U.S. Department of Health and Human Services

National Institutes of Health

Twenty-first Meeting of the Clinical Center Research Hospital Board

July 15, 2022

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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., Acting Director, NIH; and Executive Director, CCRHB

David M. Baum, PMP, Patient, Clinical Center Patient Advisory Group (pending member)

David C. Chin, M.D., M.B.A., Distinguished Scholar, Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health and School of Medicine (pending member)

Regina S. Cunningham, Ph.D., RN, FAAN, Chief Executive Officer, Hospital of the University of Pennsylvania Health System (pending member)

Norvell V. Coots, M.D., President and Chief Executive Officer, Holy Cross Health; and Chair Nominee, CCRHB

Sherin U. Devaskar, M.D., Executive Chair, Department of Pediatrics, University of California, Los Angeles (UCLA); Physician-in-Chief, UCLA Mattel Children's Hospital; and Assistant Vice Chancellor of Children's Health, UCLA Health (ad hoc consultant)

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

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

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

Antoinette Royster, Patient, Clinical Center Patient Advisory Group (pending member)

Tara A. Schwetz, Ph.D., Acting Principal Deputy Director, NIH; and Executive Secretary, CCRHB

Craig E. Samitt, M.D., M.B.A., Founder and Chief Executive Officer, ITO Advisors (pending member)

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

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

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 21st meeting, an in-person/videoconference hybrid, on July 15, 2022. The meeting was webcast live and open to the public. A video recording is available online.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer (COO) of NewYork–Presbyterian Hospital and Chair of the CCRHB, called the meeting to order at 9:02 a.m. ET, noting that after chairing the Board for 6 years, she would be handing the gavel to Norvell V. Coots, M.D., President and Chief Executive Officer (CEO) of Holy Cross Health. Dr. Forese confirmed all Board members in attendance and noted that the Board charter was finalized in June, extending its mandate to 2024.

On the occasion of its 21st meeting, Lawrence A. Tabak, D.D.S., Ph.D., Acting Director of NIH, marveled at the extraordinary impact of the Board and how much it had accomplished in such a short time. He recognized departing member Ruth Williams-Brinkley, M.S.N., and thanked her for her contributions. He also expressed his gratitude for the profound impact of Dr. Forese's service as Chair, a role she took at the Board's first meeting exactly 6 years earlier. Before that, she was also a member of the team that led to the CCRHB's creation.

Dr. Tabak reflected on the history of the CCRHB. Following a period of soul searching at NIH in 2015 and 2016, the CCRHB was established based on the recommendations in a Red Team report submitted to the Advisory Committee to the Director. The report emphasized the need to fortify the culture and practice of safety and quality at the NIH Clinical Center (CC), mainly by strengthening the authority of leadership. Among the report's recommendations was a suggestion to establish an external board that would act like the board of a local hospital, overseeing CC management, safety, and quality. The CCRHB is the direct result of that recommendation.

Dr. Tabak welcomed new members to the Board: Regina Cunningham, Ph.D., RN, FAAN, CEO of the University of Pennsylvania Hospital; and Sherin Devaskar, M.D., Executive Chair of the Department of Pediatrics at UCLA, Physician-in-Chief at UCLA Mattel Children's Hospital, and Assistant Vice Chancellor of Children's Health at UCLA Health. He also gave the Board brief updates on the process for selecting a new NIH director and appropriations hearings in Congress. Dr. Tabak announced the appointment of Nina Schor, M.D., Ph.D., as Acting Deputy Director for Intramural Research (DDIR). She will take over from Michael Gottesman, who served for 29 years as DDIR and will return full time to his lab at the National Cancer Institute (NCI).

Dr. Tabak also presented a high-level update on NIH-wide strategic planning activities around diversity, equity, inclusion, and accessibility (DEIA). In response to mandates in the fiscal year (FY) 2021 budget language for NIH and Executive Order 14035, NIH has established a working group (WG) of about 100 people from all 27 Institutes and Centers (ICs) and Offices in the Office of the Director to develop its DEIA Strategic Plan. Starting in the summer of 2021, the WG developed a framework for the plan that was approved by the IC directors in January. This was followed by a public comment period, soliciting input from both internal and external stakeholders. Currently, NIH is in Phase 4, which entails refining the framework based on the input received. The WG is drafting the plan and is on track to meet its goal of having it approved by the end of summer. The plan encompasses all NIH activities, and its aims reflect the core

objectives of NIH as a people-centered organization that is representative of the nation's diversity and where everyone has sense of belonging.

James Gilman, M.D., CEO, NIH Clinical Center, reflected on his good fortune to be chosen as the first NIH CC CEO and the privilege of working with the Board and Dr. Forese as its chair. He gave Dr. Forese several parting items.

In his report to the Board, Dr. Gilman extended his appreciation to all of the departing Board members and gave a warm welcome to the six new members of the Board: David M. Baum, PMP; David C. Chin, M.D., M.B.A.; Antoinette Royster; Craig E. Samitt, M.D., M.B.A.; Dr. Cunningham; and Dr. Devaskar. He also expressed tremendous appreciation for Dr. Coots' willingness to take on the role of Board Chair.

Dr. Gilman reported on the spring U.S. Department of Health and Human Services (HHS) departmental awards, where the CC was well represented in both individual and team categories.

Dr. Gilman gave an update on the ongoing searches to fill three leadership positions at the CC and on the progress of moving the pharmacy into its new facility.

Dr. Gilman reported on average daily census (ADC) numbers, which remain lower than before the pandemic. As of July 4, figures for 2022 are down 10% from the year before. One emerging question that the CC will need to examine in the next 2 to 3 years is what research at the CC should look like in a virtual world. Tradition and dogma say that the CC's research is focused on what cannot be done anywhere else. However, with remote capabilities, that calculation has changed. Before the pandemic, the CC had no telehealth presence, but by 2021, it handled more than 1,000 appointments monthly. Telehealth services are now accepted and continue to be widely used, with several hundred appointments every month.

The Clinical Center is still following the same COVID-19 protocols as last year, including masking, eye protection, and social distancing.

Dr. Gilman reported that recent DEIA activities at the CC include the launch of a new website with robust and continually updated resources. In addition, the CC created a new position, Scientific Diversity Advisor. As part of its ongoing assessment of workforce demographics, the CC relies on data from the NIH Office of Equity, Diversity, and Inclusion (EDI). In addition, it has conducted focus groups and engagement surveys of staff. Dr. Gilman shared the results at a town hall in the spring and made them available to internal audiences online. The CC has also completed its racial and ethnic equity plan (REEP), which outlines six initiatives, and submitted it to NIH. NIH leaders have reviewed the plan and given feedback.

The quarterly report of patient and staff safety metrics, previously presented by David Lang, M.D., M.P.H., Chief, CC Office of Patient Safety and Clinical Quality, at Board meetings, will now be made available to the Board online.

CAPT Antoinette Jones, M.S.O.D., RN, U.S. Public Health Service (PHS) Commissioned Corps; and Patient Representative, NIH Clinical Center, spoke about the role of the patient representative at the CC and how it affects the patient experience. The patient representative's role at the CC differs from the role at other hospitals in several ways, not least because the hospital organization at the CC is not one unit but represents the approaches of the 18 different ICs that run protocols there. CAPT Jones' background as a nurse and her training in

organizational development contribute to her effectiveness on the job. Her mission is to provide a timely, effective response to patient concerns and to show respect. CAPT Jones described internal processes by which staff reviews feedback from patients and their families and reviewed data on encounters with her office. She underscored the idea that an organization that listens and takes its patients' concerns to heart preserves human dignity, ensures safety, maintains protocol integrity, and improves overall patient satisfaction and public perception.

Colleen Hadigan, M.D., M.P.H., Chief Medical Officer/Clinical Director, NIH Clinical Center, presented the 2021 results of patient surveys, including breakouts by demographics. The surveys, conducted electronically, are developed by Press Ganey. They were sent to patients starting in April 2021, covering visits from January to December of that year. There was a 20% to 22% response rate. Results were presented separately for outpatient and inpatient surveys. For both, the NIH data in aggregate, the percentage of top box ratings for the overall experience, nursing care, clinician care, and access was higher than the Press Ganey benchmark. There was no clear difference in ratings by sex or language, and among responses analyzed by race—Asian, Black/African American, mixed race, and White—satisfaction ratings did not differ markedly. Patient satisfaction survey data offer one metric to assess the patient experience. This preliminary review shows similar levels of satisfaction across demographic groups. One caveat is that there were small numbers of some groups. The CC is now collecting ethnicity data. In addition, the CC plans to break down results by age categories to analyze future results.

Barbara A. Jordan, D.N.P., RN, NEA-BC, Acting Chief Nurse Officer, NIH Clinical Center, presented an update on the CC's Magnet accreditation journey. The American Nurses Credentialing Center (ANCC) awards Magnet designation to organizations that have exceeded the more than 100 standards laid out in its Magnet manual. The designation, which emphasizes nursing but is awarded to the organization as a whole, reflects an excellent work environment. The Clinical Center is charting its progress against key milestones in the timeline for Magnet designation and expects to submit its Magnet application to ANCC in January 2023. The team is currently working on developing the CC's Magnet document, which includes a narrative of the CC's story that is supported with data. The document will be submitted in April 2024, after which appraisers will review and score it and conduct a site visit. That review will be followed by a period of public comment, after which the Magnet Commission will make its decision. Dr. Jordan described in detail the progress the CC has made.

Dr. Gilman gave a detailed overview of the Clinical Center's work toward executing its strategic plan, *People, Places, and Capabilities*, which outlined four strategic aims. He also described the Clinical Center's preparation and partnership with external organizations to carry out a protocol that may become a case study for future pediatric research at the CC. This will be a topic of future conversation with the Board. In summary, Dr. Gilman assessed the CC's progress with respect to the four strategic aims outlined in the plan.

In closing remarks, Dr. Forese gave some perspective on the Red Team whose recommendations led to the creation of the CCRHB. She commended Dr. Gilman for all that has been accomplished; thanked the Board, NIH, and CC leadership; and expressed excitement for the new members.

Meeting Summary
Friday, July 15, 2022

Welcome and Board Chair's Overview

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer (COO), NewYork–Presbyterian Hospital, and Chair, Clinical Center Research Hospital Board (CCRHB)

Dr. Forese called the meeting to order at 9:02 a.m. ET, noting that after chairing the Board for 6 years, she would be handing the gavel to Norvell V. Coots, M.D., President and Chief Executive Officer (CEO) of Holy Cross Health. Dr. Forese confirmed all Board members in attendance, both in the room and on Zoom, including pending members who have yet to be officially confirmed. She noted that the Board charter was finalized in June, extending the Board's mandate to 2024.

NIH Director's Remarks

Lawrence A. Tabak, D.D.S., Ph.D., Acting Director, National Institutes of Health (NIH), and Executive Director, CCRHB

Departures and History

On the occasion of its 21st meeting, Dr. Tabak marveled at the extraordinary impact of the Board and how much it had accomplished in a short time. He recognized departing Board member Ruth Williams-Brinkley, M.S.N., and thanked her for her contributions. He also expressed his gratitude for the profound impact of Dr. Forese's service as Board Chair, a role she took at the Board's first meeting exactly 6 years earlier. Before that, she was also a member of the team that led to the CCRHB's creation.

Dr. Tabak reflected on the history of the CCRHB. In the spring of 2015, NIH underwent a soul-searching period after a whistleblower revealed unsafe procedures in the pharmacy's handling of sterile injectables. The story attracted a lot of media attention and led to a formal U.S. Food and Drug Administration (FDA) inspection of the Clinical Center's (CC) Pharmaceutical Development Section and Intravenous Admixture Unit (IVAU). The inspection confirmed that there were problems at the pharmacy. NIH responded by suspending the problematic operations and formed an internal task force (TF), which recommended the formation of an NIH Advisory Committee to the Director (ACD) Clinical Center Working Group (WG) made up of multidisciplinary experts from outside NIH. The WG, known as the Red Team, reviewed the CC's operations at the request of NIH Director Francis Collins, M.D., Ph.D.

The Red Team submitted its report to the ACD on April 21, 2016. Among its recommendations was a suggestion to establish an external board that would act like the board of a local hospital, overseeing CC management, safety, and quality. The CCRHB is the direct result of that recommendation.

The themes in the Red Team report were not surprising. The report emphasized the need to fortify the culture and practice of safety and quality at the CC, mainly by strengthening the authority of the leadership. NIH is a decentralized, federated system; the report identified a need

to strengthen oversight within that structure. The report also documented a culture of overwork at the CC. Staff felt obligated to support intramural researchers, even beyond reasonable expectations, and did not report to their leadership when they were stretched too thin.

The ACD unanimously accepted the Red Team's recommendations. The next morning, Dr. Collins, CC Director John Gallin, M.D., and Dr. Tabak presented their findings at a town hall meeting for the intramural community.

When Dr. Collins appointed Dr. Forese to lead the Board, she was overseeing six major New York area hospitals. She initially committed to lead the Board for 2 years but ultimately agreed to stay in the role for 6. It is clear that the Board's members—outside experts who are used to thinking about continuous improvement in hospital operations—were able to pinpoint structural problems in the CC's governance and funding model, despite some criticism from the NIH community. In addition to chairing the Board, Dr. Forese also led efforts to fill the new position of CC CEO.

Dr. Tabak commended Dr. Forese for her skillful leadership and noted how NIH has benefited from its relationship with her. The ribbon-cutting ceremony for the new CC pharmacy marked a watershed moment. He also thanked Ms. Williams-Brinkley, who was another member of the Board from its beginning, for her service.

Arrivals

Dr. Tabak welcomed the Board's new members:

- The CCRHB's new Chair, Dr. Coots, the President and CEO of Holy Cross Health
- Regina S. Cunningham, Ph.D., RN, FAAN, CEO of the University of Pennsylvania Hospital. Her background is in nursing.
- Sherin U. Devaskar, M.D., Executive Chair of the Department of Pediatrics at the University of California, Los Angeles (UCLA), Physician-in-Chief at UCLA Mattel Children's Hospital, and Assistant Vice Chancellor of Children's Health at UCLA Health. Her arrival is particularly timely, as NIH is in the midst of determining whether it will do more research with young patients. She will help inform that conversation.

NIH Updates

Dr. Tabak commented that he was also supposed to introduce the next NIH Director to the Board, but the President has not yet nominated a candidate. The NIH community hopes that a nominee will be announced soon and that the Senate confirmation process is conducted with reasonable speed. He reported that he and several IC directors testified before the House and Senate Appropriations committees in May, and NIH is optimistic that modest increases to its budget will be approved for fiscal year (FY) 2023, as they were for FY 2022.

Dr. Tabak also announced that NIH had appointed Nina Schor, M.D., Ph.D., as Acting Deputy Director for Intramural Research (DDIR). She will take over from Michael Gottesman, M.D., who served as DDIR for 29 years and will return full time to his lab at the National Cancer Institute (NCI). Dr. Schor is a pediatric neurologist and will start in her new role on August 1. Dr. Tabak expressed appreciation for all Dr. Gottesman had given and said he looked forward to working with Dr. Schor.

NIH Diversity, Equity, Inclusion, and Accessibility (DEIA) Strategic Planning

Dr. Tabak presented a high-level update on NIH-wide DEIA strategic planning activities. The NIH DEIA Strategic Plan responds to two mandates: language in the FY 2021 budget for NIH requiring a strategic plan and Executive Order 14035, which calls for inclusion activities across the federal workforce. A WG of about 100 people from all 27 Institutes and Centers (ICs) and the offices in the Office of the Director is developing the plan. The effort is led by Chief Officer for Scientific Workforce Diversity Marie Bernard, M.D.; Acting Director of the Office of Equity, Diversity, and Inclusion (EDI) Shelma Little, Ph.D.; and Director of the Office of Human Resources Julie Berko, M.P.A., with support from the Division of Program Coordination, Planning, and Strategic Initiatives and the Office of Evaluation, Performance, and Reporting. A steering committee is responsible for developing and implementing the plan, and all NIH leadership—including IC directors, scientific directors, executive officers, and administrators—are engaged in this effort.

Starting in the summer of 2021, the WG developed a framework for the plan, and the framework was approved by the IC directors in January 2022. The approval was followed by a public comment period, soliciting input from both internal and external stakeholders. Currently, NIH is refining the framework based on the input received. The WG is drafting the plan and is on track to meet its goal of having it approved by the end of summer.

The plan encompasses all NIH activities, and its aims reflect the core objectives of having NIH be a people-centered organization that is representative of the nation's diversity and where everyone has a sense of belonging. The plan captures activities the NIH workforce will carry out to meet the vision of the plan. It harmonizes the framework with priorities that reflect NIH's needs, opportunities, and challenges. The plan outlines three objectives:

- Grow and sustain DEIA through structural and cultural change
- Implement organizational practices to center and prioritize DEIA in the workforce
- Advance DEIA through both workforce research and health research

NIH has made a reasonable start as part of an effort that goes across government and up to the White House. Ultimately, NIH hopes to do more than its part.

Clinical Center Research Hospital Board Chairperson and Membership

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

Laura Forese, M.D., M.P.H., Executive Vice President and COO, NewYork–Presbyterian Hospital; and Chair, CCRHB

James Gilman, M.D., CEO, NIH CC

Dr. Gilman reflected on his good fortune to be chosen as the first NIH CC CEO and the privilege of working with the Board and with Dr. Forese as Chair. He gave Dr. Forese several parting items, including a letter of appreciation from the NIH leadership, a certificate, and a gavel inscribed with her name.

NIH Clinical Center Chief Executive Officer Update

James Gilman, M.D., CEO, NIH CC

CCRHB Transitions

Dr. Gilman expressed his appreciation to all of the departing Board members: founding members Dr. Forese and Ms. Williams-Brinkley and Rick Shannon, M.D., who will leave after the Board's next meeting. He then gave a warm welcome to the six new pending/candidate members of the Board:

- David M. Baum, PMP
- David C. Chin, M.D., M.B.A.
- Antoinette Royster
- Craig E. Samitt, M.D., M.B.A.
- Regina S. Cunningham, Ph.D., RN, NEA-BC, FAAN
- Sherin U. Devaskar, M.D.

Dr. Gilman expressed tremendous appreciation for Dr. Coots' willingness to take on the role of Board Chair, a position that is difficult to fill. Reflecting on their 20-year acquaintance, Dr. Gilman said he knew Dr. Coots as someone who did not shy away from a challenge.

Awards

Dr. Gilman reported that the NIH CC did well in HHS departmental awards this spring. Karen M. Frank, M.D., Ph.D., D(ABMM), who leads the Department of Laboratory Medicine, received the Secretary's Award for Meritorious Service for setting up a series of assays to do COVID-19 testing before such tests were widely available. This made it possible for the CC to do COVID-19 diagnostics even before CDC distributed tests. Leighton Chan, M.D., M.P.H., who runs the Department of Rehabilitation Medicine, was recognized for his skill at working in the interagency world—including with the Social Security Administration and various security agencies—receiving the HHS Award for Excellence in Management. CAPT Robert DeChristoforo, former Chief of the NIH CC Pharmacy, was recognized for 50 years of government service.

CC employees were also recognized as part of many team awards. Kimberly Middleton, RN, M.P.H., M.S., and Lisbeth Diane Nielsen, RN, were part of the Rapid Acceleration of Diagnostics (RADx) Initiative team awarded a Secretary's Award for Distinguished Service. RADx filled pharmacy and drugstore shelves with home tests for COVID-19. The National Institute of Allergy and Infectious Diseases' Division of Clinical Research COVID-19 Response Team also received a Secretary's Award for Distinguished Service, which recognized nursing support from Alex Artcher, RN, M.P.H., from the CC Nursing Department (CCND). Numerous volunteers at the CC and across NIH—civilians and U.S. Public Health Service (PHS) staff alike and even one IC Director—participated in the refugee resettlement effort led by the Administration for Children & Families Office of Refugee Resettlement team that was awarded the Hubert H. Humphrey Award for Service to America.

CC Staffing Update

Dr. Gilman gave an update on the ongoing searches to fill three leadership positions at CC: the Chief Nurse Officer, Chief Financial Officer, and Chief of the Pharmacy Department.

Reflecting on the beautiful new pharmacy facility, Dr. Gilman noted that the unit dose, inpatient, and outpatient pharmacy units have all moved into the new facility celebrated at a May 18 ribbon-cutting ceremony. Commissioning and training work still must be completed before the IVAU move can happen.

In addition, the return-to-work transition continues. Almost all staff are back to work, although there is more telework and more part-time work than before the pandemic.

Average Daily Census (ADC)

Dr. Gilman reported on ADC numbers, which remain lower than before the pandemic. As of July 4, figures for 2022 are down 10% from the year before. He noted that CC leaders watch these numbers closely, and the drop-off is a concern. It is unclear when the CC will see the previous volumes again.

One emerging question that the CC will need to examine in the next 2 to 3 years is what research at the CC should look like in a virtual world. Tradition and dogma say that its research is focused on what cannot be done anywhere else. However, with remote capabilities, that has changed. Before the pandemic, the CC had no telehealth presence, but by 2021, it handled more than 1,000 virtual appointments monthly. Telehealth services are now accepted and continue to be well utilized, with several hundred appointments every month. Tricia Coffey, Chief Health Information Officer, and the staff in her division continue to make improvements.

Protecting Patient and Staff Safety During the Pandemic

The Clinical Center is still following the same COVID-19 protocols as last year, including masking, eye protection, and social distancing. One of biggest issues it has had to deal with is the phenomenon of "presenteeism," when employees feel only mildly symptomatic and, testing negative on a home antigen test, feel they can safely come in to work. In some cases, these employees experience symptoms for 2 or 3 days before testing positive. If they come to work during this interim, they can interact with many people. Because of such experiences, contact tracing was rendered futile and was ultimately cut back by the CC. Hand hygiene, a priority long before the pandemic, continues to be emphasized.

DEIA at the CC

Dr. Gilman reported that recent DEIA activities at the CC include the launch of a new website with robust and continually updated resources for CC staff. In addition, the CC created a new position, scientific diversity advisor; the job description has been posted, and several candidates have applied. A review committee has been selected, and questions for the candidates that focus on the full breadth of DEIA issues are currently being refined. As part of its ongoing assessment of workforce demographics, the CC relies on data from the NIH Office of Equity, Diversity, and Inclusion. In addition, the CC has conducted focus groups and engagement surveys of staff. Dr. Gilman shared the results at a town hall in the spring and made them available to internal (NIH)

audiences online. The CC has also completed its racial and ethnic equity plan (REEP) and submitted it to NIH, whose leadership has reviewed the plan and given feedback.

Dr. Gilman introduced the six REEP initiatives outlined in the plan:

1. Apply the Racial and Ethnic Equity Lens (REEL) Framework to recognition, retention, and development programs at the CC. Similar to applying the patient safety lens that is central to its work, the CC should look at everything it does through this lens.
2. Create a written policy for hiring and advancement. The CC Nursing Department, the largest department in the hospital, will be the first to complete this policy; others will adapt it to develop their own policies.
3. Address hiring gaps in senior positions. The CC has changed position announcement language and selection parameters and is prioritizing participation in and promotion of DEIA activities in the selection criteria for senior positions.
4. Assess engagement, recruitment, and hiring from minority-serving institutions (MSIs) and historically Black colleges and universities (HBCUs). The CC has not always measured the effectiveness of outreach to these institutions but plans to be more intentional about measurement going forward.
5. Expand the CC DEIA awards and recognition program. To drive cultural change, the CC CEO annual award DEIA category will also recognize departmental accomplishments in this area.
6. Advance accessibility to all CC staff within the Building 10 complex and in all aspects of CC operations. Accessibility has been poorly understood by some staff. The CC has an important training and education effort to undertake t to make progress on accessibility.

In addition, the CC continues to recognize heritage months throughout the year. For example, Dr. Gilman introduced the CC's June Pride Month resources and activities, such as the visit of Assistant Secretary for Health ADM Rachel Levine, M.D., to NIH, where she gave opening remarks at the NIH-hosted panel discussion "How Intersecting Identities Impact Our NIH Work" and toured the CC. Dr. Gilman noted that he continues to use the "3 Main Things" messaging to address issues important to the staff, shared an example of messaging that informed the staff that the DEIA survey results would be posted internally for staff to see, and addressed the shooting in Buffalo.

Pharmacy Ribbon Cutting

Dr. Gilman shared a series of the photos of the recent ceremony, a celebration addressed earlier in the meeting by Dr. Tabak.

Clinical and Safety Performance Metrics

Dr. Gilman reminded the Board that the quarterly report of patient and staff safety metrics, previously presented at Board meetings by David Lang, M.D., M.P.H., Chief, CC Office of Patient Safety and Clinical Quality (OPSCQ), will now be made available online. Board members with questions or requests for the presentation of additional information at meetings can contact Dr. Lang or Dr. Gilman.

Dr. Gilman reviewed the rest of the day's agenda.

The Role of the Patient Representative at the NIH Clinical Center

CAPT Antoinette Jones, M.S.O.D., RN, PHS Commissioned Corps, Patient Representative, NIH CC

CAPT Jones spoke about the role of the patient representative at the CC and how it affects the patient experience. Patient representatives are an aspect of patient advocacy that has been around since the 1970s, with roots in the patients' rights movement. Hospitals accredited by The Joint Commission are required to have this role, but not all hospitals do. Although they go by many names, patient representatives have a common goal: to respond to any concern and ensure that the patient has the best experience possible.

The patient representative is the link between patients and the hospital organization. The CC patient representative's role is distinctive in several ways. One difference is that the CC serves all ICs; it is not just one hospital organization. The patient representative navigates some 18 organizations, each with its own way of doing things. The patient representative also helps patients understand what the CC offers and how it operates. Patients come with expectations of what a hospital offers and may be surprised by the CC's constraints. The patient representative also ensures patients understand their rights and responsibilities, but at the CC, patient rights look different. For example, the right to refuse care can affect a patient's eligibility to enroll in a study. To patients, it can seem as though research is more important than what the patient wants, so the patient representative must strike a delicate balance. Although patients may want a particular treatment, protocols can demand a lot of them, and the requirements can be frustrating; patients may not agree.

CC patients learn about the services of the patient representative in various ways. On admission, they get a leaflet describing the role. CAPT Jones said she also makes a point of going to a patient's unit a few days after their arrival and introducing herself to the patient and their family members. There are posters and brochure holders in 45 places in the CC, with materials available in Spanish and English. In addition, the Office of the Patient Representative is on the first floor near the travel office, patient pharmacy, and admissions office, so it is easy to find. As the sole Patient Representative, CAPT Jones serves every inpatient, outpatient, blood donor, and clinical trial and observational study participant. Her contact information is on all consent forms, which cover about 1,600 active studies. The general public also reaches out to the Office of the Patient Representative. When CAPT Jones takes leave, staff in OPSCQ provide coverage.

CAPT Jones described her background and how it contributes to her ability to do her job. She first came to the CC in 1987 as a graduate nurse and cancer nurse trainee. She gave chemotherapy and provided supportive care to inpatients in the day hospital, worked as a research nurse at NCI, and was a nurse leader for about 8 years. This experience allows CAPT Jones to understand the patient experience from every angle. Her experience also includes graduate work in organizational development, which is instrumental to understanding how humans in organizations manage change and conflict, and working in the Office of Workforce Management. CAPT Jones started as patient representative in June 2015, succeeding an incumbent who had been there 16 years. Because of the circumstances of her predecessor's departure, there was no overlap, orientation, or manual; in the first few weeks, CAPT Jones's training, background, and experience were essential. CAPT Jones described how her experience allowed her to quickly step in and understand and respond to needs. In 2020, CAPT Jones

became a CC patient herself and gained a deeper understanding of the patient experience and the fears and questions that emerge.

CAPT Jones explained her mission, which is to provide a timely, effective response to patient concerns and to show respect. She said she hopes that by the time a patient leaves, they have had the best possible experience and felt valued and cared for, even if they did not get good news or were in a challenging situation. One patient she cared for as a nurse in 1997 wrote a book about the experience and started one chapter with the sentence, "I met Toni on a Thursday." CAPT Jones said this reminds her that while CC staff may not remember every patient, the patients remember those who care for them. It inspires her to think about how she would like to be remembered by patients and how she would like them to remember their CC experience.

CAPT Jones described the key partners in her work: IC staff and leadership, the Office of Human Subjects Research Protections, the Office of General Counsel, and CC executive leadership, including CC CEO Dr. Gilman and Pius A. Aiyelawo, FACHE, the NIH CC COO. The leaders meet with the Patient Representative regularly to review and address patients' concerns. It is important to acknowledge that CC patients have a voice but that it may be hard for them to voice their concerns. They may worry that the protocol will be withdrawn if they mention concerns. As Patient Representative, CAPT Jones encourages them to give feedback, because that is how the CC grows. She acknowledged that if they feel safe, patients will tell others that the CC wants to hear feedback. An organization that listens and takes its patients' concerns to heart preserves human dignity, ensures safety, maintains protocol integrity, and improves overall patient satisfaction and public perception.

CAPT Jones presented data on encounters with the Office of the Patient Representative. Nearly 90% of the time, an encounter starts with a phone call. The call could be from another health care facility, the general public, a family member, an NIH employee calling on behalf of the patient, or a potential research volunteer, but most of the time (49%) patients initiate the contact. The most common reason people reach out is for protocol clarification (29%); often, patients do not want to ask the team for clarification about something that was already explained. They also have queries or concerns about clinical care, customer service, hospital operations, recruitment, medical records, and reimbursement. The monthly volume of calls ranges from about 50 to more than 90, with between 3 and 10 encounters a day. CAPT Jones said that she sees everyone who supports patients as holding a net, providing care, compassion, and love, and she said she feels honored to do this work.

Discussion

Dr. Forese expressed admiration for all that CAPT Jones accomplishes. She asked whether Spanish is considered a second language at the CC and used as a standard in CC communications. CAPT Jones noted that signage across the hospital is in English and Spanish, and she said that the Patient Representative brochure holders posted in 45 locations across the CC are in both English and Spanish.

Dr. Forese asked how interpretation requests are managed. CAPT Jones explained that she can make a request with the interpreters' office. When people call and leave a voicemail in a language other than English, she can reach out to colleagues in the Language Interpreter Program or use a service to call back with an interpreter.

Dr. Forese asked how often people contact the patient representative before arriving on campus. CAPT Jones said it is common. Many people call after recruitment but before arrival, to get clarification about the protocol. Others have questions about hospital operations, whether they can bring their car, or similar matters.

Dr. Shannon asked whether the CC conducts routine surveys like the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores or uses other tools to elicit feedback the way other health care delivery systems do. CAPT Jones said that the CC conducts surveys through Press Ganey. A small group of staff looks at the comments returned in the surveys weekly and decides whether action needs to be taken right away.

Stephanie Reel, M.B.A., asked whether there is an opportunity for patients to identify their preferred language at some point in the intake process. CAPT Jones said that this happens when a patient registers.

Dr. Gilman noted that a couple of years ago the Board had had a lively discussion about sequelae of the #MeToo movement and harassment on campus. In addition to her role as Patient Representative, CAPT Jones is also an Anti-Harassment Response Team (AHaRT) lead. She fully embodies the title of Chief Respect Officer. Dr. Forese agreed it should be added.

Dr. Samitt asked CAPT Jones to elaborate on the concerns that patients raise in the clinical care and customer service categories. Are there any themes that have led to process changes or improvements in how the Clinical Center works? CAPT Jones said that as in other situations where a patient perceives that something has been done inaccurately or a patient has a concern about a provider's competence, there may simply be a difference in how care was delivered by two different providers. The patient may perceive this as one provider "forgetting" to do something that the other one did. In other situations, a patient will contact the patient representative about a concern they are uncomfortable raising with a provider directly, such as if the provider comes into the room of an immunosuppressed patient without wearing a mask. Generally, the number of clinical care complaints is low. At NIH, people function at a high level, but sometimes they need training or to have an issue raised quickly and kindly. Although the number of customer service consultations is low, their impact can be huge. For example, a parent may get frustrated when they receive certain instructions in writing but are told when they arrive that they did not do the right thing. That is an opportunity for the CC as an organization to look at its communication. How people work together and talk about their work to each other is one of the most important elements. Communication is a common theme that the patient representative handles. In one case, several patients reached out separately about the communication style of one of the staff members. That was an opportunity for the IC leadership to look into what was happening that was getting in the way of prospective participants' participation in the study. Weekly comments and survey data give staff a chance to look across the board or by IC, unit, or study and look for trends.

Dr. Coots noted that people come to the CC from all over the United States and the world, and he asked how much cultural competency or implicit bias training is done with researchers to prepare them to interact with cultures whose members come in as patients. Dr. Gilman explained that all NIH staff undergo implicit bias training annually. It is an important priority for NIH and CC leadership.

Ms. Royster thanked CAPT Jones and commended her for taking patient representation to the next level. She agreed that CAPT Jones is truly a Chief Respect Officer.

Mr. Baum noted that patients now get introduced to CAPT Jones in a video about coming to the NIH campus that was produced in response to a Patient Advisory Committee recommendation. He described coming to campus as overwhelming and commented on how the breadth of CAPT Jones' background contributes to her effectiveness. He expressed support for providing funding for additional help in the Office of the Patient Representative. He said that researchers frequently do not understand how to interact with patients but that CAPT Jones is a significant contributor to the ongoing improvement in the relationship between patients and the research aspect of the CC.

Dr. Chin asked how much variation there is among ICs and how they interact with patients, given NIH's federated model. CAPT Jones acknowledged that the ICs all function differently. Although they see just one organization, patients talk to one another and pick up on differences. CAPT Jones said she tries to help patients understand why things might look different for another family. Mr. Baum asked whether there are opportunities to implement more of a standard common protocol so that patients do not have to experience that. CAPT Jones said that because of differences among ICs, individual studies, and what can be allowed, this is an issue the Patient Representative will always have to handle. Some studies are unique, so it is not possible for NIH to standardize the protocol. However, communications is an area where ICs can standardize (e.g., when explaining how to come to the CC). In secretariat meetings with the ICs, the Patient Representative shares feedback from patients. The prohibition against bringing marijuana on campus is one example of an area that the various ICs handle differently. It is worth talking with the ICs about how to make communication about campus restrictions more consistent so that a patient or family member is not stopped when they try to come on campus. Situations like that show that not saying a small thing can have a big impact.

Dr. Forese acknowledged that Dr. Cunningham had joined the meeting.

Patient Survey Data: Patient Perceptions by Demographic Indices

Colleen Hadigan, M.D., M.P.H., Chief Medical Officer/Clinical Director, NIH CC

Dr. Hadigan presented the 2021 results of patient surveys, including breakouts by demographics. The surveys, conducted electronically, were developed by Press Ganey, a large organization that collects data for many U.S. hospitals. The surveys ask patients in detail about their encounters with nurses and physicians, as well as their experience related to access to care, meals, their room, and other aspects of their visit. The CC worked with Press Ganey to include HCAHPS-standardized questions to benchmark CC results against the majority of hospitals using Press Ganey surveys. The data show the roll-up average of questions in each category for which respondents selected the top choice.

Starting in April 2021, the CC sent surveys to patients who had visited the CC in or after January 2021 and continued to collect new survey data in real time. In addition to gathering patients' feedback on their experience, the surveys collected demographic data, including participants' race and sex and the language in which they responded. In 2022, the CC started collecting information about ethnicity. The CC collected feedback from the outpatient clinics and the

medical hospital; this did not include behavioral health units, which use a pen-and-paper survey that is not comparable. There are no direct sex and race comparators in the Press Ganey comparator group, so the comparison used is for all responses from other Press Ganey hospitals, a group of about 1,700 institutions. For the NIH data in aggregate, the percentage of top box ratings for outpatient experience overall and for nursing care, clinician care, and access was between 75% and 85%; in each case, it was higher than the Press Ganey benchmark. There was no clear difference in ratings by sex or language, although it should be noted that the vast majority of responses were in English (more than 3,000, compared with 71 in Spanish). In addition, responses were analyzed by race—Asian, Black/African American, mixed race, and White—and satisfaction ratings did not differ markedly by race.

The census was lower for inpatient experience data. There was roughly a 20% to 22% response rate to surveys. NIH overall scoring is 10 to 20 percentage points higher than Press Ganey overall data. There does not appear to be a significant difference between responses from male and female participants; however, in the outpatient group, women gave slightly lower ratings than men, and in the inpatient results, that is reversed. According to Press Ganey, their results tend to show lower ratings from women than from men. Inpatient results by language show percentages of top box ratings that are as high or higher for patients responding in Spanish as those responding in English for all categories, but here again the number of responses in Spanish is small (12 versus 351 in English). Likewise, when responses are classified by race, some groups have fewer than 20 responses, which could account for some variability; however, there is no clear pattern of one group giving lower scores than the others.

Patient satisfaction survey data offer one metric to assess the patient experience. This preliminary review shows similar levels of satisfaction across demographic groups. One caveat is that some groups have only a small number of responses. The CC is now collecting ethnicity data. In addition, the CC plans to break down results by age categories to analyze future results.

Discussion

Noting the overall 20% to 22% survey response rate, Dr. Cunningham asked whether response rates by race or gender had been examined. Dr. Hadigan acknowledged that response rates were lower for both mixed race and African American respondents, but they were not too disparate, ranging from 18% to 22%.

Dr. Shannon asked whether 2021 was the first year when surveys were collected and whether responses to the electronic survey format are elicited through the Internet. Dr. Hadigan explained that before 2021, the CC used a different survey mechanism. Paper surveys are now used only in behavioral health units, which have had a long-standing reluctance to use electronic surveys because of the sensitivity of the diagnoses they handle. However, the CC is moving toward e-surveys for those units, too. Dr. Shannon asked what percentage of the outpatient total the 3,100 responses represented. Dr. Hadigan noted that there is no simple answer. Outpatient volume is the total number of visits, but there are restrictions on how many times patients receive a survey. For example, a patient who visits the CC 15 times in a year does not get 15 surveys. In addition, there is a hierarchy for distributing surveys based on the type of visit—for example, inpatient and ambulatory surgery patients receiving care are given surveys before outpatients. Because of factors like these, it is not possible to say how the total survey numbers compare to actual visits.

Dr. Samitt asked about the availability of more detailed results. A deeper examination of the questions that got poor ratings or of patterns in the comments could reveal areas where the CC could improve. Dr. Hadigan said that Press Ganey does have tools for digging deeper into the results. In addition, every week, a group including the Chief Medical Officer, a patient safety officer, a health management records officer, and CAPT Jones reviews every written comment and identifies patterns. One month they noticed repeated complaints about wait times in phlebotomy. When this information was conveyed to the phlebotomy leadership, the leaders discovered that there were two critical staff illnesses that had affected staffing. The Nursing Department is also looking at data as part of the Magnet journey.

Ms. Royster asked about plans to offer the survey in languages other than English and Spanish. Dr. Hadigan noted that the results include surveys in other languages, but the numbers were not significant enough to show in aggregate. The platform offers surveys in 20 languages, and the capability for patients to write comments in other languages is built into the system. These comments are then translated. For patient privacy reasons, patients are not observed while taking the survey or offered translation for the process. They receive the survey after leaving the hospital.

Noting that benchmarking is always a challenge for the CC, Dr. Shannon suggested that a year-over-year top box score might be better than Press Ganey's 1,700-hospital benchmark as a comparator for the NIH CC. Another reasonable comparator could be St. Jude's Hospital for Children: It has many comparable phenotypes, it is also a research facility and does not charge, and it has 75 beds. Dr. Hadigan agreed that trends over time are most important. Although it is possible to drill down within the Press Ganey data to include only small academic hospitals in the comparison group, identifying the correct comparator is difficult.

Magnet Journey Updates

Barbara A. Jordan, D.N.P., RN, NEA-BC, Acting Chief Nurse Officer, NIH CC

Dr. Jordan presented an update on the Clinical Center's Magnet accreditation journey. ANCC awards Magnet designation to organizations that have exceeded the more than 100 standards laid out in its Magnet manual. The Magnet designation, which emphasizes nursing but is awarded to the organization as a whole, reflects an excellent work environment. Only 9% of U.S. hospitals have Magnet designation, and those that do have a good reputation among health care workers and tend to draw highly qualified candidates. The key organizational drivers of Magnet designation are patient safety, a culture of excellence, high-quality clinical outcomes, and an empowered and highly skilled workforce.

A systematic review of studies reporting hospital data showed that accredited hospitals have better patient outcomes, offer higher-quality care, and are safer than nonaccredited hospitals. Magnet hospitals have 14% lower mortality rates, 5% fewer patient falls, 21% fewer pressure injuries, and lower nosocomial infection and central line–associated bloodstream infection (CLABSI) rates. They also report higher support for evidence-based practice implementation, higher quality of care as perceived by nurses, higher patient satisfaction ratings, lower rates of missed care, and lower workplace accident rates. The Clinical Center is working with its survey data provider to link quality outcomes and satisfaction data, for example, and glean more insights from data the CC collects.

The overall improved performance translates to shorter stays and cost savings. Although the CC does not bill patients, lower costs are important for its fiscal accountability. Magnet designation also lends itself to a positive workplace environment: It is thought to have a preventive effect on bullying, reduce turnover and burnout, and be linked to a higher employee satisfaction rate.

The Clinical Center is charting its progress against key milestones in the timeline for Magnet designation and to submit its Magnet application to ANCC in January 2023. The CC has signed an agreement documenting its intention to apply for Magnet designation, which gives it the right to use the "Journey to Magnet" logo and the services of an ANCC consultant to answer questions about the program's standards. Currently, the team is working on the labor-intensive process of developing the CC's Magnet document, which includes a narrative of the CC's story supported with data. This is the biggest piece of work aside from the task of documenting the CC's standards and how the CC is addressing gaps. The Magnet document will be submitted in April 2024, after which appraisers will review and score the document and conduct a site visit. They meet with everyone, comparing what they see and hear with the details in the submitted documentation. Prior to the Magnet appraiser site visit, the document is posted online and public comments are invited during this period. The appraisers submit a summary report of their findings to the Magnet Commission who makes the final decision on accreditation.

Dr. Jordan described some of the progress the CC has made. In collaboration with the Office of Communications & Media Relations (OCMR), a Magnet journey banner has been developed. It is now hung in locations around the CC. Working with the NIH Office of Strategic Planning and Management Operations (OSPMO), the Nursing Department has also updated its mission statement. Having accomplished what was set out in its mission previously, to advance the specialty of clinical research nursing and develop a model of care, the CC Nursing Department's mission has been revised to say, "We improve human health by supporting cutting-edge clinical research and providing compassionate, evidence-based nursing care to a diverse population of patients and their families."

In response to a question in the chat, Dr. Jordan noted that the CC does collect demographic information from patients on admission (e.g., gender, preferred language, race and ethnicity).

A 3-year Nursing Department strategic plan is also under development. Despite setting annual goals and following the NIH and CC strategic plans, to date the CCND has not had its own strategic plan. The CC started working with OSPMO a year ago to address this gap. In addition to revising the mission, the process included looking at the Magnet manual and conducting a gap analysis to identify strategic goals the organization needed to work toward. Key stakeholders provided feedback, including CCND leadership and Magnet ambassadors. A detailed plan will be created from the high-level plan, which stakeholders are currently introducing broadly to the department.

The four components of the Magnet model make up the chapters of the strategic plan: transformational leadership, structural empowerment, exemplary professional practice, and new knowledge, innovation, and improvements.

In this way, the work of the CC has been aligned around the Magnet journey. Overseeing the work is a Magnet Steering Committee, which held its inaugural meeting on July 6. Its role is to provide oversight, hold leadership accountable, and ensure inclusivity. Subgroups reporting to

the Steering Committee are the Magnet Document Team, Magnet ambassadors, and Magnet Communications, partnering closely with OCMR.

To aid staff with the development of the Magnet document, the CC has acquired the services of an independent Magnet consultant, who has been invaluable in providing guidance. To identify narratives to incorporate into the Magnet document, sessions with nurse leaders were held in spring 2022. Dr. Lang and the Office of Patient Safety and Clinical Quality have been valuable partners in the ongoing collection of quality and safety data tracking. The CC's patient satisfaction data exceed requirements for Magnet designation. The Magnet program manager is finalizing the timeline for compiling the document.

Engagement with the wider community is being carried out through Magnet information booths in two CC locations, updates at meetings with IC partners, and the Magnet ambassadors.

Discussion

Mr. Baum expressed his support for the CC's efforts to attain Magnet designation and asked whether the documentation process is primarily about describing ongoing activities or whether it also involves investment in making changes. Dr. Jordan explained that there are elements of both. For example, there is a lot of evidence to demonstrate the CC's strong shared governance structure, which has been in place for years. A peer review process was introduced 2 years ago in the Nursing Department when that gap was identified. Another area that is lacking is a formal mentorship program. The CC will need to address how it plans to meet those areas. The document identifies both what the organization does and where it has gaps.

Dr. Cunningham commended the thorough overview and expressed surprise that the CC was not already a Magnet-designated organization. She asked about the role of staff nurses in developing and vetting the strategic plan. Dr. Jordan explained that direct care nurses were in the group who drafted the plan. The draft was also shared with the Magnet ambassadors and CC nursing leadership. The Nursing Practice Council is part of the CC's shared governance. Dr. Cunningham added that the Magnet appraisers will want to know these kinds of details and meet with staff nurses. She added that the multidisciplinary Magnet Steering Committee is commendable. The appraisers will also want to talk about the role of nurses with those from other disciplines, such as physicians, so structuring things like this is great preparation for the site visit. Dr. Jordan, reflecting on her experience seeing a hospital in Pittsburgh through the Magnet journey, said one of its greatest successes was getting the participation of all the hospital's departments. She emphasized that the work toward Magnet designation is a team effort.

Mr. Baum asked whether patients and families are allowed to contribute during the comment period. Dr. Jordan said yes; it is open to anyone. Including patient stories and experiences in the document submission could be valuable. Perhaps there is an opportunity to bring this up at a future meeting of the Patient and Family Advisory Council. Achieving Magnet designation is not merely about getting a pin. What is important is that it shows that the CC has met stringent criteria of excellence that benefit patients.

Mr. Baum noted that NIH has a lot of nurses in roles other than direct care and asked whether that affects the CC's application. Dr. Jordan said yes, all nurses in the CC go through a privileging process through the Office of the Chief Nurse. The CC also works closely with

nurses in other departments and across IC research units. Although its focus is nursing, Magnet designation is an organizational designation.

Mr. Baum asked what the ongoing commitments are once Magnet certification is achieved. Dr. Jordan explained that maintaining Magnet designation is even harder than achieving it, given the program's rising standards. ANCC issued its 2023 manual, and while the CC was solid on the last edition, the CC has identified opportunities for improvement based on the 2023 standards. The CC is assessing all of its practice changes through the lens of sustainability.

Julie A. Freischlag, M.D., Dean of the Wake Forest University School of Medicine, noted the increasing difficulty of maintaining such standards, given today's staffing problems and the increase in travel nurses. Fewer staff have long-term experience. She also asked about the data showing that Magnet designation can diminish attacks on and poor treatment of nursing staff. What contributes to the decrease in abuse of nurses at bedside—staffing, education, experience? Dr. Jordan said the Clinical Center is fortunate to have a culture and organizational commitment to providing a safe environment; for example, patients and visitors are greeted by guards when they arrive on campus. Although the CC does not have an emergency department, some of the clinical conditions treated there can lead to impulsive behavior. The CC has established a Code "BERT" (Behavioral Emergency Response Team) and an AHaRT, which is led by CAPT Jones. NIH has done a lot of work to educate staff on proper behavior, setting the tone. The CC experience is different from what is happening in hospitals in the community, but the CC has also made the effort to establish a respectful practice environment, where responders are trained to de-escalate situations and where problems with patients or family members potentially abusing staff members are addressed right away.

Dr. Forese noted that Ms. Williams-Brinkley had joined the meeting. Dr. Forese reflected on conversations about Magnet designation in the early days of the Board, noting how thrilling it is to see this progress. She congratulated the team.

2019 Clinical Center Strategic Plan: Status Report

James Gilman, M.D., CEO, NIH CC

Dr. Gilman gave an overview of the Clinical Center's work toward executing its strategic plan. In 2015, the FDA inspected the CC's pharmacy, and in 2016, the Red Team submitted its report. When Dr. Gilman arrived in 2017, staff almost never mentioned the report; it was a difficult thing for them to think about. However, there was agreement on things that needed fixing, and staff went to work on making improvements. After becoming familiar with NIH and hiring a COO about 17 months after he became CEO, Dr. Gilman focused on the CC's strategic plan. Titled *People, Places, and Capabilities*, it was published in 2019.

Dr. Gilman reviewed the CC's seven guiding principles and the statement of its mission: "We provide hope through pioneering clinical research to improve human health." He noted the emphasis on patient safety and high reliability principles, putting safeguards in place to prevent problems. The strategic plan identifies four strategic aims:

- Continuing to lead the world in conducting safe first-in-human clinical research in rare and refractory diseases
- Increasing the use of the CC by the NIH Intramural Research Program

- Demonstrating profound respect for our patients, our full partners in the clinical research enterprise
- Partnering with ICs to recruit, develop, and retain the next generation of NIH clinical researchers and the CC staff who will support their efforts

People

Dr. Gilman said that he has aimed to provide personalized, inclusive health care leadership for CC staff. Measures promoted since that time emphasize taking care of the front-line employees, a priority that draws on his Army career. Improvements include a focus on accurate position descriptions and timecards; encouraging staff to use their annual leave with available opportunities to use it; supporting CC staff in creating individual development plans, which outline aspirational goals and are separate from the performance evaluation; providing additional leadership training opportunities at multiple levels within the organization, developed in collaboration with the Office of Workforce Management and Development; and discontinuing the use of the terms "ancillary" and "support" to refer to staff to underscore the collaborative nature of the CC research environment. All of these efforts focus on staff development and emphasize the value of all staff in this clinical research setting.

Dr. Gilman also described staff recognition programs at the CC. In part, the CC aims to recognize the work that enables scientific achievement as much as the scientific accomplishments so well recognized across NIH. Dr. Gilman reported that his recognition efforts began with length-of-service awards, a type of recognition that is important to everyone. Part of the CC award culture is that it allows the CEO to not just meet employees but interact with them at several points in their career. At first, employees were recognized in person at quarterly town hall meetings, but since the start of the pandemic, the town hall meetings have been virtual. Instead, Dr. Gilman has arranged to meet awardees individually, whenever works for them. This has been an especially meaningful way to overcome some of the isolation of the pandemic, and all staff who have been with the government for at least 5 years get an opportunity to meet the CEO personally. In 2018, the CC instituted a special annual awards program for clinicians and advanced practice providers, including IC staff, and CC administrators. The CCND has its own award program, and OPSCQ coordinates quarterly patient safety awards.

Dr. Gilman said he has also urged that staff clinicians be included as voting members on search committees to give them more of a voice in staff selection, and he approved the selection of three new members of CC leadership from the CC staff clinician ranks: the Chief of Radiology, the Chief of Lab Medicine, and the Chief Medical Officer. These clinicians were selected based on proven track records of providing exceptional patient care as well as outstanding CVs.

Highlights of staff communications include the CC's quarterly town hall meetings, which are now recorded so that people can watch when it is convenient, and emails personally written by the CEO highlighting "3 Main Things" that go out at least once per week to all CC and clinical research staff. The CEO also has an opportunity to talk to individuals during his daily hospital walk-arounds, an especially important avenue for communication during the pandemic.

Dr. Gilman explained that many people, including those with long tenures at the CC, are retiring. Finding the next generation of staff is a focal point of the plan. Dr. Gilman announced new hires in the following leadership positions:

- Chief Operating Officer
- Chief Medical Officer
- Executive Officer
- Chief, Radiology and Imaging Sciences (RADIS)
- Chief, Department of Laboratory Medicine
- Chief, Department of Transfusion Medicine, Center for Cellular Engineering
- Chief, Office of Patient Safety and Clinical Quality

The CC is conducting a national search to fill three additional roles following the incumbent's retirement: Chief Nursing Officer, Chief Financial Officer, and Chief of the Pharmacy Department.

Dr. Gilman next reported on several initiatives to assure staff safety and well-being. Establishing Code BERT gives the CC the internal capability to respond to patients or family members who act out. The code also serves the crucial role of providing reassurance to staff, especially those working nights and on weekends. The CC now also has an AHaRT. The Spiritual Care Department, which previously served only patients, now also supports staff. There was also a considerable amount of effort around screening, testing, personal protective equipment (PPE), and other CC policies to protect staff safety during the pandemic.

One reflection of staff response to these changes is the annual Federal Employee Viewpoint Survey (FEVS), a measure of employment engagement. The most recent results are from 2020, as there was no survey in 2021 and the 2022 survey is still in progress. The CC is showing a good response rate (48% to 49%), higher than the rate for NIH as a whole. Previous results have shown improvement each year. For example, responses indicating that staff believe FEVS results are used to improve the workplace improved 7% in 2020 and have improved 12% since 2017. The Employee Engagement and Global Satisfaction indicators both increased 12 percentage points or more between 2016 and 2020.

Places

Dr. Gilman said that the first priority regarding facilities outlined in the strategic plan was the Surgery, Radiology, and Laboratory Medicine Building (SRLM) wing project. Getting this work moving required extensive internal collaboration to develop a narrative that illustrated the need. CC staff conveyed this narrative in meetings with a National Academies of Sciences, Engineering, and Medicine study group and with HHS and congressional staff. As part of this process, the Board provided a letter to Dr. Collins to encourage this work. Money has been appropriated, but the project will not be finished until 2028. One lesson learned was the importance of having a consistent message for all audiences.

At the Board's last meeting, Marilyn Farinre, Pharm.D., M.B.A., Chief of Pharmacy Operations, gave a detailed presentation about the pharmacy. This project received a huge investment from NIH ($50 million over 6 years). The renovation and transition to the new space has been a major undertaking. Staff were housed in swing space during the 3 years of renovation work, during which time the pharmacy also had interim leadership. Currently, the outpatient pharmacy and the unit-dose pharmacy have moved into the new space. Rehousing of the IVAU is expected in the winter of FY 2023. The changes are expected to have a positive impact on pharmacy costs and patient safety.

The radiopharmacy project is still on the drawing board. There is an approved plan, but progress has been delayed while funding for the SRLM is secured. This project is expected to be on track again in FY 2023.

The Center for Cellular Engineering (CCE), which initially was a dated facility in a dated building, has been modernized and soon will have a modular building built just for cell engineering work. When the E wing renovation is complete, the Department of Transfusion Medicine, including part of the CCE, will relocate there. Being housed in an area where it is not influenced by the environment in areas of the building around it is better for the CCE's research. The move to the E wing, where the CCE will be more isolated, is expected in FY 2023. The Board received updates on the status of this effort from Harvey Klein, M.D., in February 2018 and from David Stroncek, M.D., in April 2021.

The strategic plan mentions an Enhanced Simulation Center, but there are no plans for it yet, and such a facility may not be necessary, as discussed below.

Capabilities

Regarding the CC's patient safety capabilities, Dr. Gilman reported on the Safety Tracking and Reporting System (STARS), which replaced the previous occurrence reporting system with no drop-off in use. It consistently produces 600 reports per month. Extensive failure mode and effects analyses conducted at the CC allow staff to focus on problem prevention. The CC frequently contacts The Joint Commission to report or consult about adverse outcomes and frequently performs root cause analyses to look for opportunities for improvement. When invited to the CC for a visit, the Institute for Safe Medication Practices made 90 recommendations, clearly critical to patient outcomes, which CC leadership has prioritized and is concertedly working through. The daily patient safety huddle is still the most important meeting of the day. Dr. Gilman also noted that the CC now has a greater ability to bring in people from outside to observe its operations and offer their feedback; outside experts have had valuable insights into the organization.

The CC can spend up to $50 million annually from its Capital Investment Fund, although it typically does not use the full amount. Tara Palmore, M.D., at the time the CC's Hospital Epidemiologist and Chief of the Hospital Epidemiology Service, had previously updated the Board on facilities renovations, including resizing the water supply line to reduce sludge and biofilm and re-piping patient rooms to decrease the possibility that immunocompromised patients would catch an opportunistic infection. The fund has been used to renovate patient rooms, the outpatient clinics, much of the Department of Laboratory Medicine, and now the inpatient rooms and to acquire new imaging equipment. The biggest use of the fund is in information technology (IT), for extensive investments in security and network design. The CC experienced a complete network outage about 2 years ago, after which the network was redesigned to eliminate single points of failure within it. The CC is now working on a transition from 10G to 100G to accommodate the increasing number of devices on the network while maintaining low latency.

Theresa Jerussi, PA-C, of the NIH Clinical Center, previously gave a presentation to the Board on the Blood and Immune Deficiency–Cellular Therapy Program (BID–CTP) at the CC. Creating a trans-NIH clinical program like this can be challenging at NIH. Now all the ICs

involved in cell therapy are working together to form a team for the Transplantation and Cellular Therapy initiative.

Dr. Hadigan and staff at the National Institute on Deafness and Other Communication Disorders (NIDCD) formed the Difficult Airway Response Team (DART) in June to improve management of complex airway issues.

There are also ongoing conversations regarding pediatric research, and the pediatric intensivists and hospitalists, who have served as consultants, now have a greater presence in the CC. The CC is looking into the possibility of doing more research with pediatric patients and reorganizing existing resources into something that would resemble the pediatric care department at an academic hospital.

Dr. Gilman reported on the CC's efforts to incorporate telehealth services into its offerings. The CC had no telehealth capability before the pandemic but quickly developed a new policy and procedures early in the pandemic. Part of building out this capability involves replacing Microsoft Teams with a more flexible platform. Staff are requesting more capacity. To be a national resource, the CC must be a more robust virtual resource, but its historical mission is to do research that cannot be done anywhere else. This will be a discussion as we move forward.

For a long time, the CC had a simulation program, but its focus was narrow. Mabel Gomez-Mejia, M.D., a cardiologist with specialized training in medical simulation, was hired to develop a simulation strategy for the CC. Her plan prioritizes expanding simulation where it will be used instead of creating a big, complex, high-tech simulation center as the strategic plan proposed. The CC has now invested in better equipment, hired a simulation technologist, and given the initiative an executive sponsor. Simulation is being deployed where it had not been before—for example, in radiology and imaging sciences, to better prepare for contrast reaction. This work is expected to continue, and Dr. Gilman is very encouraged by their efforts to date.

Dr. Gilman also reported on the creation of a hospice suite. Before 2017, the CC had not considered building a hospice, in part because the CC was not thought of as a place where people came to die. However, there were champions for hospice services, including Ann Berger, M.D., M.S.N., chief of the Pain and Palliative Care Service. The ribbon-cutting for the new facility was in July 2018. Hospice also supports clinical research for protocols requiring rapid autopsy. Dr. Berger reported on hospice suite use at the October 2021 CCRHB meeting.

Internal organizational changes that have occurred at the CC include combining the Department of Clinical Research Informatics and the Health Information Management Division, moving the animal program to align with the Chief Scientific Officer, and assessing where the Sterile Processing Service belongs.

Dr. Gilman explained that the CC undertook a major test of its capabilities in the summer of 2021, when it conducted a study with two infants with GM1 gangliosidosis, a neurodegenerative condition. The CC partnered with Children's National Hospital and the research—a gene therapy protocol—was funded by an outside company. A principal investigator (PI) from the National Human Genome Research Institute (NHGRI) led the study. Many CC departments were involved, and they spent 6 months preparing for the study, including extensive classroom and simulation training. They conducted an extensive failure modes and effects analysis, during which Dr. Schor, the new Acting Deputy Director for Intramural Research, was instrumental.

Once the patients were admitted, the care teams experienced many of the contingencies that had been imagined and got them both through the protocol. It was a real accomplishment. To date, the presence of pediatric patients in CC has been limited to children over age 3 and over 15 kilograms. The experience with the GM1 protocol suggests the CC can do more with a good partner, and there is interest in doing more, though only if it can continue to be done safely. The near-term requirements of expanding pediatric research in the CC to younger children has been evaluated by one intramural work group, and another, led by *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Director Diana Bianchi, M.D., is further evaluating the options. Dr. Devaskar will lead a group of extramural thought leaders to evaluate the reports of the intramural groups and present their assessment to the Board. Dr. Gilman expressed a deep appreciation for her willingness to take on the task.

Before she retired from NIH, the previous Director of Patient Safety and Clinical Quality, Laura Lee, M.Sc., RN, did a 2020 Culture of Patient Safety Survey. The results showed that the CC had improved significantly in each of 12 domains compared with 2017. The CC will likely do the survey again in 2023. Responses were equivalent to Agency for Healthcare Research and Quality comparators, with improvements in each of the 12 assessed domains.

In summary, Dr. Gilman assessed the CC's progress with respect to the four strategic aims outlined in the plan. Using a green-amber-red rating scale, he assessed the CC's progress as follows:

- Continuing to lead the world in conducting safe first-in-human clinical research in rare and refractory diseases: **Green**
- Increasing the use of the CC by the NIH Intramural Research Program: **Red**, largely (but not exclusively) because of the pandemic
- Demonstrating profound respect for our patients, our full partners in the clinical research enterprise: **Green**
- Partnering with ICs to recruit, develop, and retain the next generation of NIH clinical researchers and the CC staff that will support their efforts: **Amber**, signifying that several key positions still need to be filled

The last 2 to 3 years have made it challenging to follow the plan, but staff have made efforts to stay the course. This work has aimed to not just maintain the CC but also develop it for what is to come in the next 10 years.

Discussion

Ms. Reel asked about the status of the infants with GM1. Dr. Gilman reported that one of the girls has died. The other girl seems to be doing better. She had an older sister who died with GM1 but has now achieved milestones her sister did not. The Board will hear more about what the CC did to prepare for the two patients' care at its October meeting. Dr. Devaskar requested information for the Board on the lessons learned from taking care of these children.

Mr. Baum encouraged Dr. Gilman to also take credit for creating the rapid response team (called to intervene on patient conditions before they progress to critical), which has had a profound positive impact for patients. Dr. Gilman noted that it had existed before 5 years ago. What changed is that family members can now activate it—a change that was made because of a

discussion from the Board. Dr. Gilman also noted another change: The CC now participates in OpenNotes, providing patients access to their clinical notes. Dr. Gilman said he pushed for that change after hearing an OpenNotes advocate speak at the National Committee for Quality Assurance and remarked that it had been a positive change.

Mr. Baum added that during the July 2019 network outage mentioned earlier, there was no adverse patient impact, thanks to the CC's regular backup testing. Root cause analysis identified no evidence of adverse patient reactions. This outcome may be considered for the Magnet process. Mr. Baum also commented that many recent protocols have decreased the use of in-person long-term stays solely for testing, which has affected the census.

Dr. Samitt asked how the CEO strikes a balance between bringing in outside expertise versus developing internal talent. Dr. Gilman noted the incredible amount of talent at NIH but acknowledged it can be an insular community. The hiring process takes a lot of work, both to prepare to issue an announcement and to navigate the government rules around hiring, which is one reason why national searches take a long time. The existing NIH training is also excellent. NIH has invested heavily in leadership training and other courses.

Noting the desire to increase ICs' use of the CC, Dr. Chin, asked whether such a change faces friction. Dr. Gilman said that there is a palpable tension. Clinical research is more complex than work researchers can do in the lab. In addition, for physician-scientists at NIH, a clock is ticking; they have to show results, which makes it easy to prioritize whatever research will help them achieve their milestones. This tension has been exacerbated by pandemic circumstances, which have influenced flexibility for inpatients' CC access.

Dr. Forese commented that encouraging intramural research at the CC is a huge question that will bear fruitful discussion at a future meeting. The Board has engaged in conversation on this topic before, and it represents a real opportunity for NIH.

Ms. Williams-Brinkley noted her disappointment at not being on the Board to hear the continuation of that discussion. She said she was proud of what the Board had accomplished and invoked its bright future. She thanked everyone and noted what a pleasure it was to work with the chair, the Board, and the staff.

Closing and Farewell Remarks

In closing remarks, Dr. Forese gave some background on the Red Team, which is a term used in industry and cybersecurity to describe a group of outside experts brought in to do an assessment. She explained that although the CC had not experienced a safety issue, there was concern that something bad could happen. The team was a diverse group, including CEOs of major hospitals around the country. They worked quickly and determined that if NIH expanded its focus to include patient safety as well as research, it could prevent problems from occurring and up its game. However, the report was distressing for the team, and no one talked about it after it was released. To keep forward momentum, hiring a CEO was essential, and Dr. Forese commended Dr. Gilman for all that has been accomplished.

Dr. Forese thanked the Board and expressed excitement for the new members. She urged Board members to visit the NIH campus regularly, experience its vibrancy, and meet the talented CC

team. She expressed her pride in the gem of an organization that the NIH is and thanked Drs. Tabak, Collins, Schwetz, and Gilman.

Adjournment

Dr. Forese adjourned the meeting at 12:58 p.m.

/ Laura Forese /

Laura Forese, M.D., M.P.H.
Chair, NIH Clinical Center Research Hospital Board
Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital

/ Lawrence A. Tabak /

Lawrence A. Tabak, D.D.S., Ph.D.
Executive Director, NIH Clinical Center Research Hospital Board
Acting Director, NIH

Abbreviations and Acronyms

ACD	Advisory Committee to the Director
ADC	average daily census
AHaRT	Anti-Harassment Response Team
ANCC	American Nurses Credentialing Center
BERT	Behavioral Emergency Response Team
BID–CTP	Blood and Immune Deficiency–Cellular Therapy Program
CC	Clinical Center
CCE	Center for Cellular Engineering
CCND	Clinical Center Nursing Department
CCRHB	Clinical Center Research Hospital Board
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CLABSI	central line–associated bloodstream infection
COO	chief operating officer
COVID-19	coronavirus disease 2019
DART	Difficult Airway Response Team
DDIR	Deputy Director of Intramural Research
DEIA	diversity, equity, inclusion, and accessibility
EDI	Office of Equity, Diversity, and Inclusion

FEVS	Federal Employee Viewpoint Survey
FDA	U.S. Food and Drug Administration
FY	fiscal year
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HBCUs	historically Black colleges and universities
HHS	U.S. Department of Health and Human Services
ICs	Institutes and Centers
IT	information technology
IVAU	intravenous admixture unit
MSI	minority-serving institution
NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIH	National Institutes of Health
OCMR	Office of Communications & Media Relations
OPSCQ	Office of Patient Safety and Clinical Quality
OSPMO	Office of Strategic Planning and Management Operations
PHS	U.S. Public Health Service

PI	principal investigator
PPE	personal protective equipment
REEP	racial and ethnic equity plan
SRLM	Surgery, Radiology, and Laboratory Medicine Building
STARS	Safety Tracking and Reporting System
TF	Task Force
UCLA	University of California, Los Angeles
WG	working group