U.S. Department of Health and Human Services

National Institutes of Health

Twenty-Eighth Meeting of the Clinical Center Research Hospital Board

October 18, 2024

Contents

Clinical Center Research Hospital Board

Leadership

*Monica M. Bertagnolli, M.D., Director, National Institutes of Health (NIH)

Jack Leslie, Former Chair, Weber Shandwick; Senior Visiting Fellow, Duke Global Health Institute; Distinguished Professor, Georgetown University; Chair, NIH Clinical Center Research Hospital Board (CCRHB)

*Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research, NIH, and Executive Secretary, Designated Federal Official, CCRHB

Janice Lee, D.D.S., M.D., M.S., Deputy Director for Intramural Clinical Research and Acting Designated Federal Official, CCRHB

Members

David M. Baum, PMP, Patient, NIH Clinical Center (CC) Patient Advisory Group

David C. Chin, M.D., M.B.A., Distinguished Scholar, Johns Hopkins Bloomberg School of Public Health, and Johns Hopkins University School of Medicine

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

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

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

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

Stephanie Reel, M.B.A., Assistant Professor, Johns Hopkins University School of Medicine, Division of General Internal Medicine

Antoinette Royster, NIH Research Participant and Patient Advocate

*Craig E. Samitt, M.D., M.B.A., Founder and CEO, ITO Advisors

*Absent

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 28th meeting in person and via videoconference on October 18, 2024. The meeting was webcast live and open to the public. A video recording is available online.

Jack Leslie began the meeting at 9:00 a.m. ET.

He said he was humbled to take on the position of CCRHB Chair after the passing of Norvell Coots V. Coots, M.D. He thanked James K. Gilman, M.D., who will be retiring from his term as Chief Executive Officer (CEO) of the Clinical Center (CC), for his service. Mr. Leslie introduced members of the board who were present at the meeting or attending virtually.

Standing in for Nina F. Schor, M.D., Ph.D., Janice Lee, D.D.S., M.D., M.S., announced changes in leadership for the intramural research program: Roland A. Owens, Ph.D., is the Deputy Director in the Office of Intramural Research (OIR); Charles Dearolf, Ph.D., is the Associate Director for Research Operations in OIR; A. Parker Ruhl, M.D., M.H.S., is the Associate Director for Clinical Faculty Affairs in the Office of Faculty Development; and Risa Isonaka, Ph.D., is Assistant Director at the Office of Faculty Development.

Dr. Lee reviewed the NIH Research Festival on September 23–25, funding opportunities under the upcoming 25th Bench-to-Bedside Research Award, and NIH Industry Day in 2025. She announced several award recipients: Swee Lay Thien, D.Sc., for the Shaw Award; Nora Volkow, M.D., for the Gerard Prize; Michelle Jones-London, Ph.D., for the Marshall Award; and Dr. Schor for the Grafstein Award for Advancing Women in Neuroscience. Following her presentation, Dr. Lee answered questions about Industry Day and advances in drug development for children.

Dr. Gilman thanked attendees for their support during his tenure as CC CEO, and thanked Mr. Leslie for taking on the role of CCRHB Chair. Dr. Gilman announced the death of John I. Gallin, M.D. There will be a memorial service in the CC to celebrate Dr. Gallin's 22-year tenure as CEO of the CC.

Dr. Gilman gave the CEO update. He summarized the following leadership appointments in the CC: Leighton Chan, M.D., M.P.H., became Chief of Rehabilitation Medicine; Melika Smith, LCSW-C, LICSW, became the Chief of the Social Work Department; David Wu, M.D., became the Chief of Pain and Palliative Care Service; Julie George, M.S.N., M.B.A., RN, NEA-BC, CNLM, NC-BC, became the Service Chief for Neuroscience, Behavioral Health, and Pediatrics in the Nursing Department; Jennifer Kramer, M.S.N., RN, NEA-BC, became the Service Chief for Nursing Operations in the Nursing Department; and CAPT Antoinette L. Jones, M.S.O.D., RN, became Director in the Office of Global Research Division of Intramural Research, National Heart, Lung, and Blood Institute. Sophia Grasmeder, RN, is currently Acting Patient Representative. Two child life specialists will join the Department of Pediatrics on October 21, 2024.

The CC also has a new strategic aim to improve information use and accessibility. The CC should hear a final decision on Magnet accreditation from the American Nurses Credentialing Center in November or December. Dr. Gilman reviewed activities for the 2024 NIH Combined Federal Campaign starting on October 9. Construction is underway for the Surgery, Radiology, and Laboratory Medicine Wing. Outpatient visits have gone up since 2023, but have not increased significantly in 2024. Among the Diversity, Equity, Inclusion, and Accessibility

(DEIA) updates were DEI certification, the Racial Ethnic Equity Plan, national commemorations, and several recent DEIA events. Dr. Gilman announced CC Length of Service Honorees: Tsehai Crockett, Delores Bell, Chauncey Buford, Eli Lewis, Kadine Foreman-Westly, and Martha Ochia. Dr. Gilman shared the CC Quarterly Report and transition issues to consider going forward. Discussion praised Dr. Gilman's work across the Magnet assessment, pediatrics, and his personal commitment to staff.

Alison Han, M.D., M.S., reported that masking and admission testing will resume November 4 or sooner, if public health authorities recommend it or if NIH's weekly review of state and regional metrics indicates a rise in respiratory activity. Masking and admission testing will end when metrics indicate that respiratory virus activity has declined. Discussion after the presentation was focused on the supply of personal protective equipment, vaccination rates, and lessons learned from the coronavirus disease (COVID-19) pandemic and the 1918 influenza pandemic.

David Lang, M.D., M.P.H., shared data from the Safety Tracking and Reporting System (STARS), which the CC uses, filed between 2018 and 2023. On a deeper dive into reports involving medication infusion pumps, he found reports of equipment malfunction in 82% of reported cases. However, in follow-up with the Biomedical Engineering (BIOMED) and Property Management Section, malfunctioning equipment was only confirmed in 20% of events where pumps were tested, and only a single event where the pump delivered at the incorrect rate. These metrics indicate an opportunity for messaging about pump usage and also about sending pumps for investigation. BIOMED could help address this issue, and help with the investigation, by providing final determinations on investigations. Malfunctioning equipment should be sent to BIOMED for further testing. Dr. Lang recommended that staff receive clarification and messaging on what should be sent to BIOMED, and tips on equipment use. Discussion covered the use of STARS as a standard reporting mechanism in the CC, and other use cases for STARS reporting.

Julie L. Gerberding, M.D., M.P.H., President and CEO of the Foundation for the National Institutes of Health (FNIH), described some of the ways that FNIH supports the mission of the NIH. FNIH helps "build bridges to breakthroughs" by developing and managing collaborative private-public-patient partnerships that link NIH scientists to their counterparts in life science companies, academia, foundations, and patient organizations. The Accelerating Medicines Partnerships (AMP) program is a long-standing exemplar of how such programs help identify new disease pathways and treatment targets and then catalyze investments in translational research. More recently, FNIH is focusing on accelerating the timelines for these programs by starting design and start-up even before the NIH budget contribution is available. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership is another successful partnership created in record time in the context of the pandemic emergency. ACTIV successfully screened more than 800 candidate compounds, developed 33 master protocols, and demonstrated that six agents were useful for COVID-19 treatment. The FNIH Biomarkers Consortium (BMC) and the Bespoke Gene Therapy Consortium (BGTC) are other examples of partnership platform programs. The BMC aims to improve the efficiency of clinical trials by validating biomarkers as predictors and endpoints for clinical trials, in close collaboration with FDA. Likewise, the BGTC aims to standardize approaches to gene therapy vector manufacturing, as well as to improve regulatory certainty about approval standards for approaches that address rare and ultra-rare diseases. Finally, FNIH aims to raise the profile of biomedical scientists and supports many training programs, lectureships, and honors, including

the newly endowed Paul-Gallin Trailblazer Prize for Physician–Scientists, which will bear Dr. Gallin's name. (Dr. Gallin and his wife Elaine originally started the award after he retired as NIH CC Director.) ACD discussion covered contracting with vendors, data aggregation, future therapeutics, and the importance of science communication as a way to build trust.

The next meeting of the CCRHB is slated for February 21, 2025.

Mr. Leslie adjourned the meeting at 12:42 p.m. ET.

Meeting Summary
October 18, 2024

Welcome and Introductions

Mr. Jack Leslie, Former Chair, Weber Shandwick, Senior Visiting Fellow, Duke Global Health Institute, Distinguished Professor, Georgetown University and Current Chair, National Institutes of Health (NIH) Clinical Center (CC) Research Hospital Board (CCRHB)

Mr. Leslie began the meeting at 9:00 a.m. ET.

He said that he had chaired other advisory boards and that in his experience, board membership makes participants better advocates. He said that the information acquired is fodder that members can use to advocate for the CC. He received his first tour of the CC from Anthony Fauci, M.D., and was humbled to take on the position of board chair after Norvell "Van" Coots, M.D., whose passing he called a devastating loss. Mr. Leslie thanked Dr. Gilman, who will be retiring, for his term as Chief Executive Officer (CEO) of the CC; this will be the last meeting of the CCRHB that Dr. Gilman attends. Mr. Leslie said that someone with a military background such as Dr. Gilman's was needed during the coronavirus disease (COVID-19) pandemic, and that there would be time to pay tribute to his contributions at the end of the meeting. Mr. Leslie also thanked the staff who helped with the CCRBH meeting and asked that members of the board introduce themselves:

- Mr. David Baum is a patient member of the CCRHB and works as a special volunteer to the Chief Information Officer.
- Dr. Regina Cunningham has been the CEO at the University of Pennsylvania for 8 years, but her background was as an oncology nurse. She has been on the board for more than a year.
- Dr. David Chin is a scholar at the Johns Hopkins University. He teaches value-based health care and says he is privileged to be part of the board.
- Dr. Sherin Devaskar is a Professor at the University of California, Los Angeles and Chair of the Department of Pediatrics. She said she also considers serving on the CCRHB to be a privilege.
- Ms. Antoinette Royster has been a patient at the CC for 25 years and said that it is a privilege to serve as a patient advocate.
- Mr. Steven I. Goldstein, M.H.A., is President and CEO of Strong Memorial Hospital and Highland Hospital and is Vice President of the University of Rochester Medical Center. He heads eight hospitals, leads seven nursing homes, and chairs various boards. He has served on the CCRHB for a number of years.
- Dr. Julie Freischlag is the Chief Academic Officer, the Executive Vice President of Advocate Health, and the CEO of Atrium Health Wake Forest Baptist. She was the Dean of the Wake Forest School of Medicine for a number of years, and is now Chair Elect to the Board of Directors of the Association of American Medical Colleges. A vascular surgeon, she was for years Chair of the Department of Surgery at Johns Hopkins University.
- Barbara Jordan, D.N.P., RN, NEA-BC, is the Chief Nurse for the CC. She is currently attending a conference that supports nurses.

NIH Director's Remarks

Janice Lee, D.D.S., M.D., M.S., Deputy Director for Intramural Clinical Research and Acting Designated Federal Official, CCRHB

Mr. Leslie introduced Dr. Lee, who is standing in for Dr. Schor as the designated federal official. Dr. Schor is not present today.

Dr. Lee is the Deputy Director for Intramural Clinical Research and the Clinical Director for the National Institute of Dental and Craniofacial Research. She introduced individuals who have taken on new roles for the intramural research program.

Familiar Faces in New Roles

- Roland A. Owens, Ph.D., is the Deputy Director in the Office of Intramural Research (OIR), which he joined in 2008. He has developed and implemented the Distinguished Scholars Program, oversees the Stadtman Program for tenure-track investigators and the NIH Equity Committee, and serves as Chief Diversity Officer for OIR.
- Charles Dearolf, Ph.D., is the Associate Director for Research Operations in OIR. He facilitates NIH programs, including the Laskar Research Scholars Program. He is instrumental in data management sharing. He also organizes monthly meetings for scientific and clinical directors, and all award nominations in the OIR.
- A. Parker Ruhl, M.D., M.H.S., is the Associate Director for Clinical Faculty Affairs in the Office of Faculty Development. Currently at the National Institute of Allergies and Infectious Diseases (NIAID), she is part time in the OIR—where she focuses on the clinical faculty—and plays a role in professional development for staff clinicians.
- Risa Isonaka, Ph.D., is Assistant Director at the Office of Faculty Development. She joined the National Institute of Neurological Disorders and Stroke (NINDS) as an intramural scientist.

Recent Intramural Events

On September 23–25, the NIH Research Festival celebrated research on campus from trainees (postbaccalaureates and postdoctoral fellows), tenure-track investigators, and National Academy of Sciences (NAS) awardees.

Dr. Lee mentioned that it is the 25th year of the Bench-to-Bedside Research Award, which was established by John I. Gallin, M.D., in 1999, and supports intramural and extramural collaborations. This year 15 applications will be funded. The program is currently led by the Office of Clinical Research Education and Collaboration Outreach.

In 2025, NIH Industry Day will examine drug development. It will take place in person, though the day of the meeting is still to be determined.

New Awards

Dr. Lee highlighted numerous awardee recipients. The Shaw Prize in Life Science & Medicine went to Swee Lay Thein, D.Sc., the head of the Sickle Cell Disease Branch. Other awardees included: Nora Volkow, M.D., for the Ralph R. Gerard Prize in Neuroscience; Michelle Jones-London, Ph.D., for the Louise Hanson Marshall Special Recognition Award; and Dr. Schor for the Bernice Grafstein Award for Outstanding Accomplishments in Mentoring.

Discussion

- Dr. Gilman said that the people mentioned by Dr. Lee represent Dr. Schor's efforts at more coherent organization for the OIR; this is just a clarification of what they are already doing and how they do their jobs.
- Dr. Cunningham asked about Industry Day—specifically whether there are productive collaborations, and whether they have led to the development of new compounds.
- Dr. Lee said that Industry Day relates to the work of the National Center for Advancing Translational Sciences (NCATS), whose purpose is to accelerate drug therapy research, though that can take decades. The focus now is on the importance of partnerships among the groups involved.
- Dr. Devaskar asked about drug development for children, and whether this topic is a priority.
- Dr. Lee said that pediatrics needs to be rethought, but she mentioned a relevant gene therapy study at CC and said that the issue is of strong interest. She added that the topic of pediatric research would be brought back to the Organizing Committee for Industry Day.
- Dr. Gilman said that there are collaborations between the NIH and the U.S. Food and Drug Administration (FDA) that focus on rare diseases, many of which occur in children and may respond to gene therapy. He said that these studies are going on behind the scenes.
- Dr. Devaskar said that most of these therapies are expensive, which is why industry may not take them up.
- Dr. Gilman said that NIH has participated in efforts to create pathways to approval. NIH may have some influence on what a commercial firm can require someone to pay for a therapy; that is part of the impetus behind the program.

CC CEO Update

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

Leadership Changes, Loss, and Farewells

Dr. Gilman thanked everyone present for their interest in the CC and for their support of him, both personally and professionally. He has worked in this position for almost 8 years, which is his longest ever job tenure.

Dr. Gilman thanked Mr. Leslie for taking on the role of Chair of the CCRHB in August 2024. He said that Mr. Leslie's expertise and career experiences in packaging information will benefit the NIH brand in the future. Mr. Leslie has already committed to his duties as the CCRHB Chair. He said that Dr. Coots would be happy that Mr. Leslie has become his successor.

Dr. Gilman also indicated that NIH is mourning Dr. Gallin, who died about a week ago. There will be a memorial service in the CC, after Dr. Gallin's family has a private event. Staff want there to be an enduring legacy for Dr. Gallin's 22-year tenure as CEO of the CC.

Dr. Gilman summarized recent leadership appointments in the CC, which included:

- Leighton Chan, M.D., M.P.H., became the Chief of Rehabilitation Medicine.
- Melika Smith, LCSW-C, LICSW, became the Chief of the Social Work Department.
- David Wu, M.D., became the Chief of Pain and Palliative Care Service.
- Julie George, M.S.N., M.B.A., RN, NEA-BC, CNLM, NC-BC, became the Service Chief for Neuroscience, Behavioral Health, and Pediatrics in the Nursing Department.

- Jennifer Kramer, M.S.N., RN, NEA-BC, became the Service Chief for Nursing Operations in the Nursing Department.

Dr. Gilman indicated that a search for CC Executive Officer is nearing completion and may result in an appointment in about a month.

Dr. Gilman congratulated CAPT Antoinette L. Jones, M.S.O.D., RN, on her new position as Director in the Office of Global Research, Division of Intramural Research, National Heart, Lung, and Blood Institute (NHLBI). Replacing her for now is the current Acting Patient Representative, Sophia Grasmeder, RN, Nurse Consultant in the Office of Patient Safety and Clinical Quality, and Leader of Recognition Awards in Safety, Tracking, and Reporting System (STARS).

Innovations in the CC

Dr. Gilman quoted from Jack Masur, M.D., while discussing skepticism toward pediatric research at the CC. Dr. Gilman has been part of efforts to ensure that children's diseases have more of a place in the CC. He quoted from a statement Dr. Masur made in 1963 to show that the need for more focus on children at the CC is still a concern, even after more than 60 years. On a positive note, he announced the October 21 arrival of two child life specialists in the department of pediatrics. Though 2025 will be a difficult budget year, these hires are important to ensure that children in the CC receive the best possible care. These specialists will collaborate with members of the interdisciplinary health care team and provide developmentally appropriate interventions for pediatric patients who undergo procedures that may cause pain or anxiety.

The CC has a new strategic aim: to improve the ability to access and use information of all types. Dr. Bertagnolli has supported the approach that is being taken on electronic health records (EHRs). Dr. Gilman mentioned the CC's new website and said that feedback is still being received, but he is generally happy with its launch.

Magnet Journey Updates

Dr. Gilman began by providing some context, noting that just 9% of U.S. hospitals achieve Magnet accreditation. Such accreditation signifies organizational excellence, high quality, safe care, and an engaged nursing workforce. The designation is data-driven and evidence-based.

Magnet accreditation entails several steps, the penultimate one being a visit from the American Nurses Credentialing Center. This year it occurred on August 28–30. The CC's Magnet document was found to have five deficiencies, but they were all typos or document-upload issues, and there were no substantive deficiencies to address. That outcome led directly to a site visit, which is exceedingly rare for first-time applicants. CC Magnet ambassadors, leadership, and interprofessional teams were involved in getting the CC ready for the visit. The visit itself took 3 full days and consisted of interview sessions with executives and nursing groups, unit visits, presentations, and an informational session chosen by the CC. The feedback from the visit emphasized the presence of strong interprofessional collaboration and relationships, staff alignment with the vision of the CC and the Clinical Center Nursing Department (CCND), and an impressive caliber and quality of nursing.

After the appraisal team submits its report, a final decision is expected in November or December.

2024 NIH Combined Federal Campaign (CFC)

Dr. Gilman mentioned the 2024 CFC, which starts on October 9 and is led by the CC. Activities that are part of the campaign include the Virtual Fall Charity Fair and Costume Contest on October 31, and the Director's Challenge—Cornhole: Throwdown in the CC Atrium on November 21.

Surgery, Radiology, and Laboratory Medicine (SRLM) Wing at the CC

Dr. Gilman showed photographs that indicate construction is well underway for this wing, and is far along relative to where it was a year ago. He said that when he and Dr. Gallin looked at the progress of the SRLM from the fifth floor of the CC, it was the last time that he saw Dr. Gallin—an image that he'll always treasure and one of his fondest memories of working with Dr. Gallin. The SRLM had been a priority for Dr. Gallin, and Dr. Gilman was happy that he could share the progress on this wing with him.

CC Statistics

Dr. Gilman showed the average daily census for the CC, going back several years and up to September 30. After a decline in activity during the COVID-19 pandemic, outpatient visits went up in 2023 but did not rise again significantly in 2024. Telehealth visits increased slightly this past July, but switching from in-person care to telehealth is difficult if the written protocol requires that a patient visit the CC.

Diversity, Equity, Inclusion, and Accessibility (DEIA) Updates

Dr. Gilman discussed several DEIA updates, including DEIA certification, the Racial Ethnic Equity Plan, and national commemorations (e.g., National Hispanic Heritage and National Disability Employment Awareness—Project Search "Take Your Legislator to Work Day," on October 8).

Recent DEIA events included "Language Access: A Decade of Progress for Hispanic and Latino Health Equity," led by Brenda Robles on October 15, and "Cultural Competence: My Spanish Does Not Sound Like Yours," on October 9. The 2024 DEIA Symposium was on the topic of "Lessons Learned From COVID-19: Promoting Representation of Diverse Populations in Research." The Education, Diversity, and Inclusion (EDI) Forum 2024, which occurred on October 8–9, provided opportunities for NIH employees to meet EDI staff.

CC Length of Service Honorees

Dr. Gilman said that awards for length of service used to be given out at town hall meetings. Now he goes to visit staff where they work, which he prefers. Between 70 and 90 people are honored each quarter based on having 5 or more years of service. Dr. Gilman posed with members of the CC Materials Management and Environmental Services Department staff: Tsehai Crockett, Delores Bell (30 years of service), Chauncey Buford (35 years), Eli Lewis (5 years), Kadine Foreman-Westly (5 years), and Martha Ochia (5 years). Dr. Gilman, who likes to learn the honorees' personal stories, shared the fact that both Ms. Foreman-Westly and Ms. Ochia emigrated to the United States.

What to Expect in Fall 2024 and Winter 2025

Dr. Gilman said that the CC will focus on staff and patient well-being, research participants, care of pediatric patients, DEIA, and budget and staffing issues. Efforts will also be made to finish the Magnet journey and transition CEO duties to the acting CEO.

CC Quarterly Report

Dr. Gilman indicated that the CC Quarterly Report is provided to CCRHB members before every meeting, and that after each one, the report is posted on the CC website for public viewing.

Transition Issues

Dr. Gilman indicated that the following issues should be considered going forward:

- Whether the CC is the same as other institutes and centers (ICs)
- Handling a No Fun Budget Year
- What kind of research should be done in the CC (e.g., whether it should continue to focus on what cannot be done elsewhere, which does not attract scientific talent)
- What CC's involvement should be with regard to research sites beyond Building 10
- SRLM—the initial outfitting and modification of plans developed long ago
- Completing EHRs
- Dealing with the current funding model
- Working in an increasingly unionized environment

Dr. Gilman concluded his presentation by summarizing the remaining talks at today's meeting: Dr. Han will address masking (which will resume in 2 weeks; this was a topic that the CCRHB's Craig Samitt, M.D., M.B.A., asked about at the last meeting); Dr. Lang will discuss the STARS program by doing a deep dive into data; and Dr. Gerberding will present on the Foundation for the National Institutes of Health (FNIH).

Discussion

The following discussion ensued:

- Mr. Leslie said that Dr. Gilman's report is terrific and illustrates Dr. Gilman's hands-on approach. He was reminded of the herculean effort required for the Magnet assessment and hopes that the good news of a positive determination will be shared when it arrives. Mr. Leslie called out Justin Cohen, M.S., M.A., for his work on the new website. Mr. Leslie added that website design is a difficult task, and that making websites navigable is not easy. The redesigned website, he said, is light years ahead of where it used to be.
- Mr. Baum said that Mr. Cohen has made the website into an easy-to-navigate resource. People in other ICs want to see how their data relate to the CC's new EHRs; the boundary between these sources of data is not well understood. The role of the CC and what it gets involved with is an important strategic objective.
- Dr. Gilman said that some research intramural needs to go where patients are (i.e., community-based research). He acknowledged that there may be problems with issues such as personal and patient safety.
- Dr. Cunningham said that the pictures of Dr. Gilman with the staff honorees reflect his personal commitment and sense of connection, which shape an organization's culture.
- Dr. Devaskar said that Dr. Gilman is amazing and has put his heart and soul into supporting pediatrics at the CC. She said that 20% of the population are children, but they will eventually become 100% of the population. She asked about the use of magnetic resonance imaging (MRIs) in outreach centers rather than in the CC.
- Dr. Gilman said that there are plenty of MRIs in the CC, but one investigator wants to use an MRI in the community and is trying to address potential issues with safety. Dr. Devaskar said that she has a stroke van at her institution, which could help address such issues.

- Dr. Devaskar asked whether EHRs can interface with one another when patients are transferred. She also said that many institutions are struggling with lack of intravenous (IV) fluid because of recent hurricanes.
- Dr. Gilman said that there is not yet an IV fluid problem at CC. The supply is centralized whenever there is a concern, but that has not had to happen with the IV. With regard to communication among EHRs, Dr. Gilman said that there are amazing abilities to interface through PDFs and secure faxes; the CC uses electronic means and little paper to send and receive information. He added that third-party software has led to complicated architecture, but that it permits this communication. Stephanie Reel said that she agreed with Dr. Gilman's assessment. Dr. Gilman said that Dr. Bertagnolli has been concerned with getting cancer data, and that her advocacy at the Department of Health and Human Services (HHS) level has been important in getting the new EHR system for the CC.
- Ms. Royster said that she was struck by the awards ceremony and impressed by Dr. Gilman's part in it; she particularly liked the 5-year recognition for retention purposes. She said that she too hates to see Dr. Gilman leave, and asked whether he plans to return to NIH as either a volunteer or a contractor.
- Dr. Gilman said that he will return when the pharmacy is finally completed, and that he will be invited back when the SRLM is finally finished. However, he said that the next CEO will not want to see him. He added that while he will answer a phone call from the new CEO, he will never stick his nose into that person's job. It is now someone else's turn to run things.
- Ms. Royster mentioned a lyric from the song "Hotel California": "You can check out any time you like, but you can never leave." She said that Dr. Gilman should make a showing at the CC every now and then.

Masks in the Clinical Center: Past/Present/Future

Alison Han, M.D., M.S., Chief, Hospital Epidemiology Service (HES), CC

Dr. Han has served as Chief of HES for >one year and shared the shifting policy on masks, from before the pandemic to the early pandemic, then the present and the future.

Dr. Han discussed a number of transmission-based precautions, such as respiratory isolation, enhanced respiratory isolation, airborne isolation, enhanced contact isolation, and contact isolation. Enhanced contact isolation is used for patients with certain types of multidrug-resistant organisms. Dr. Han then focused on the role of masks and respirators to stop transmission by respiratory droplets (e.g., influenza, respiratory syncytial virus [RSV], or rhinovirus) or airborne transmission (e.g., measles, tuberculosis). Patients with respiratory infections wear masks when they leave their rooms.

Dr. Han provided a brief overview of the COVID-19 pandemic, from January 2020 (when laboratory-confirmed cases were reported outside of China) to March 2020 (when the World Health Organization [WHO] declared a public health emergency, which included shutdowns and travel restrictions). Dr. Han said that at NIH, testing became available on March 3, teleworking began on March 16, surgical masks were required to enter the CC on April 2, and asymptomatic testing of staff began on May 21, 2020.

NIH implemented multiple mitigation strategies, such as universal masking, physical distancing, screening (both symptomatic and asymptomatic), and isolation and quarantine. Existing components of isolation were modified, and universal masking became standard. Patient care activities were also modified: Staff implemented universal masking, eye protection when within

six feet of patients, and enhanced respiratory isolation of suspected or confirmed COVID-19 cases; patients underwent screening before and at arrival, admissions testing, and restrictions on visitation; rooming in visitors underwent admissions testing; pre-aerosol-generating procedure (AGP) testing was conducted before certain medical procedures were performed; and a COVID-19 unit was created.

Dr. Han said that masking procedures work, and referenced three discussion pieces: two from Ideas and Opinions articles in *Annals of Internal Medicine* and one from Cochrane Library. She also displayed Centers for Disease Control and Prevention (CDC) graphs from the National Respiratory and Enteric Virus Surveillance System.

Dr. Han said that in early 2020, masks and event cancellations reduced community respiratory viral infections (i.e., infections other than COVID-19) among CC patients. However, these viruses came back when mitigation strategies were lifted. One type of influenza B virus is no longer seen, and that virus is no longer part of standard flu vaccines (i.e., they are trivalent for three influenza virus types rather than quadrivalent for four virus types). She also presented a graph on COVID-19 deaths and percent positivity in the U.S. from January 2020 to the present from CDC's COVID Data Tracker.

In 2023, select mitigation strategies were lifted at the CC, based on recommendations from multiple professional societies. In April, pre-AGP testing was no longer required, nor was quarantine of international travelers who were not fully vaccinated. The recommendation to test before travel was also lifted. In May, the CC's COVID-19 unit closed, and COVID-19 patients stayed in their home units. In June, masks were required only in patient care areas, and became optional elsewhere.

Dr. Han provided the timeline that indicated when admission testing was initiated for respiratory viruses: COVID-19 testing on admission has occurred since 2020; from November 2022 to April 2023 and from September 2023 to May 2024, there was testing for influenza A, influenza B, and respiratory syncytial virus. These measures are designed to prevent transmission of these infections in the hospital.

Dr. Han displayed the results from two staff posters that are being presented this week at a national infectious diseases conference to show why policy recommendations are moving forward the way that they are. One is from Robin Odom, M.S., CIC; the other is from La Toya A. Forrester, M.P.H., CIC. Ms. Odom looked at the positive tests since 2021, which showed both symptomatic and asymptomatic results for multiple viral infections. The data indicate that there is higher concern in the fall and winter, when circulation of respiratory viruses is highest. Ms. Forrester looked at the data from 2010 to 2024 for multiple infections, including hospital-acquired infections. Fortunately, large numbers were not reported. After masking was implemented in 2020, there was no hospital-acquired influenza A/B infections likely because of policies that were implemented. There were, however, instances of parainfluenza, which the CC does not test for at admission. There was a decrease in hospital-acquired RSV infection, to just one case.

Dr. Han said that after consultation with HES, Occupational Medical Service, Infectious Diseases, Clinical Center Nursing Department (CCND), and public health authorities, masking and admission testing will resume on November 4. Masking and admission testing may begin even earlier, if recommended by public health authorities, or if NIH weekly review of state or regional metrics indicates a rise in respiratory activity. Masking and admission testing will end when metrics indicate that respiratory virus activity has declined.

Dr. Han concluded that COVID-19 and other respiratory virus infections remain a serious threat to the CC's patients, but mitigation strategies have affected transmission. Masking was temporarily associated with a decline in hospital-acquired respiratory viral infections at the CC. Routine review of respiratory virus surveillance will occur at the CC, in Maryland, regionally, and nationally. Masking and admission testing are expected to ultimately be seasonal.

Discussion

The following discussion ensued:

- Mr. Leslie said that he was reminded of shortages of personal protective equipment (PPE) during the pandemic and asked if any lessons were learned.
- Dr. Gilman said that the CC's PPE has been centrally controlled; it started using PPE on April 2, 2020, when Materials Management and Environmental Services Department said that enough masks had been acquired that they could be given to people as necessary. There was a time when people reused their N95 masks until they were told that those were no longer necessary.
- Dr. Cunningham commented on the CC's practice of routinely testing for flu, COVID-19, and RSV. She asked whether vaccinations were offered to those whose test results were negative. Dr. Han said that Dr. Cunningham's suggestion was something to consider in the upcoming season. Dr. Cunningham noted that this practice would improve the health of patients.
- Dr. Cunningham asked whether vaccination is mandatory or strongly encouraged for staff; if it's not mandatory, she said, then she wanted to know the vaccination rate. Dr. Han said that there is a mandatory influenza policy for those who are in contact with patients, unless an individual declines for religious reasons or medical contraindications from the vaccination. Pre-pandemic, the vaccination rate was above 90%, and it later dropped to 80%; last year, it was 89%.
- Ms. Reel compared this pandemic with the 1918 influenza pandemic and asked whether any lessons have been learned this time. Dr. Han said that there have been lessons—regarding which strategies worked—and that she is optimistic about the future. Ms. Reel said that she hopes that notes were kept someplace on what to do in the future.
- Dr. Devaskar asked about visits from family members. Dr. Han said that there were restrictions initially on family members, but these were lifted later. There was testing for those who stayed in the same rooms as the patients, i.e., rooming in visitors, but not for visitors who came and went.

Research for the STARS: Deep Dive Involving Infusion Pumps

David Lang, M.D., M.P.H., Director, Office of Patient Safety and Clinical Quality, CC

Dr. Lang gave a presentation on what can be done with years of data by using STARS.

Every hospital has a reporting system related to safety, and STARS is the one used by the CC. STARS is a web-based program that has been used since April 2017. It is voluntary and based on user entry; it reflects what people think is important. At the end of 2023, 35,000 entries were included. In the system, results are broken down by type of event where safety issues may arise, such as the handling of laboratory specimens or medications. Reports can also be given for high-quality service.

STARS reports are based on the words that a person enters. Each report is reviewed by the CC Office of Patient Safety and Clinical Quality and assigned to appropriate reviewers (e.g., a report

about laboratory results would go to the Laboratory Department). File managers review the report and provide recommendations based on what was found.

Each event gets individual attention, and some may require root cause analysis. Over time, patterns can be established; if there are trends, there may be institutional fixes for recurring issues. A question is whether common data elements could be created to be included in reports.

This presentation was a first proof of concept on whether a deep dive into the data is useful. Specifically, Dr. Lang looked at two possible issues related to pumps: (1) a pump malfunction in either IV or patient-controlled analgesia pumps, and (2) a problem related to medication or fluid in the pump, which could include an incorrect rate of fluid flow or issues with the pump's programming. Between 2018 and 2023, 269 reports were entered in STARS based on these categories.

Dr. Lang listed the types of medications involved in these reports, with potassium chloride infusion being the most frequent; this medication can be harmful if it is administered at the wrong rate. Dr. Lang further narrowed his search to reports of malfunctioning equipment during infusion. Of these reports, 82% of reporters (n = 126) said that the issue was due to equipment or device malfunction.

Dr. Lang next examined rates of follow-up from the Biomedical Engineering (BIOMED) and Property Management Section. From report narratives, BIOMED follow-up was reported in just 60% of these reports. Of these responses, (n = 76), a malfunctioning pump issue was identified by BIOMED in just 20% of the cases. With these considerations in mind, potassium chloride fell off the list of the top 10 medications with equipment malfunction issues; the problems with potassium chloride resulted from issues in ordering the incorrect dose.

Pump issues were identified in 15 reports, related to just a few medications. Follow-up from BIOMED resulted in just one case for a pump that was running too fast and required servicing. In all other cases, problems came from a battery or a maintenance issue; these were not problems that stemmed from infusion rate issues.

Other reported issues when the pump was not the fault included:

- Tubing problems, which caused occlusions and would force the pump to shut down, which is supposed to happen
- Information entered incorrectly when pump results were compared with what was reported
- Under-delivery, but within the 5% standard
- A misunderstanding of PCA lockout parameters, which were reported as "errors."
- Documentation and transposition issues
- BIOMED being unable to determine what had happened

Dr. Lang said that many of the reported errors were not, in fact, errors but were instead misunderstandings. Misunderstandings are still useful, because they indicate a messaging problem for new staff coming onboard. When new processes are put in place, staff may require lessons for implementation. Dr. Lang also said that, after their testing, BIOMED can provide information on the history of the programs and which infusions have occurred over the past 24 hours; this information could help future investigations. Dr. Lang encouraged sending pumps to BIOMED to help understand what is going on with equipment.

Dr. Lang concluded that this exercise was a useful proof of concept. When there is a binary field, the reporting system helps to identify what was thought to have contributed. Only one out-of-

parameter infusion rate was discovered from 76 reports. The remainder were programming errors or other issues. Pumps were tested by BIOMED 60% of the time, which suggests that there should be efforts to get more pumps to BIOMED. These findings support the need for closer examination of STARS reports.

Going forward, Dr. Lang said that there should be clarification and messaging on what should be sent to BIOMED (e.g., not just the pumps but also the cartridge models). Other efforts could include giving quick tips, identifying systemic ordering and labeling vulnerabilities (e.g., programming incorrectly), aligning messaging with repeated misunderstandings, and identifying more event types amenable to this type of analysis.

Discussion

The following discussion ensued:

- Mr. Baum said that this is a useful proof of concept and asked whether STARS is going to become the standard reporting mechanism in the CC.
- Dr. Lang said that STARS contains what people put in, and that yes, events such as falls would typically go in there.
- Mr. Baum asked whether STARS is the de facto system of record for patient safety. He also asked whether equipment is tracked.
- Dr. Lang said that BIOMED would track equipment.
- Dr. Devaskar asked whether STARS could detect near misses.
- Dr. Lang confirmed that entering near misses would be helpful. Dr. Devaskar said that the process could be changed.

The Foundation for the National Institutes of Health

Julie Louise Gerberding, M.D., M.P.H., President and Chief Executive Officer, FNIH

Dr. Gerberding began by congratulating Dr. Gilman on his retirement. She thanked him for his support and everything that he has contributed to "our nation's hospital."

Dr. Gerberding explained that FNIH "builds bridges to breakthroughs" in support of the NIH mission as the "middleware" between NIH and non-government sectors. These breakthroughs are achieved through building collaborative science, supporting scientists, and earning trust in science. These breakthroughs will help accelerate and amplify the value and impact of NIH's research on people's health and health equity.

Dr. Gerberding explained that FNIH public–private partnerships must:

- Meet significant unmet need and have high potential patient impact
- Clearly support NIH's mission
- Be uniquely suited to a public-private-patient partnership mechanism
- Have a significant value proposition for all partners
- Have executive-level sponsorship from stakeholder organizations, including NIH

Dr. Gerberding then explained the partnership models and flow of funds. FNIH raises funds from private sector companies, foundations, patient organizations, and philanthropists and uses these resources to augment NIH's collaborative investments in academic research. FNIH can also fund projects directly. Transparency, accountability, and shared governance are hallmarks of these alliances. All data must also end up in open sources to be available to researchers.

FNIH's work is relevant at every stage of the biomedical research pipeline: basic biology, target identification, candidate therapeutics, preclinical studies, clinical studies, regulatory approvals, post-approval studies, and equitable access and uptake.

Dr. Gerberding provided information on FNIH Accelerating Medicines Partnerships (AMP)—one of its signature programs. The program has supported 10 projects, both completed and ongoing. A total investment of $834 million has been made over a 10-year period, with 34 industry partners, 16 NIH ICs, and 37 nonprofit organizations. Dr. Gerberding showed a timeline of AMP from 2014 to 2027, as well as the impact of AMP on target prioritization and drug development related to Alzheimer's disease, rheumatoid arthritis, and type 2 diabetes.

She used amyotrophic lateral sclerosis (ALS) as a case study of how AMP is accelerating the process from idea to implementation. In a world where speed matters, the AMP ALS timeline went from conception to launch in just 8 months. Dr. Gerberding said that FNIH's own development funds and its handling of efficient contracting mechanisms helped accelerate this timeline.

Dr. Gerberding also shared an overview of Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), which resulted in screening 800 compounds, developing 33 master protocols, and finding six agents useful for COVID-19 treatment. NIH has an incredible network of clinical trials that ACTIV was able to repurpose for COVID-19 treatment trials. Dr. Gerberding expects that ACTIV's network will continue to expand beyond its current pharmaceutical, nonprofit, and government partners. She also suggested that this model could be adapted to evaluate therapeutics for Long COVID or other emerging threats.

Dr. Gerberding reviewed the Lung Master Protocol (Lung MAP) approach to precision cancer therapy. Traditional clinical trials for cancer treatment take a long time to evaluate the efficacy of a single treatment. Lung MAP instead evaluates the characteristics of each patient's tumor and successively adds new drugs into the program that are good matches for that patient. This process allows for faster cycling of new investigational drugs, which can quickly be assessed across a broad range of geographically diverse sites. This process speeds up many cancer trials and allows them to be completed in just 12 months.

FNIH also works to speed up the regulatory process in partnership with the FDA. Dr. Gerberding singled out Peter Marks, M.D., Ph.D., the Director of FDA's Center for Biologics Evaluation and Research, as the co-lead of one of FNIH's major projects who has worked tirelessly to expedite safe and efficient drug development.

Dr. Gerberding said that the Biomarkers Consortium is one of the most valuable things that FNIH has created, as it has improved the efficiency of clinical trials and encourages private sector investments. The partnership functions as a membership organization, and representatives from participating organizations make decisions about what studies will be conducted, which are then managed by FNIH.

FNIH is also coordinating efforts to expedite the development of gene therapies for rare diseases through the Bespoke Gene Therapy Consortium (BGTC), which selected eight rare diseases amenable to treatment with AAV vectors. The BGTC has a broad base of partners including FDA, 10 NIH institutes, large and small biopharmaceutical companies, foundations, and patient organizations, Dr. Gerberding noted that some patient organizations are participating in the consortium even though their specific disease is not being supported in clinical trials, because they believe the BGTC will unlock approaches to vector development that could ultimately help them.

Dr. Gerberding said that the most important – and most challenging – dimensional of translating the pipeline of science into better health is to help ensure equitable access and uptake of new therapies. For that reason, FNIH has an end-to-end focus on patients and includes the insights and leadership advice of people with lived experiences across its entire portfolio. FNIH has also established a Patient Engagement Council and a cadre of patient ambassadors to help people understand the value of clinical research and contribute to its evolution.

Dr. Gerberding touched on supporting scientists and promoting trust. Dr. John Gallin was the former NIH CC Director and a renowned clinician–scientist. He and his wife Elaine initiated the Trailblazer Prize for Clinician–Scientists at FNIH, which is now endowed and will bear his name as the Paul-Gallin Trailblazer Prize for Physician Scientists. FNIH also announced the new Kovler Prize for Trust in Life Science Journalism. The inaugural recipient was Katherine J. Wu, Ph.D., who was honored for her reporting on COVID-19 for *The New York Times*.

Dr. Gerberding said that serving FNIH is her most joyful job and feels privileged to have the opportunity to help amplify the critical work of NIH partnerships across such a broad portfolio of unmet health needs. She attended the recent Friends of Patients at the NIH dinner, which reminded her of how critical the CC is to patients and their families, and then thanked the Board for its service to that mission.

Discussion

The following discussion ensued:

- Mr. Baum asked about contracting with vendors.
- Dr. Gerberding said that contracting is done by source. She said that it is good to have standard language when writing contracts.
- Dr. Chen asked about data aggregation. He said that there are large for-profit data aggregations, and asked whether the FNIH could be an intermediary. He mentioned the *All of Us* Research Program as an example.
- Dr. Gerberding said that it is hard to change overnight how institutes operate. FNIH is brokering the building of federated data access in an interoperable way. Dr. Gerberding said she wants to hear what both the private sector and the government want for interoperability, which is a major benefit for data. Culture and data are working at cross purposes, and data centers are all over the map. Getting people to cooperate about data still requires work. Dr. Gerberding said that this is the most strategic question that she deals with.
- Dr. Cunningham asked about therapeutics in the future: Is the focus on novel therapeutics or older therapeutics that could be applied elsewhere?
- Dr. Gerberding said that NCATS is concerned with drug repurposing, and that FNIH studied ivermectin as part of this focus. In general, the AMPs are designed to motivate new targets and new approaches but are now moving to a systems biology approach. She mentioned the GLP-1 drugs that treat different conditions upstream; understanding the complexities of the upstream pathways is important. The most recent AMP is on system biology. Yesterday, NIH and FNIH approved studies of novel alternative methods with less reliance on animal models. Researchers need to know models' predictive power relative to existing animal data.
- Ms. Royster said that this was a great presentation. She liked acknowledging journalists for addressing misinformation and disinformation, and said she thought that this will encourage them to report the truth.

- Dr. Gerberding said that Judith Kovler and her husband have wanted to create this award for a long time. There was a jury to assess potential candidates, many of whom were credible even in the first year. But there is more work to be done here.
- Dr. Gilman said that there is a flipside to the issue of science information. He said that having scientists communicate to the public with more humility would be good. Dr. Collins said that scientists sometimes forgot to tell people that what is known may change. Dr. Gilman asked whether FNIH will teach scientists to communicate differently.
- Dr. Gerberding said that the scientists trying to being transparent with data should focus on what is known today and combine their statements with humility. Politicians, by contrast, want to be seen as having everything under control. Dr. Gerberding said that she recalls people being worried about contracting HIV from a needle stick. She said that some scientists need to be better communicators, and to be taught how to translate their findings into frameworks that others can understand. FNIH could be helpful in this, and the organization has worked with the American Association for the Advancement of Science (AAAS); by collaborating, a better bench could be built.
- Mr. Leslie said that communication, trust, and collaboration are important to him as well. He thanked Dr. Gerberding and the FNIH for creating a great first start.
- Dr. Gerberding thanked the CC for longstanding support of the FNIH.

Closing Remarks and Adjournment

Mr. Leslie said that the next meeting of the CCRHB will be on February 21, 2025.

He added that after this official meeting concluded, there would be additional comments related to Dr. Gilman's retirement.

The official meeting adjourned at 12:42 p.m. ET.

/s/

Nina F. Schor, M.D., Ph.D.

Executive Secretary and Designated Federal Official (DFO),
NIH Clinical Center Research Hospital Board

Deputy Director for Intramural Research, NIH

/s/

Mr. Jack Leslie

Chair, NIH Clinical Center Research Hospital Board

Former Chairman, Weber Shandwick
Senior Visiting Fellow, Duke Global Health Institute
Distinguished Professor, Georgetown University

Abbreviations and Acronyms

AAAS	American Association for the Advancement of Science
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
AGP	aerosol-generating procedure
ALS	amyotrophic lateral sclerosis
AMP	Accelerating Medicines Partnerships
BIOMED	Biomedical Engineering and Property Management Section
CC	Clinical Center
CCND	Clinical Center Nursing Department
CCRHB	Clinical Center Research Hospital Board
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CFC	Combined Federal Campaign
COVID-19	coronavirus disease
DEIA	Diversity, Equity, Inclusion, and Accessibility
EDI	Education, Diversity, and Inclusion
EHRs	electronic health records
FDA	U.S. Food and Drug Administration
FNIH	Foundation for the National Institutes of Health
HES	Hospital Epidemiology Service
HHS	Department of Health and Human Services

ICs	Institutes and Centers
IV	intravenous
Lung MAP	Lung Master Protocol
MRI	magnetic resonance imaging
NAS	National Academy of Sciences
NCATS	National Center for Advancing Translational Sciences
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NINDS	National Institute of Neurological Diseases and Stroke
OIR	Office of Intramural Research
PPE	personal protective equipment
RSV	respiratory syncytial virus
SRLM	Surgery, Radiology, and Laboratory Medicine
STARS	Safety, Tracking, and Reporting System
UCLA	University of California Los Angeles
WHO	World Health Organization