U.S. Department of Health and Human Services

National Institutes of Health

Eighteenth Meeting of the Clinical Center Research Hospital Board

July 23, 2021

Contents

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

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

*Norvell V. Coots, M.D., President and Chief Executive Officer, Holy Cross Health (*ad hoc* member)

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 (*ad hoc* member)

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

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

*Absent

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 18th meeting via videoconference on July 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 Member Norvell V. Coots, M.D., and *Ex Officio* Member Francis S. Collins, M.D., Ph.D., were unable to attend the meeting.

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH, outlined recent NIH-supported activities related to the coronavirus disease 2019 (COVID-19) pandemic. He briefed the Board on the proposed 2022 budgets for NIH. The President's 2022 budget proposes allocating nearly $52 billion for NIH, of which $6.5 billion would support an initiative to create a new Advanced Research Project Agency for Health (ARPA-H). The appropriations bill of the U.S. House of Representatives proposes a $49 billion budget for NIH, an increase of $6.5 billion above the FY 2021 level. That bill includes $3 billion to establish ARPA-H. The Senate has not yet weighed in with a budget proposal.

Dr. Tabak said that ARPA-H would be a major effort. Most likely, it will be positioned as a division of NIH, but it will be necessary to balance the uniqueness and autonomy of ARPA-H with the ability to capitalize upon the equities that NIH brings in terms of biomedical research. Congress ultimately will decide how to position ARPA-H.

Dr. Tabak also announced several key personnel changes.

Mental health support for NIH staff during the pandemic was the topic of a presentation by Maryland Pao, M.D., Clinical and Deputy Scientific Director, National Institute of Mental Health (NIMH), and Acting Clinical Director, National Center for Complementary and Integrative Health. Dr. Pao described the myriad resources—videos, well-being workshops, spiritual care, call centers, and an employee assistance program (EAP)—that are available for staff who are under stress or in distress.

NIH is fully committed to ending structural racism in all its forms. Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; Marie A. Bernard, M.D., Chief Officer for Scientific Workforce Diversity, NIH, and Deputy Director, National Institute on Aging; and Alfred C. Johnson, Ph.D., Deputy Director for Management, NIH, explained the components of the NIH UNITE initiative. The speakers discussed UNITE's initial recommendations and highlighted progress to date. NIH is implementing approaches to enhance portfolio diversity and close racial gaps in research funding. Future plans include expanded funding for research on health disparities, minority health, and health equity; development of programs to spur institutional culture change in support of inclusivity and equity; expanded career opportunities for underrepresented groups; and increased interactions between NIH and Tribal colleges, historically Black colleges and universities, and other minority-serving institutions.

NIH Clinical Center Demographics for Workforce and Patients

Daniel Lonnerdal, M.S., FACHE, Executive Officer, NIH Clinical Center; Justin Cohen, M.S., M.A., Chief, NIH Clinical Center Office of Communications and Media Relations and Office of Patient Recruitment; and John I. Gallin, M.D., Associate Director for Clinical Research, NIH,

and Chief Scientific Officer, NIH Clinical Center, presented demographic data on the Clinical Center's workforce and patients. The Office of Patient Recruitment offers services to recruit study participants, help members of the public identify studies of interest and connect with research teams, and maintain a registry of healthy volunteers to serve as controls for clinical trials.

Dr. Gallin addressed Clinical Center patient demographics and structural racism initiatives. 2019 data on nearly 24,000 patients showed that nearly 65% identified as white, 12% as Hispanic/Latino, and 17% as African American/Black. Dr. Gallin also discussed the Clinical Center's structural racism initiatives. Transitions in Clinical Center staff have bolstered diversity. The Clinical Center is building a pipeline to bring in new investigators to enhance diversity.

James Gilman, M.D., Chief Executive Officer, NIH Clinical Center, announced several key staffing changes and mentioned employees who were recently honored for their outstanding service.

Dr. Gilman observed that the hospital census numbers are slowly rebounding and now approach 2020 inpatient levels. The number of telehealth visits has hovered around 1,000 per month since October 2020. The total number of telehealth visits as of April 2021 is just over 10,000.

Dr. Gilman updated the board on screening and testing of staff for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). More than 1.5 million people have been screened, with the highest number (6,000) occurring on June 24, 2021. Asymptomatic testing continues at the Clinical Center, with a weekly average of 900 tests. Twelve percent of tests are saliva-based. Nearly 16,000 people have been vaccinated at the Clinical Center. Eighty percent of NIH federal employees and 53% of contracted staff have received at least one vaccine dose.

The Clinical Center continues to prepare for a full Joint Commission survey in 2021. Also, a new patient perception survey is being put into place. Patients will complete the surveys online. Dr. Gilman underscored the continuing importance of help-seeking behavior. Resources remain available, including the Clinical Center Spiritual Care Department, the EAP, and emergency national services, including the National Suicide Prevention Lifeline.

The meeting concluded with a presentation by Harvey J. Alter, M.D., NIH Distinguished Scholar and 2020 Nobel laureate, on the history of hepatitis C research at NIH. He highlighted the discovery of the virus and how the development of tests has reduced transfusion-related hepatitis C to negligible levels. Cure rates exceeding 90% are now possible with direct-acting antiviral drugs.

Meeting Summary
Friday July 23, 2021

Welcome and Board Chair's Overview

Laura Forese, M.D., M.P.H., NewYork–Presbyterian; Hospital Board Chair

Dr. Forese called the meeting to order at 9:00 a.m. ET and checked attendance, noting that Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH), was not able to attend. She announced that Ned Sharpless, M.D., Director, National Cancer Institute (NCI), would likely attend certain parts of the meeting. The meeting was being videocast live and recorded.

The meeting participants briefly discussed Joint Commission activity at their respective institutions. James Gilman, M.D., reported that the Clinical Center has not undergone a survey in 3 years.

Regarding the state of the pandemic, Dr. Forese said that the country seems to be in a better position now than last summer, although "we're not out of the woods yet." On behalf of the CCRHB, Dr. Forese said that they were all proud of everything NIH is doing to conquer the pandemic and of the courage of its leaders.

Dr. Forese said she hopes that the next meeting of the CCRHB can take place in person rather than by Zoom.

NIH Deputy Director's Remarks

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

Pandemic Response

Dr. Tabak reviewed recent NIH-supported activities related to the coronavirus disease 2019 (COVID-19) pandemic:

- Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) is a public–private partnership between NIH and other federal counterparts, including FDA, with 20 companies. ACTIV has initiated several protocols, the most recent being ACTIV-6, which is aimed at repurposing existing drugs for outpatient treatment. Initial enrollment was slow, but with the recent surge in COVID-19 cases, there has been an uptick.
- Tracking Resistance and Coronavirus Evolution (TRACE) is an ACTIV initiative building on the many streams of information related to SARS-CoV-2 evolution. This work is being done in collaboration with industry partners to create a "watch-list" of SARS-CoV-2 variants relevant to therapeutic approaches.
- Say Yes! COVID Test is a community-based public health effort to make rapid antigen home tests available. Currently, this is being piloted in three communities in North Carolina, Tennessee, and Michigan. The market research surveys from North Carolina and Tennessee suggested that people did not test as often as recommended (three times per week). With frequent testing, the sensitivity of rapid antigen lateral flow tests approaches that of PCR (polymerase chain reaction) tests. When the program began,

vaccinations were rising and cases were declining, but these trends do not fully explain why people did not use the tests. The Michigan site recently started operations. The public health department aims to distribute more than 20,000 tests. Participants are asked to test only twice per week. Now, with cases on the rise and a lower target in terms of test frequency, people may be more amenable to using the kits.

- The goal of the Rapid Acceleration of Diagnostics (RADx[SM]) initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing. RADx Underserved Populations (RADx-UP) has a goal of understanding the factors associated with disparities in COVID-19 morbidity and mortality and to lay the foundation to reduce disparities for underserved and vulnerable populations that are disproportionately affected by the COVID-19 pandemic.
- The Safe Return to School Diagnostic Testing Initiative Phase 2 launched during the week of July 19, 2021. This initiative is designed to identify the optimal way of testing in K–12 environments. The results will provide a basis for guidance for students, teachers, and staff, particularly in areas with vulnerable and underserved populations. The lessons learned can be put to good use as many schools reopen in the late summer and early fall.
- RADx-Radical (RADx-rad) is progressing well. This initiative is moving a few creative ideas into the RADx-Tech innovation funnel. An effort to apply certain available technologies to develop predictive diagnostics for long COVID syndrome is underway.
- In late June 2021, NIH announced the SARS-CoV-2 Vaccines in Pregnancy and Postpartum (MOMI-Vax) trial, which is funded by the National Institute of Allergy and Infectious Diseases.
- A study funded in part by the National Institute on Drug Abuse found that an estimated 1.5 million children around the world have lost at least one caregiver—a parent or custodial grandparent—to COVID-19.[1]

NIH Budget

The President's 2022 budget, released at the end of May, proposes allocating nearly $52 billion for NIH, of which $6.5 billion is for an initiative to create a new Advanced Research Project Agency for Health (ARPA-H). This is a $9 billion increase over fiscal year (FY) 2021. The appropriations bill of the U.S. House of Representatives proposes a $49 billion budget for NIH, an increase of $6.5 billion above the FY 2021 level. That bill includes $3 billion to establish ARPA-H.

Dr. Tabak said that the budget proposal would amount to about a 5% increase for each Institute or Center (IC), except for a somewhat greater allocation for NCI. The budget would include increases for research on health disparities, a universal influenza vaccine, maternal health, mental health of children, effects of climate change on human health, and Alzheimer's disease and related dementias.

[1] Hillis S, Unwin HJT, Chen Y, et al. Global minimum estimates of children affected by COVID-19-associated orphanhood and death of caregivers. *Lancet*. 2021;398(10298):391-402. doi:10.1016/S0140-6736(21)01253-8

The 2022 budget awaits further congressional action predicated on input from the U.S. Senate. Dr. Tabak said that he is grateful for the confidence the Biden administration and the House have in NIH.

ARPA-H

The idea for ARPA-H was inspired by the Defense Advanced Research Projects Agency (DARPA). With its high-risk, high-reward approach, DARPA has driven breakthrough advances for the Department of Defense.

Dr. Tabak said that ARPA-H will require a major effort to implement, as it will be a large and complex enterprise. Most likely, it will be positioned as a division of NIH, but it will have a very different "phenotype" than the rest of NIH. It will be necessary to balance the uniqueness and autonomy of ARPA-H with the ability to capitalize upon the equities that NIH brings in terms of biomedical research. Congress ultimately will decide how to position ARPA-H.

Drs. Collins and Tabak, along with Tara Schwetz, Ph.D., and Eric Lander, Ph.D., published a commentary[2] in *Science* that lays out the current vision for ARPA-H. NIH is in the midst of intensive consultative sessions. The White House's Office of Science and Technology Policy (OSTP), in collaboration with NIH, is conducting four listening sessions. NIH, in collaboration with OSTP, is running 10 additional sessions involving professional societies, patient advocacy groups, philanthropies, venture capitalists, and industry groups. Other entities (e.g., physics, engineering, mathematics groups) that are not traditionally part of the clinical research enterprise are also engaging in the sessions.

Dr. Tabak said that he and IC directors are also working on ARPA-H plans. NIH leaders are planning for various contingencies.

Personnel Updates

Dr. Tabak announced several key personnel changes:

- In May 2021, Dr. Collins selected Marie Bernard, M.D., to succeed Hannah Valentine, M.B.B.S., MRCP, as the Chief Officer for Scientific Workforce Diversity. Dr. Bernard will help promote diversity, equity, and inclusion (DEI) and coordinate programs across NIH that operate in this space.
- Maria Freire, Ph.D., will be stepping down in September 2021 as the president and executive director of the Foundation for the National Institutes of Health (FNIH). She has served in that role since November 2012, making her the longest-serving leader of FNIH. Her many accomplishments include coordination the ACTIV program, which has proven the value of public-private partnerships. David Wholley, M.Phil., will serve as the interim president and executive director while FNIH conducts a search for the next president and executive director.
- Michael Gottesman, M.D., Deputy Director for Intramural Research, is leaving that role after 28 years. He plans to continue leading the NCI Laboratory of Cell Biology where his team is working on the challenge of chemotherapeutic resistance.

[2] Collins FS, Schwetz TA, Tabak LA, Lander ES. ARPA-H: Accelerating biomedical breakthroughs. *Science*. 2021;373(6551):165-167. doi:10.1126/science.abj8547. PMID: 34244402.

Dr. Gottesman said his goal as the Deputy Director was to build a safe and effective clinical research program at NIH. He thanked the board for its guidance in striving toward that goal and expressed gratitude to everyone he worked with at NIH. Dr. Forese thanked Dr. Gottesman for his support of the Clinical Center and the board.

Discussion

Richard P. Shannon, M.D., echoed Dr. Forese's remarks about Dr. Gottesman and gave his heartfelt thanks for Dr. Gottesman's role in establishing an effective partnership between the board and the Clinical Center.

William Hait, M.D., Ph.D., said he read Michael Lewis's book *The Premonition: A Pandemic Story*. Mr. Lewis suggests that modeling indicated that the best approach for controlling infections would have been to close the schools, vaccinate children, and keep them at home. Dr. Hait asked whether that formulation by the modelers is accurate and, if so, what NIH is thinking regarding the current situation, since young children are not yet being vaccinated.

Dr. Tabak said that he thinks that Mr. Lewis's thesis assumes that a vaccine was available and could have been deployed for children right away. The U.S. Food and Drug Administration (FDA) has only recently authorized the Pfizer and Moderna vaccines for use in children as young as 12. Low-dose vaccines are presently being studied in children between ages 5 and 11; the FDA anticipates that the vaccines will be authorized for this age group around midwinter. With the existing vaccine development and authorization structure, a strategy based on closing schools and vaccinating children would not be possible.

Dr. Hait said that in the absence of an authorized vaccine, perhaps keeping children at home would have been even more important. Dr. Tabak pointed out that the consequences of keeping children at home are significant. Dr. Gilman noted that a scientific, medical decision is not the same as a political decision, which involves many "layers" of government. The isolation approach is probably as old as epidemics are. John I. Gallin, M.D., underscored the importance of vaccinating children in controlling the pandemic. All indications are that the vaccines are not harmful and could make a real difference.

Dr. Forese commented on vaccine mandates. New York–Presbyterian hospitals have come out publicly about requiring all of their 48,000 employees to be vaccinated against COVID-19 unless they have a valid exemption. Many other institutions are waiting for full FDA approval of vaccines before requiring employees to be vaccinated. Full approval of the vaccines will be an important step in getting more institutions to issue vaccine mandates.

Dr. Tabak said that even the federal government (including NIH) cannot require employees to get a vaccine that is not fully FDA approved. He anticipated that some news on this topic will be coming out soon. Another challenge is the need to boost vaccine confidence. Dr. Tabak recalled a discussion about vaccination with a group of military personnel. The most often cited reason for not getting vaccinated was lack of full FDA approval. Audience members also expressed concerns about possible effects on fertility, which Dr. Tabak was able to address. Dr. Gilman commented that much of the hesitancy on using non-FDA approved drugs may stem from prophylactic use of pyridostigmine bromide, which had not been approved by the FDA, during the first Gulf War, which has been suggested as one of the causes of Gulf War Syndrome.

Dr. Hait spoke about the challenges involved in FDA approval of drugs and vaccines when low case numbers make it difficult to accrue enough data to provide to the FDA. The data likely will come more quickly as the number of cases rises.

Dr. Shannon said that Duke Health and seven other large health systems in North Carolina are mandating vaccination of employees by September 10. The state is seeing a substantial uptick in cases; vaccination is imperative to protect the health care workforce to avoid the spiraling events observed in 2020. Given the substantial body of evidence on the safety and effectiveness of the authorized vaccines, unintended consequences are unlikely, so the North Carolina health systems are moving forward with vaccination mandates.

Action Item

- Dr. Tabak asked CCRHB members to notify people they know who may be interested in one of the open positions at NIH.

Mental Health Support for NIH Staff During the Pandemic

Maryland Pao, M.D., Clinical and Deputy Scientific Director, National Institute of Mental Health (NIMH), and Acting Clinical Director, National Center for Complementary and Integrative Health

As a child psychiatrist and pediatrician by training, Dr. Pao said that spikes in rates of suicide among children due to the pandemic might have been expected, but such a trend was not observed, primarily because children were staying home. Younger children were affected less by the transition to remote learning than older children were. Dr. Pao anticipates a substantial increase in new mental health disorders among children in older age groups. She underscored the need to acquire more data.

Timeline of NIH's COVID-19 Response

Dr. Pao reviewed the NIH timeline of COVID-19 activities, starting during the spring of 2020. Milestones included the following:

- March 2020: Maximum telework flexibilities and the Clinical Center shutdown began. Frontline workers remained in place.
- April 2020: An effort to gather mental health resources for employees began.
- May 2020: Group A employees returned to work on site, and the Wellness Resources intranet page was launched.
- July 2020: Group B1 staff returned to onsite work.
- August 2020: Group B2 returned to work on site.
- December 2020: A panel session on navigating mental health resources at NIH was held.
- February 2021: The NIH Vaccination Program began.

The Clinical Center set up COVID-19 screening and surveillance for employees in 2020. Dr. Pao reported that nearly 70% of NIH staff have been vaccinated.

NIH Response to Address Mental Health Needs of Staff

Dr. Pao said NIH set up many wellness programs throughout the pandemic. Resources are tailored to align with the nation's and NIH employees' mental states.

The Trans-NIH Mental Health Response Team formed in early April 2020 based on a plan developed by mental health experts from across NIH to provide coping resources for staff. Stress and anxiety among employees were immediately recognized. The co-chairs are Dr. Pao and Courtney Aklin, Ph.D., who serves as the acting associate deputy director of NIH and a senior advisor with the Immediate Office of the Director. Prior to Dr. Aklin joining, Dr. Tara Schwetz served as the co-Chair for the first year before being detailed to the White House.

The Trans-NIH Mental Health Response Team has three goals:

- Leverage NIH expertise and create partnerships with stakeholders on well-being, resilience, and mental health to share information with NIH staff, trainees, and contractors.
- Advise NIH leadership on identifying people in need of support and referring them to resources.
- Develop a continuous needs assessment to identify trends and meet changing needs of staff.

The team consolidated resources on wellness and coping on the NIH intranet.

Educating and Supporting Staff

Dr. Pao spoke about providing universal quick guidance and about workshops and resources available to staff.

The Mental Health Response Team distributed posters on mental health care and effective handwashing techniques across NIH campuses and online.

Concern that NIH's Employee Assistance Program (EAP) would be overwhelmed, NIMH set up a staff support line to supplement the EAP.

Dr. Pao and Ms. Deborah Snyder, M.S.W., LCSW-C, developed virtual roadshows on managing stress and anxiety, delivering 48 presentations to more than 7,700 attendees across NIH and federal partners. Part 1 focused on managing stress during the pandemic, and Part 2 focused on fostering meaningful connections in the virtual workplace. The sessions were tailored to each audience and included live question-and-answer periods. A few had breakout groups.

The EAP also delivered 49 presentations to ICs and other groups on coping with COVID-19, focusing on skills and resources for dealing with pandemic-related stress and anxiety. More than 5,000 people participated in the sessions.

NIH leadership participated in all the mental health programs. In the Clinical Center, Dr. Gilman championed employee well-being programs with his message, "Help-seeking is a sign of strength." He encouraged staff to reach out for help dealing with psychological stress. Employee well-being is a priority at NIH. Other resources available to staff include a peer-to-peer (buddy) support system, Clinical Center connections, chaplain chats offered through the Spiritual Care Department, the Nurse Wellness Committee, and Code Lavender.

The Office of Intramural Training & Education (OITE) supported trainees who were among the most affected by events. Activities included Wellness Wednesday virtual brown-bag discussions, virtual medication sessions, and affinity group meetings. Workshops focused on building resilience and career development during the pandemic.

OITE hosted small group sessions to discuss stress management throughout the pandemic and during Mental Health Awareness Month.

Dr. Pao listed a variety of NIH-wide stakeholder groups involved in providing employee well-being and mental health support. The list includes the NIH Child Care Board, the Aging and Adult-Dependent Care Committee, the Nurse Wellness Committee, and a Working Caregivers Taskforce. The Office of the Director also set up support groups, including General Wellness, Caregivers of Elderly and Adult Loved Ones (which generated the most interest and had the highest attendance numbers of the support groups), and Parents and Caregivers of Children.

Additional tools for mastering stressful moments include wallet cards and screensavers that offer quick tips for dealing with stress in the moment.

Continuous Assessment

NIH, being a research institution, collected data to track resource utilization and identify staff needs. Dr. Pao reported an NIH survey receiving more than 15,000 responses designed to assess the impact of mental health on productivity by age. Between 9% and 26% of employees reported that awareness of mental health was one of the most impactful factors on productivity among Clinical Center staff. The positive effect of this awareness declined with age.

Three mental health–related videos on employee resources for coping with COVID-19 were viewed more than 700 times.

OITE produced many workshops for trainees and staff that many participated in:

- Meditation sessions and mindfulness study: 1,729 participants
- Becoming a Resilient Scientist lecture series: 9,408 participants
- Drop-in wellness groups: 1,650 participants
- Mental health webinars: 6,601 participants

The NIH staff support line helped more than 105 callers. The support line closed after 1 year in May 2021. Callers were concerned about not only the pandemic but also the events of January 6, when the capitol was breached. Events related to the death of George Floyd also heightened stress levels.

More than 500 EAP contacts occurred each month between March 2020 and March 2021. The peak of 1,000 contacts occurred around January and February 2021. The proportion of contacts focusing on COVID-19 concerns (34%) is rising. More clients are reporting mental health concerns.

Dr. Pao said that the nine NIMH resources on stress and COVID-19 have received tens of thousands of page views. The NIMH Director's Message "Coping with Coronavirus: Managing Stress, Fear, and Anxiety" received more than 96,000 public page views.

Potential Stressors for NIH Employees During the Summer of 2021

Dr. Pao said that the main stressors for staff will likely center on the return to the physical workspace, emotional dysregulation, vaccine decision making, and concerns for unvaccinated children.

NIH has an abundance of resources, but these were often siloed in ICs and Offices (ICOs). One silver lining of the pandemic is that mental health has been brought to the fore. The pandemic pointed to the need for more formalized roles for leaders, nurses, social workers, and so forth.

Dr. Pao said that many hospitals have made strong cases for setting up well-being resources for employees. The Clinical Center's well-being program is justified by the business case (costs associated with professional burnout and reduced productivity), the tragedy of suicide, a moral case (the right thing to do for staff), nationwide recognition as a top-tier program, and the regulatory case built on legal requirements and accreditation, such as by the Magnet® Recognition Program.

NIMH had been investigating these well-being programs for at least 3 years prior to the pandemic. Dr. Pao believes that the Clinical Center is ready to take steps to formalize the program.

Discussion

Stephanie Reel, M.B.A., acknowledged the needs of the silent who are affected by events but do not seek help or express their concerns about their mental health.

Dr. Shannon agreed that every health system in the country is taking mental health and well-being very seriously. He asked whether the Clinical Center has made special efforts to support health care workers who are on the front lines of the pandemic at NIH. In his institution, a core group of health care providers has borne the heaviest burden dealing with the pandemic daily. Dr. Pao said that the buddy system was intended for frontline staff. Often, staff do not want to acknowledge a need. Buddies can encourage each other to seek help. Code Lavender provides supportive measures for nurses. Employees also have access to chaplain services. Dr. Pao said that even construction workers have participated in yoga sessions. The roadshow offers many tips for managing day-to-day stress.

Ellen Berty asked whether the Clinical Center supports are available to patients who need help. Dr. Pao said that patients may access chaplains, as well as psychiatric and mental health care.

Ruth Williams-Brinkley, M.S.N., asked about plans for the next phase of the pandemic as another surge occurs, considering the mental health needs of exhausted staff. Dr. Pao referred to efforts to normalize care-seeking behaviors and anticipate which employee groups are having trouble. NIMH used crowdsourcing to get ideas from people who are struggling. For example, some employees have been teleworking since the shutdown began. To minimize the impact of online meetings, Dr. Pao suggested scheduling adequate time between meetings to allow people to take a break; the breaks substitute for the time people would normally spend walking between buildings. Some groups observe "No-Meeting Fridays." Dr. Gilman said that the *Eunice Kennedy Shriver* National Institute on Child Health and Human Development has set aside one week per month to be free of meetings. Obviously, IC leaders do not have control over NIH-level meetings, but they can control what goes on in their own ICs.

Ending Structural Racism

Dr. Tabak announced that he and two other speakers would cover various related topics during this session.

NIH UNITE Initiative

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; Marie A. Bernard, M.D., Chief Officer for Scientific Workforce Diversity, NIH, and Deputy Director, National Institute on Aging; and Alfred C. Johnson, Ph.D., Deputy Director for Management, NIH

The events of the past year brought into sharp relief the racial injustice in the United States and everyone's responsibility to address it. A series of intense meetings brought IC Directors together to identify issues. Two affinity groups—8CRE (Eight Changes for Racial Equity) and a group of African American/Black (AA/B) scientists—met with NIH leaders for candid discussion that formed the basis for next steps. NIH, as an agency, is committed to addressing structural racism.

Dr. Tabak said that the following initial issues were identified:

- We must ensure that biomedical research and the administrative system that supports it are devoid of hostility grounded in race, sex, and other federally protected characteristics.
- With this new initiative, we are committed to delineating elements that may perpetuate structural racism in biomedical research within both NIH and the extramural community, leading to a lack of personnel DEI.
- All ideas must be given an equal and fair review without regard to current dogma, precedents, or who presents the ideas.
- As the pandemic has made clear, health disparities and inequities continue to exacerbate morbidity and mortality in our nation. We must redress the fundamental causes of these disparities and inequities and identify research programs that could lead to effective interventions.

The UNITE initiative has five elements, each supported by a dedicated committee:

U Understanding stakeholder experiences through listening and learning
N New research on health disparities, minority health, and health equity
I Improving the NIH culture and structure for equity, inclusion, and excellence
T Transparency, communication, and accountability with internal and external stakeholders
E Extramural research ecosystem: changing policy, culture, and structure to promote workforce diversity

Dr. Bernard presented the initial recommendations stemming from the UNITE initiative. An important step occurred on February 26, 2021, when NIH publicly committed to identifying and correcting any NIH policies or practices that may have helped to perpetuate structural racism. Dr. Bernard also described progress in fulfilling the recommendations.

In response to another recommendation, NIH committed to continuing to implement approaches to address the Ginther Gap and enhance portfolio diversity. In 2011, Ginther et al. reported a significant racial gap apparent in NIH R01 funding.[3] That report noted that the funding rate for R01 applications from AA/B scientists was 10 percentage points lower than for all other groups after the data were controlled for an applicant's educational background, country of origin, training, previous research awards, publication record, and institution characteristics. Other groups (e.g., Hispanic, Asian, American Indian/Alaska Native) were also disadvantaged. However, after the data were controlled for multiple factors, the disadvantage disappeared except for AA/B scientists.

[3] Ginther DK, Schaffer WT, Schnell J, et al. Race, ethnicity, and NIH research awards. *Science*. 2011;333(6045):1015-1019. doi:10.1126/science.1196783

Dr. Bernard presented data updated from Dr. Valentine's 2018 report showing that few AA/B scientists submitted R01 applications in 2013, but in 2020 the number of applicants had increased and the funding gap had somewhat improved. However, the numbers were still quite low as compared with the representation in the biomedical ecosystem and the general population. Work to close the Ginther gap is ongoing, but there is still much to do.

NIH launched a multiphase, multitiered, integrated Common Fund initiative focused on transformative health disparities research initiatives to reduce health disparities and inequities. Up to $24 million was dedicated to the effort in the first two years. Two Funding Opportunity Announcements (FOAs) were released on March 26, 2021:

- RFA-RM-21-021 Transformative Research to Address Health Disparities and Advance Health Equity (U01 Clinical Trial Allowed): https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-021.html
- RFA-RM-21-022 Transformative Research to Address Health Disparities and Advance Health Equity at Minority Serving Institutions (U01 Clinical Trial Allowed): https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-022.html

To ensure enterprise-wide commitment, 25 ICOs have committed up to $30.8 million to support a National Institute on Minority Health and Health Disparities (NIMHD) FOA to understand the effects of structural racism and discrimination on health disparities and inequities and encourage funding levels that are commensurate with overall IC resources.

In addition, Dr. Bernard said that the trans-NIH Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative recognized a lack of diversity in biospecimens for research as well as the scientists conducting the research. To expand diversity and close the knowledge gap, BRAIN released an FOA (https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-21-180.html) that includes a scoring factor based on plans to enhance diverse perspectives among the research team. . If this approach works, it could be replicated.

NIH also committed to developing a sustainable process to systematically gather and make public the demographics of NIH's internal and external workforce.

The Office of Extramural Research published a report (https://report.nih.gov/sites/report/files/docs/NIH_Principal_Investigators_by_Gender_Race_Ethnicity_and_Disability_2016-2020_02_23_2021_PDF.pdf) listing principal investigators by grant mechanism and gender, race, ethnicity, and disability.

An NIH workforce profile (https://www.edi.nih.gov/people/resources/advancing-racial-equity/nih-workforce-profile-fy21q02) presents internal race/ethnicity and disability data for staff in scientific occupations, infrastructure occupations, and health and research occupations.

Another UNITE recommendation focused on implementing policy changes to promote anti-racism and remove barriers to professional growth for staff from diverse backgrounds, including those from underrepresented groups. One outcome of the recommendation was the formation of the Anti-Racism Steering Committee (ARSC), composed of more than 480 members from across NIH. The ARSC, which has great diversity in terms of race/ethnicity, job categorizations, and pay levels, addresses issues regarding NIH policies and procedures but does not address individual cases.

Dr. Bernard discussed UNITE's recommendation to implement a performance expectation for IC directors based on accountability for DEI efforts and actively participating in NIH-wide diversity efforts through a DEI officer or other means.

Finally, UNITE recommended expanding the Distinguished Scholars Program to senior investigators hired with tenure and enhancing recruitment of researchers from underrepresented groups. This work has been initiated and seems to be succeeding.

Dr. Johnson said that the journey to end structural racism is a long one. There is much left to do. He outlined plans for the next 6 months:

- The President's budget proposes more funding for NIMHD; the National Institute of Nursing Research; the National Heart, Lung, and Blood Institute (NHLBI); and the Fogarty International Center. The funding would facilitate research on health disparities, minority health, and health equity.
- Continue to listen to and learn from a wide variety of stakeholders, including those who are not frequently engaged.
- Develop actionable data dashboards to track and provide visualizations of the intramural workforce and NIH's investments in health disparities, minority health, and health equity with key performance indicators and metrics.
- Issue additional FOAs that focus on IC-specific disease and topic areas related to health disparities, minority health, and health equity.
- Develop programs to spur institutional culture change in support of inclusivity and equity.
- Expand career opportunities for underrepresented groups, starting with increasing IC participation in Science Education Partnership Awards targeting K–12 science and technology, engineering, mathematics, and medicine (STEMM) education.
- Increase interactions between NIH and Tribal colleges, historically Black colleges and universities, and other minority-serving institutions.
- Examine interactions between NIH staff (e.g., program officers, scientific review officers) and applicants to address bias or inequities that may affect funding opportunities.
- Ensure that physical and virtual representations in NIH buildings and environment reflect the diversity of our society.
- Publish revised NIH internal guidance for reporting racial discrimination.

Dr. Johnson underscored the role of UNITE in bringing about an end to racial injustice, quoting Reverend Martin Luther King, Jr.: "Injustice anywhere is a threat to justice everywhere. We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly, affects all indirectly."

Dr. Johnson called attention to a June 2021 commentary in *Cell* about the UNITE initiative.[4] He presented the roster of the UNITE committee members, including himself, Dr. Bernard, and Dr. Tabak as co-chairs.

[4] Collins FS, Adams AB, Aklin C, et al. Affirming NIH's commitment to addressing structural racism in the biomedical research enterprise. *Cell*. 2021;184(12):3075-3079. doi:10.1016/j.cell.2021.05.014. PMID: 34115967.

Discussion

Dr. Shannon said that this was a day of role reversals. He said he is learning more from NIH than he is sharing. He appreciated the chance to understand the depth and breadth of work underway at NIH to address systemic racism. NIH's leadership is powerful and catalyzing and deeply influences "downstream" institutions. A partnership between NIH and academic institutions would likely have synergistic effects in bringing about an end to structural racism. Dr. Tabak noted that UNITE is directed not only internally but also externally.

Dr. Bernard said that NIH is focusing on learning from successes and working across the board with academic and research institutions. A recently renewed FOA (https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-21-025.html) aims to transform culture at NIH-funded institutions by building a community of scientists committed to diversity and inclusive excellence through mentoring and other activities. NIH received a robust response to the initial solicitation. Dr. Bernard also mentioned the SEA [STEMM Equity Achievement] Change initiative of the American Association for the Advancement of Science. SEA Change is a comprehensive self-assessment process to effect sustainable change regarding DEI in STEMM fields at U.S. institutions of higher education.

Ms. Berty expressed support for STEM programs in schools, where change needs to start. She asked about the types of physical and environmental changes UNITE is recommending. Dr. Johnson mentioned portraiture and displays. The UNITE committee is reviewing and working with facilities staff to make some changes so all sorts of people can see people like themselves represented in the physical environment at NIH.

Dr. Hait spoke about the role of industry in health equity. As companies develop new products, pricing keeps many of those products out of reach for many people, especially underrepresented groups. Dr. Hait asked whether NIH is reaching out to industry. He expressed interest in ensuring that industry is upholding the health equity aspect of product development. Dr. Tabak said that thus far, NIH has not formally engaged industry in discussions about health equity, but that would be a great idea for many reasons. He thought that Dr. Bernard would be interested in following up on this idea.

Dr. Shannon suggested breaking down Clinical Center data on quality and safety measures by race/ethnicity to identify trends that may affect some communities more than others. Dr. Gilman thought this might be possible, although it would be necessary to accrue data over longer periods than quarters. Dr. Shannon asked that the CCRHB be updated on efforts to parse the data in this way. Dr. Forese said that NewYork–Presbyterian leaders have tried to do this but had to acknowledge that data collection was hampered by the lack of a system for allowing people to self-identify their race/ethnicity. It is important to explain the rationale behind such questions and avoid making assumptions about how people would categorize themselves.

Ms. Reel spoke about people jumping to conclusions about a person's role based on their attire and race/ethnicity. A senior executive might assume that an AA/B in casual attire is there to fix the printer. Dr. Gilman said that similar incidents have occurred at NIH.

Action Items

- Dr. Bernard will follow up with Dr. Hait regarding his offer to help ensure that industry considers health equity in terms of access to new and costly drugs.

- Dr. Gilman will follow up with the CCRHB's request to see safety and quality data broken down by race/ethnicity.

NIH Clinical Center Demographics for Workforce and Patients
Daniel Lonnerdal, M.S., FACHE, Executive Officer, NIH Clinical Center; Justin Cohen, M.S., M.A., Chief, NIH Clinical Center Office of Communications and Media Relations and Office of Patient Recruitment; and John I. Gallin, M.D., NIH Associate Director for Clinical Research, NIH, and Chief Scientific Officer, NIH Clinical Center

Mr. Lonnerdal presented data on the Clinical Center's workforce demographics. The Clinical Center employs about 2,000 federal employees, and about 5,800 people from various ICs work in Building 10. NIH employs nearly 19,000 federal employees.

The Clinical Center reviews and assesses federal workforce demographics in terms of race, sex, disability, and other metrics. The Federal Employee Viewpoint Survey showed that 81% of Clinical Center staff believe that their supervisors are committed to a workforce representative of all segments of society. This represents an increase of 9% over the 2019 survey.

In terms of DEI efforts, Mr. Lonnerdal noted that all Building 10 staff go through onboarding and new employee orientation. All must meet annual and periodic training requirements. One of the four Clinical Center core competencies is diversity appreciation and cultural competency.

Mr. Lonnerdal compared the NIH workforce with the U.S. civilian labor force (CLF), comprising government and nongovernment entities. In terms of hospital comparators, the American Hospital Association does not track workforce demographics.

From 2018 through the first half of 2021, the proportion of whites in the NIH workforce declined slightly (from 56% to 54%), while the proportions of AAs/Bs and Asians increased slightly (from 20% to 21% and from 18% to 19%, respectively). The proportion of Hispanic/Latino people has remained constant at 4%. Race/ethnicity was self-reported. The Clinical Center data are similar to NIH data overall, but 15% more AAs/Bs and 15% fewer whites work in the Clinical Center—a strong positive for the Clinical Center.

Compared with the CLF data, race/ethnicity demographics show that the Clinical Center does well in terms of representation by AAs/Bs in miscellaneous administrations and programs (54.3% in the Clinical Center compared with 12.5% as the CLF benchmark), but the data shows there are many opportunities to enhance diversity.

Compared with the CLF benchmark, the Clinical Center has a greater proportion of female employees, likely because of being a hospital environment. Mr. Lonnerdal also acknowledged that there are more gender categories than just "male," "female," and "unknown." The Clinical Center plans to work with NIH on more self-identification options.

In terms of disability demographics, Mr. Lonnerdal said that the Equal Employment Opportunity Commission's targeted disability benchmark is 2% and the reportable benchmark is 12%. The Clinical Center's proportions of employees with nontargeted disabilities and targeted disabilities are consistently 5% and 2%, respectively. Between 5% and 7% have unidentified disabilities. The statistics for NIH overall are similar.

Mr. Lonnerdal highlighted several Clinical Center DEI efforts in addition to UNITE and other NIH initiatives. These include a Clinical Center DEI Workgroup and Committee Planning Group, which are working on a DEI Climate Assessment (an all-employee survey, tentatively planned for August 2021) and a DEI video and program kickoff planned for the first quarter of FY 2022.

Few comparison data are available from similar institutions and hospitals. The Clinical Center would be interested in partnering with other organizations, including CCRHB members' institutions.

Mr. Cohen spoke about the Clinical Center's Patient Recruitment Call Center, focusing on the demographics of call center referrals. The functional areas of the Office of Patient Recruitment include:

- *Recruitment services:* Recruitment experts support researchers in enrolling study participants. Recruiters create tailored campaigns, including social media marketing, public service announcements, posters, and community outreach initiatives. The recruitment center staff are mindful of regulatory compliance issues, screening questions, and screening parameters.
- *Contact Center:* Information specialists help members of the public find studies of interest and connect them to NIH research teams. Every year, specialists speak with nearly 32,000 patients, healthy volunteers, and healthcare providers, resulting in more than 10,000 referrals to NIH studies. The Contact Center works in tandem with communications staff. For example, if a media piece is coming out, the Contact Center will be alerted so they are ready to handle inquires. The center handles 30,000 to 40,000 inquiries via phone and email each year.
- *Clinical Research Volunteer Program*: Program specialists provide guidance and training to research teams on compensation for study participants. Staff maintain a registry of more than 24,000 healthy people who are willing to take part in research.

Mr. Cohen said that the Office of Patient Recruitment has quality assurance/quality control reviewers. The standard is to keep people on hold no more than 2 minutes. Some people who call are in great distress. Some threaten self-harm or violence.

The mix of studies enrolling patients affects the demographic data of study volunteers. Between 2018 and 2020, 40% to 50% of callers identified as white, 25% to 30% identified as AA/B, and 6% to 8% identified as Hispanic/Latino. No data were available for the remainder of volunteers.

In general, most volunteers in clinical trials (about 58%) identify as female. According to the literature, one reason that women are more likely than men to participate in studies is that they are more proactive about seeking out healthcare options than men are.

Mr. Cohen envisions several operational improvements in the future:

- Update the collection of gender and ethnicity data and align them with Clinical Center admission categories (e.g., transgender male/female).
- Hire a consultant to review database processes and the Contact Center platform to assess alignment with industry best practices.
- Pilot new recruitment tactics to enroll participants in NIH intramural clinical trials (e.g., the Nextdoor app, digital advertising).

- Upgrade the software platform. The current virtual Contact Center (Verizon) has many limitations. The plan is to switch to an in-house system that includes NIH technical support.
- Launch an online, healthy-volunteer self-registry. The tool will help capture data points and allow volunteers to select studies they are interested in. This tool likely will skew toward a younger population.

Dr. Gallin addressed Clinical Center patient demographics and structural racism initiatives. Local initiatives to address structural racism and change the Clinical Center workforce include the membership of the Board of Scientific Counselors (BSC) and actions of the Medical Executive Committee (MEC), training programs, and extramural regional partnerships.

In terms of Clinical Center demographics, Dr. Gallin presented data from 2019 on nearly 24,000 patients broken down by race/ethnicity. Nearly 65% identified as white, 12% identified as Hispanic/Latino, and 17% identified as AA/B. During 2020, the number of patients dropped to 14,000, but the distribution by race/ethnicity stayed about the same.

Dr. Gallin discussed the Clinical Center's structural racism initiatives, starting with the BSC. Every scientist gets reviewed at least once every 4 years. The Board is chaired by Kari Nadeau, M.D., Ph.D., of the Stanford University School of Medicine. In addition, structural racism discussions occurred at research department head meetings and town hall meetings.

Dr. Gallin also spoke of transitions in Clinical Center staff that have bolstered diversity. Of four recently tenured investigators, three are women, and one belongs to an underrepresented group. Overall, the Clinical Center has 21 tenured scientists, of whom 29% are women and 14% belong to underrepresented groups. Among six current tenure-track investigators, two are women.

Dr. Gallin reported that among the 19 Clinical Center department and clinical service chiefs, more than 68% are women and 16% belong to underrepresented groups.

The Clinical Center is building a pipeline to bring in new investigators to enhance diversity. Dr. Gallin outlined several changes to bring this about:

- The Clinical Center has developed a new tenure-track position in partnership with NIMHD. The title of the position is "Ethics of Underrepresented Minorities in Clinical Research." A new senior clinician search is underway; the BSC has recommended Nadia Biassou, M.D., Ph.D.
- The BSC also recommended Nicole Farmer, M.D., for the tenure track within the new Translational Biobehavioral Health Disparities Branch in Nursing.
- Ifeanyi Anidi, M.D., Ph.D., just completed a critical care medicine/pulmonary fellowship and is preparing for an assistant clinical investigator position with NHLBI.
- Ousmane Cissé, Pharm.D., Ph.D., in the Critical Care Medicine Department, was awarded an honorary NIH associate scientist title for his work on *Pneumocystis carinii*. An effort is underway to advance him as a tenure-track investigator.
- The Clinical Center added two Accreditation Council for Graduate Medical Education (ACGME) clinical fellowships. Between 125 and 140 fellows come to the Clinical Center each year. The percentage identified as being underrepresented minorities doubled from 10% in 2018–2019 to 20% in 2020–2021.

- The aim of the Medical Research Scholars Program is to expose scholars to medical research. The proportion who identified themselves as underrepresented minorities went from 7% in 2018–2019 to almost 20% in 2020–2021.

Dr. Gallin highlighted other efforts to diversify the Clinical Center by expanding the number of speakers at grand rounds who belong to underrepresented minorities. In 2018–2019, only 5% of speakers identified as being an underrepresented minority. This increased to 22% in 2020–2021.

In 2020–2021, two clinical research training courses enrolled 18,000 participants in 151 countries. Some participants inquire about participating as fellows to get additional training. This outreach has a global impact.

The MEC has recently focused on social determinants of health (SDOH), defined in *Healthy People 2030* as conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[5] Anna Maria Nápoles, Ph.D., M.P.H., Scientific Director of NIMHD, is taking a leadership role in examining NIH research on SDOH.

The Clinical Center's top 10 SDOH include unemployment, occupational exposure to toxic agents, personal history of physical or sexual abuse in childhood, insufficient social insurance and welfare support, and disappearance or death of a family member. Dr. Nápoles is figuring out how to develop protocols to study these dimensions.

In terms of extramural regional partnerships, Dr. Gallin explained the creation of a master agreement to sign up other institutions. Eight institutions have signed agreements. The idea is to establish micro-networks for increasing diversity of NIH study participants while enhancing research opportunities for regional institutions. The first partnership was between NIH and Howard University under a master agreement signed in 2019. The Howard–NIH Partnership Executive Team meets monthly.

Seven Howard colleges and schools are partnering with a dozen NIH ICs. Activities include mentorship of graduate students, as well as of tenure-track and junior faculty. Clinical research projects cover a variety of topics ranging from sickle cell disease to bioethics.

Under the auspices of the UNITE team initiative, a proposal has been advanced to start a new NIH–Howard Medical School Scholars Program. Ten Howard students would come to NIH for summer internships and a 3-year mentoring program.

In conclusion, Dr. Gallin said that the Clinical Center has initiated numerous approaches to addressing structural racism through new recruitments, advancement of staff, training programs, and partnerships with local institutions to change the culture locally within the NIH community.

Action Item

- Mr. Lonnerdal expressed interest in partnering with CCRHB members' institutions to obtain comparator data for analyzing demographics of the Clinical Center workforce.

[5] https://health.gov/healthypeople/objectives-and-data/social-determinants-health

Discussion

Ms. Reel credited "the Fauci effect" with increasing the number of applicants for medical school. She lauded NIH's efforts, saying that they are encouraging more students of underrepresented minorities to choose science.

Dr. Shannon congratulated Clinical Center leaders for the remarkable increases in diversity in the ACGME and Medical Research Scholars Program. To achieve a doubling of participation by underrepresented groups is unheard of. Dr. Gallin explained that the successes resulted from a systemic effort across the campus to engage at the highest leadership levels and all the way through organizational cultures. It is important to ask people what they are doing and have open discussions. At NIH, diversity is discussed in the same way as patient safety. The leaders of both programs have been very responsive; they go out and reach the institutions where they recruit to ask them to help NIH. With Howard, for example, NIH set up a committee for "matchmaking" to encourage candidates to come to NIH.

Dr. Tabak said that people too often think that a lack of diversity is merely a pipeline issue, but that focus has led to failure. Structural changes need to occur to ensure that diverse staff find accepting, supportive, and enabling environments. The structural aspects of racism have been overlooked for too long.

Dr. Hait remarked on the great depth and breadth in NIH leaders' thinking about expanding diversity. The pipeline is important, but it is not the whole answer. When Johnson & Johnson recruits for positions, the person often selected does not have a minority background. When a candidate from a minority background is not selected for a certain position, the company sometimes creates a new role to allow the person to pursue a career. Too often, good candidates are overlooked during the selection process, although they could have promising careers. Dr. Gallin strongly agreed, saying that creating new positions can be very helpful.

Dr. Hait said that the clinicaltrials.gov website offers a comprehensive approach to inclusion and exclusion criteria for clinical trials. He asked whether it would be possible to make the website more accessible, easier to use, and more engaging for people from minority backgrounds. Dr. Gallin said that the Inspector General is looking at how NIH is doing in terms of recruiting diverse study participants for intramural and extramural studies. The objective of clinicaltrials.gov was to reach all residents of the United States. However, there has been no specific, high-level focus on this service. Dr. Gallin acknowledged the need for discussion with leadership at the National Library of Medicine to come up with better ways of presenting the information in a more user-friendly format.

Ms. Berty said she has personal experience using clinicaltrials.gov. Searching is not easy. The sorting mechanism is complex. She agreed with the idea of making the website easier to use, and she volunteered to help with the effort.

Julie Freischlag, M.D., said that Wake Forest saw a remarkable jump in medical school applications from people from underrepresented groups, a change largely fueled by virtual interviews.

Dr. Freischlag also remarked that Wake Forest has started bystander training in addition to implicit bias training. She acknowledged that the number of employees from underrepresented groups is still too low to provide a comfortable environment for them.

Action Item

- Explore options in collaboration with the National Library of Medicine for revamping clinicaltrials.gov to make it more accessible, user-friendly, simple, and engaging and useful for diverse groups. Ms. Berty volunteered to assist with the effort.

NIH Clinical Center Chief Executive Officer Update

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

Dr. Gilman announced that the *Clinical and Safety Performance Metrics Executive Dashboard* had been distributed to the CCRHB members before the meeting. The document is also available online (https://ccrhb.od.nih.gov/documents/07232021_Dashboard.pdf).

Staff Changes

- Bernard Harper, Chief of Materials Management Department, NIH Clinical Center, is leaving NIH. He demonstrated great commitment and resourcefulness as a dedicated CC leader, and his dedicated efforts helped to ensure that the Clinical Center staff had the personal protective equipment needed to work in the hospital throughout the pandemic..
- Tara Palmore, M.D., the Clinical Center's hospital epidemiologist, is leaving NIH after 20 years to accept a position at the George Washington University Hospital. She was recently honored with the 2020 Department of Health and Human Services (HHS) Excellence in Management Award. An offer was extended to a new epidemiologist; there will be only a few weeks of underlap between Dr. Palmore and the incoming epidemiologist.
- Gwenyth Wallen, Ph.D., RN, former Chief Nurse Officer, is returning to her prior role in health disparities research. Dr. Barbara Jordan will be acting Chief Nurse. Dr. Wallen wants to remain engaged with the Clinical Center's Magnet® journey.
- Robert Lembo, M.D., Director of Education and Training and Executive Director of Graduate Medical Education, is retiring. His position will be filled by two individuals In addition to the Chief of OCRTME, a newly created position, Designated Institutional Official for Graduate Medical Education.
- A search is underway for a Chief Medical Officer; most likely, the position will be filled by the next CCRHB meeting.
- The Clinical Center is close to hiring a Chief for the Office of Patient Safety and Clinical Quality.

HHS Departmental Honors

- Susan Nsangou, Chief of the Clinical Center Purchasing and Contracts Department, received the 2020 HHS Secretary's Award for Meritorious Service.
- CDR Todd Campbell, Pharm.D., with the Clinical Center Pharmacy Department, received the 2020 HHS Secretary's Award for Distinguished Service.

Office of Communications and Media Relations (OCMR) Update

The OCMR marked the 50th anniversary of *Clinical Center News*. The first issue hit the stands in June 1971.

OCMR has many successes to celebrate, including the electronic message boards introduced last year. The idea had long been considered, but the vision became reality due to the late Beatrice Bowie's advocacy to declutter posters around the Clinical Center. (Ms. Bowie served on the CCRHB.) Twenty-four screens have been activated, and 13 more will be activated in the Magnuson Building in the fall of 2021. The content is designed by OCMR visual information specialists. The electronic message boards present timely messages and video for all CC constituents.

Hospital Census

The average daily census plunged in the spring and summer of 2020 due to the pandemic. The 3-year average for FY 2017–2019 was 119. At the end of FY 2020, the average census was 87.

Numbers are slowly rebounding and now approach 2020 inpatient levels. Outpatient numbers have recovered to the 2020 levels. If in-person and telehealth visits are combined, Clinical Center visits are at the same level as before the pandemic. The number of telehealth visits has hovered around 1,000 per month since October 2020. The total number of telehealth visits as of April 2021 was just over 10,000.

Safety and Quality

Staff hand hygiene compliance consistently exceeds 90%. During the second quarter of 2021, compliance was 94%, although Dr. Gilman acknowledged a need to increase the number of observations.

The NIH Blood Bank has low blood product inventory, which is linked to nationwide shortages. The Clinical Center's need for blood transfusions remains constant to support patients who have cancer or are undergoing surgery. NIH staff provide a significant proportion of blood donations.

Upcoming Joint Commission Accreditation

The Clinical Center continues to prepare for a full survey in 2021. The last survey occurred during July 2018. The Office of Patient Safety and Clinical Quality developed a readiness guidebook to help prepare for the survey. Staff have been prepared for effective virtual communication and information sharing.

Clinical Center Emergency Management

A spring exercise was conducted in June 2021. The goal is to test the Clinical Center's ability to respond in a crisis focusing on communications and processes. A larger-scale exercise involving other NIH stakeholders will be conducted during the fall of 2021.

ACGME Clinical Learning Environment Review

A committee site visit occurred on July 19, 2021.

These reviews began in 2012, with a commitment to formative assessment and feedback regarding graduate medical education engagement. They cover six areas of focus, including patient safety and professionalism. The July visit included an assessment of the COVID-19 pandemic's impact on the clinical learning environment.

Patient Perception Surveys

The Clinical Center is adopting a new approach through a contract with Press Ganey Associates, an industry leader in health care surveys. The new surveys will be sent to patients by email and can be completed online. The surveys are much shorter and more targeted but still capture key components of the health care experience.

The hope is that the new approach will boost response rates. These data are important to the Magnet® accreditation effort.

COVID-19 Screening, Testing, and Vaccinations in Building 10

Dr. Gilman said that another building entrance has been opened. More than 1.5 million people have been screened, with the highest number (6,000) getting screened on June 24, 2021. Asymptomatic testing continues at the Clinical Center, with a weekly average of 900 tests. Twelve percent of tests are saliva based.

Nearly 16,000 people have been vaccinated at the Clinical Center. Eighty percent of NIH federal employees and 53% of contracted staff have received at least one vaccine dose. Vaccinations are now provided in the Occupational Medical Services area on the sixth floor. NIH encourages everyone to be vaccinated, but vaccinations cannot be mandated.

Dr. Gilman outlined the public health measures that are still in effect at the Clinical Center. He explained that some staff were unable to visit families who live outside of the United States. As travel restrictions are loosened, NIH can provide testing that employees need for foreign travel.

NIH, including the Clinical Center, is planning for federal employees and contractors to return to the physical workplace. However, the Occupational Safety and Health Administration has issued emergency temporary standards to protect health care workers from COVID-19. NIH must notify staff if anyone in their area tests positive for COVID-19. Facilities must conduct hazard assessments and have a written COVID-19 plan to mitigate disease transmission.

Employee Well-Being

Many people are still under stress or in distress due to the pandemic and other events. Dr. Gilman underscored the continuing importance of help-seeking behavior. Resources remain available, including the Clinical Center Spiritual Care Department, the EAP, and emergency national services, including the National Suicide Prevention Lifeline.

The Hepatitis C Story

Introduction

Barbara Bryant, M.D., Chief, NIH Clinical Center Department of Transfusion Medicine and Center for Cellular Engineering

Dr. Bryant introduced Harvey Alter, M.D., co-winner of the 2020 Nobel Prize in Physiology or Medicine with Michael Houghton and Charles M. Rice for the discovery of the hepatitis C virus (HCV). Dr. Bryant highlighted Dr. Alter's academic and research accomplishments.[6] Dr. Alter joined NIH in 1961, working in the Clinical Center's Department of Transfusion Medicine. His research led to the co-discovery of HCV. Thanks to his collaborative work, the risk of transfusion-related HCV infection has been eliminated.

History of Hepatitis C Research at NIH

Harvey J. Alter, M.D., NIH Distinguished Scholar and 2020 Nobel Laureate

Referring to a photo of the Clinical Center, Dr. Alter said he has spent his entire professional career in the building. This story would not have been possible anywhere else. Through the NIH

[6] More details are available on the NIH Clinical Center website: https://clinicalcenter.nih.gov/meet-our-doctors/halter.html .

Clinical Center, he had access to patients and was able to conduct long-term studies that could not be done in academia. NIH also fostered valuable collaborations.

Dr. Alter presented a timeline of hepatitis history, starting with Hippocrates, who was the first to describe icterus and *kirrhos* (cirrhosis), which he attributed to an excess of bile. During recurrent wars, hepatitis was often called "campaign jaundice," but progress in the hepatitis field stalled until the 1960s, when Dr. Alter co-discovered the Australia antigen, the hepatitis B surface antigen, with Baruch Blumberg, M.D., D.Phil., of the National Institute of Allergy and Infectious Diseases (NIAID).

Dr. Alter described a breakthrough study of transfusion-associated hepatitis done in collaboration with NIAID. Samples of blood from patients and donors were collected and stored. Although no specific hepatitis test was available, the samples were tested for alanine aminotransferase (ALT) levels—a measure of liver inflammation. More than 30% of patients who underwent open-heart surgery showed enzymatic evidence of hepatitis. The risk of hepatitis was highly dependent on the source of donor blood. Blood from paid donors was associated with a 51% chance of hepatitis, but blood from volunteers had only a 7% chance of causing hepatitis in the recipient. Going to 100% volunteer-donated blood greatly reduced the incidence of HCV infection although the volume of blood transfused remained the same.

Subsequent accomplishments in the field included development of hepatitis B antigen tests and the discovery of hepatitis A. Dr. Alter coined the term "non-A, non-B hepatitis" for the remaining cases of hepatitis, because transmissibility had not yet been proven, so he could not yet attribute these cases to hepatitis C. Transmission studies were performed in chimpanzees, which developed mild ALT elevations but did not become sick. Dr. Alter's team demonstrated transmission of the disease to chimpanzees from patients with acute non-A, non-B hepatitis and from asymptomatic, implicated donors. A reliable disease model was now available.

Dr. Alter described the case of Mr. H, whose samples proved invaluable for the research. Five weeks post-transfusion, his ALT level began to rise and then fell dramatically. A unit of blood was collected by apheresis from Mr. H. and then administered to a chimpanzee. The experiments showed that the disease was transmissible.

Subsequent work by others demonstrated the presence of a lipid in the HCV capsule, meaning that it was likely that the etiologic agent was a flavivirus. The development of an assay for HCV was difficult, although it was possible to study the clinical consequences. A collaborative study with the National Institute of Diabetes and Digestive and Kidney Diseases that involved liver biopsies on eight patients with mild to moderate disease showed that some had cirrhosis and some had advanced hepatitis. A quarter of the patients progressed to cirrhosis—a proportion that has remained unchanged.

Chiron Corporation cloned the non-A, non-B hepatitis virus with what was then the latest molecular technology: the lambda gt11 expression vector. The scientists extracted RNA from a chimp with a high titer and then reverse-transcribed the RNA to cDNA. Chiron generated enough antigen to develop an immunoassay. The company tested the system on patients who were assumed to have an antibody in their plasma. The assay detected antibodies in three chronic patients and four implicated donors. The test correctly detected 100% of cases. Based on these results, Dr. Alter predicted that 90% of transfusion cases could be prevented. As many as 4.8 million transfusion-related HCV infections were prevented between 1970 and 1990. HCV testing prevented 2.4 million transmissions from 1990 to 2010.

Many HCV patients develop asymptomatic but persistent infection due to the quasi-species nature of HCV. The virus can mutate rapidly, making it possible to observe the evolution of HCV quasi-species in patients with rapidly progressive chronic HCV. The same phenomenon is being observed with COVID-19, and it is one of the main reasons why vaccines for HCV (and HIV) have not been developed.

Most HCV patients have stable or slowly progressive disease, but some have severe and progressive disease, and others have rapidly progressive disease with development of cirrhosis within 5 years or so, likely due to nonalcoholic steatohepatitis or alcoholism. Rapid HCV progressors tend to have high levels of profibrinogenic monocyte chemotactic protein. Slow progressors often have increased levels of interferon-gamma and another beneficial cytokine.

Fortunately, there has been a drastic change in HCV care. Oral direct-acting antiviral (DAA) medications can cure between 90% and 100% of cases. With cure rates approaching 100%, no one should develop cirrhosis or die from HCV anymore. However, as many as half of infections remain undetected. Case identification needs to improve, along with access to DAA. The cost of treatment (about $84,000) is out of reach for many countries.

Global eradication of HCV would be a huge challenge, but it would be theoretically possible. To detect all HCV carriers, a rapid test that can be used in the field, at the point of care, or in the home would be necessary. Then all carriers would have to take drugs to clear HCV. Dr. Alter pointed out that only a 3-month course of treatment is necessary. Side effects are few. The political, corporate, philanthropic, and moral will to make it happen would be needed.

Discussion

Dr. Forese thanked Dr. Alter for "a master class in science and history, made even more interesting with humor, insights, and poetry." Dr. Shannon said it was an honor to spend this time with a humble genius.

Dr. Gilman said that the Nobel Prize was awarded to Dr. Alter at the Natcher Conference Center, because the pandemic made travel to Sweden impossible.

Adjournment

Dr. Forese thanked the presenters, NIH staff, and Board members. The next meeting is scheduled for October 15, 2021.

Dr. Forese adjourned the meeting at 1:17 pm.

/Laura Forese/

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

Chair, NIH Clinical Center Research Hospital Board

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

/Lawrence A. Tabak/

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/Francis S. Collins/

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

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

AA/B	African American/Black
ACGME	Accreditation Council for Graduate Medical Education
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
ALT	alanine aminotransferase
ARPA-H	Advanced Research Project Agency for Health
ARSC	Anti-Racism Steering Committee
BSC	Board of Scientific Counselors
BRAIN	Brain Research Through Advancing Innovative Neurotechnologies®
CCRHB	Clinical Center Research Hospital Board
CLF	civilian labor force
COVID-19	coronavirus disease 2019
DAA	direct-acting antiviral
DARPA	Defense Advanced Research Projects Agency
DEI	diversity, equity, and inclusion
EAP	Employee Assistance Program
8CRE	Eight Changes for Racial Equity
FDA	U.S. Food and Drug Administration
FNIH	Foundation for the National Institutes of Health
FOA	Funding Opportunity Announcement

FY	fiscal year
HCV	hepatitis C virus
HHS	Department of Health and Human Services
ICs	Institutes and Centers
ICOs	Institutes, Centers, and Offices
MOMI-Vax	SARS-CoV-2 Vaccines in Pregnancy and Postpartum
MEC	Medical Executive Committee
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
OCMR	Office of Communications & Media Relations
OITE	Office of Intramural Training & Education
OSTP	Office of Science and Technology Policy
RADx	Rapid Acceleration of Diagnostics
RADx-rad	RADx Radical
RADx-UP	RADx Underserved Populations
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2

SDOH	social determinants of health
STEMM	science, technology, engineering, mathematics, and medicine
TRACE	Tracking Resistance and Coronavirus Evolution