

Fourteenth Meeting of the Clinical Center Research Hospital Board

October 18, 2019

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Clinical Center Research Hospital Board

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

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

Ellen Berty, Special Education Teacher, Book Author, and Former NIH Research Participant

Beatrice Bowie, Facilitator, Sickle Cell Support Group, Adventist HealthCare Shady Grove Medical Center; and Board Member, NIH Patient Advisory Group

Ruth Brinkley, M.S.N., President, Northwest, Kaiser Foundation Health Plan and Hospitals (by telephone)

Brig Gen James Burks, M.B.A., M.M.A.O.S., Director, Manpower, Personnel, and Resources, and Chief, Medical Services Corps, U.S. Air Force

*Jeanette Erickson, D.N.P., RN, FAAN, Senior Vice President for Patient Care Services and Chief Nurse, Massachusetts General Hospital

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

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Reed Tuckson, M.D., Managing Partner, Tuckson Health Connections

*Absent

Executive Summary

The 14th meeting of the Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) took place on October 18, 2019, on the main campus of NIH. The meeting was open to the public and webcast live.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork-Presbyterian Hospital, and Chair, CCRHB, called the meeting to order at 9:03 a.m. ET and welcomed everyone in attendance. Dr. Forese announced that Carolyn Clancy, M.D., Deputy Under Secretary for Discovery, Education and Affiliate Networks (10X), Veterans Health Administration, U.S. Department of Veterans Affairs, is no longer a member of the CCRHB, but the CCRHB will have three new members in April.

Francis Collins, M.D., Ph.D., Director of NIH, provided an update on the NIH fiscal year (FY) 2020 budget, including efforts to get funding for needed buildings and facilities updates.

James Gilman, M.D., Chief Executive Officer of the Clinical Center, presented an update about recent awards and honors and staffing at the Clinical Center. He also presented the Clinical Center's efforts to address violence and harassment in the workplace.

There was a presentation about the Medical Research Scholars Program (MRSP) from Thomas R. Burklow, M.D., the program's director. The MRSP is a career development program to enable medical, dentistry, and veterinary students to perform research at NIH and to encourage careers in biomedical research.

Laura Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality, presented an update on the Joint Commission standards, new performance metrics, a review of the year, and future plans for the Office of Patient Safety and Clinical Quality.

Alissa Mun, M.S., Senior Quality Assurance Manager at the Clinical Center Office of Research Support and Compliance (ORSC), presented an update about the progress of the Quality Improvement Assessment (QIA), particularly addressing reporting requirements. Virginia Guptill, Ph.D., Director of the ORSC, presented an overview about the six sections of the office and the ways they support NIH.

Tara N. Palmore, M.D., Hospital Epidemiologist at the Clinical Center; Anna F. Lau, Ph.D., D(ABMM), Chief, Sterility Testing Service, Department of Laboratory Medicine, Clinical Center; and Jonathan N. Yoo, Engineering Team Chief, Division of Facilities Operations and Maintenance, Office of Research Facilities (ORF), presented a recent effort to understand an incidence of *Sphingomonas koreensis* infections at the Clinical Center and the subsequent reengineering efforts to the water system.

The CCRHB discussed and approved a letter about infrastructure challenges for the Clinical Center that will be used by Dr. Collins to support his budget negotiations with Congress.

Dr. Forese thanked the Board members for attending and sharing their insights. Dr. Forese adjourned the meeting at 2:32 p.m.

The next face-to-face CCRHB meeting is scheduled for April 17, 2020.

Meeting Summary

Friday, October 18, 2019

Welcome and Board Chair's Overview

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

The 14th meeting of the CCRHB took place on October 18, 2019, on the main campus of the National Institutes of Health (NIH). The meeting was open to the public and webcast live.

Dr. Forese called the meeting to order at 9:03 a.m. ET and welcomed all present. Ruth Brinkley, M.S.N., President, Northwest, Kaiser Foundation Health Plan and Hospitals, and Richard Shannon, M.D., Executive Vice President, Health Affairs, and Professor of Medicine, University of Virginia Health System, participated via teleconference.

Dr. Forese said that, based on previous discussions, the CCRHB will have three meetings in 2020. There will not be a meeting in January, and the next meeting will be on April 17, 2020.

Carolyn Clancy, M.D., Deputy Under Secretary for Discovery, Education and Affiliate Networks (10X), Veterans Health Administration, U.S. Department of Veterans Affairs, is no longer part of the CCRHB, because there is a conflict of interest between her current position and serving on the Board. On behalf of the CCRHB, Dr. Forese thanked Dr. Clancy for her hard work as a Board member.

Three new CCRHB members should be able to join the group by the April 17 meeting. Julie A. Freischlag, M.D., FRCS, Ed. (Hon), is the Chief Executive Officer of Wake Forest Baptist Health and Dean of Wake Forest School of Medicine; Steve I. Goldstein is the President and Chief Executive Officer of Strong Memorial Hospital, University of Rochester Medicine; and William N. Hait, M.D., Ph.D., is the Global Head at Johnson & Johnson External Innovation. Dr. Forese thanked *ex officio* member Francis S. Collins, M.D., Ph.D., Director, NIH; CCRHB Executive Director Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; and James Gilman, M.D., Chief Executive Officer, NIH Clinical Center, for their work in recruiting these new members, who should add value to the CCRHB.

Dr. Forese said that as the CCRHB moves into 2020 with new members, the group should think about the CCRHB's focus and the best ways to support the activities and challenges of the Clinical Center. The group can discuss this during the meeting and offline.

NIH Director's Remarks

Francis Collins, M.D., Ph.D., Director, NIH

Dr. Collins welcomed and thanked everyone on the CCRHB. He thanked Dr. Forese for being a wonderful chair. Dr. Clancy can no longer serve on the CCRHB, because of a new rule that an employee of a government agency cannot be an advisor on a committee for another government agency. While this is a loss for the CCRHB, this is a good opportunity for new membership and new talents.

Dr. Collins thanked Dr. Tabak for his contributions to the CCRHB and acknowledged that Dr. Tabak recently received an honorary degree from King's College London.

Dr. Collins said that he appreciated how the Clinical Center continues to provide excellent care for patients in need. Dr. Collins receives many letters and emails from grateful patients about their dedicated care teams and excellent experiences at the Clinical Center. Many Clinical Center staff have received awards for excellence, including W. Marston Linehan, M.D., Chief, Urologic Oncology Branch, and Senior Investigator, National Cancer Institute, a leader in defining the genetic basis of kidney cancer and one of 24 finalists for the Service to America Medals.

Update on the NIH Budget

Congress has not passed a budget for fiscal year (FY) 2020, but there is a continuing resolution (CR) that funds the government through November 21. The NIH budget was on a good track through Congress. The FY 2019 budget for NIH was \$39 billion; the House of Representatives proposed increasing the FY 2020 budget by \$2 billion, and the Senate proposed increasing the budget by \$3 billion. If the Senate's proposed budget is adopted, the NIH budget will be \$42 billion, a 40% increase from the FY 2015 budget.

The major issues with passing the FY 2020 budget are the potential impeachment and the fight to fund the border wall. If the budget is not resolved or another CR is not passed by November 21, there will be a government shutdown. NIH was not affected by the government shutdown of 2018–2019 because its budget for FY 2019 was already approved, but if the government shuts down this year, NIH will have to stop operations.

During the 16-day government shutdown in 2013, the Clinical Center could not admit any new patients unless they were extremely ill and near death or were approved by the U.S. Office of Management and Budget. The Clinical Center was forced to turn away hundreds of people who were scheduled to be admitted, and staff and volunteers who were not critical for patient care were barred from the NIH campus. Students, postdoctoral fellows, and researchers were prohibited from conducting research, resulting in failed experiments and lost work. Hopefully, these devastating circumstances will not happen again.

The aging of the building and facilities of the Clinical Center has numerous consequences. There are limitations on how appropriations can be spent for buildings and facilities, and Congress is less enthusiastic about allowing spending for these needed repairs and upgrades. [“Managing the NIH Bethesda Campus Capital Assets for Success in a Highly Competitive Global Biomedical Research Environment,”](#) a report commissioned by Congress from the National Academies of Science, Engineering, and Medicine, strongly supports the need to take action to upgrade NIH's buildings and facilities. According to the report, NIH needs \$1.3 billion in funding to upgrade its buildings and facilities, with \$700 million needed over 5 years for maintenance needs and \$600 million for new facilities and projects, such as the new Surgery, Radiology, and Laboratory Medicine (SRLM) Building. This document and NIH's strong relationship with Congress will help these maintenance efforts. The issues with the buildings and facilities are getting worse, and NIH cannot accomplish medical and scientific breakthroughs if the spaces are not well-maintained.

Discussion

- Reed Tuckson, M.D., said that the CCRHB toured the Clinical Center, and while the group admired the progress that has been made with the space, there were concerns with various maintenance issues. The CCRHB could share these concerns in a letter that could be used as a supporting document during the congressional budget discussions. Dr. Collins said that a letter that supports funding building and facilities maintenance would be very welcome, particularly since the CCRHB is composed of outside experts. Dr. Forese and the other Board members agreed with Dr. Tuckson's suggestion. Dr. Tuckson agreed to write a draft letter that can be reviewed by the group.
- Stephanie Reel, M.B.A., asked whether the CCRHB could also provide support for adopting an FY 2020 budget or CR and avoiding a government shutdown by sharing the terrible consequences of a shutdown for NIH. Dr. Collins said that the damage to NIH and Clinical Center was prominently publicized during the last government shutdown, so there may not be a need for added support, but NIH will lean on the Board if necessary.
- Brig Gen James Burks, M.B.A., M.M.A.O.S., agreed with Ms. Reel's suggestion and said that the Board members should lend their support for other issues as well, such as the alarming problem of turning patients away from the Clinical Center during a government shutdown. Dr. Collins said that the CCRHB letter about the buildings and facilities will be timely for the upcoming budget discussion with Congress, since these maintenance issues cannot be delayed any longer.

NIH Clinical Center Chief Executive Officer Update

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

After greeting the CCRHB members, Dr. Gilman said that similar to the CCRHB, Douglas Lowy, M.D., Acting Director of the National Cancer Institute (NCI) and Chair of the Clinical Center Governing Board (CCGB), and the CCGB have initiated a "re-visioning" process as well.

Clinical Center Census

Dr. Gilman reported that the Clinical Center's average daily census (ADC) was low for the first quarter of FY 2019, but there was a steady increase over the course of the year. The ADC for FY 2019 was 116, which is three patients higher than the ADC for FY 2018.

Awards and Recognitions

The second annual Clinical Recognition Program: Trans-NIH awards were held recently, and three awards were presented. The Staff Clinician of the Year Award was given to Douglas Rosing, M.D., from the National Heart, Lung, and Blood Institute (NHLBI). Ruth Parker, DNP, FNP, from the Clinical Center, received the Nurse Practitioner of the Year Award, and Elise Ferre, PA-C, M.P.H., from the National Institute of Allergy and Infectious Diseases (NIAID), was named Physician Assistant of the Year. A new award was added this year to honor outstanding administrative excellence in support of the Clinical Center's mission. Maureen McDonnell, from the Office of Workforce Management and Development at the Clinical Center,

won the Clinical Center Administrator of the Year Award after a unanimous vote by the awards committee.

Several Clinical Center staff recently received national awards.

- Joseph A. Kovacs, M.D., a Senior Investigator, Head of the AIDS Section, and Head and Scientific Director of the 4D Lab at the Critical Care Medicine Department, won the American College of Physicians Award for Outstanding Work in Science as Related to Medicine.
- Ann Berger, M.D., M.S.N., Chief of the Pain and Palliative Care Department, was honored with the 2019 University of Toledo College of Medicine and Life Sciences Distinguished Alumna Award.
- The 2019 American Society for Bioethics and Humanities Lifetime Achievement Award was given to Christine Grady, Ph.D., M.S.N., Chief of the Department of Bioethics and Head of the Section on Human Subjects Research.

Staffing Updates

There have been some recent staffing changes at the Clinical Center.

- Daniel Lonnerdal, M.S., FACHE, is the Clinical Center Executive Officer.
- Richard DeCederfelt, Pharm.D., is the Acting Chief of the Pharmacy Department
- Harvey Klein, M.D., retired as the Chief of the Department of Transfusion Medicine (DTM). Cathy Conry-Cantilena, M.D., is now the Acting Chief of the DTM.
- Jose Galvez, M.D., is leaving his position as Chief of the Biomedical Translational Information System (BTRIS) for a new position at the U.S. Food and Drug Administration (FDA). Jon McKeeby, D.Sc., will serve as Acting Chief of BTRIS in addition to his role as Chief of the Department of Clinical Research Informatics

There will be a search for a new Chief of BTRIS, and in the interim the BTRIS Chief's salary dollars will support hiring assistance for Dr. McKeeby. There are two national search committees in process at the CC for the Chief Medical Officer and the Chief of the DTM and the Center for Cellular Engineering.

Dr. Klein retired as the Chief of the DTM in September after 36 years at NIH. His work made U.S. blood transfusions safe. He was recently appointed as an NIH Scientist Emeritus, but his presence at the Clinical Center will be missed. Dr. Forese proposed that the CCRHB send a statement of appreciation to Dr. Klein for the support and guidance he provided to the Board. The group agreed.

Dr. Gilman said that David Henderson, M.D., will retire as the Deputy Director for Clinical Care and the Associate Director for Hospital Epidemiology and Quality Improvement at the end of December. He has worked at the Clinical Center for 40 years and has been a wonderful friend and support at the Clinical Center. He will serve as the President of the Society of Healthcare Epidemiology of America in 2020. The CCRHB expressed their appreciation to Dr. Henderson, who was present at the meeting.

Clinical Center Facility Updates

Dr. Gilman reported that since the release of the report from the National Academies of Science, Engineering, and Medicine, conversations about funding building and facilities updates with members of Congress who tour the Clinical Center have been encouraging, particularly about the amount of and urgency for funding. NIH and Clinical Center leadership are optimistic.

The outpatient pharmacy is relocating on November 18 to allow for renovations of the space and the intravenous admixture unit (IVAU). There is a large communication plan to inform staff and patients about the new location of the outpatient pharmacy. The outpatient pharmacy will remain in this relocated space until 2021, when the pharmacy renovations should be complete.

2019 Priorities: Violence in the Workplace and Anti-Harassment Campaign

The Clinical Center established four priorities for 2019, two of which focused on staff safety: violence in the workplace and NIH's anti-harassment campaign. While the Clinical Center is very safe, it is important for staff to know how to handle an insider threat, such as an unhappy or belligerent family member, patient, or staff member.

The goal is to hire additional patient care technicians, provide training to nursing staff and others in crisis response and de-escalation, and respond as a group when one of these events occurs. Additionally, there are plans to have health care providers available after hours and on weekends to write orders or prescribe medications if needed during an event. This initial work is being led by Walter Koroshetz, M.D., Director of the National Institute of Neurological Disorders and Stroke (NINDS), and others at NINDS. These training and response efforts should be in place at the beginning of 2020.

Dr. Collins and NIH leadership are working hard to eliminate harassment at NIH. Capt Antoinette Jones, M.S.O.D., RN, and a response team of Clinical Center staff are leading an effort to address inappropriate behavior and harassment by patients and visitors toward Clinical Center staff. The NIH Civil Program at the Office of Human Resources is training this response team in how to handle and assess harassment situations. The team is also writing policies and formulating an educational toolkit for frontline staff, as well as a chart of penalties; for example, if the harassment was a one-time offense, the caretaker will be reassigned. If the perpetrator persists in their harassment, there will be stronger penalties. These trainings and policies will also launch in early 2020.

Professionalism was another Clinical Center priority for 2019. In July, Jo Shapiro, M.D., FACS, Director at the Center for Professionalism and Peer Support at Brigham and Women's Health Hospital, gave a seminar about the key to a culture of trust with the Clinical Center's Medical Executive Committee and during Clinical Center Grand Rounds. These presentations were very well received, and many Institute and Center (IC) clinical directors want Dr. Shapiro to speak with their groups.

Discussion

- Dr. Forese asked about whether the Clinical Center is considering the nuances of harassment within the anti-harassment plan. There are gray areas involved with harassment, such as gender preference for caretakers or issues with cultural competency. Dr. Gilman said that Capt Jones and her team are considering these issues, but a major issue is that incidents of harassment are often not reported and can be more common for certain groups of staff; for example, members of housekeeping and nutrition staff often

experience harassment. The first step is to codify, quantify, and track harassment issues at the Clinical Center. Then the Clinical Center will create a team trained to respond and assess harassment events in order to provide consistency. Finally, there will be a set of penalties based on the type and frequency of harassment. This will be a gradation of penalties that will set a high threshold before a patient will be turned away. The goal is to have a system to document offenses and communicate to Clinical Center staff that their safety and freedom from harassment is a priority.

- Dr. Forese said that there needs to be consistency when assessing and penalizing harassment. New York-Presbyterian Hospital has a Chief Respect Officer who has a legal background and provides some consistency when looking at reported incidents of harassment; it could be beneficial to have a similar position at the Clinical Center. Dr. Gilman suggested that consideration could be given to expanding the role of the Clinical Center Patient Representative to include these responsibilities.
- Dr. Shannon said that employees involved in clinical care want to identify best practices for addressing violence in the workplace. Staff at the Clinical Center have a unique opportunity to share their experiences about how to intervene appropriately in instances of violence and harassment.

Medical Research Scholars Program (MRSP)

Thomas R. Burklow, M.D., Director, MRSP

Dr. Burklow thanked the Board for the opportunity to speak about the MRSP. The mission of NIH is “to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.” NIH must support the growth of a workforce that helps this mission. In recent years, the number of graduates from medical school has been increasing, but the number of physicians who remain in medical education and research remains flat. While the R01 award rate by physician applicants is high, the overall number of R01-funded physicians is decreasing.

The Howard Hughes Medical Institute (HHMI)–NIH Research Scholars Program, which started in 1985, was for students to receive research training at NIH. The Clinical Research Training Program (CRTP) was active from 1997 to 2012 and provided a clinical or translational research opportunity for medical and dental students. In 2012, HHMI withdrew support for the Research Scholars Program, so the CRTP expanded and created the MRSP. Since 2012, the MRSP has been a comprehensive, year-long residential research enrichment program for medical, dental, and veterinary students.

The MRSP is funded mostly by intramural NIH funding and also by the Foundation for NIH, which receives donations from the Doris Duke Charitable Foundation, Genentech, the American Association for Dental Research, the Colgate-Palmolive Company, and others.

The MRSP is not simply a research program for medical, dental, and veterinary students but rather is a career development program for students seeking careers as leaders and investigators in biomedical research that is centered on a robust investigative experience. The MRSP wants to nurture students’ research interests and investigative abilities in the fields of basic, translational, and clinical research; teach scholars how top-tier science is conducted and help them develop

effective verbal and written communication skills; and instill the highest standards of professional behavior.

Several key facets of the MRSP make it a comprehensive career development program that is unique.

- A core investigative experience with a mentor and advisors assigned to scholars. Scholars conduct research that spans a range of disciplines, including basic, translational, and clinical research.
- Process of Discovery seminars where investigators share their work, insights about their career path, and the art of clinical care.
- Clinical teaching rounds.
- A didactic journal club where each session has a topic or theme (e.g., bioethics, Phase I trials, meta-analysis) and scholars provide background and share articles about the topic.
- Optional workshops that range from peer support with past scholars offering advice to current scholars, CV writing, interview skills, and work–life balance. These workshops are meant to help scholars successfully compete for grants and professional positions.
- Ongoing seminars from world-renowned researchers.

A published outcomes study about the CRTP found that most graduates of the program participated in research during their residency and that many obtained faculty positions after their medical training. In the area of cancer research, for example, several CRTP alumni currently hold senior director positions at biotechnology or pharmaceutical companies. Since the MRSP was established in 2012, the program has supported 319 scholars. Although only 30% of MRSP alumni have returned post-program surveys, the responses indicate that more than half of MRSP alumni have participated in research during residency, and more than half have published at least one scholarly publication after receiving their professional degree. Of the 25 alumni who completed their residencies, 22 entered a fellowship training program after residency.

There were 37 scholars in the MRSP Class of 2018–2019. Additionally, the program is proud that several graduates are extending their research endeavors. Two scholars matriculated into the NIH Oxford-Cambridge Scholars Ph.D. Program, one scholar entered the Graduate Partnership Program (GPP) with University College London, one scholar began a NIH postdoctoral research fellowship, and another scholar continued as a second year fellow in the NIH Postbaccalaureate Intramural Research Training Award (IRTA) program to continue his research. These post-program results indicate that the MRSP is inspiring individuals to remain in research.

The scholars are exposed to many opportunities that are unique to NIH, including using cutting-edge technologies (e.g., flow cytometry, state-of-the-art imaging modalities), taking on-campus courses with the Foundation for Advanced Education in the Sciences, learning statistical programming, publishing their research, traveling to conferences, and participating in public speaking.

Most students who enter the MRSP are between their third and fourth years, with some in between their second and third year. There are a few students who defer graduation to participate

in MRSP after completing their fourth year of studies. There are 39 medical, dental, and veterinary schools represented among the current and former MRSP scholars. The MRSP seeks a diversity of ideas, gender, geography, and race when accepting students.

The MRSP scholar benefit package includes a monthly stipend, relocation expenses to and from Bethesda, residential furnished housing in Building 60 on the NIH campus, health insurance, and a personal education fund for conferences, courses, and textbooks; the scholar's laboratory usually provides additional funding for these professional expenses.

The application deadline for the 2020–2021 MRSP is January 10. Last year, the program received 133 applications, but this number is expected to increase for 2020–2021. Applications will be reviewed by a panel of NIH staff, and 90 to 95 students will be invited to NIH for interviews. Accepted students must respond by mid-March, coinciding with the acceptance deadlines of other research training programs, including the Sarnoff Fellowship Program and the Doris Duke Charitable Foundation's International Clinical Research Fellowship. The program will begin in July 2020.

The MRSP is continually working on outreach to schools, because students often do not know about the program. Dr. Burklow reaches out to medical school deans, student bodies, and associations and professional societies to arrange in-person visits or informational webinars to promote the program.

Discussion

- Dr. Tuckson expressed appreciation for the fact that 22% of the 2018–2019 scholars were from underrepresented minorities and suggested that the MRSP should work with Hannah Valantine, M.D., M.R.C.P., to continue promoting diversity in the program. Dr. Tuckson also said that among the list of represented universities, there were no Historically Black Colleges and Universities (HBCUs), and he could work with the MRSP to engage with those schools about the program. Dr. Burklow thanked Dr. Tuckson and said that engaging with HBCUs is one of his goals. John Gallin, M.D., said that NIH is working to build a stronger clinical research relationship with Howard University, including partnering with two tenure-track faculty and having students participate in NIH summer research programs.
- Dr. Gallin said that even though measurement of the CRTP and MRSP outcomes shows that only about half of alumni have careers in clinical research, there is still value in this program to expose future care providers to the importance of clinical research. All medical students should be exposed to research, so that once they become doctors, they can recommend their patients for relevant clinical trials. Dr. Burklow agreed and said that the MRSP wants scholars to become leaders in their systems and facilitators of clinical research by implementing best practices and coordinating care with research institutions.
- Dr. Tuckson agreed with Dr. Gallin and Dr. Burklow's sentiments, and said, speaking as a member of a number of National Academy of Medicine committees, that the common question is how to create a learning health system and engage clinical professionals with this process. NIH should continue this work of training future doctors but also reach out

to practicing physicians to reinforce the importance of being involved with clinical research.

- Ms. Bowie asked whether students from international schools were able to participate in the MRSP. Dr. Burklow said that scholars can be from international schools but must be U.S. citizens or permanent residents.
- Dr. Shannon thanked Dr. Burklow for the update and said that there was a recent [New York Times opinion piece](#) about the need for more physician-scientists. Although this is an issue, medical school curricula are making it difficult for students to participate in research. Some schools have a research requirement, but there are very few programs that are as rigorous as the MRSP. The MRSP is unique because this opportunity does not cost students, who are actually paid to conduct research—an advantage for students with loan debt. Additionally, the MRSP, Sarnoff, and the Doris Duke Charitable Foundation should consider forming aggregate data about program outcomes to understand their impact. Dr. Burklow appreciated these suggestions. The MRSP is also interested in publishing more comprehensive data about the program's outcomes. Regarding the student stipend, scholars can enter a loan repayment deferral program.
- Ms. Reel asked whether there were data science requirements, since many investigators have limited data and statistics skills. Dr. Burklow said that Norman E. Sharpless, M.D., recently made a presentation about big data at a Process of Discovery seminar. There are also opportunities for MRSP scholars to focus their research on aggregate data, so they can enhance their knowledge of data and statistics.
- Dr. Tabak said that medical and dental schools are packing their curricula and not allowing students time to leave the school to pursue scholarly research. The top 10 medical schools may become the only schools that give students time for scholarly research, and representation from other medical schools will fall. Dr. Burklow agreed and said that the MRSP is focused on establishing relationships with schools so they understand the importance of allowing their students to participate in this program. Dr. Forese also agreed with Dr. Tabak's point and emphasized the importance of promoting the prestige and benefits of the MRSP.
- Dr. Forese said that while the percentages of underrepresented minorities and women in the MRSP are good, reaching out to diverse schools and working with Dr. Tuckson and Dr. Valentine to promote diversity in the program are important.
- Dr. Tuckson said that he will be meeting with the new president of the Association of American Medical Colleges (AAMC), David J. Skorton, M.D., to finalize a set of priorities for the association and could share information about the MRSP with him. Dr. Forese agreed and said that the MRSP deserves the AAMC's attention.
- The group discussed the importance of networking and sharing the impact of the MRSP. Dr. Forese thanked Dr. Burklow for sharing information about the program with the Board.

Patient Safety and Clinical Quality Update

Laura Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality

Joint Commission Engagements

Ms. Lee said that the Joint Commission's unannounced visit to the Clinical Center to assess ligature and electrical wiring risks for suicide prevention went well. The surveyor provided some recommendations, and the Clinical Center was able to resolve those issues and remains compliant with ligature and electrical wiring risks.

Two sentinel events were reported to the Joint Commission. One incident involved a spark that came from a tool that crimps tubes on blood collection bags and the spark caused a minor abrasion of a patient's thumb. The Joint Commission requires that any events involving sparks, fire, or smoke be reported, so the Clinical Center Office of Patient Safety and Clinical Quality reported the event to the Joint Commission and submitted the results of the organization's root cause analysis to the Joint Commission. The Joint Commission accepted the root cause analysis findings and recommendations for improvement.

The second event was an unexpected operative death that was reported to the Joint Commission. After discussions with staff from the Joint Commission's Office of Quality Monitoring, the incident was not considered a sentinel event, based on the complexity of the case and the patient's comorbidities. Nevertheless, the Office of Patient Safety and Clinical Quality performed a root cause analysis with the surgical teams and will share this case and the analysis at an upcoming Systems-based Morbidity and Mortality Rounds.

Performance Metrics

There was an increase in bloodstream infections in the second quarter of 2019, with infections occurring in three patients. Two were long-term patients who had suboptimal personal hygiene practices that might have contributed to these infections. There was also a shortage of the caps required for the central line that could also have been an underlying cause. These incidents will be investigated so that improvements can be made.

Surgical site infections tripled in the last quarter, occurring in 11 patients. These cases were reviewed by Tara N. Palmore, M.D., Hospital Epidemiologist, Clinical Center, with the chief surgeon. They found that there were no trends associated with this increase, but these metrics will continue to be monitored.

The Clinical Center is compliant with perioperative administration of antibiotics less than 60 minutes before incision more than 90% of the time. The rate of compliance for postoperative antibiotic discontinuation within 24 hours is also over 90%. The decrease in compliance for postoperative antibiotic discontinuation in the second quarter of 2019 was due to complex patients.

The number of inpatient falls at the Clinical Center is decreasing and is well below the national benchmark. Pressure injury prevalence is also decreasing, due to a combination of training and new equipment.

The goal for medication administration barcode use is 100%; however, the Clinical Center rate is around 99%. Multiple factors contribute to this 1% discrepancy, including electronic health record configuration for select medications and the occasional missing barcode labels on topical medication tubes. In addition, the Clinical Center has not implemented barcoding in radiology. Implementation in the imaging environment will be launched in 2020. Human error is a contributing factor for a very small subset of barcode nonuse cases.

The Clinical Center is working on an outcomes project focused on pain management. The first phase of the project analyzed acute postoperative pain, using patient self-assessment scores. A more detailed presentation about these results will be shared during the April CCRHB meeting, but the preliminary results show that there was a decrease in mild, moderate, and severe pain post-pharmacologic interventions. Patients who indicated having high pain had the most significant response to pain management interventions. These data and the role of adjuvant therapies need to be analyzed further. The second phase of this project will focus on chronic pain.

2019 in Review

There were several key organizational initiatives for 2019.

- To ensure that patients who require urgent medical attention during off-hours, weekends and holidays receive it, an unplanned admissions triage process was developed for unexpected patient readmissions.
- A massive transfusion protocol was developed to guide the management of blood transfusions during massive bleeds. Clinical Center staff are actively using this protocol, and an assessment occurs each time the protocol is triggered. The staff and fellows at the Department of Transfusion Medicine have been very active in the development and implementation of this protocol and have provided guidance to clinicians when there is a massive bleeding crisis.
- NINDS has been an integral part in developing the Brain Code, which outlines the process of transferring patients who are suspected of having a stroke to Suburban Hospital for rapid assessment and treatment.
- At the suggestion of the CCRHB, the Clinical Center now allows patients and families to activate the Rapid Response Team (RRT). This option has been activated since September, and, to date, there have been no patient-activated RTTs. The Office of Patient Safety and Clinical Quality will continue to publicize this resource to patients and families.
- The SuperSTARS program and awards recognizes Clinical Center staff who go above and beyond the call of duty or who notice and address an issue to keep patients safe.
- The Safe Patient Handling Initiative, which focuses on keeping employees safe while they move patients around the Clinical Center, includes training, new equipment, and a culture shift to have employees slow down so that they stay well.

- OpenNotes™, a collaboration with Beth Israel Deaconess Medical Center to open progress notes to patients, has been well-received at the Clinical Center. A few patients have contacted their clinicians to ask them to correct aspects of their notes, and it is great to see that patients are using and reviewing these notes. The sites that use OpenNotes across the United States are looking at how patients are using the program. There were some preliminary analyses to determine which types of documents inpatients and outpatients viewed. Inpatients most commonly viewed patient education notes, while outpatients looked at progress notes.

Looking ahead to 2020, the pain management project will continue with a hospital-specific opioid stewardship program, and a memorandum of understanding will be established with Walter Reed National Military Medical Center to provide support for vascular surgeries. There will also be efforts for simulation, telehealth, and medication reconciliation. The Clinical Center will establish a process improvement coordinator role as well.

Discussion

- Dr. Forese said that since barcode scanning has not been implemented in radiology, then the data from radiology should not be included in the barcode use analysis. Ms. Lee agreed and said she took a deep dive into the data to understand the cause of barcode scanning deviations. Dr. Shannon agreed with Dr. Forese's comment but said the exercise of carefully analyzing beyond the aggregate data is a good practice. In response to a question from Dr. Gilman, Ms. Lee said that the Clinical Center will implement barcode scanning in radiology soon.
- Brig Gen Burks said that it is important to remember that the percentage of barcode scanning used to be around 90%. The fact that barcode scanning is at 99% speaks to the successful effort to find and address the barriers with scanning over the past 3 years.
- Dr. Tuckson asked whether the pain management project was meant for internal improvement or could be published. Ms. Lee said that the project's primary focus is internal improvement but that the Clinical Center could provide guidance to others in particular areas of interest. The Clinical Center Pain and Palliative Care group is integrated with the project and could be involved in creating a publication. Dr. Tuckson said that it would be best to think proactively about how to shape the questions and analyses for publication.
- Dr. Tuckson asked about the difficulties of tracking metrics. Ms. Lee said that there is a struggle in tracking events around surgical complications, because there is a low volume of unique cases.
- Dr. Tuckson asked whether the two patients with bloodstream infections who had suboptimal hygiene habits also had behavioral health comorbidities that could have affected their hygiene. Ms. Lee said that the two patients did not have any known behavioral health patients, but they were long-term patients with chronic health issues. In addition to the personal hygiene factor, both patients required many medications and blood draws, so their ports were continually being accessed. Caring for long-term patients

can be a challenge for the Clinical Center. There is now a guideline that long-term patients must change rooms at certain intervals so rooms can be cleaned thoroughly.

- Dr. Gallin said that the OpenNotes process is exciting, particularly in that inpatients have access to their progress notes, and asked whether the group could track whether OpenNotes affected how staff wrote their progress notes. Ms. Lee said that the OpenNotes team released a survey that asked these questions of clinical staff before the launch and will release a follow-up survey within a year to compare responses and determine progress. After Dr. Gallin's comment, Ms. Lee said that OpenNotes is not a company or a vendor; it is a health care movement focused on fostering transparency in health care.
- Dr. Forese asked whether the Clinical Center will be conducting a research project with the OpenNotes group. Ms. Lee said it would. Dr. Forese liked that there will be research and said that it was fascinating to see the differences in what inpatients and outpatients were viewing in their OpenNotes, and specifically that inpatients were viewing education notes.
- Ms. Reel said that the staff at Johns Hopkins University and Health System found that patients had better outcomes and understanding of interventions when they had sustained engagement with clinical or nursing staff. Therefore, while OpenNotes will make a difference, it is important to remember to promote more interactions with the patients. Ms. Lee agreed and said that the Clinical Center is actively working to improve the clarity and timeliness of practitioner documentation.
- Ellen Berty said that she loved OpenNotes and did not think they were in a cut-and-paste style. Ruth Brinkley, M.S.N., said that she also loved the concept of OpenNotes, because it allows patients and families to be involved in care. It is also great that the Clinical Center will be involved in research about the OpenNotes process.
- Dr. Shannon said that the Clinical Center continues to grow in measuring inpatient safety. While there are relatively few safety issues, there is also a unique opportunity to analyze and understand these events deeply.
- Dr. Forese said that the Clinical Center is looking to receive Magnet® designation. Dr. Gilman said that the Clinical Center hired Rachel Perkins, RN, as a Magnet coordinator, and the goal is to put together the work for the application in 2020 and apply in 2021.
- Ms. Berty asked about the Magnet designation. Dr. Gilman said that this designation indicates that the health care organization values nurses and is a place where nurses love to work. Dr. Forese said that it was an exciting opportunity.

Update on the Quality Improvement Assessment (QIA) from the Clinical Center Office of Research Support and Compliance (ORSC)

Virginia Guptill, Ph.D., Director, Clinical Center ORSC

Alissa Mun, M.S., Senior Quality Assurance Manager, Clinical Center ORSC

Dr. Guptill thanked the CCRHB for the opportunity to provide an update about QIA, which is the first major initiative from the ORSC.

In 2016, an NIH investigator received an FDA Form 483 for failing to report deaths, serious adverse events, and unanticipated problems that occurred during their study. In response to this event, the ORSC sent a data call to NIH investigators, asking whether they reported these types of events to FDA or the Office of Human Research Protections (OHRP) within the required reporting time frame and whether there were any additional events that were not reported. The results indicated that NIH was not compliant with reporting requirements. The ORSC developed a corrective action plan in collaboration with the Office for Human Subjects Research Protections (OHSRP).

The corrective action plan decided to increase awareness across ICs via training initiatives that focused on what reportable events are, to whom these events should be reported, and how promptly to report events. These training initiatives were required for all NIH investigators. At the end of the training ORSC wanted to know how to measure the training's success, whether there were other areas of compliance that were lacking at NIH, and how to assess protocol compliance globally.

Ms. Mun said that the ORSC established a QIA working group (WG) of subject matter experts in quality assurance for protocol monitoring and auditing. The WG asked ICs for their protocol monitoring processes and defined baseline measurements and key components for human subject protections, informed consent processes, documentation of eligibility, and unanticipated problem reports that were required to be reported to the institutional review board (IRB) or sponsor. The WG also identified a third-party reviewer to provide a global assessment of the intramural program's progress.

The QIA WG reviewed 105 protocols from the Intramural Research Program and 18 ICs, including off-campus sites, and gathered data from the third-party reviewer to analyze global NIH trends for process improvement. The WG found that more than 80% of reporting involved documentation problems for informed consent and eligibility. The ORSC's Clinical Research Quality Management (CRQM) section analyzed the issues with documentation of informed consent and found that there were limitations with capturing how consents occurred. Also, the progress note in the Clinical Research Information System (CRIS) was not being used, because clinicians either did not know about the note or were required to use the note. The WG and the CRQM section revised the documentation of consent note in CRIS and worked with the OHSRP and Health Information Management Department (HIMD) to update policies to require documentation of the consent process in the medical record or research record. This note will launch in January 2020.

The third-party reviewer recommended that the ORSC develop training programs for the clinical research staff. The CRQM section created a 3-day in-person training, called the Good Clinical Practice (GCP) training, for NIH investigators. Based on the investigation feedback, the GCP program is currently being revised. The section also created an online refresher training for NIH IRP sponsors. Another training developed by the section is the Corrective Action and Preventative Action (CAPA) training. This training involves three seminars for investigators and research staff to learn the basics of CAPA, when it is required, the process for developing a CAPA plan, and the tools to use for CAPA.

Based on the QIA, there will be an NIH-wide audit in 2020 to analyze the informed consent process, eligibility, problem reporting, protocol compliance, regulatory documentation, patient safety, and CAPA. This audit will measure the success of trainings, the implementation of documentation for informed consent, and the updated policies.

The QIA resulted in additional collaborative assessments. The Clinical Center Investigational Drug Control Unit (IDCU) worked with the ORSC to define consistent roles and responsibilities of the IDCU, investigators, and sponsors for distribution of investigational products. Another collaborative assessment with OHSRP is meant to identify trends and processes during the transition of the 12 IRBs within NIH to a single entity.

The collaboration between the ORSC CRQM and OHSRP resulted in two projects. The first is an NIH Event Reporting dashboard that tracks reportable events submitted to FDA and the Office of Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (HHS). This dashboard is used to identify global NIH trends, where NIH can improve, and where NIH has improved, and the section generates quarterly and annual reports for Dr. Gilman; Michael Gottesman, M.D.; and Jonathan Green, M.D., M.B.A., that identify key trends, responses by office and section, and recommendations for further action. The dashboard has the capability to track the types of events that are reported and who is reporting these events. One of the trends noted in the NIH Event Reporting dashboard is more than 60% of reports are identified by study team members, indicating that training about reporting is effective.

The second collaboration with OHSRP is improving the quality improvement and quality assurance data call. The purpose of this data call is to ensure the NIH is meeting the standard set forth by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) on how ICs measure improvements, quality and effectiveness in compliance, policies, and procedures. The data call is now in an accessible smart form with standardized data elements and branching logic.

In the future, the ORSC CRQM Section plans to develop an auditing and monitoring program for ICs who do not have functionality, reconvene with QIA WG to standardize the process of documenting eligibility, and develop a data warehouse for reportable events forms for the IRB, to be separate from the dashboard that tracks events submitted to HHS agencies. The ORSC CRQM will also develop training for Part 11 Compliance on electronic records and signature compliance for sponsors, investigators, and data managers and will continue creating a quality management system.

Dr. Guptill provided an overview of four of the five sections of the ORSC. The work of the Clinical Research Quality Management section was described by Ms. Mun:

- The Protocol Navigator section provides support to clinical investigators with every step of writing and submitting protocols to the IRB. As the 12 IRBs become one centralized IRB, this section is working to develop a checklist of processes and procedures and is offering quality control checks for protocols to ensure it follows the new IRB standards.
- The Regulatory Support section for investigational drugs and devices (INDs/IDEs) acts as the sponsor's authorized representative. The IC acts as a sponsor, and the director acts as the signatory sponsor. This section communicates with FDA for the sponsor, helps with initial and continuing applications, determines whether investigators need to submit an IND or IDE, and supports clinical investigators during FDA inspections.
- The Research Regulatory Affairs-Facilities section provides regulatory support for aseptic processing facilities on campus and develops standard operating procedures, guidance documents, and templates to ensure the facilities stay in compliance and meet regulatory requirements. The section also provides trainings in GMP and environmental and specialized monitoring, assists with FDA inspections of facilities, implements document management control systems, and manages the facilities' specialized contracts.
- The Protocol Coordinator section is the newest section and is staffed by clinical research nurses and people with clinical research experience. This section provides operational support for the conduct and implementation of protocols and helps investigators understand their responsibilities.

The ORSC is a research support organization that continues to grow in both personnel and operations. If the research is done correctly, compliance is part of the research business. Dr. Guptill thanked Dr. Gilman, Dr. Gottesman, and Dr. Henderson for their support, and the Clinical Center Governing Board for their financial support.

Discussion

- Dr. Forese thanked Dr. Guptill and Ms. Mun and asked whether it was optional for investigators to work with these sections. Dr. Guptill said that the Research Regulatory Affairs-Facilities organization is a centralized support that is required for facility operations, but the support of the other sections is optional.
- Dr. Gilman said that ICs with larger budgets already have these resources, but smaller ICs may not be able to afford the staff and resources required for compliance. The ORSC is a coordinating point for these IC offices. Dr. Guptill said that the Protocol Navigator section was formed based on feedback from ICs that wanted support through the new IRB process. The section fully supports five ICs and partially supports three ICs, but investigators are always welcome to ask for help.
- Dr. Forese said that the ORSC could begin to create best practices for various issues as more ICs are reaching out for support.

- Ms. Brinkley asked whether the ORSC shares best practices with the larger ICs to maintain consistency. Dr. Guptill said that Ms. Mun runs and participates in WGs (e.g., QIA and Quality Assurance Professional Advisory Committee) and that anyone from the ICs is welcome to participate.

***Sphingomonas koreensis* Investigation and Management of Nosocomial Reservoirs**

Tara N. Palmore, M.D., Hospital Epidemiologist, Clinical Center

Anna F. Lau, Ph.D., D(ABMM), Chief, Sterility Testing Service, Department of Laboratory Medicine, Clinical Center

Jonathan N. Yoo, Engineering Team Chief, Division of Facilities Operations and Maintenance, Office of Research Facilities (ORF)

Dr. Palmore said that there are millions of nosocomial infection cases in patients in the United States every year. Although nosocomial infections are often associated with equipment or devices, they were never really associated with hospital infrastructure, particularly the water system, apart from Legionnaire's disease. Municipal water systems are tested for bacteria, especially fecal coliforms such as *Escherichia coli*, and treated with chlorine; however, the water is not tested for every type of bacteria or pathogen. Bacteria in municipal water can concentrate in water distribution systems, cooling towers, and point-of-use plumbing, such as sinks and ice machines.

Bacteria can concentrate in the pipes of a hospital water system, because the chlorination of the water dissipates as water travels through miles of pipes. Pipes can also develop biofilms, which are low-nutrient environments where bacteria can live for a long time and be protected from chlorine. Biofilms form in stagnant, or "dead leg," pipes, where there is a low flow of water. These factors promote nosocomial transmission of bacteria through water, such as water getting on patients after a health care provider washes their hands or droplets spraying on patients from a sink. Usually immune-suppressed patients or patients with invasive devices are most vulnerable to waterborne pathogens.

At the Clinical Center in 2016, a 20-year-old man with congenital immunodeficiency had pneumonia and was intubated in the intensive care unit (ICU). His blood cultures grew *Sphingomonas koreensis* that was resistant to carbapenems, cephalosporins, aminoglycosides, and piperacillin/tazobactam, which are first-line antibiotics used to treat pneumonia and sepsis. The *S. koreensis* cultures were susceptible only to ciprofloxacin and trimethoprim/sulfamethoxazole. The patient was treated with multiple antibiotics but died 3 days later.

Dr. Lau said *Sphingomonas* is a Gram-negative bacterium that produces bright yellow opaque colonies. *Sphingomonas* is ubiquitous across the environment and is found in low concentrations in tap, mineral, and distilled water. The bacterium has sphingolipids in its cell walls, making it a low-pathogenicity organism that can survive in nutrient-poor conditions.

In 2016, six Clinical Center patients had *Sphingomonas* species isolated from various clinical cultures. Four of the isolates had an unusual resistance to aminoglycosides, monobactams, cephalosporins, carbapenems, and beta-lactam combinations. These cultures had mixed susceptibility to fluoroquinolones and true susceptibility to trimethoprim/sulfamethoxazole.

The research group decided to review clinically relevant Clinical Center patient isolates from 2001–2016. The group identified 89 isolates reported in the medical record that had *Sphingomonas* species. Of these reported isolates, 66 were available and viable from frozen stock, and they represented 37 unique patients. The stocks' identities were confirmed by mass spectrometry and sequencing. The group tracked the various species of *Sphingomonas* in these 37 unique patient isolates. Interestingly, *S. koreensis* appeared only after the new section of the Clinical Center opened in 2005. The construction was completed and pipes were filled with water in 2004, and the space was occupied in 2005, so the water sat stagnant for a year.

For the plumbing of the sinks, the incoming hot water transverses into the mixing valve box to be mixed with cold water to produce warm water under the faucet. The sink piping in the wall is a mixture of vertical and horizontal piping, with many bends and crevices where biofilm can form. A biofilm culture from the rubber gasket in the piping and water from a horizontal pipe between two patient rooms tested positive for *S. koreensis*. Over a 15-month surveillance period, 54 *S. koreensis* isolates were identified in 17 patients' rooms and 22 sinks.

Dr. Palmore said that the isolates from the six 2016 patients were analyzed by Julia A. Segre, Ph.D., Senior Investigator in the Microbial Genomics Section of the National Human Genome Research Institute (NHGRI). Dr. Segre performed whole-genome sequencing and found that four of the patients were infected with *S. koreensis*; the four isolates were more than 99.9% genomically identical. The other isolates were two different and unrelated *Sphingomonas* species. Among 20 *Sphingomonas* samples from Clinical Center patients between 2006 and 2016, 12 were highly related to *S. koreensis* and had only 11– to 40–base pair differences, indicating that these samples were incredibly similar even over a span of 11 years. All of these *S. koreensis* isolates were highly antibiotic resistant. The genome of 40 *S. koreensis* isolates from the water and sinks differed from patient isolates by only 12 to 29 base pairs. Identical *S. koreensis* strains were found in adjoining rooms that shared water pipes. *S. koreensis* isolates from the Centers for Disease Control and Prevention (CDC) and the New York State Department of Health were genetically distinct from the Clinical Center isolates. The group concluded that the identification of highly clonal clinical *S. koreensis* isolates from 2006 to 2016 and highly genetically related isolates in the water supply suggest diffuse point sources resident in the Clinical Center.

Mr. Yoo said that water from the city enters the building at the B2 level and is distributed vertically and horizontally through interstitial spaces between the floors of the hospital. The cold water is kept fresh by a large number of sinks, toilets, showers, and other fixtures used throughout the day. The hot water is heated on B2 and kept fresh by a recirculation system. Within patient rooms, cold and hot water drop down from interstitial spaces through the main distribution, and the sinks have an automatic faucet with a mixing valve and aerator. The distribution of water to patient rooms is a problem when a patient room is not used. There is a

30-foot dead leg section of pipe from the main distribution pipe that can promote the growth of biofilm and dissipation of chlorine. Water stagnation can range from a few days to weeks, depending on room occupancy and faucet use. The U-shaped pipe trap, automatic faucet, and aerator all tested positive for *S. koreensis*.

In addition to the infrastructure issues, the chlorine levels in the water were analyzed. CDC and the World Health Organization (WHO) recommend maintaining free chlorine levels of at least 0.5 milligrams per liter in water. The chlorine levels in the water that comes into the building, in the main distribution, and in the interstitial space were all good, but levels at sinks low. Hot water has lower levels of chlorine due to the heating process, which increases the evaporation rate, and the recirculation process, which increases water age.

These issues were addressed as a collaborative effort between the ORF and the Clinical Center. The group was able to perform the work in phases to minimize downtime. The group first removed the aerators to reduce the places where biofilm can build up. The group also reengineered the piping distribution by eliminating the 30-foot dead leg section and the bends and turns in the pipes, rerouting the cold water distribution to the room level, improving water flow by placing high-use fixtures downstream of patient rooms (e.g., in public restrooms), and extending the recirculation of hot water to room level to keep the dead leg as short as possible. These reengineering efforts allowed the dead leg to be shortened to 1 foot. Additionally, the automatic faucet was replaced with a gooseneck faucet with a wrist blade.

Before these reengineering efforts, the average chlorine levels at the faucets were 0.27 milligrams per liter, and four faucet and water cultures tested positive for *S. koreensis*. After reengineering, the hot and cold water chlorine levels averaged 0.76 and 0.99 milligrams per liter, respectively. Other automatic faucets tied to the two reengineered patient rooms had an average chlorine level of 0.21 milligrams per liter. The free chlorine levels in the reengineered hot and cold water pipes have remained consistently above 0.5 milligrams per liter. All new faucets tested negative for *S. koreensis*.

The group will continue to reengineer the rest of the ICU and intermediate care unit patient rooms, using phased implementation, with an expected completion date of March 2020. Using capital improvement funding provided by NIH leadership, the group is moving forward with additional water safety projects, including improving the main water distribution system, replacing aging hot water heaters, and installing new portable water filters to reduce sediment and potential biofilm growth. The goal is to reengineer the pipes for 114 inpatient rooms in the Clinical Center—specifically, all the rooms that may house immunocompromised patients. An [article](#) on this work was recently published in the *New England Journal of Medicine*.

Mr. Yoo acknowledged all the colleagues across NIH involved in this investigation and remediation, and he thanked Dr. Gilman, Dr. Henderson, and Dan Wheeland, the director of ORF, for their support.

Discussion

- Dr. Tuckson asked why a waterborne pathogen does not become resistant to chlorine. Dr. Gallin said that the oxidation process in our bodies produces chlorine to protect against

bacteria. Dr. Gottesman said that there are routinely used disinfectants that can result in bacterial resistance.

- Dr. Gallin said that this design problem encountered at the Clinical Center may also exist in other hospitals and asked how the group is sharing these findings beyond the medical community and with architects and engineers. Mr. Yoo said that the group will present these in-depth engineering solutions at the American Society of Hospital Engineering conference and in publications with other journals. The plumbing in many hospitals meets codes but does not take into account the issue of waterborne bacteria and immunocompromised patients. Dr. Gallin said that the codes may need to change.
- Dr. Palmore said that in early October the group also presented at IDWeek, an annual meeting hosted by the Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, the HIV Medical Association, and the Pediatric Infectious Diseases Society. Once reengineering of the ICU is complete, the group will present at engineering conferences, infectious disease conferences, and epidemiology conferences.
- Ms. Lee said that Michele R. Evans, Dr.P.H., the Clinical Center Hospital Safety Officer, has said that hospitals are too tethered to code and do not consider risk. Dr. Palmore said that Dr. Evans is on the board for the Facilities Guidelines Institute, where she is actively raising this issue.
- Brig Gen Burks asked whether other uses of water in the Clinical Center need to be analyzed as potential waterborne pathogen risks (e.g., water used for sterile processing). Mr. Yoo said that the Clinical Center uses processed water for sterilization, but the ORF and Clinical Center are considering other locations in the facility where exposure may cause harm, though the main focus is patient rooms.
- Dr. Gilman said that while *Sphingomonas* has always been in the water, the issue is about the type of patients who come into contact with the bacteria. Hospitals that care for immunocompromised patients need to consider specific design issues to accommodate these patients. Because this waterborne pathogen problem appeared in the newest part of the Clinical Center, the updated wing did not fix the issue. Dr. Henderson said that he was amazed by the genetic similarity of the *S. koreensis* samples, but bacteria live in the biofilm and do not divide.
- Ms. Reel asked whether this finding at the Clinical Center was similar to that for the infant deaths from waterborne bacteria at Geisinger Medical Center. Dr. Palmore said that the infections at the Clinical Center occurred over the span of a year, whereas Geisinger faced a rapidly moving outbreak. The Clinical Center was able to quickly correct chlorine levels to prevent further infections, and there have not been any *Sphingomonas* cases since 2016. The Clinical Center had time to thoughtfully process good engineering solutions. Also, *Sphingomonas* only affects immunocompromised patients, a small subpopulation of hospital patients. Dr. Forese said that these infections may be similar to those in nursing homes and hospitals with *Legionella pneumophila* outbreaks. Dr. Palmore agreed.

- Ms. Reel asked why the team installed gooseneck faucets. Mr. Yoo said that the nursing staff preferred the gooseneck faucet. The main issue with the automatic faucets was that they harbored pathogens.
- Dr. Forese said that this work was fabulous. Dr. Forese said that Dr. Shannon had to leave the meeting early but he suggested having a conference with leadership from various hospitals to discuss this water engineering and infection issue, though the group's efforts to present and publish the work are accomplishing this goal. Dr. Forese agreed with Dr. Gilman's point that this reengineering strategy does not have to be everywhere if it is not practical, but hospitals must think about a patient's risk profile.

Discussion of the CCRHB Letter About Infrastructure Challenges

Dr. Tuckson shared a second draft of the CCRHB's letter of support for funding necessary infrastructure updates to NIH buildings and facilities. The draft was unanimously approved by the CCRHB. Dr. Tuckson will share the letter with the appropriate NIH staff, and Dr. Forese will sign the letter on behalf of the CCRHB.

Dr. Tuckson added that no NIH members were involved in the advocacy efforts of this letter. Information about the building and facilities issues was presented to the CCRHB, and the CCRHB members decided to provide their opinion on the matter.

Closing Statement and Adjournment

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, New York-Presbyterian Hospital, and Chair, CCRHB

Dr. Forese closed the 14th meeting of the CCRHB by thanking the presenters and the CCRHB members.

The next face-to-face meeting of the CCRHB is scheduled for April 17, 2020.

Dr. Forese adjourned the meeting at 2:32 p.m.

/ Laura Forese /

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

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, New York-Presbyterian Hospital

/ Lawrence A. Tabak /

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

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

/ Francis S. Collins /

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

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

AAHRPP	Association for the Accreditation of Human Research Protection Programs
AAMC	Association of American Medical Colleges
ADC	average daily census
BTRIS	Biomedical Translational Research Information System
CAPA	Corrective Action and Preventative Action
CCGB	Clinical Center Governing Board
CCRHB	Clinical Center Research Hospital Board
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CR	continuing resolution
CRIS	Case Record Interactive Search
CRQM	Clinical Research Quality Management
CRTTP	Clinical Research Training Program
FDA	U.S. Food and Drug Administration
FY	fiscal year
GCP	Good Clinical Practice

HBCUs	Historically Black Colleges and Universities
HHMI	Howard Hughes Medical Institute
HIMD	Health Information Management Department
HHS	U.S. Department of Health and Human Services
ICs	Institutes and Centers
ICU	intensive care unit
IDCU	Investigational Drug Control Unit
INDs/IDEs	investigational drugs and devices
IRB	institutional review board
IRTA	Intramural Research Training Award
IVAU	intravenous admixture unit
MRSP	Medical Research Scholars Program
NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
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
OHRP	Office for Human Research Protections
OHSRP	Office of Human Subjects Research Protections
ORF	Office of Research Facilities
ORSC	Office of Research Support and Compliance
QIA	Quality Improvement Assessment
SRLM	Surgery, Radiology, and Laboratory Medicine
WHO	World Health Organization
WG	working group