. When the pandemic hit, many NIH employees were diverted to remote work. Grants and peer review staff have transitioned almost seamlessly to online work. Bench researchers face more challenges, though.

Researchers have been divided into three groups for a phased return to the workplace. Group A researchers are essential for patient or animal care or for research on COVID-19. This group has already returned to campus. Group B researchers are slightly less critical; NIH is now preparing for their return. NIH is very stringent about mask wearing and social distancing.

A car queue has been set up for employee testing. The ability to conduct pooled testing has increased efficiency. To date, 270 NIH staff members have tested positive for SARS CoV-2.

Infections had been trending downward in the District of Columbia, but the downward trend has plateaued. Prince George's County, MD, is a hot spot of infections at the moment.

Discussion

On behalf of the CCRHB, Dr. Forese thanked Dr. Collins, Dr. Fauci, and other NIH leaders and staff. Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; and Executive Director, CCRHB, welcomed the new members of the Board.

Update from the NIH Clinical Center CEO

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

Dr. Gilman thanked the Board members for their guidance to the Clinical Center. He acknowledged the passing of former members Ms. Bowie and Mr. O'Neill.

Hospital Census

One of goal of the [Clinical Center Strategic Plan](#) is to increase utilization of the Clinical Center. The inpatient census was trending upward, but then the pandemic struck, and the census has been declining since mid-March. NIH deferred elective clinical and research procedures. The Clinical Center staff also anticipated the need to free up space to prepare for a possible influx of COVID-19 patients. Many research participants were discharged to home, and others were advised not to come to the Clinical Center. Since mid-May, the census has been slowly rising, but people are reluctant to travel and enter hospitals unless absolutely necessary. In the meantime, transplants and surgeries have resumed, but the census has not bounced back yet. Compared with 2019, admissions are down 28% and outpatient visits are down 30%.

Leadership Changes

Two national searches, for a new chief medical officer and for the chief of the Transfusion Medicine Department, are nearing completion.

NIH has made further changes in the leadership of the Clinical Center Pharmacy Department. CAPT Richard DeCederfelt, Pharm.D., is now Acting Chief of the Pharmacy Department. He previously ran the pharmacy's procurement division. A national search will be launched to fill the position permanently. Marilyn Farinre, Pharm.D., M.B.A., DPLA, has stepped in as the Chief of Pharmacy Operations Service. She came to NIH from Sibley Memorial Hospital. Marcus Ferrone, Pharm.D., J.D., was recruited from the University of California, San Francisco, where he was an R01-funded investigator. He filled a quality control role initially but is now the Chief of the Clinical Pharmacy and Investigational Drug Research Unit.

Blood and Immune Deficiency–Cellular Therapy Program

The new [Blood and Immune Deficiency–Cellular Therapy Program](#) at NIH consolidates three or four separate inpatient services. The National Heart, Lung, and Blood Institute; NIAID; the National Cancer Institute (NCI); and the National Human Genome Research Institute (NHGRI) are working together, combining their small bone marrow transplantation programs and sharing ideas. Theresa Jerussi, M.S., PA-C, of the NIH Clinical Center is Chief Operating Officer of the program, which began about a year ago.

The idea behind the consolidation is to build a transplant and cell therapy community based on best practices with the goal of providing the highest-quality and safest care, optimize resource utilization of the Clinical Center and the NIH Institutes and Centers (ICs), leverage expertise to optimize the design of clinical trials, ensure physician competency in the fields of bone marrow transplantation and cell therapy, and increase efficiency and clinical care experience among clinicians previously practicing separately.

2020 Priorities

Dr. Gilman outlined five goals for 2020:

- Achieve Magnet recognition, as was discussed later during the meeting.
- Improve detection of neurologic effects of medications. Avindra Nath, M.D., Intramural Clinical Director of the National Institute of Neurological Disorders and Stroke, is taking part in this effort, along with nursing staff.
- Implement two initiatives focusing on staff safety (i.e., Anti-Harassment Response Team [AHaRT] and Behavioral Emergency Response Team [BERT]).
- Improve talent management.
- Focus on simulations and telemedicine.

Employee Safety

Although NIH is well protected from outside threats, sometimes patients or visitors exhibit disruptive or violent behavior that may be an effect of diseases or treatments. To deal with these incidents, NIH launched Code BERT in February 2020. When a Code BERT is called, the team helps with patients (or visitors or family members) to manage uncontrolled, escalating, disruptive, or violent behavior if efforts by the primary team have been ineffective or medical and nursing teams need support in managing a patient. A trained team arrives to provide verbal or physical crisis de-escalation. After each Code BERT incident, a debriefing takes place. Since BERT's launch, the team has been called upon seven times—more often than anticipated. NIH is partnering with a simulation expert to prepare for BERT events.

CAPT Antoinette L. Jones, M.S.O.D., RN, is leading AHaRT, established to address inappropriate behavior and harassment by patients and visitors toward Clinical Center staff. Disruptive behavior affects staff and the care of other patients. To date, 16 reports of verbal abuse (e.g., yelling, profanity, disparaging remarks), involving two pediatric patients and three adults, have been dealt with. One patient was referred for care elsewhere.

New Clinical Simulation Program

The 2019 Strategic Plan identified the need to standardize and improve the hospital's simulation capabilities and establish a clinical simulation center. To meet these needs, the Clinical Center has procured the services of Mabel Gómez Mejia, M.Sc., who completed a medical simulation fellowship at Harvard Medical School. NIH clinicians perform a great deal of high-complexity, low-volume work; simulations may be beneficial for training and maintaining skills. In addition, simulations may help people learn how to request autopsies and communicate with families. Dr. Gilman presented the four proposed work streams for the simulation center: clinical simulation, translational simulation, research simulation, and innovations in simulation.

Telehealth and Telemedicine at the Clinical Center

NIH selected the Microsoft® Teams platforms, which has substantial privacy protections. A new policy was developed in just 3 weeks as a strategy to cope with the pandemic. During May and June this year, 785 telehealth visits took place. The Clinical Center Health Information Management Department provides telehealth concierge services, which manages all the technology and coordination aspects of telemedicine. Telehealth services at NIH are likely to expand—a positive outcome of the pandemic because of the convenience for patients and providers. The plan is move to a long-term solution in 2021 that fully integrates with NIH’s electronic health record system.

Grieving Loss and Confronting Social Injustice

Two years ago, Dr. Gilman reported that more than 2,000 NIH employees had completed implicit bias training, but much more needs to be done. Following the tragic death of George Floyd and the subsequent outcry across the country, there has been a movement inside and outside NIH to address social justice and racism in all its forms. As Dr. Gilman wrote in an email to Clinical Center staff, “We must do more than wait for this to pass. This time we need to be better than that. This time I must do more. This time I must be better than I have in the past.”

Racism must be confronted as a public health concern: “Public health is called upon to recognize the pervasive role of racism in public health and to reshape our discourse and agenda so that we all actively engage in racial justice work.”¹

Returning to Work

Dr. Gilman underscored the importance of ensuring the safety of patients and staff. NIH issued [guidance](#) on provisions for safe return to work; facial coverings are required. Campaigns on hand hygiene and coughing/sneezing hygiene are in place. Employees are returning to work in phases, and the inpatient census will slowly rise. No more than 10 people may be in a room. One team of a given service is always sequestered at home so that not all service staff are potentially exposed.

Patients wear masks when staff enter the room. Two tests to rule out SARS CoV-2 infection are performed before procedures that might result in aerosolization.

To bolster employee morale, music performances are recommencing in the atrium of the Clinical Center, where there is a grand piano. Although vocal music, woodwinds, and brass are contraindicated, strings, percussion, and keyboards will be performing.

Discussion

Dr. Hait asked about the role of diagnostic testing in decisions about returning to work. He also noted that people are often good about safety practices at work, but they ride in carpools, dine in restaurants, and engage in other risky activities when they are outside of the workplace.

Dr. Gilman said NIH is testing about 1,000 staff members every week with next-day turnaround. Every patient and visitor is tested. The rates of asymptomatic infections have been very low for

¹ García JJ-L, Sharif MZ. Black Lives Matter: A Commentary on Racism and Public Health. *Am J Public Health*. 2015;105(8):e27-e30. doi:10.2105/AJPH.2015.302706. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504294/>. Accessed July 29, 2020.

staff and nil for patients. Increased infection rates in Montgomery County, MD, are raising questions about returning more staff to the workplace.

Richard Shannon, M.D., expressed his support for the simulation program, which could be transformative in terms of safety. Team preparation and training are instrumental; simulations will be a major enhancement.

Dr. Shannon thought that the multi-Institute collaboration on cellular therapies and transplantation was an important advance. Many organizations are creating service lines, in which people from different disciplines come together to build an excellent service. Dr. Shannon recommended establishing metrics to document success.

Dr. Shannon said that the reduced census was to be expected during the pandemic, but he asked about the consequences of deferring care for patients whose clinical needs are being met to some extent through their participation in research. Dr. Gilman noted that investigators have had to be more selective about procedures. Some surgeries were postponed for a week or a month with no discernable impact on outcomes. Transplant communities implemented some temporizing measures. If clinicians think a procedure should not be delayed, they may reach out to Dr. Gilman. When investigators make a sound case for clinical urgency, requests are usually approved. Investigators have been very forthright in their assessments of patients whose procedures could not be delayed. Dr. Gilman said that one positive outcome of the pandemic is improved lines of communication, including with the nursing department. Dr. Gilman has been updating Dr. Tabak weekly. The 17 ICs that contribute patient resources to the Clinical Center were very cooperative.

Jeanette Erickson, D.N.P., RN, FAAN, is looking forward to Shannon N. Zenk, Ph.D., M.P.H., RN, FAAN, [joining NIH as the incoming Director of the National Institute of Nursing Research \(NINR\)](#) in the fall of 2020. Dr. Zenk's focus is on inequities and disparities in health.

Follow-Up Items:

- Be explicit about success measures for the Blood and Immune Deficiency–Cellular Therapy Program in terms of efficiencies, cost, and clinical outcomes.
- Follow up with the Board about the possible consequences of deferred care for patients who normally would receive some clinical care at the Clinical Center.

Patient Safety and Clinical Quality Update

Laura Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality; and Madeleine Schuyler Deming, M.D., Staff Clinician and Assistant Research Physician, Clinical Center Internal Medicine Consult Service

Performance Metrics

Ms. Lee highlighted several performance metrics from the [Executive Dashboard](#) for the Clinical Center:

- *Patient perceptions:* Inpatients and outpatients have a consistently positive perception of the Clinical Center, and most would recommend the Clinical Center to others. Both measures were well above the benchmarks.

- *Infection control metrics:* Handwashing compliance consistently hovers around 90%. The central line–associated bloodstream infection (CLABSI) rate reached 0% in the first quarter of 2020. In the intensive care unit, the CLABSI rate and the catheter-associated urinary tract infection (CAUTI) rate have remained at 0% for more than a year. For the surgical oncology service, the CAUTI rate had been at 0%, but in the fourth quarter of 2019, the rate jumped to 9 infections per 1,000 Foley catheter days. Ms. Lee reviewed the cases. Surgical site infections are down, but the rate remains above benchmarks.
- *Inpatient falls:* Ms. Lee reported a slight upward trend in falls and falls with injury, but rates remain below national benchmarks.
- *Pressure injuries:* After a couple of quarters’ reductions in pressure injuries, a slight uptick in the prevalence of pressure injuries has occurred since the third quarter of 2019. Prevalence remains well below benchmarks, however. Two patients had stage 1 or 2 injuries that resolved; no stage 3 or 4 pressure injuries were reported.
- *Medication administration barcode compliance:* Compliance is 99%, just shy of the 100% goal. Per the CCRHB’s request, Ms. Lee did not include data from hospital areas that do not use barcode scanning.
- *Blood and blood product use:* The goal for the Clinical Center’s crossmatch-to-transfusion ratio is 2 or less. This goal is consistently met, which is important for ensuring that blood is not held unused in reserve when it could be available for another patient. Transfusion reactions occur in less than 0.5% of transfusions; the majority of reactions are of the febrile, nonhemolytic type. The percentage of blood bank specimens that were improperly collected or labeled has remained under 2.0% with the exception of the second quarter of 2019, when it approached 2.5%.
- *Occupational injury and illness:* The most important metric is days away, restricted, or transferred (DART). Numbers have ranged between 9 and 23 per quarter for the past five quarters. Musculoskeletal injuries are most often reported (43% of occupational injuries and illnesses). Wounds (24%) are almost always minor cuts, scratches, and sterile needle sticks.

Accreditation Activities

Ms. Lee announced that the Clinical Center is within the 18-month window for the next Joint Commission assessment. The last survey occurred in July 2018. The Clinical Center undertakes an annual self-assessment to check adherence with more than 1,400 individual standards of performance. During the most recent self-assessment, four noncompliant standards (i.e., findings) were identified.

A review of pain management data revealed a lack of a systematic way to look at the pain management from an aggregate or organizational perspective. A system is being set up to present to the Joint Commission. Also, for graduate medical education, the assessment indicated a need for written descriptions of the roles, responsibilities, and patient care activities of the participants of the graduate education program. This deficiency has already been corrected.

Patient Safety Event Reporting

Ms. Lee presented the dashboard for the Safety Tracking and Reporting System (STARS), which is used to identify trends in patient safety events. This electronic reporting system is available to all staff to share information about errors, near misses, process issues and instances of high-quality service. Ms. Lee reviewed some recent STARS data.

Of 4,000 reports between October 2019 and July 2020, nearly 8% were high-quality service reports. Very few anonymous reports are submitted, which Ms. Lee attributes to a healthy reporting culture that makes people comfortable about reporting safety events. The top 10 general events include meals/fluids, laboratory/specimens, and clinical care and treatment. The main specific events include orders not entered into the Clinical Research Information System (CRIS), incorrect blood draw volumes, and Code Blue events.

Medication delays used to be the most common safety event, but pharmacy and nursing staff have collaborated to improve medication delivery. These delays are now fourth in terms of frequency, and pressure events are the most common.

Harm Outcomes Assessment: The Trigger Tool

The Trigger Tool is a qualitative peer review of factors that contribute to individual patient harm events. In 2017, Ms. Jerussi convened the Trigger Tool group led by Dr. Deming and Naomi O’Grady, M.D. Ms. Lee relies on the Trigger Tool team to understand the state of care in the Clinical Center.

Dr. Deming said that the Trigger Tool team reviews three cases each month, totaling 47 to date. These deep-dive peer reviews have highlighted some significant systems issues and led to some significant organizational changes. Each trigger case is categorized by clinical performance level:

- Level I: Most providers would have handled the case similarly.
- Level II: Some providers would have handled the case differently.
- Level III: Most providers would have handled the case differently.

According to Dr. Deming, the Trigger Tool screened and reviewed a total of 453 intensive care unit (ICU) admissions between July 2019 and March 2020. The 287 planned admissions (mainly postoperative admissions following uneventful surgeries) and 90 unplanned Level I admissions during this period reflect the high complexity of Clinical Center cases. However, 25 (6%) of ICU admissions were deemed to be Level III. Among 26 Level III harms identified in an 8-month review, 18 were attributed to clinical management, 4 were attributed to system failures, 1 was attributed to a patient factor (noncompliance with a care plan), 1 was attributed to disease progression, and 2 were attributed to adverse events related to a medication side effect and procedural intervention.

Of the 19 Level III and unexpected ICU admissions identified in an 8-month review, most included harm events attributed to the clinical management. The Trigger Tool team found that Level III harm events were spread among 13 Institute branches, 17 attending teams, and multiple care units in the hospital, so no clear trends emerged. The team identified some common themes associated with Level III harms: protocol research—attending physician engagement, handoff

lapses and transitions of care, and delays in recognizing acute changes. Dr. Deming provided three case examples of the themes and described mitigation efforts:

- An I-PASS system in CRIS to improve patient handoffs
- A new clinical decision document for electrolyte management
- Neurologic assessment training for clinical staff

Dr. Deming stated that the Trigger Tool team and the Office of Patient Safety and Quality are working together to identify and address important opportunities for improving clinical care and hospital systems. Their efforts are leading to systems improvement, with the overarching goal of improving patient safety and quality of care.

In the News

Ms. Lee announced that a manuscript about the Clinical Center's suicide risk screening program had been accepted for publication.²

Discussion

Dr. Forese remarked that she was struck by themes that are common to the Clinical Center and other major academic medical settings.

Ms. Berty commented on the Clinical Center's continued improvements in safety and quality indicators.

Ms. Erickson said that the dashboard data would serve as very helpful evidence to support the Clinical Center's submission for the Magnet Recognition Program®.

Dr. Goldstein was impressed with the data on the Clinical Center, given the number of ICs that use Clinical Center resources and potential problems with communication and patient handoffs.

Ruth Williams-Brinkley, M.S.N., spoke about the remarkable culture of safety for patients and employees that is developing at the Clinical Center.

Launching the Journey for Magnet Recognition Program® Accreditation

Gwenyth Wallen, Ph.D., RN, Chief Nurse Officer, Clinical Center Nursing Department; and Rachel Coumes Perkins, M.S.N., RN, Nurse Consultant, Clinical Center Nursing Department

Dr. Wallen introduced Ms. Perkins as the Magnet Recognition Program® manager who is working with nursing staff and with an analyst to get NIH into planning mode for achieving Magnet recognition. The American Nurses Credentialing Center (ANCC) established the program to recognize "health care organizations that truly value nursing talent.... Magnet Recognition is...proof of a hard-earned commitment to excellence in health care, with contented nurses at its heart."

Dr. Wallen reviewed the components of Magnet accreditation and noted that process and structure were the traditional focus, but now empirical outcomes comprise the core of the

² Snyder DJ, Jordan BA, Aizvera J, et al. From Pilot to Practice: Implementation of a Suicide Risk Screening Program in Hospitalized Medical Patients. *Jt Comm J Qual Patient Saf.* 2020;46(7):417-426. doi:10.1016/j.jcjq.2020.04.011

Magnet model. [Why is the Clinical Center embarking on a Magnet journey?](#) Dr. Wallen said that Magnet hospitals:

- Have better patient outcomes—lower rates of mortality, falls, failure to rescue, and nosocomial infections
- Attract and retain high-quality providers through better nurse satisfaction, along with lower rates of turnover and burnout
- Improve quality and safety, with better support for evidence-based practice, higher quality of care, and higher patient ratings
- Realize financial benefits in terms of lower nurse turnover and shorter lengths of stay for patients

Dr. Wallen listed several potential benefits for the NIH Clinical Center, including having a rigorous and data-driven analysis of hospital and patient outcomes, an opportunity to identify gaps in quality while developing strategies for improvement, a more collaborative culture, and enhanced public visibility to showcase clinical research and attract high-quality candidates in nursing and medicine.

Many nurses, fellows, and physicians wonder why the Clinical Center is not already a Magnet hospital. People need to feel the pride of working in a center of excellence.

Gap Analysis

Ms. Perkins said that the Clinical Center excels in many areas, including a robust shared governance structure, a highly visible chief nursing officer, and an impressive nursing research portfolio. There are areas that need improvement, however. For example, the Clinical Center offers many opportunities for academic and professional development, but they are not equally accessible to all staff. Sometimes, nurses are so involved with their work that they underestimate the importance of their stories about the work. Staff are now starting to write and save their stories. Dr. Wallen also envisions increasing her visibility, and that is already happening through Microsoft Teams meetings and other platforms.

The NIH CC Magnet Journey in 2020

Dr. Wallen's team has met four times with the ANCC Senior Magnet Program Analyst. Based on those discussions, she anticipates that it will take about 3 years to develop and submit documents in support of the Clinical Center's application for Magnet status. Information about the Magnet journey is posted on the electronic information boards in the Clinical Center. Because it is very important that all nursing staff "own" this effort, Magnet Ambassador teams will be set up. James Gulley, M.D., of NCI is the first physician ambassador. Patients and stakeholders will be included to gather their input.

Dr. Wallen clarified that nurses who work directly for ICs are not under her direct supervision, but she does credential and privilege all the registered nurses for NIH. IC nurses will be part of the Magnet journey too.

Future tasks will include integrating the model of care for clinical research nursing with a professional practice model to come up with a model that makes sense for patient care and for clinical research. Although NIH has very structured annual nursing goals, there is no nursing

strategic plan. The idea is to develop a plan that cascades from the NIH Clinical Center Strategic Plan.

Dr. Wallen announced that the Magnet kickoff event slated for October 2020 will probably take place online.

Discussion

Ms. Erickson congratulated Dr. Wallen, Ms. Perkins, and Dr. Gilman on their progress toward Magnet recognition. She said that everyone with the Magnet program is very excited that our nation's research hospital is on this journey, and she offered to help in any way needed. Ms. Erickson recommended focusing on the inter-professional team; the whole infrastructure of the Clinical Center will come to bear.

Ms. Erickson recommended holding the virtual kickoff as planned. All site visits are now conducted virtually. Dr. Forese reported that her hospital is getting ready for a virtual Magnet visit; the Joint Commission assessment was also done virtually.

Dr. Gilman recognized the importance of the Nursing Department. The Clinical Center nurses are well led. Dr. Gilman supports the Magnet journey because it is good for patients. It is easy to get the idea that Magnet is all about nursing, but the program is really focused on patients. Dr. Forese noted that being a Magnet hospital makes the whole team, not just nurses, better.

Dr. Hait asked about the event that triggered this journey. Two reasons that Dr. Gilman hired Dr. Wallen as the Chief Nurse Officer were her focus on patients and community and her desire to achieve Magnet status. Dr. Wallen also acknowledged the important roles that Dr. Gilman as CEO and the CCRHB have played in supporting this goal.

Ms. Berty suggested collecting stories from patients in addition to those from nurses. Dr. Wallen agreed, saying that the core team plans to attend a future meeting of the Patient Advisory Group. Patients are partners in this effort. Ms. Berty also expressed support for having a patient on the core team.

Stephanie Reel, M.B.A., has taken part in Magnet reviews in the past. One hospital was struggling with several issues but decided to embark on a Magnet journey anyway. The hospital staff discovered that the journey encouraged teamwork in unexpected ways. There is never an ideal time for the journey, but striving for Magnet status is the right thing to do for the hospital, the team, and patients.

On behalf of the CCRHB, Dr. Forese expressed support for the NIH Clinical Center pursuing Magnet recognition. The Board believes strongly that the time is right to forge ahead. Dr. Wallen said she appreciated the support.

Dr. Shannon said that Magnet Recognition is an important step toward becoming a high-reliability organization. Many hospitals that have gone through the process tapped consultants to help build necessary capabilities. Dr. Shannon volunteered to connect the Clinical Center's core team with his organization's leaders who could share their insights and serve as informal consultants.

Follow-Up Items:

- Maintain the current goal of holding the Magnet kickoff meeting in October 2020.
- Identify the Magnet Recognition Program® staff person who will be working with the Clinical Center.
- Dr. Shannon is willing to connect NIH Magnet core team members with leaders at his organization who have gone through Magnet reviews previously.

Clinical Center Activities Regarding the Novel Coronavirus Pandemic

James Gilman, M.D., NIH Clinical Center CEO; Ann Marie Matlock, D.N.P., RN, NE-BC, Chief, Medical–Surgical Specialties Clinic, and Captain, United States Public Health Service, Clinical Center; Karen Frank, M.D., Chief, Department of Laboratory Medicine (DLM), Clinical Center; and Tara Palmore, M.D., Chief, Hospital Epidemiology Service (HES), Clinical Center

Dr. Gilman presented some data from the [Coronavirus Resource Center](#), which was established by the Johns Hopkins University Center for Systems Science and Engineering. Early in the pandemic, scientists were surprised by the rapid spread of the virus; that knowledge galvanized actions at NIH. The number of patients seen at NIH has remained low because of trends in Maryland, which has flattened the curve to the extent that the state has thus far avoided abrupt saturation of hospital resources, such as hospital beds, ICU beds, and ventilators.

Protecting Patients and Staff

Dr. Gilman said that NIH is committed to its existing patients, many of whom have immune disorders or are transplant recipients, and others develop immunosuppression because of treatments. The threat of infections is very worrisome to them. Also, the NIH investigator population and the Clinical Center population are a little older than national averages, putting them at greater risk.

The issues facing the Clinical Center are very similar to those confronting all U.S. hospitals: shortages of personal protective equipment (PPE), a lack of tests, and a lack of training and preparation from a personnel standpoint. Dr. Gilman said he was surprised at the paucity of preparedness among personnel, because patients with Ebola virus disease were treated here; however, clinicians caring for the Ebola patients volunteered for that duty. With COVID-19, not all the clinicians would be volunteers.

Dr. Gilman outlined some measures at NIH that help people keep safe:

- The building was designed for single-pass air without recirculation of air.
- The Special Clinical Studies Unit has state-of-the-art infrastructure that allows for isolation capabilities and infection control.
- NIH's HES is excellent.
- Strong SARS-CoV-2 testing support (multiple platforms, rapid results) is available through the DLM.
- Numbers of inpatient admissions and outpatient visits have been drastically reduced.
- Visitors are not allowed, with a few exceptions, such as for patients at the end of life and parents of pediatric patients.

- Everyone—patients, staff, and visitors—entering the building is screened.
- Everyone must wear a mask for source control.
- Masks plus face shields are required for people who have close contact with patients.
- Elective procedures are being deferred.

Pandemic preparations at the Clinical Center, including practicing procedures while wearing PPE, started at the end of January. The hospital centralized PPE and put it under tight control.

NIH testing platforms support up to 1,800 tests per day, and capacity can be multiplied through pooled testing.

The Clinical Center provides employees with well-being and resilience resources. Psychosocial well-being is critical as employees cope with pivotal events, such as the current pandemic and the Black Lives Matter movement. Seeking help is a sign of strength and should not be stigmatized.

Dr. Gilman extended his thanks to Bernard Harper and the entire Materials Management and Environmental Services (MMES) team. The crew has done an excellent job of ensuring that staff have PPE to keep safe.

Building 10 Entry Point Screening

CAPT Matlock said that the 165 entry points for Building 10 have been reduced to 3, in the south lobby, the north lobby, and the P1 parking lobby. All people entering the building at any time are screened. So far, one person who entered has tested positive. A total of 12,500 people are being screened each week.

The symptom screening is based on guidance from CDC. The list consists of new cough, new fever, shortness of breath or difficulty breathing, muscle aches, chills, diarrhea, recent loss of taste or smell, headache, and sore throat.

Starting on April 2, 2020, people who screen negative have been given surgical masks to wear while in the building. The symptom screening process entails some screening questions and a temperature check. People who screen negative receive a sticker and mask after the staff confirm that they have an appointment at the Clinical Center. A body temperature above 37.5°C is considered a positive screen. Patients who screen positive are escorted to the fifth floor for testing. Visitors are screened the same way, but if their test result is positive, they are referred to local health providers.

The only employees allowed into Building 10 are those involved in animal or patient care or in direct COVID-19 research. Employees do not have their temperatures checked; they are only asked about symptoms. Employees with positive symptom screens exit the building, call their supervisors, and go to the car line for testing. As of July 1, 2020, more than 200,000 screenings have been performed.

Asymptomatic Testing

CAPT Matlock explained that routine staff testing is necessary to increase the hospital census and staffing in the Clinical Center. Testing has three phases: the sampling production line, the DLM phase, and follow-up and contact tracing.

Testing is required for all Building 10 employees and contractors. After registering in the testing system, agreeing to the conditions of use, and providing a personal email address, employees can set up a patient portal for self-scheduling of testing appointments, which occur between 7:30 a.m. and 4:30 p.m. in 15-minute blocks on weekdays. Appointments are also available in the evenings and on weekends.

CAPT Matlock presented the plan of the fifth floor, which has been set up to allow social distancing and can accommodate up to 49 people. She also listed the resources required for the testing program in terms of space, supplies, and personnel. As of July 9, 2020, nearly 1,900 tests of asymptomatic people have been performed.

DLM Phase

Dr. Frank presented a schematic showing how different countries use different SARS-CoV-2 gene targets in their testing platforms.³ The World Health Organization published a polymerase chain reaction (PCR) assay on January 13, 2020. The U.S. Food and Drug Administration approved the CDC assay on February 4, 2020, but there were problems with the reagents. NIH received its first kits from CDC and began testing on February 28, 2020.

Early in the pandemic, tests were in short supply. NIH investigators donated their RNA extraction kits and test platforms. NIH performed many test validations and found that the Abbott ID NOW™ system has a lower sensitivity (81%) compared with NIH running the CDC kit. (ID NOW is used by the White House.) The Cepheid assay gives rapid results in 1 hour, but these tests are in very limited supply and are being reserved for urgent staff and patient needs.

On May 21, NIH started pooling up to 10 specimens from asymptomatic employees. The DLM's validation tests demonstrated a slight loss of sensitivity with pooled samples (four cycle threshold levels), but very low viral loads could still be detected. NIH's testing capacity is now up to 18,500 per day with pooling in batches of 10. Current test volume is about 1,000 per week, although the theoretical maximum approaches 130,000. Availability of instruments is no longer a limiting factor, but staffing is. Staff have been approved but are not yet hired or trained.

According to Dr. Frank, three testing instruments are in use at the Clinical Center. The Applied Biosystems™ 7500 Fast Dx instrument has been the DLM's workhorse thus far. Dr. Frank reported that the Hologic Panther Fusion® System went live in June and the Roche cobas® 6800 System was scheduled to go live at the end of July 2020.

In terms of sample collection, Dr. Frank said that nasopharyngeal swabbing is the gold standard, but NIH has changed to a less invasive collection method—mid-turbinate swabs—for testing asymptomatic employees. Nasal swabs have not been used because of reduced sensitivity.

The Institutional Review Board approved a protocol to collect samples and assess sensitivity of saliva testing, but because of the currently low prevalence in Maryland, the number of available samples is insufficient. Results of saliva testing at other centers have been mixed. Staff are

³ Ahn D-G, Shin H-J, Kim M-H, et al. Current Status of Epidemiology, Diagnosis, Therapeutics, and Vaccines for Novel Coronavirus Disease 2019 (COVID-19). *J Microbiol Biotechnol.* 2020;30(3):313-324. doi:10.4014/jmb.2003.03011

collecting some saliva samples from the car line at NIH. NIH is collaborating with the Maryland Department of Public Health and the Washington Hospital Center emergency department to obtain additional samples.

HES

Tara Palmore, M.D., said that HES has been working closely with the Occupational Medical Service (OMS) during the pandemic. So far:

- Sixteen Clinical Center patients have tested positive.
- Twenty patients with COVID-19 have been admitted to the Clinical Center. Eleven were brought to NIH to participate in COVID-19 studies, and two preexisting NIH patients enrolled in NIAID's COVID-19 studies.)
- A total of 256 NIH employees and contract staff members, including 43 healthcare personnel, have tested positive. Seven staff members (five asymptomatic, one symptomatic, and one presymptomatic) were found to be positive via asymptomatic surveillance testing. Once a person has tested positive, Dr. Palmore queries them about symptoms and starts contact tracing.

PPE Timeline

According to Dr. Palmore, since late March 2020, all patient care staff have been required to wear masks, and on April 1, the requirement extended to all Building 10 staff and patients. Inpatients are asked to don masks when healthcare personnel enter their room. On June 26, providers started using face shields over surgical masks for essentially all patients encounters. At each phase, MMES ascertained that supplies were adequate and could be maintained at par levels given the burn rate.

Screening and Testing of Patients for COVID-19

Ahead of appointments or admissions, the appropriate study team asks patients by telephone about their symptoms and exposures. Upon arrival at the Clinical Center, patients are screened and given masks. Patients who have a fever or two symptoms of COVID-19 are directed to the fifth floor for testing. People whose screens are negative proceed to the clinic, where they are rescreened. Those who are scheduled for aerosol-generating procedures undergo testing.

Dr. Palmore reported that 35 contact studies were completed over the course of 3 months. HES does the investigations for patients, and OMS does the tracing for healthcare personnel and contractors. HES has undertaken about 15% of contact investigations. Four secondary cases have occurred among clinical staff, and no secondary cases have been found among patients. One employee was infected by a patient, and three were infected by other staff members. The three secondary infections occurred before universal masking.

Discussion

Dr. Hait asked whether HES has started modeling to identify prevalence rates in the community that would raise a red flag and, if so, what might be done differently in the Clinical Center, short of closing the facility. Dr. Palmore said that only Group A staff are working at NIH at the moment—this group comprises essential staff for patient and animal care. Groups B and C staff

are not yet entering the campus. Decisions about when to bring in Groups B and C will be based on thresholds in the community.

Dr. Tabak said that he, David Henderson, M.D. (a consultant to HES); and Steven Holland, M.D. (Director of NIAID's Division of Intramural Research), meet with Dr. Collins every morning to discuss the situation. Currently, the rate of positive tests is about 7%; if the rate rose to, say, 10%, that would be a major cause for concern. Other important factors include the percentage of ICU beds occupied by COVID-19 patients in the area. At the beginning of the pandemic, the Clinical Center reduced the census to 20% by discharging patients. When Group A employees returned to campus, the census grew to 30%. When Group B staff return, the census could grow to 35%. Dr. Tabak underscored the need to maintain a safe environment. Employees' roles have figured prominently in NIH's stratification plan for returning to work. About 60% of staff can work effectively via telework; the likelihood of bringing them back to NIH is low for the time being. NIH staff come from the District of Columbia, Maryland, and Northern Virginia.

Dr. Gilman added that staff who have symptoms are asked to stay home. They are denied entry into the Clinical Center, but if someone who has symptoms comes to an entry point, they are not criticized. Messaging focuses on getting tested through the car line or through OMS. Dr. Tabak further explained that NIH is using a text and email prompt system. If someone is symptomatic, they are directed to fill out the Research Electronic Data Capture (REDCap) survey. Survey responses have led to detection of a few positive cases. A discussion about implementing an app-based system is underway.

Ned Sharpless, M.D., Director of NCI, said that NCI, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), and CareEvolution have been working on a novel approach to symptom screening and contact tracing using a web-based app. Some other countries are using similar apps. CareEvolution supports the *All of Us* Research Program, the Framingham Heart Study, and other major research initiatives. The NCI-NIBIB effort to develop a web-based app has been challenging because of privacy considerations, but these problems are being worked on. The plan is to roll out the app at NCI soon. The Google/Apple contact tracing system will be added later as part of a research effort. Dr. Sharpless volunteered to provide additional information to anyone interested in learning more.

Dr. Forese commented that she does not know of any medical center in New York City that is testing all employees. Contact tracing is also an issue in New York, where testing supplies are again low.

Ms. Berty asked whether patients can self-refer for a COVID-19 test if they do not have symptoms. Dr. Gilman clarified that tests need to be ordered by medical providers.

Dr. Shannon asked about the potential use of next-generation sequencing technologies for prevalence studies and contact tracing as a means to track the virus and its mutations. Dr. Black reported that this was discussed with Dr. Henderson and with NHGRI staff recently. The question is whether such testing would add value; that is, what are people finding at a large scale when they use these systems? Also, whole genome sequencing (WGS) and bioinformatics take

time. Dr. Gilman said that Dr. Palmore has worked with NHGRI using WGS to track clusters of hospital infections; that research is of academic interest but limited practical utility.

Dr. Sharpless mentioned a *60 Minutes* program on using artificial intelligence to track epidemics. Universities might be good settings for using digital tools for contact tracing, but they would need to be powered with adequate testing.

John I. Gallin, M.D., Chief Scientific Officer and Scientific Director of the Clinical Center, said that NIH has 40 clinical protocols on COVID-19, including 29 taking place at the Clinical Center. He noted that the sharing of specimens among investigators has been extremely helpful in driving knowledge about treatments and the pathobiology of the disease as well as. Dr. Tabak remarked on extramural investigations of new technologies for point-of-care testing. Some candidate technologies have been identified that could be scaled up to handle millions of tests.

Dr. Gilman mentioned the challenge of modifying the many contracts that NIH has in place to permit testing of contract staff. Housekeeping staff and some nursing personnel are working under contracts. Testing is still voluntary. Saliva testing would make more people feel comfortable about getting tested.

Follow-Up Item:

- Anyone interested in learning more about the NCI–NIBIB web-based app for screening and contact tracing should contact Dr. Sharpless.

Adjournment

Dr. Forese said that the Board is very impressed with what is going on at NIH and is proud to be connected with the NIH Clinical Center. Dr. Forese thanked Gretchen Wood and other NIH team members who support the CCRHB.

The next meeting of the CCRHB is scheduled for October 16, 2020.

Dr. Forese adjourned the meeting at 12:55 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, New York–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 |
| AHaRT | Anti-Harassment Response Team |
| ANCC | American Nurses Credentialing Center |
| BERT | Behavioral Emergency Response Team |
| CAUTI | catheter-associated urinary tract infection |
| CCRHB | Clinical Center Research Hospital Board |
| CDC | Centers for Disease Control and Prevention |
| CEO | chief executive officer |
| CLABSI | central line–associated bloodstream infection |
| COVID-19 | coronavirus disease 2019 |
| CRIS | Clinical Research Information System |
| DART | days away, restricted, or transferred |
| DLM | Department of Laboratory Medicine |
| HES | Hospital Epidemiology Service |
| ICs | Institutes and Centers |

| | |
|------------|---|
| ICU | intensive care unit |
| MMES | Materials Management and Environmental Services |
| NCI | National Cancer Institute |
| NHGRI | National Human Genome Research Institute |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIBIB | National Institute of Biomedical Imaging and Bioengineering |
| NIH | National Institutes of Health |
| OMS | Occupational Medical Service |
| PPE | personal protective equipment |
| REDCap | Research Electronic Data Capture [software] |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| STARS | Safety Tracking and Reporting System |
| WGS | whole genome sequencing |